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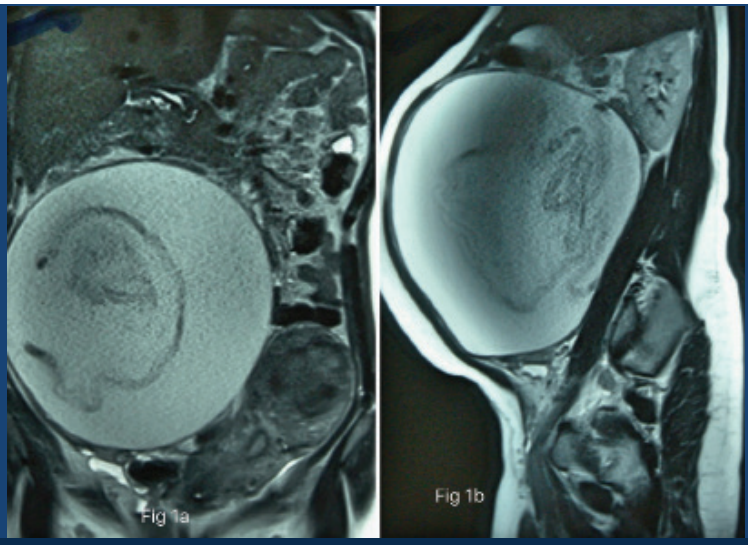

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Yazz® 24+4 film kaplı tablet: Formülü: Her biri 3 mg drospirenon ve 0.02 mg etinilestradiol içeren 24 film kaplı tablet ve bunları takip eden 4 plasebo tablet. **Terapötik endikasyonlar:** Gebeliği önleyici etkisinin yanı sıra antimineralokortikoid ve antiandrogenik etkileri sayesinde, hormona bağlı su tutulması ve buna bağlı belirtiler gösteren kadınlarda, Oral kontrasepsiyon isteyen hastalarda akne vulgaris tedavisi, Premenstruel disforik bozukluk (PMDD; Premenstrual Dysphoric Disorder) semptomlarının tedavisinde endikedir. **Pozoloji/uygulama sıklığı, süresi ve şekli:** Tabletler paketin üstünde gösterildiği yönde, her gün yaklaşık aynı zamanda bir miktar su ile alınmalıdır. Tablet alımı süreklidir. Birbirini izleyen 28 gün boyunca her gün bir tablet alınır. Her bir sonraki pakete önceki kutudaki son tablet alımının ertesi günü başlanır. Tabletler normal siklusun ilk günü (kanamanın ilk günü) alınmaya başlanmalıdır. **Kontrendikasyonlar:** Kombine oral kontraseptifler aşağıdaki koşulların varlığında kullanılmamalıdır ve ilk kez kombine oral kontraseptif kullanımı sırasında bunlardan herhangi biri ortaya çıkacak olursa, tedavi hemen kesilmelidir. Venöz veya arteriyel trombotik/tromboembolik olayların (örn. derin ven trombozu, pulmoner emboli, miyokard enfarktüsü) veya serebrovasküler bir olayın varlığı ya da öyküsü, Tromboz prodromu varlığı veya öyküsü (örn. geçici iskemik atak, angina pektoris), Fokal nörolojik belirtili migren öyküsü, Vasküler tutulumlu diabetes mellitus, Venöz veya arteriyel tromboz için ciddi olan tek, ya da birden fazla risk faktörünün varlığı da bir kontrendikasyon oluşturabilir (bkz. Uyarılar/Önlemler), Ağır hipertrigliseridemi ile bağlantılı pankreatit veya pankreatite benzer öykü. Karaciğer fonksiyon değerleri normale dönmedikçe, ciddi karaciğer hastalığı öyküsü veya varlığı, Ağır veya akut böbrek yetmezliği, Karaciğer tümörü varlığı veya öyküsü (iyi veya kötü huylu), Eğer seks steroidlerinden etkileniyorsa genital organların veya memenin bilinen ya da şüpheli malign hastalıkları, Tanı konulmamış vaginal kanama, Bilinen gebelik veya şüphesi Etkin ya da yardımcı maddelerden herhangi birine aşırı duyarlılık hali. **Özel kullanım uyarıları ve önlemleri:** Özel kullanım uyarıları: Aşağıda belirtilen durumlardan herhangi birinin ortaya çıkması durumunda kombine oral kontraseptiflerin kullanımına ait yararlar olası risklere karşı tartılmalı ve tedaviye başlamadan önce kullanacak olan kadınla birlikte tartışılmalıdır. **Dolaşım bozuklukları:** Epidemiyolojik çalışmalar, kombine oral kontraseptif kullanımıyla miyokard enfarktüsü, inme, derin ven trombozu ve akciğer embolisi gibi arteriyel ve venöz trombotik/tromboembolik hastalıkların risk artışı arasında bir ilişki bulunduğunu belirtmektedirler. Bu olaylar ender olarak ortaya çıkmaktadır. Derin ven trombozu ve/veya pulmoner emboli şeklinde ortaya çıkan venöz tromboemboli (VTE) tüm kombine oral kontraseptiflerin kullanımı sırasında ortaya çıkabilir. Tümörler: Servikal kanser için en önemli risk faktörü süregelen human papilloma virüs (HPV) enfeksiyonudur. Bazı epidemiyolojik çalışmalarda uzun süre kombine oral kontraseptif kullanımının servikal kanser riskinde artışa neden olabileceği bildirilmiştir ancak bu bulguların kombine oral kontraseptif kullanımının hangi etkilerine bağlı olabileceği (servikal inceleme, hormonal olmayan kontraseptif kullanımı dahil olmak üzere seksüel davranış) halen tartışılmaktadır. 54 epidemiyolojik çalışmayı kapsayan bir meta-analiz sonuçlarına göre halen kombine oral kontraseptif kullanan kadınlarda meme kanseri teşhis edilmesi bağıl riskinde (bağıl risk = 1.24) hafif bir artış olduğu rapor edilmiştir. Bu risk artışı kombine oral kontraseptif kullanımının kesilmesiyle birlikte 10 yıl içinde göreceli olarak ortadan kalkar. Diğer uyarılar: Böbrek yetmezliği olan hastalarda potasyum atılım kapasitesi sınırlı olabilir. Hipertrigliseridemisi olan ya da bu şekilde bir aile öyküsüne sahip bulunan kadınlarda, kombine oral kontraseptif kullanımıyla pankreatit gelişimi riskinde artış ortaya çıkabilir. Kombine oral kontraseptif alan kadınların çoğunda kan basıncında hafif artış görüldüğü bildirilmesine rağmen, klinik olarak anlamlı artış enderdir. Drospirenon, antimineralokortikoid etkisinden dolayı diğer kombine oral kontraseptifleri kullanan normal tansiyonlu kadınlarda etinilestradiole bağlı gelişen tansiyon yükselmesini olumlu yönde etkileyebilir. Bununla beraber, kombine oral kontraseptif kullanımı sırasında ortaya çıkan klinik olarak belirgin bir hipertansiyon gelişiminde, hekimin kombine oral kontraseptif kullanımını kesmesi ve hipertansiyon tedavisine başlaması gerekir. Kolestaza bağlı sarılık ve/veya kaşıntı, safra taşı oluşumu, porfiri, sistemik lupus eritematozus, hemolitik üremik sendrom, Sydenham koresi, herpes gestationis, otoskleroza bağlı işitme kaybı gibi durumların gebelik ve kombine oral kontraseptif kullanımı sırasında ortaya çıktığı ya da kötüleştiği bildirilmişse de, bunların kombine oral kontraseptiflerle olan ilişkisi kesinlik kazanmamıştır. Ailesel anjiyoödemi olan kadınlarda egzojen estrogenler anjiyoödem belirtilerinin ortaya çıkmasına veya alevlenmesine yol açabilirler. Karaciğer fonksiyonlarında görülen akut ve kronik değişiklikler, kombine oral kontraseptif kullanımının fonksiyon testi değerleri normale dönene dek kesilmesini gerektirebilir. Gebelik sırasında ilk kez ortaya çıkan ya da daha önce seks steroidlerinin kullanıldığı sırada görülmüş olan kolestatik sarılığın nüks etmesi kombine oral kontraseptif kullanımının kesilmesini gerektirir. Crohn hastalığı ve ülseratif kolit kombine oral kontraseptif kullanımı ile ilişkilendirilmiştir. Özellikle kloazma gravidarum öyküsü olan kadınlarda daha belirgin olmak üzere kloazma ortaya çıkabilir. Azalmış etkinlik: Kombine oral kontraseptiflerin etkinliği tablet alımı unutulduğunda (bkz. Tablet alımı unutulduğunda), mide-bağırsak bozuklukları olması halinde (bkz. Mide-bağırsak bozuklukları durumunda), ya da eş zamanlı ilaç tedavilerinde (bkz. İlaç etkileşmeleri) azalabilir. Azalmış siklus kontrolü: Tüm kombine oral kontraseptiflerde, özellikle kullanımın ilk aylarında düzensiz kanamalar (lekelenme veya kırılma kanamaları) gelişebilir. Bu nedenle herhangi bir düzensiz kanamanın araştırılması yaklaşık 3 siklusluk bir adaptasyon süresinden sonra anlamlıdır. **Etkileşimler:** Oral kontraseptifler ve diğer ilaçlar arasındaki etkileşimler kırılma kanamalarına ve/veya kontraseptif başarısızlığa yol açabilirler. Aşağıdaki etkileşimler literatürde bildirilmiştir. Hepatik metabolizma: Mikrozomal enzimleri etkileyen ilaçlarla (örn. fenitoin, barbitüratlar, primidon, karbamazepin, rifampisin ve muhtemelen okskarbazepin, topiramat, felbamat, griseofulvin ve "St. John's wort (Sarı kantaron)" içeren ürünler) olan etkileşimler, seks hormonlarının klerensinin artması ile sonuçlanabilir. Gebelik kategorisi X'dir. **YAZZ® 24+4** gebelik döneminde uygulandığı takdirde ciddi doğum kusurlarına yol açmaktadır. **YAZZ® 24+4** gebelik döneminde kontrendikedir. **YAZZ® 24+4** film kaplı tabletlerin kullanımı sırasında gebelik meydana gelmesi durumunda kullanım durdurulmalıdır. Laktasyon, anne sütünün miktarında azalmaya ve bileşiminde değişikliğe yol açabileceğinden, kombine oral kontraseptifler tarafından etkilenebilir. **İstenmeyen etkiler:** Kombine oral kontraseptiflerin kullanımıyla ilişkilendirilen en ciddi yan etkiler "Uyarılar/önlemler" bölümünde ele alınmıştır. Aşağıdaki diğer yan etkiler kombine oral kontraseptif kullanıcılarında bildirilmiş ve ilişkileri ne doğrulanmış ne de yanlışlığı kanıtlanmıştır. Göz: Seyrek: Kontakt lense toleranssızlık Gastrointestinal sistem: Yaygın: Bulantı, batında ağrı, Yaygın olmayan: Kusma, diyare İmmün sistem bozuklukları: Seyrek: Hipersensitivite İncelemeler: Yaygın: Kiloda artış, Seyrek: Kiloda azalma Metabolizma ve beslenme: Yaygın olmayan: Sıvı tutulumu Sinir sistemi: Yaygın: Baş ağrısı, Yaygın olmayan: Migren Psikiyatrik düzensizlikler: Yaygın: Depresif duygu durumu, duygu durum değişiklikleri Yaygın olmayan: Libido azalması, Seyrek: Libido artışı Üreme sistemi ve meme: Yaygın: Meme ağrısı, meme hassasiyeti, Yaygın olmayan: Memede hipertrofi, Seyrek: Vaginal akıntı, memede akıntı Cilt ve cilt altı: Yaygın olmayan: Döküntü, ürtiker, Seyrek: Eritema nodozum, eritema multiforme. Ailesel anjiyoödemi olan kadınlarda egzojen estrogenler anjiyoödem belirtilerinin ortaya çıkmasına veya alevlenmesine yol açabilirler. Raf ömrü: 48 ay. Saklamaya yönelik özel tedbirler: 25°C'nin altında oda sıcaklığında saklayınız. **Ambalajın niteliği ve içeriği:** PVC/Aluminyum blister'de etkin madde içeren 24 adet ve etkin madde içermeyen 4 adet film kaplı tablet. **Ruhsat Sahibi:** Bayer Türk Kimya San. Ltd. Şti., Çakmak Mah. Balkan Cad. No:53 34770 Ümraniye - İstanbul Tel: (0216) 528 36 00 Faks: (0216) 538 37 40 **Ruhsat Numarası:** 126/93 **Ruhsat Tarihi:** 02.03.2009 Daha geniş bilgi için firmamıza başvurunuz. **KDV dahil perakende satış fiyatı:** 34.83 TL (20.02.2017).

QLAIRISTA® tablet: Her biri 3 mg estradiol valerat içeren 2 adet koyu sarı renkli, 2 mg estradiol valerat ve 2 mg dienogest içeren 5 adet kırmızı renkli, 2 mg estradiol valerat ve 3 mg dienogest içeren 17 adet açık sarı renkli, 1 mg estradiol valerat içeren 2 adet koyu kırmızı renkli, 2 adet beyaz film kaplı (hormon içermeyen) toplam 28 tablet. **Terapötik endikasyonlar:** Oral kontrasepsiyon Pozoloji/uygulama sıklığı, süresi ve şekli: Tablet alımına doğal siklusun (menstrüel kanamanın) birinci gününde başlanmalıdır. Tabletler kutunun üzerinde belirtilen sırayla, her gün günün aynı saatinde, yeterli miktarda su ile alınmalıdır. Birbirini izleyen 28 gün boyunca her gün, günde bir tablet alınacaktır. Önceki kutudaki son tabletin alındığı günün ertesi günü, bir sonraki kutuya başlanır. Yan etkiler: Organ sınıfları ve sıklık derecesine göre; Psikiyatrik bozukluklar: Yaygın: Depresyon/Depresif duygudurum (%1.6), emosyonel dengesizlik (%1.4), libido azalması ya da kaybı (%1.1) Sinir sistemi: Yaygın: Migren (%1.9) Kardiovasküler sistem: Seyrek: Venöz ve arteriyel tromboembolik olaylar (<%0.1) Gastrointestinal sistem: Yaygın: Bulantı (%3.1) Ürogenital sistem ve meme: Yaygın: Meme ağrısı (%5.8), düzensiz uterin kanama (%4.4) Yaygın olmayan: Genital sistem kanaması (%0.4) Seyrek kategorisi altında listelenen tüm yan etkiler, sadece 1-2 gönüllü de ortaya çıkmıştır (<%0.1). Etkileşimler: Enzim indükleyicileri ya da inhibitörleri (CYP 3A4): Seks hormonları esas olarak, hem intestinal mukoza hem de karaciğerde bulunan sitokrom P450 3A4 (CYP 3A4) sistemi tarafından metabolize edilirler. Bu nedenle, fenitoin, barbitüratlar, pirimidon, karbamazepin, rifampisin ve muhtemelen okskarbazepin, topiramat, felbamat, griseofulvin, nevirapin ve St. John bitkisi [Hypericum perforatum] gibi CYP 3A4 indükleyicileri ya da azol grubu antifungaller, simetidin, verapamil, makrolidler, diltiazem, proteaz inhibitörleri, antidepresanlar ve greyfurt suyu gibi bilinen inhibitörler ilacın metabolizmasını etkileyebilir. Enzim indüksiyonu nedeniyle seks hormonları klirensinin artması, terapötik etkisini azaltabilir. Enzim inhibisyonuna bağlı olarak seks hormonları klirensinin azalması, indüksiyona bağlı olarak ise artması istenmeyen etkiler ile sonuçlanabilir. Diğer etkileşim şekilleri: Progestagen kullanımı bazı laboratuar testlerinin sonuçlarını etkileyebilir. Pediyatrik popülasyon: Pediyatrik popülasyonda etkileşim çalışması yapılmamıştır. Diğer etkileşim şekilleri: Oral kontraseptifler belirli başka ilaçların (örn. lamotrigin) metabolizmasını etkileyebilir ve sonuçta plazma konsantrasyonlarında yükselme veya azalmaya neden olabilirler. Özel popülasyonlara ilişkin ek bilgiler: Böbrek Yetmezliği: Böbrek yetmezliği olan hastalarda özel olarak çalışılmamıştır. Mevcut veriler bu hasta popülasyonunda tedavi değişikliği yapılmasına ilişkin veri sağlamamıştır. Karaciğer Yetmezliği: Şiddetli karaciğer hastalığı olan kadınlarda kontrendikedir. Pediyatrik popülasyon: Yalnızca menarştan sonra endikedir. Geriyatrik popülasyon: Geriyatrik popülasyonda kullanımı ve menopozdan sonra endikasyonu yoktur. **Kontrendikasyonlar:** Kombine oral kontraseptifler (KOK) aşağıda belirtilen tabloların herhangi birisinin varlığında kullanılmamalıdır. KOK kullanımı sırasında bu tablolardan herhangi biri ilk kez ortaya çıkarsa, ilaç derhal kesilmelidir. Aktif venöz tromboembolik hastalık, arteriyel ve kardiyovasküler hastalık varlığı ya da öyküsü, kontrendikasyon meydana getirebilecek venöz ya da arteryel tromboza yönelik ağır bir risk faktörü veya çok sayıda risk faktörleri, fokal nörolojik semptomlarla birlikte migren öyküsü,vasküler tutulum ile birlikte diabetes mellitus, şiddetli karaciğer hastalığı ve karaciğer fonksiyon testlerinin henüz normale dönmemiş olması, karaciğer tümörü varlığı ya da öyküsü, seks steroidlerinden etkilenen malignitelerin (örn. genital organlarda ya da memelerde) bulunması veya böyle bir malignite kuşkusu, tanısı konulmamış vajinal kanama, Gebelik varlığı veya şüphesi, etken ya da yardımcı maddelere karşı aşırı duyarlılık. **Özel kullanım uyarıları ve önlemleri:** Aşağıda sözü edilen tablolardan/risk faktörlerinden herhangi biri bulunuyorsa, ilaç kullanma kararı verilmeden önce, KOK kullanımının yararları her kadın bireydeki olası risklere karşı tartılmalı ve konu kadın ile de görüşülmelidir. Estradiol/estradiol valerat içeren KOK'ların etkilerine yönelik epidemiyolojik çalışma bulunmamaktadır. Aşağıdaki bütün uyarılar ve önlemler, etinilestradiol içeren KOK'lara ilişkin klinik ve epidemiyolojik verilerden alınmıştır. Bu uyarılar ve önlemlerin QLAIRISTA® için geçerli olup olmadığı bilinmemektedir. Dolaşım bozuklukları: VTE riski güncel olarak bilinmemektedir. Epidemiyolojik çalışmalarda, etinil estradiol içeren KOK kullanımı ile, derin ven trombozu, pulmoner embolizm, miyokard enfarktüsü ve serebrovasküler olay gibi arteryel ve venöz trombotik ve tromboembolik hastalık riskinde artış arasında bir bağıntının varlığı gösterilmiştir. Bu olaylar ender olarak ortaya çıkarlar. Venöz tromboembolizm riski, ilk kullanım yılında en yüksek düzeydedir. Bu risk artışı ilk olarak bir KOK başlanması, aynı KOK ya da farklı bir KOK ile tekrar tedaviye başlanması (en az 4 hafta aradan sonra) sırasında mevcuttur. Geniş ölçekli, prospektif ve 3 kollu çalışma verileri bu risk artışının esas olarak ilk 3 ayda mevcut olduğunu ileri sürmektedir. Düşük doz östrojen (< 50 mg etinilestradiol) içeren KOK kullanlarda toplam venöz tromboembolizm (VTE) riski, gebe olmayan ve KOK kullanmayanlara göre 2-3 kat artmıştır ancak gebelik ve doğum ile ilişkili riskten daha düşüktür. KOK kullananlarda son derecede ender olarak diğer kan damarlarında, örn. hepatik, mezenterik, renal, serebral ya da retinal venler ve arterlerde tromboz oluştuğu bildirilmiştir. Bu olayların KOK kullanımıyla ilişkili olup olmadığı konusunda bir uzlaşı bulunmamaktadır. Tümörler: Serviks kanseri için en önemli risk faktörü, kalıcı HPV enfeksiyonudur. Bazı epidemiyolojik çalışmalarda uzun süreli KOK kullanımının, artmış olan bu riski daha da artırabileceğine işaret edilmiştir; ancak bu bulgunun diğer bazı sonuca ulaşmayı güçleştirici faktörlere (örn. servikal tarama ve bariyer kontraseptiflerin kullanımını da içeren cinsel davranışlar) ne ölçüde bağlı olduğu konusunda tartışmalar devam etmektedir. Elli dört epidemiyolojik çalışma üzerinde yürütülen bir meta analizde, halen KOK kullanan kadınlarda meme kanseri tanısı konulma relatif riskinde hafif bir artış (RR = 1.24) olduğu bildirilmiştir. Bu risk fazlalığı, KOK kullanımı kesildikten sonraki 10 yıl içerisinde aşamalı olarak kaybolmaktadır. Kırk yaş altındaki kadınlarda meme kanseri ender olduğu için, halen KOK kullanmakta olan ya da yakın zamanda kullanmış olan kadınlardaki fazla meme kanseri tanısı sayısı, genel meme kanseri riskine kıyasla küçüktür. Bu çalışmalar nedenselliğe yönelik veri sağlamamaktadır. Gözlenen risk artışı paterni, KOK kullanıcılarında meme kanseri tanısının daha erken konulmasına, KOK'ların biyolojik etkilerine ya da bu ikisinin bir kombinasyonuna bağlı olabilir. Yaşamlarının herhangi bir döneminde KOK kullananlarda tanısı konulan meme kanseri, hiç kullanmamış kadınlarda tanısı konulanlardan, klinik olarak daha az ilerlemiş olma eğilimindedir. KOK kullananlarda ender olgular şeklinde benign karaciğer tümörleri ve çok daha ender olarak malign karaciğer tümörleri bildirilmiştir. **Diğer uyarılar:** Hipertrigliseridemisi olan veya aile özgeçmişinde olan kadınlarda, KOK kullanırken pankreatit riski artabilir. KOK almakta olan çok sayıda kadında kan basıncında küçük artışlar bildirilmiş olmakla birlikte, klinik önem taşıyan artışlar enderdir. Aşağıdaki tabloların hem gebelik hem de KOK kullanımı sırasında ortaya çıktığı ya da kötüleştiği bildirilmiştir, ancak KOK kullanımı ile aradaki ilişkiye yönelik veriler kesin değildir; kolestaza bağlı sarılık ve/veya pruritus, safra taşı oluşumu, porfiri, sistemik lupus eritematozus, hemolitik üremik sendrom, Sydenham koresi, herpes gestasyonis, otoskleroza bağlı işitme kaybı, Herediter anjiyoödemi olan kadınlarda eksojen östrojenler anjiyoödem semptomlarını indükleyebilir veya alevlendirebilir. KOK'lar periferik insülin direnci ve glukoz toleransı üzerinde etkili olabilmekle birlikte, düşük dozlu (<0.05 mg etinilestradiol içeren) KOK kullanan diyabetiklerde terapötik rejimin değiştirilmesi ihtiyacına yönelik kanıt bulunmamaktadır. Ancak diyabetik kadınlar KOK kullanımı sırasında dikkatle gözlenmelidir. Crohn hastalığı ve ülseratif kolit KOK kullanımıyla ilişkili bulunmuştur. Özellikle öyküsünde kloazma gravidarum olan kadınlarda, zaman zaman kloazma ortaya çıkabilir. Kloazma eğilimi taşıyan kadınlar, KOK kullanırken güneşe maruz kalmaktan veya ultraviyole radyasyondan kaçınmalıdır. Unutulan tabletler: Alınması unutulan hormon içermeyen beyaz tablet ise önemsenmeyebilir. Ancak, hormonsuz tablet döneminin istemeden uzatılmasından kaçınmak için, unutulan bu tabletler atılmalıdır. Eğer tablet alınması unutulan süre 12 saatten kısa ise, kontraseptif korunmada azalma söz konusu değildir. Hatırlanır hatırlanmaz tablet alınmalı, ve sonraki tabletler olağan zamanlarında alınmaya devam edilmelidir. Eğer tablet alınması için unutulan süre 12 saatten uzun ise, kontraseptif korunmada azalma olabilir. Aynı anda iki tablet birden alma anlamına gelse bile, hatırlanır hatırlanmaz tablet alınmalıdır. Daha sonraki tabletler ise olağan zamanlarında alınmaya devam edilmelidir. Gastrointestinal rahatsızlıklar durumunda öneriler: Şiddetli gastrointestinal rahatsızlıklar durumunda, emilim tam olmayabilir ve ek kontraseptif önlemlere gerek duyulabilir. Laktoz: QLAIRISTA® ambalajında bulunan 5 farklı formülasyondaki tabletlerin her biri farklı miktarlarda laktoz monohidrat içermektedir; Koyu sarı renkli tabletlerin her biri 48.360 mg, kırmızı renkli tabletlerin her biri 47.360 mg, açık sarı renkli tabletlerin her biri 46.360 mg, koyu kırmızı renkli tabletlerin her biri 50.360 mg, plasebo tabletlerin her biri ise 52.1455 mg laktoz monohidrat içerir. Galaktozemi, kalıtımsal galaktoz intoleransı, Lapp laktoz yetmezliği ya da glukoz galaktoz malabsorpsiyon problemi olan hastaların bu ilacı kullanmaması gerekir. Gebelikte kullanım kontrendike olup gebelik kategorisi X'tir. Kullanım sırasında gebelik oluşursa, ilaç alımı kesilmelidir. Ancak etinil estradiol içeren KOK'larla yapılan kapsamlı epidemiyolojik çalışmalarda, gebelik öncesinde KOK kullanmış olan kadınların doğurduğu çocuklarda doğum defekti riskinde artış görülmemiştir. Laktasyon döneminde kulanılmamalıdır çünkü bu ajanlar sütün miktarını azaltabilir ve bileşimini değiştirebilir. Araç ve makine kullanma becerileri üzerinde herhangi bir etki gözlenmemiştir. **Doz aşımı ve tedavisi:** Doz aşımı sonucunda, sağlığı bozucu şiddetli etkilerin bildirildiği bir rapor bulunmamaktadır. Hormon içeren film kaplı tabletlerin doz aşımı oluşturacak şekilde alınması sonucunda oluşabilecek semptomlar bulantı, kusma ve genç kızlarda hafif vajinal kanamadır. Antidotu yoktur ve tedavi semptomatik olmalıdır. **Raf ömrü:** 60 ay. Saklamaya yönelik özel tedbirler: 30°C'nin altında, oda sıcaklığında saklanmalıdır. Ambalajın niteliği ve içeriği: Polivinil klorürden yapılı transparan filmler ve ısıyla işlenmiş aluminyumdan yapılı metalik folyolardan oluşan blister ambalajda 28 tablet. **Ruhsat sahibi:** Bayer Türk Kimya San. Ltd. Şti., Çakmak Mah. Balkan Cad. No:53 34770 Ümraniye - İstanbul Tel: (0216) 528 36 00 Faks: (0216) 538 36 12 **Ruhsat numarası**:131/95 **İlk ruhsat tarihi:** 17.08.2011 Daha geniş bilgi için firmamıza başvurunuz. **Fiyatı:** 38.58 TL (20.02.2017)

Yasmin® film kaplı tablet: Formülü: Her bir film kaplı tablet, 3 mg drospirenon ve 0.03 mg etinilestradiol içerir. **Endikasyonları:** Gebeliği önleyici etkisinin yanısıra antimineralokortikoid ve antiandrogenik etkileri sayesinde, hormona bağlı su tutulması ve buna bağlı belirtilerle, akne ve seboreden yakınan kadınlarda etkilidir. **Kontrendikasyonları:** Kombine oral kontraseptifler aşağıdaki koşulların varlığında kullanılmamalıdır ve ilk kez kombine oral kontraseptif kullanımı sırasında bunlardan herhangi biri ortaya çıkacak olursa, tedavi hemen kesilmelidir. Venöz veya arteriyel trombotik/tromboembolik olayların (örneğin derin ven trombozu, pulmoner emboli, miyokard enfarktüsü) veya serebrovasküler bir olayın varlığı ya da öyküsü, Tromboz prodromu varlığı veya öyküsü (örneğin geçici iskemik atak, anjina pektoris), Fokal nörolojik belirtili migren öyküsü, Vasküler tutulumlu diabetes mellitus, Venöz veya arteriyel tromboz için ciddi ya da bir çok risk faktörünün varlığı da kontrendikasyon olarak kabul edilir (Bkz. Uyarılar/Önlemler), Pankreatit veya şiddetli hipertrigliseridemi ile bağlantılı pankreatit öyküsü. Karaciğer fonksiyon değerleri normale dönmedikçe, ciddi karaciğer hastalığı öyküsü veya varlığı, Şiddetli veya akut böbrek yetmezliği, Karaciğer tümörü varlığı veya öyküsü (iyi veya kötü huylu), Eğer seks steroidlerinden etkileniyorsa genital organların veya memenin bilinen ya da şüpheli malign hastalıkları, Tanı konulmamış vaginal kanama, Bilinen gebelik veya şüphesi, Etkin ya da yardımcı maddelerden herhangi birine aşırı duyarlılık hali. **Uyarılar/Önlemler:** Dolaşım bozuklukları: Epidemiyolojik çalışmalar, kombine oral kontraseptif kullanımıyla miyokard enfarktüsü, inme, derin ven trombozu ve akciğer embolisi gibi arteriyel ve venöz trombotik/tromboembolik hastalıkların risk artışı arasında bir ilişki bulunduğunu belirtmektedirler. Bu olaylar ender olarak ortaya çıkmaktadır. Derin ven trombozu ve/veya pulmoner emboli şeklinde ortaya çıkan venöz tromboemboli (VTE) tüm kombine oral kontraseptiflerin kullanımı sırasında ortaya çıkabilir. Kombine oral kontraseptif kullananlarda, çok ender olarak, hepatik, mezenterik, renal, serebral veya retinal venler ve arterler gibi diğer kan damarlarında da tromboz bildirilmiştir. Kombine oral kontraseptif kullanımı ile bu olayların ortaya çıkması arasındaki nedensel ilişki halen tartışmalıdır. Venöz veya arteriyel trombotik/tromboembolik durumlar ya da serebrovasküler olay riski aşağıdaki faktörlerle artar: Yaş, Sigara kullanılması, Olası aile öyküsü, Obesite, Dislipoproteinemi, Hipertansiyon, Migren, Kalp kapak hastalığı, Atriyal fibrilasyon, Uzun süreli immobilizasyon. Lohusalık döneminde tromboemboli gelişimi riskinin arttığı göz önüne alınmalıdır. Kombine oral kontraseptiflerin kullanılması sırasında, migrenin sıklığında ve şiddetinde artış ortaya çıkması (bir serebrovasküler olayın habercisi olabilmesi açısından) ilacın derhal kesilmesi için bir neden olabilir. Tümörler: Bazı epidemiyolojik çalışmalarda uzun süre kombine oral kontraseptif kullananlarda servikal kanser riskinde artış görüldüğü bildirilmiştir. Ancak bu bulguların seksüel davranış ve human papilloma virus (HPV) gibi diğer faktörlerle bağlantısı da halen tartışılmaktadır. 54 epidemiyolojik çalışmayı kapsayan bir meta-analiz sonuçlarına göre halen oral kontraseptif kullanan kadınlarda meme kanserine rastlanma oranında hafif bir artış olduğu rapor edilmiştir. Bu risk artışı oral kontraseptif kullanımının kesilmesiyle birlikte 10 yıl içinde göreceli olarak ortadan kalkar. Meme kanseri görülme sıklığı 40 yaşın altındaki kadınlarda düşük olduğundan, bu açıdan meme kanseri riski fazla anlamlı değildir. Kombine oral kontraseptif kullanıcılarında nadir olgularda iyi huylu, çok nadiren de habis karaciğer tümörleri gözlemlenmiştir. Sınırlı olguda bu tümörler yaşamı tehdit eden batın içi kanamalara yol açar. **Diğerleri:** Böbrek yetmezliği olan hastalarda potasyum atılım kapasitesi sınırlı olabilir. Hipertrigliseridemisi olan ya da bu şekilde bir aile öyküsüne sahip bulunan kadınlarda, kombine oral kontraseptif kullanımıyla pankreatit gelişimi riskinde artış ortaya çıkabilir. Kombine oral kontraseptif alan kadınların çoğunda kan basıncında hafif artış görüldüğü bildirilmesine rağmen, klinik olarak anlamlı artış enderdir. Karaciğer fonksiyonlarında görülen akut ve kronik değişiklikler, kombine oral kontraseptif kullanımının fonksiyon testi değerleri normale dönene dek kesilmesini gerektirebilmektedir. Gebelik sırasında ilk kez ortaya çıkan ya da daha önce seks steroidlerinin kullanıldığı sırada görülmüş olan kolestatik sarılığın nüks etmesi kombine oral kontraseptif kullanımının kesilmesi gerekliliğini göstermektedir. Kombine oral kontraseptif kullanan diyabetik kadınlar dikkatle gözlenmelidir. Crohn hastalığı ve ülseratif kolit kombine oral kontraseptif kullanımı ile ilişkilendirilmiştir. Özellikle gebelik maskesi öyküsü olan kadınlarda daha belirgin olmak üzere kloazma ortaya çıkabilir. Kloazma eğilimi olan kadınlar kombine oral kontraseptif kullanımı esnasında güneşe çıkmaktan ya da ultraviyole ışınlarına maruz kalmaktan kaçınmalıdır. Azalmış etkinlik: Kombine oral kontraseptiflerin etkinliği tablet alımı unutulduğunda (Bkz. Tablet alımı unutulduğunda), mide-barsak bozuklukları olması halinde (Bkz. Mide-barsak bozuklukları durumunda), ya da eş zamanlı ilaç tedavilerinde (Bkz. İlaç Etkileşmeleri) azalabilir. Azalmış siklus kontrolü: Tüm kombine oral kontraseptiflerde, özellikle kullanımın ilk aylarında düzensiz kanamalar (lekelenme veya kırılma kanamaları) gelişebilir. Eğer kanama düzensizliği devam eder veya kanamalar düzenliyken ortaya çıkarsa non-hormonal etkenler göz önüne alınmalı ve malignite veya gebeliğin ekarte edilmesi için kürtajın da dahil olabileceği uygun tanısal girişimlerde bulunulmalıdır. Bazı kadınlarda tablet alınmayan dönemde çekilme kanaması oluşmayabilir. **Yan etkiler/advers etkiler:** Kombine oral kontraseptiflerin kullanımıyla ilişkilendirilen en ciddi yan etkiler "Uyarılar/Önlemler" bölümünde ele alınmıştır. Aşağıdaki diğer yan etkiler kombine oral kontraseptif kullanıcılarında bildirilmiş ve ilişkileri ne doğrulanmış ne de yanlışlığı kanıtlanmıştır. Göz: kontakt lense toleranssızlık; Gastrointestinal sistem: bulantı, kusma, batında ağrı, diyare; Immun sistem: hipersensitivite; Metabolizma ve beslenme: sıvı retansiyonu, ağırlık artışı, ağırlık azalması; Sinir sistemi: başağrısı, migren, libido azalması, libido artışı, depresif duygu durumu, duygu durum değişiklikleri; Üreme sistemi ve meme: meme hassasiyeti, meme ağrısı, memede hipertrofi, memede akıntı, vaginal akıntı; Cilt ve ciltaltı: döküntü, ürtiker, eritema nodozum, eritema multiforme. **İlaç etkileşmeleri:** Oral kontraseptifler ve diğer ilaçlar arasındaki etkileşimler kırılma kanamalarına ve/veya kontraseptif başarısızlığa yol açabilirler. Aşağıdaki etkileşimler literatürde bildirilmiştir. Hepatik metabolizma: Mikrozomal enzimleri etkileyen ilaçlarla (ör. fenitoin, barbitüratlar, primidon, karbamazepin, rifampisin ve muhtemelen okskarbazepin, topiramat, felbamat, ritanovir, griseofulvin ve "St. John's wort" içeren ürünler) olan etkileşimler, seks hormonlarının klerensinin artması ile sonuçlanabilir. Enterohepatik dolaşımla etkileşmeler: Belirli antibiyotik ajanların (ör. penisilinler, tetrasiklinler) verilmesi durumunda estrogenlerin enterohepatik dolaşımının azalabileceğini ve bunun da etinilestradiol düzeylerini azaltabileceğini savunan klinik raporlar mevcuttur. Kullanım şekli ve dozu: Kullanım: Tabletler paketin üstünde gösterildiği yönde, hergün yaklaşık aynı zamanda bir miktar suyla alınmalıdır. Birbirini izleyen 21 gün boyunca hergün bir tablet alınır. Her bir sonraki pakete 7 günlük, sıklıkla çekilme kanamasının izlendiği, tablet alınmayan dönemi takiben geçilir. Bu kanama genellikle son tabletin alınmasını takiben 2.-3. gün başlar ve bir sonraki pakete başlandığında kesilmemiş olabilir. Tablet alımı unutulduğunda: Eğer kullanıcı tabletini almakta 12 saatten daha az geç kalmışsa, kontraseptif koruyuculuk azalmaz. Hatırlanır hatırlanmaz tablet alınmalı ve bir sonraki tabletler de her zamanki gibi alınmaya devam edilmelidir. Eğer 12 saatten daha fazla gecikme olmuşsa kontraseptif koruyuculuk azalmış olabilir. Mide-barsak bozuklukları durumunda: Şiddetli gastrointestinal bozuklukların olması durumunda emilim tam olmayabilir ve ek kontraseptif önlemler alınmalıdır. **Ticari takdim şekli:** 21 tabletlik blisterde. Schering AG, Almanya'da imal edilmiştir. **Ruhsat tarihi:** 20.02.2002, **Ruhsat no:** 111/87, **Ruhsat sahibi:** Bayer Türk Kimya San. Ltd. Şti., Çakmak Mah. Balkan Cad. No:53 34770 Ümraniye - İstanbul Tel: (0216) 528 36 00 Faks: (0216) 538 37 40 Reçete ile satılır. 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Aims and Scope

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The target audience of Journal of the Turkish-German Gynecological Association includes gynaecologists and primary care physicians interested in gynecology practice. It publishes original work on all aspects of gynecology. The aim of Journal of the Turkish-German Gynecological Association is to publish high quality original research articles. In addition to research articles, reviews, editorials, letters to the editor are also published.

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Present the detailed findings supported with statistical methods. Figures and tables should supplement, not duplicate the text; presentation of data in either one or the other will suffice. Emphasize only your important observations; do not compare your observations with those of others. Such comparisons and comments are reserved for the discussion section.

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State the importance and significance of your findings but do not repeat the details given in the Results section. Limit your opinions to those strictly indicated by the facts in your report. Compare your finding with those of others. Provide information on the limitations of the study. No new data are to be presented in this section.

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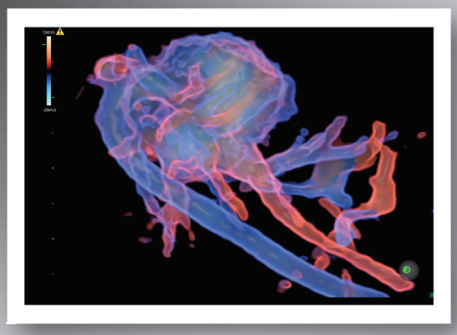

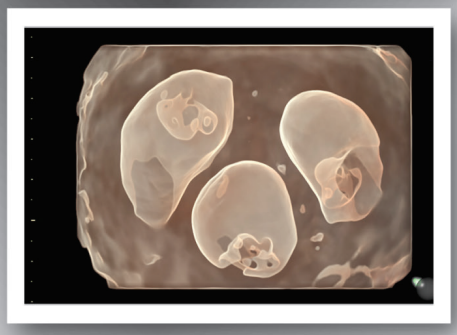

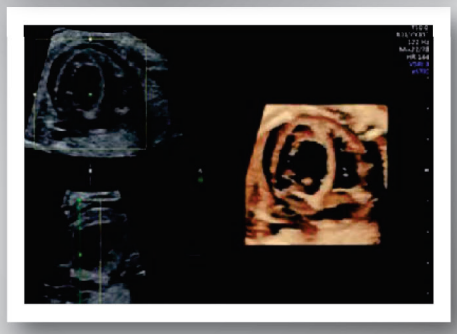

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Editorial

Dear Colleagues,

I am delighted to introduce the second issue of the *J Turk Ger Gynecol Assoc* in the publishing year of 2017.

J Turk Ger Gynecol Assoc is the Official Publication of the Turkish German Gynecology Association (TAJEV). Our journal publishes original articles and research studies on: scientific advances, new medical and surgical techniques, obstetric management, and clinical evaluation of drugs and instruments.

In addition to its authoritative articles and studies, *J Turk Ger Gynecol Assoc* continues to feature the sections that obstetricians and gynecologists around the world have come to depend upon: Current Commentaries, Expert Clinical Series, Personal Perspectives, Editorials, and Letters. *J Turk Ger Gynecol Assoc* rigorous editorial policies ensure that all articles are of the highest quality and that they are published while current. These policies have made The Journal one of the most respected and most consulted journals in the world.

J Turk Ger Gynecol Assoc is the most complete and reliable source of information on current developments in women's health care. Audience: Obstetricians, Gynecologists, General Practitioners, Family Practitioners, Endocrinologists, Gyno-Oncologists.

Today I will give you some information about Impact Factors (IF) and ten highlight points on how to increase your impact factor. Impact factors are heavily criticized as measures of scientific quality. However, they still dominate every discussion about scientific excellence. They are still used to select candidates for positions as PhD student, postdoc and academic staff, to promote professors and to select grant proposals for funding. As a consequence, researchers tend to adapt their publication strategy to avoid negative impact on their careers. Until alternative methods to measure excellence are established, young researchers have to learn the "rules of the game" and young scientists often need advice how to reach higher impact factors with their publications.

Young researchers often wonder whether the impact factor or the number of citations is more relevant. This question is difficult to answer. My very personal view is that citations become increasingly important with increasing maturity of the career of a scientist.

The following strategies are well known among senior scientists and will primarily help young researchers to look for feasible ways to improve their studies within the limits of their contract and budget.

1. Look for a mechanism not for a phenomenon
2. Address the same question with additional methods
3. Re-analyse your samples with a different or more complex method
4. Add fancy techniques
5. Develop a fancy technology
6. Collaborate with a statistician
7. Fuse smaller studies
8. Collaborate with experts in the field
9. Look for a journal with the perfect scope and check where your competitors publish
10. Submit to a journal with a much higher impact factor to get reviewers comments

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Editorial

The June issue has traditionally concentrated on systematic reviews and randomised controlled trials. The papers in this issue come from Turkey, Germany, United Kingdom and our neighbour Greece. The prevalence of unsuspected uterine sarcomas in those undergoing uterine fibroid surgery is of concern, and this issue is particularly important when laparoscopic power morcellation is used. A retrospective single-center study from Germany; the records of all 2275 patients with uterine fibroids and uterine sarcomas from 2003 to 2015 were reviewed and they found the frequency of unsuspected uterine sarcomas was 1/2269 (0.044%) among women who underwent myomectomies and hysterectomies to treat presumed benign uterine fibroids. Another interesting paper from Germany focused on breast cancer surgery technique. The impact of local tumor control on the survival of patients with breast cancer is also influenced by the precision of radiotherapy. Additionally, patients demand an appealing cosmetic result. This makes "clinical" markers such as scars unreliable for radiotherapy planning. A simple way of identifying the tissue at risk is by intra-surgical clipping of the tumor bed. Their results show that the use of surgical clips can reduce the diameter of the radiotherapy field and increase the accuracy of radiotherapy planning. With the placement of surgical clips, more tissue at risk is included in the radiotherapy field. Less normal tissue receives radiotherapy with the use of surgical clips. You will find a good study from expert surgeons that studying surgical staging in locally advanced cervical cancer. This issue's subjects are mainly focused on oncology. A good paper from United Kingdom and Greece focused on robotic intervention for vulvar carcinomas. Robotic inguinal lymph node dissection is a safe and oncologically effective but expensive and time-consuming approach in patients with penile cancer or melanoma. However, it is related with less postoperative complications, especially less lymphocele or lymphedema rates, and can improve the patients' quality of life while minimizing cost for health systems.

I hope you will enjoy reading the articles mentioned above and all the other articles in this particular issue.

I would also like to inform you about the sixth Social Responsibility Project of Turkish German Gynecological Education and Research Foundation (TAJEV), which will be held on September 8-9, 2017, in Antakya - Turkey. Antakya is a city of great religious importance. It was the home of several Roman temples and its suburb, Daphne. Antakya also played an especially important role in Christian history: it was the base for Paul's missionary journeys, where Jesus' followers were first called "Christians" (Acts 11:26) and where the Gospel of Matthew was probably written. The project held in this beautiful city is traditionally organized from four steps; public awareness meeting with participation of the locals, the scientific meeting with participation of health professionals, performing of the advanced operations and medical examination/screening to local women, and finally a medical device donation to a local hospital. We believe our project could be considered a success if only one maternal death is prevented. Since it is these small steps which may one day make the difference. We would be excited to have our colleagues join us in this intense scientific activity.

Sincerely,

Prof. Cihat Ünlü, M.D.
Editor in Chief of *J Turk Ger Gynecol Assoc*
President of TAJEV

Frequency of uterine sarcomas in patients admitted for uterine fibroid surgery

Liselotte Mettler[1], Nicolai Maass[1], Khulkar Abdusattarova[1], Astrid Dempfle[2], Ibrahim Alkatout[1]

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Abstract

Objective: To estimate the frequency of unsuspected uterine sarcoma identified postoperatively in women undergoing surgery for presumed benign uterine fibroids at a single university hospital.

Material and Methods: This was a retrospective single-center study; the records of all 2275 patients with uterine fibroids and uterine sarcomas from 2003 to 2015 were reviewed. Descriptive statistics were used to analyze demographic and clinical characteristics. To calculate confidence intervals (CIs), the Clopper-Pearson Exact method was applied.

Results: Preoperatively, 2269 patients had presumed benign uterine fibroids, and six patients had suspected uterine sarcoma. Among the 2269 patients who underwent surgery for presumed uterine fibroids, endometrial stromal sarcoma was histopathologically revealed in only one patient [0.044%, 95% CI: (0.001-0.25)] after laparoscopic subtotal hysterectomy with morcellation. All six patients who were preoperatively diagnosed having uterine sarcoma underwent direct conventional cancer treatment. Histopathologic analyses confirmed four cases of uterine leiomyosarcoma, one high-grade undifferentiated uterine sarcoma, and one embryonal rhabdomyosarcoma. Altogether, seven women were diagnosed as having uterine sarcomas over this twelve-year period.

Conclusion: In our institution, the frequency of unsuspected uterine sarcomas was 1/2269 (0.044%) among women who underwent myomectomies and hysterectomies to treat presumed benign uterine fibroids. (J Turk Ger Gynecol Assoc 2017; 18: 62-6)

Keywords: Uterine fibroids, myomectomy, hysterectomy, uterine sarcoma

Received: 11 January, 2017 **Accepted:** 2 April, 2017

Introduction

The prevalence of unsuspected uterine sarcomas in those undergoing uterine fibroid surgery is of concern, and this issue is particularly important when laparoscopic power morcellation is used (1). Unintentional morcellation of uterine sarcomas can occur if a patient is misdiagnosed as having uterine fibroids or when a uterine sarcoma is found within a "fibroid" uterus. Preoperative diagnoses of uterine sarcomas are still difficult despite the implementation of various diagnostic methods, including biochemical and immunologic markers, imaging modalities, and ultrasound-guided core needle biopsies (2-5). Diagnostic challenges can delay the accurate diagnosis of uterine sarcoma and may lead to inappropriate surgical procedures such as morcellation. The inadvertent morcellation of an undiagnosed uterine sarcoma can cause upstaging of a cancer and worsen the prognosis of the patient (6, 7).

Another potential problem is that a concern over the potential presence of sarcoma may decrease the frequency of laparoscopic surgeries to patients with uterine fibroids due to the risk associated with uterine sarcomas, which may negatively influence clinical outcomes. Minimally invasive surgery is offered to many patients with uterine fibroids because of its advantages over open surgery, which include less intraoperative blood loss, a reduced chance of postoperative wound infection, less post-operative pain, and shorter convalescence times (8). Thus, this study aimed to evaluate the frequency of postoperative histologic diagnoses of uterine sarcoma following myomectomy or hysterectomy for presumed benign uterine fibroids. Additionally, this study analyzed the clinical

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and immunohistopathologic characteristics of all uterine sarcoma cases during a twelve-year period in our clinic.

Material and Methods

Data were collected retrospectively from the records of patients with uterine fibroids and uterine sarcomas treated between 2003 and 2015. The database included data from patients who signed an informed consent form allowing the use of their specimens and clinical data for research purposes. In compliance with ethical standards and local data protection regulations of the University Hospitals Schleswig-Holstein, anonymous data were generated for statistical analysis.

The files of patients who underwent hysterectomies and myomectomies for presumed benign uterine fibroids were reviewed according to the International Classification of Diseases code (D25) in combination with at least one German procedure classification code. Demographic and clinical data were only collected for women with uterine sarcomas and were not collected for women with only uterine fibroids. All cases of uterine sarcoma were assessed based on the morphologic codes of the International Classification of Diseases for Oncology, third edition (ICD-O-3). Uterine carcinosarcomas were not included in this study because they are no longer classified as a subtype of uterine sarcoma but instead are considered as uterine carcinomas. Unexpected sarcomas were defined as cases where uterine sarcoma was confirmed via postoperative pathologic analysis, in which it was not suspected preoperatively and there was no clinical preoperative suspicion or indication of malignancy. The staging of uterine sarcomas was performed based on the updated International Federation of Gynecology and Obstetrics Classification 2009. The following variables were retrieved from the medical records of the women who were diagnosed as having uterine sarcomas: patient age, body mass index (BMI), clinical symptoms, image modalities, intraoperative frozen-section examination results, surgical procedures performed, additional treatment, survival status, histologic evaluation and the results of immunohistochemical analyses, which included smooth muscle actin (SMA), CD 10, CD117, CEA, CA 19-9, SCC, Ki67, CA125, p53 vimentin, desmin, calponin, actin, h-caldesmon, estrogen receptors (ERs), progesterone receptors (PRs) and mitotic index measurements.

Statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS, version 18.0). Data are presented as the mean and standard deviation for continuous variables and as percentages for categorical variables. To calculate the 95% confidence intervals (CIs) for the proportion of patients in each category based on the binomial distribution, the Clopper-Pearson Exact method was used.

Results

Between 2003 and 2015, 2269 women received a preoperative diagnosis of presumed benign uterine fibroids. Of these, 938 (41.3%) women had myomectomies and 1331 (58.7%) women had hysterectomies, only one patient was postoperatively diagnosed as having endometrial stromal sarcoma (ESS) based on a pathohistologic analysis; the patient was aged 48 years and her BMI was 26.5 (kg/m^2) at the time of diagnosis, and she reported hyper and polymenorrhea. The patient's medical history was otherwise unremarkable. Ultrasound examination showed a hypoechogenic lesion (8.5 cm) with a clear borderline on the left posterior wall of the uterus. Physical examination of the external genitalia, vagina and cervix showed no abnormalities. Pelvic examination revealed a uniformly enlarged uterus, and no adnexal masses were palpated. The primary diagnosis was symptomatic transmural leiomyoma. The patient underwent a laparoscopic subtotal hysterectomy (LSH) with morcellation. The final pathohistologic results detected ESS, and the specimen weighed 294 g. Immunohistochemical analysis showed the following results: CD10(+), desmin(+), SMA(−), actin(−) and 5% Ki67(+). Furthermore, immunohistochemical assays for ERs, PRs, and p53 showed the following results: ER (+++), PR (+++) and p53 (−). Two weeks after the initial surgery, a laparotomic removal of cervical stump with bilateral salpingo-oophorectomy and an omentectomy was performed. The final pathologic report described no signs of any metastatic lesions.

Six patients who were diagnosed preoperatively as having suspected uterine sarcoma were treated and followed up according to the treatment protocol for uterine sarcomas (see Table 1).

The four women diagnosed as having uterine leiomyosarcoma (ULMS) were postmenopausal, and their dominant presenting symptom was postmenopausal bleeding. The mean age of the women with ULMS at the time of diagnosis was 73.7±3.9 years (range, 68-79 years), and their mean BMI was 27.2±3.7 kg/m^2 (range, 22.2-30.8 kg/m^2). Two of these women had advanced-stage ULMS with multiple metastases at the time of diagnosis. Preoperative biopsy confirmed the suspicion of uterine sarcoma. Moreover, preoperative diagnostic testing resulted in a high clinical suspicion of uterine sarcoma due to the patients' postmenopausal age, clinical factors, rapidly growing uterine mass, and the irregular appearance of the tumors detected via ultrasonographic examination, computerized tomography (CT) or magnetic resonance imaging (MRI) scans. Intraoperative "frozen section" analyses were performed, and the suspicion of malignancy was confirmed in each case. The results show that tumor cells were positive for calponin, SMA, and CD117, and that the proliferative activity of Ki-67 was elevated. Patients diagnosed as having ULMS were treated according to the

Table 1. Cases of uterine sarcoma and endometrial stromal sarcoma in patients treated between 2003 and 2015 among 2297 patients undergoing surgery for uterine fibroids

No	Age (y)	BMI (kg/m²)	Primary diagnosis at biopsy	Surgery	Uterine weight (g)	Pathohistologic diagnosis	Stage	Treatment	Current status (2016)
1	79	30.8	Uterine sarcoma or LMs	TAH/BSO	1228	ULMS coexisted LMs	IA	Chemotherapy	Alive (recurred)
2	76	22.2	Uterine sarcoma or LMs	TAH/BSO, PPALND	1118	ULMS coexisted LMs	IIB	Chemotherapy	Alive (recurred)
3	68	29.2	Uterine sarcoma	TAH/BSO	840	ULMS	IIIA	Chemotherapy	No information (multiple metastases)
4	72	26.6	Uterine sarcoma	TAH/BSO	308	ULMS	IIB	Chemotherapy	Alive (multiple metastases)
5	49	26.5	Uterine fibroid, No biopsy performed	LASH, then laparotomy (CSR, BSO, omentectomy)	294	ESS	IA	Hormonal therapy	Alive
6	48	24.4	Uterine sarcoma or LMS	TAH/BSO	398	HGUS	IB	Chemotherapy	No information
7	67	34.6	Uterine sarcoma	TLH/BSO	300	ERMS	IA	Chemotherapy	Deceased (recurred)

BMI: body mass index; ULMS: uterine leiomyosarcoma; LM: leiomyoma; ESS: endometrial stromal sarcoma; HGUS: high-grade undifferentiated uterine sarcoma; ERMS: embryonal rhabdomyosarcoma; TAH: total abdominal hysterectomy; LSH: laparoscopic supracervical hysterectomy; TLH: total laparoscopic hysterectomy; CSR: cervical stump resection; BSO: bilateral salpingo-oophorectomy; PPALND: pelvic and para-aortic lymphadenectomy

treatment guidelines for ULMS, which include an exploratory laparotomy with radical hysterectomy and bilateral salpingo-oophorectomy. The mean uterus weight of women with ULMS was 873.5±410.8 g (range, 308-1128 g). In two patients, ULMS coexisted with leiomyoma. Definitive diagnoses of uterine sarcoma were obtained through histologic and immunohistochemical analyses. The immunohistochemical results were positive for SMA, CD 10, desmin, and h-caldesmon, and they indicated a high proliferative activity of Ki67. The mean mitotic index for the ULMS cases was 35.75±12.81 mitoses/HPF (range, 22-54).

A woman aged 48 years with high-grade undifferentiated uterine sarcoma (HGUS) presented to the emergency unit with acute abdominal pain and abnormal uterine bleeding. Her initial diagnosis was uterine fibroids. A hysteroscopy was performed to clarify the cause of bleeding. It was noted that the surface of the uterine fibroid observed via hysteroscopy was irregular, and the histologic analysis indicated HGUS. In addition to these results, a CT of the abdominal cavity revealed a 6x7-cm intramural tumor, no enlarged lymph nodes, and no evidence of abdominal metastases. Tumor markers CEA, CA 19-9, SCC were within normal ranges, but the CA125 level was elevated (230.5 units/mL). Consequently, an open hysterectomy with bilateral salpingo-oophorectomy and omentectomy was performed. The final pathologic report described no signs of any metastatic lesions. The weight of the uterus was 398 g, the size of the tumor was 5 cm, and the mitotic index was 12 mitoses/10 HPF.

A woman aged 67 years with embryonal rhabdomyosarcoma (ERMS) also had polycystic kidney disease and renal failure (hemodialysis since 2011), which resulted in secondary anemia and hyperparathyroidism. Her BMI was 34.6 kg/m², and she had postmenopausal uterine bleeding. An endocervical curettage biopsy was performed, and the initial pathologic examination indicated HGUS. MRI revealed a heterogeneously enhanced huge mass, measuring approximately 15×10 cm in diameter, possibly arising from the uterine corpus and showing no definite evidence of metastases in the lymph nodes or other organs. A total laparoscopic hysterectomy with salpingo-oophorectomy was performed. The weight of the uterus was 300 g, and the size of the tumor was 5 cm. An immunohistochemical examination concluded that the ERMS cells were characteristically positive for vimentin and desmin, but were negative for CD10, calponin, and SMA. The frequency

of unsuspected ULMS, HGUS, and ERMS was 0/2269. For ESS, it was 1/2269 [0.044%, 95% CI: (0.001-0.25)] among the women in this study who underwent myomectomies and hysterectomies for the treatment of presumed benign uterine fibroids. The total number of patients with uterine sarcoma was seven during the twelve-year period. Out of them, 6 were diagnosed through biopsy prior and during their larger surgical intervention, as described in Table 1. Only one ESS was diagnosed after a laparoscopic subtotal hysterectomy.

Discussion

Currently, there is no clear agreement among the available datasets on the prevalence of postoperative detection of uterine sarcoma associated with surgery for uterine fibroids. In our study, the frequency of unexpected ULMS in patients who underwent surgery for uterine fibroids was 0% (0/2269). Picerno et al. (9) presented a retrospective study that showed no cases of ULMS among 1004 women who underwent surgery for uterine fibroids. In addition, Pritts et al. (10) found a low percentage of these cases from a comprehensive analysis of 133 studies, in which there was a 0.051% prevalence of unsuspected ULMS among more than 30,000 women. A recent study from the Food and Drug Administration (FDA) that analyzed 12,402 women who underwent surgery for uterine fibroids estimated that the prevalence of unexpected ULMS was 0.064% (11). In a retrospective analysis of 8720 women who underwent laparoscopic supracervical hysterectomies for presumed uterine fibroids, Bojahr et al. (12) found that the postoperative histologic analyses revealed two cases of ULMS (0.023%). Recently, Kho et al. (13) conducted a prospective cohort study and found that among 10,119 women who underwent a hysterectomy for benign gynecologic indications, five unexpected cases of ULMS were identified, corresponding to a 0.049% incidence rate for unexpected ULMS.

The present study found that the frequency of unexpected ESS among women who underwent surgery for presumed benign uterine fibroids was 0.044% (1/2269). Other studies have reported the following statistics: Graebe et al. (14) identified three unexpected ESS cases among 1361 patients who underwent surgery for uterine fibroids (0.22%), Bojahr et al. (12) reported four unexpected cases of ESS among 10,119 laparoscopic supracervical hysterectomies (0.037%), and Kho et al. (13) reported two cases of unexpected ESS among 10,119 hysterectomies (0.019%).

Overall, our study found 6 cases of preoperatively suspected uterine sarcoma and one unsuspected case among 2269 patients undergoing myomectomy and hysterectomy who had indications of benign uterine fibroids during a 12-year period. Kho et al. (13) reported 64 cases of preoperatively suspected uterine sarcoma and 9 cases of unexpected uterine sarcoma among 10,119 hysterectomies performed due to benign indications within a 13-year period.

The prevalence of unexpected uterine sarcomas among patients undergoing uterine fibroid surgery appears to be low, but morcellation can negatively impact the patient's future with regard to the recurrence of disease and survival. Bogani et al. (15) concluded that open power morcellation was associated with a 3- and 4-fold increase in overall and intra-abdominal recurrence of ULMS, respectively, as well as a 2.5-fold decrease in overall survival compared with patients whose tumors were removed intact. Guyon et al. (16) concluded that morcellation might expose patients to increased morbidity in cases of unrecognized malignancy due to the intra-abdominal dissemination of cancer.

Selecting the method of surgical treatment for patients with large uterine fibroids currently poses a dilemma for gynecologists due to the risks associated with myomectomy and morcellation in pre-malignant and malignant uterine tissue. Until a modified morcellation method, such as contained morcellation, can be agreed upon and implemented for clinical practice, it is important to consider the findings of a recent retrospective study. The study by Harris et al. (17) included a comparative analysis of 18,299 hysterectomies performed in the 15 months leading up to and the 8 months after the FDA safety communication was released in April 2014. The results show that the application of abdominal (1.7%) and vaginal hysterectomies (2.4%) increased, whereas there was a 4.1% decline in laparoscopic hysterectomies. An overall higher rate of complications was observed (excluding blood transfusions) from 2.2 to 2.8% after the date of the FDA safety communication, and the rate of hospital readmissions within 30 days also increased from 3.4 to 4.2% (17).

To decrease the risks of unintended morcellation of uterine sarcomas, a preoperative differential diagnosis between uterine fibroids and uterine sarcoma should be performed by utilizing a combination of clinical findings, image modalities, and immunologic and biochemical factors.

The main limitations of our study are its retrospective design and that it is a single-center study. Also, the results of post-operative screening for uterine cancers after myomectomy and cervical cancer screening after subtotal hysterectomy were not analyzed. The strength of this study is that the demographic data, detailed clinical data, and specific immunohistochemical markers were available for all cases of uterine sarcoma.

Conclusion

The frequency of unsuspected uterine sarcoma was 1/2269 [0.044%, 95% CI: (0.001-0.25)] among the women in this study who underwent myomectomies and hysterectomies for the

treatment of presumed benign uterine fibroids. The risk of uterine sarcoma after a preoperative selection of women with presumed benign fibroids appears to be very low.

Ethics Committee Approval: *Approval was not required because we used an anonymous database.*

Informed Consent: *Written informed consent was obtained from all patients who participated in this study.*

Peer-review: *Externally peer-reviewed.*

Author Contributions: *Concept – L.M.; Design – L.M.; Supervision – L.M., A.D.; Materials – N.M.; Data Collection and/or Processing – L.M., K.A., A.D.; Analysis and/or Interpretation – K.A., A.D., Literature Review – L.M., K.A.; Writer – K.A., Critical Review – N.M., A.D., I.A.*

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To clip or not to clip the breast tumor bed? A retrospective look at the geographic miss index and normal tissue index of 110 patients with breast cancer

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Abstract

Objective: Planning of breast radiation for patients with breast conserving surgery often relies on clinical markers such as scars. Lately, surgical clips have been used to identify the tumor location. The purpose of this study was to evaluate the geographic miss index (GMI) and the normal tissue index (NTI) for the electron boost in breast cancer treatment plans with and without surgical clips.

Material and Methods: A retrospective descriptive study of 110 consecutive post-surgical patients who underwent breast-conserving treatment in early breast cancer, in which the clinical treatment field with the radiologic (clipped) field were compared and GMI/NTI for the electron boost were calculated respectively.

Results: The average clinical field was 100 mm (range, 100-120 mm) and the clipped field was 90 mm (range, 80-100 mm). The average GMI was 11.3% (range, 0-44%), and the average NTI was 27.5% (range, 0-54%). The GMI and NTI were reduced through the use of intra-surgically placed clips.

Conclusion: The impact of local tumor control on the survival of patients with breast cancer is also influenced by the precision of radiotherapy. Additionally, patients demand an appealing cosmetic result. This makes "clinical" markers such as scars unreliable for radiotherapy planning. A simple way of identifying the tissue at risk is by intra-surgical clipping of the tumor bed. Our results show that the use of surgical clips can reduce the diameter of the radiotherapy field and increase the accuracy of radiotherapy planning. With the placement of surgical clips, more tissue at risk is included in the radiotherapy field. Less normal tissue receives radiotherapy with the use of surgical clips. (J Turk Ger Gynecol Assoc 2017; 18: 67-71)

Keywords: Breast cancer, clips, radiotherapy, geographic miss index, normal tissue index, boost, reduction

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Introduction

Wide local excision is the current surgical treatment for most early breast cancers. With the oncologic benefit taken for granted, the cosmetic results are becoming more important (1). In today's practice, surgeons 'hide' scars around the areola, laterally in the lower axilla or underneath the breast. Guidelines recommend that breast conserving surgery is accompanied by whole breast irradiation. The benefit of guideline-adherent radiotherapy has been clearly demonstrated (2-5); however, clinical 'landmarks' (i.e. scars) for radiotherapy treatment planning are becoming less reliable. Therefore, the use of surgical clips has been discussed in the last decade (6-9). Though practical, the use of clips has not been established routinely in some centers, as such proof for the dosimetric advantage is still pending. To estimate the accuracy of radiotherapy treatment, the geographic miss index (GMI) and the normal tissue index

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(NTI) for the electron boost are used (Figure 1). Ideally, the GMI and the NTI should be as low as possible.

Material and Methods

Between November 2008 and December 2010, 110 patients with breast cancer who underwent breast conserving surgery with intra-mammary clips and axillary lymph node dissection (ALND) or sentinel node biopsy (SNB) were treated at the Breast Centre Radiotherapy Department with Adjuvant Radiotherapy.

To determine the GMI and NTI in our Breast Cancer Centre, we retrospectively analyzed the radiotherapy treatment plans of 110 patients who underwent breast conserving surgery followed by radiotherapy between 2008 and 2010.

Statistical analysis

GMI is defined as the percentage of the radiologically-defined field (RF) that is not predicted using clinical landmarks [shared field=SF; GMI=(RF-SF)/RF]. This area represents tissue within the tumor bed, at high risk of local recurrence, which would not have been included in a clinically-marked electron boost field. NTI measures the percentage of the clinically-marked field (CF) that is not part of the RF ('simulation' field'), which receives high-dose treatment [NTI=(CF-SF)/CF].

In our standard surgical protocol, at least three clips are inserted at the margins of the excision cavity and additionally in areas of tumor extension. The volume that the clips cover encloses the former tumor volume. The walls of the excision cavity are approximated at the time of surgery.

Descriptive statistics were calculated with SPSS for Windows (IBM Corp. Released 2010. IBM SPSS Statistics for Windows, Version 19.0. Armonk, NY: IBM Corp) and are given as means, standard deviation (SD), minimum (Min) and maximum (Max).

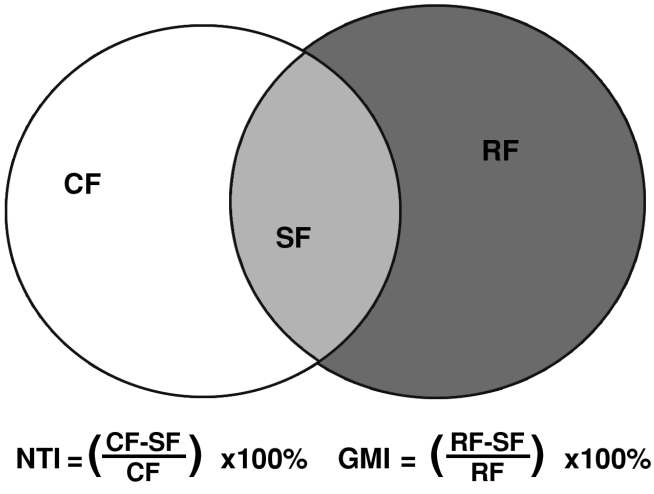

Figure 1. Geographic miss index (GMI) and normal tissue index (NTI): Clinical field (CF); shared field (SF); radiological field (RF)

Radiation therapy

External beam radiotherapy was planned four to six weeks after completion of chemotherapy or surgery, depending on the clinical situation. Postoperative radiation is given by using a linear accelerator (Elekta Precise) from two (up to four) opposed tangential breast fields, thereby providing a cumulative radiation dose of 50 Gy photons as recommended by the International Commission on Radiation Units&Measurement (10). Mixed energies of 6- and 10-MV photons were used in patients with large breasts. The therapy was administered over a five-week period using 2-Gy daily fractions and a wedge compensator to achieve a uniform dose. The planned target volume encompassed the entire ipsilateral breast. Photon radiation of the entire breast was followed by an electron boost, usually delivering an additional dose of 10 Gy, also in 2-Gy daily fractions.

Clinical markers (scar, memory of patient, hematoma) were used to plan a clinical field area for the electron boost. A 100-mm diameter metal ring was then placed on the breast. X-ray imaging was used to show the clips. On a treatment plan simulation, the clips were outlined and a 30-mm margin was added. The RF ring was then placed around this window. The diameter was taken and the GMI and NTI were calculated.

The study is a descriptive study for standard treatment and did not require ethical approval.

Results

A total of 110 consecutive patients who underwent breast conserving surgery were included in the study. The average age was 58 years (28-87 years). The average tumor diameter was known in 97.3% of cases. One patient had a complete remission under neoadjuvant treatment and two patients' final histology data were missing from the database. The diameters ranged from 3 to 52 mm (average 19 mm). After surgery, 75 patients were classified as T1, 31 as T2, two patients had a T4b, and a further two had ductal carcinoma in situ (DCIS). All patients completed the surgical treatment prior to radiotherapy. Ninety-three patients had positive hormone receptors (16 negative) and 19 had herceptin receptor over expression (86 negative, five unknown; further details are provided in Table 1).

The average follow-up was 41 months (30-57 months). One patient had a local recurrence, two had local and distant recurrence, and two had distant recurrences. Of these patients, two died of a tumor-related cause (distant metastasis). One patient died unrelated to the tumor diagnosis (traffic

accident). One patient was diagnosed as having contra lateral breast cancer after 47 months. One hundred six patients had hormone therapy +/- chemotherapy. Two patients had a large (>50 mm), high-grade DCIS and therefore hormonal or chemotherapy was not recommended. No further treatment information was available for two cases. After excluding these 4 patients from further analysis, the average clinical field was 100 mm (range, 100-120 mm) and the radiologic field was 90 mm (range, 80-100 mm). The average GMI was 11.3% (range, 0-44%), and the average NTI was 27.5% (range, 0-54%) (see Table 2).

Table 1. Overview of the tumor data, resection margins and lymph nodes, TNM classification used for tumor size (T), node involvement (N), and grading (G)

Variable	No of patients (%)
Nodes	
N0	74 (67%)
N1+	36 (33%)
More than 3+ LN	7 (6%)
Tumor size	
Tis	2 (2%)
T1	75 (68%)
T2	31 (28%)
T3+	2 (2%)
Estrogen receptor	
Positive	90 (82%)
Negative	16 (15%)
Unknown	4 (4%)
Progesterone receptor	
Positive	83 (75%)
Negative	23 (21%)
Unknown	4 (4%)
Her2neu	
Positive	19 (12%)
Negative/unknown	91 (88%)
Grading	
G1	20 (18%)
G2	50 (45%)
G3	39 (35%)
Unknown	1 (1%)
Reexcision	16 (15%)
Final margin status	
<2 mm	21 (19%)
2-5 mm	50 (45%)
>5 mm	39 (35%)

Table 2. Patients miss indices in quartile distribution

Indices	0-24.9%	25-49.9%	50-74.9%	75-100%
Number for GMI	94	16	0	0
Number for NTI	37	71	2	0
GMI: geographic miss index; NTI: normal tissue index				

Discussion

Local disease control is associated with overall survival (11). Efforts have been made to reduce the rate of local recurrence with surgical, systemic therapy, and radiotherapy (12). The influence of systemic therapy on local and distant recurrence has been accepted (13, 14). The surgical resection margin has also been identified as a marker for recurrence rates and the influence of boost radiation (15, 16). The accuracy of the boost can be judged by the GMI and NTI. These indices measure the accuracy of radiotherapy towards the tumor bed. Traditionally, the surgical scar has been used to locate the tumor bed, but breast surgeons and radiation oncologists (17) are becoming more and more concerned about the cosmetic results of their surgery. This results in a scar being a very poor clinical marker for tumor location (6, 18). Patients memory regarding the tumour location is also variable. Fifteen (14%) of our patients had a GMI of 25% or more. This number was lower than the GMI published by Harrington et al. (19). One of the reasons might be the surgical technique of placing the incision immediately over the tumor, which is the common approach of our breast surgeons. Harrington et al. (19) published a GMI depending on the margins between 32.9% (1-cm margin) and 18.6% (3-cm margin) and gave an NTI between 14.6% and 9.7%. Kirby et al. (20) had a GMI of 37% and an NTI of 9%. Twenty-seven cases had a GMI of 0%, meaning that the 'simulation' field was completely covered by the clinical field. With a smaller diameter, the radiologic field resulted in more accurate targeting. In our case series, the NTI was 0% in two patients, with an NTI on average of 27.5%. This shows that even with a good clinical field, one third of high-risk tissue might be missed.

In addition to the above discussion of GMI and NTI, which is based on 2D radiographs, clips offer a further advantage. The dose distribution of the electron boost can be calculated on the basis of computerized tomography (CT) images and 3D planning software. The visibility of the clips allows to select the optimum electron energy that is high enough to cover the clips, but as low as possible to minimize the dose in the lung.

The German Society of Radiooncology practical guidelines for radiotherapy of Breast Cancer I (21) gave the option of placing intra-operative clips, and additionally using presurgical mammography and CT-scans or ultrasound to locate the tumor

bed. In the current version, no recommendation is published (22). The S3 guidelines recommend the use of intra surgical clips (13).

One of the limitations of our study is the use of 'classic' external beam radiotherapy. Though it is still commonly in use, the forefront in radiotherapy is shorter treatment protocols, intra-surgical radiation and others (23). Also, it needs to be considered that the intention of the paper was not to provide information on disease-free survival even though the number of patients was fair, but to show the necessity of marking the tumor bed with clips in order to make radiotherapy more precise. The follow-up time was only adequate for early relapses.

Our data clearly demonstrate that with the use of clips in CT radiotherapy planning, the diameter of the field can be reduced by 10 mm on average while increasing the accuracy of the radiotherapy treatment compared with clinical placement with a larger diameter. We think that this can be stated even with such a small case series. Despite this, the common use of intra-surgical clips is not yet established.

Ethics Committee Approval: *Ethics committee approval was not needed according to the ethics committee of the university Heidelberg as the study is a retrospective analysis of existing treatment data.*

Informed Consent: *Written informed consent was obtained from patients who participated in this study.*

Peer-review: *Externally and internally peer-reviewed.*

Author Contributions: *Concept – G.W., A.R., F.E.; Design – P.M., G.W., A.R., F.E.; Supervision – A.W., A.R., G.W.; Materials – P.M., A.R., F.E.; Data Collection and/or Processing – A.D., N.D., F.E.; Analysis and/or Interpretation – J.W., F.E., N.D., A.W.; Literature Review – F.E., A.D.; Writer – F.E., G.W.; Critical Review – A.R., J.W., A.W.*

Conflict of Interest: *No conflict of interest is declared by the authors.*

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The level of using family planning methods and factors that influence the preference of methods in the Konya-Meram area

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Abstract

Objective: To determine the level of contraceptive method use and factors that influence the preference of method among women of reproductive age that live in Meram, the central district of Konya.

Material and Methods: Parameters such as age, duration of marriage, number of pregnancies and births, socioeconomic status, education level, and preferred contraceptive method of women who presented to the family planning outpatient clinic of our hospital over a five-year period between January 1st, 2010, and December 31st, 2015, were recorded and evaluated.

Results: The mean age of the women was identified as 31.57±8.14 years, the mean duration of marriage was 10.3±8.14 years, the mean number of births was 1.92±1.01, and the mean number of children was 1.83±0.90. Among the women in the study group, 65% were high school graduates, 88.92% had social security, and 82.84% were in the middle-income group according to their financial status. Only 31 patients were not married officially. It was observed that the most preferred method was intrauterine device (IUD), and the least preferred method was subcutaneous implant (SI). The use of IUD, oral contraceptives, and SI increased as the socioeconomic status and educational level improved ($p<0.05$).

Conclusion: To ensure that women of reproductive age use effective family planning methods, the education levels and socioeconomic status of women must be improved. (J Turk Ger Gynecol Assoc 2017; 18: 72-6)

Keywords: Family planning method, education level, financial status, reproductive period

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Introduction

Family planning is defined as the health care service that has the primary goal of improving maternal and child health, and preventing maternal and infant deaths, thereby enabling women of reproductive age to have as many children as they wish while providing adequate care (1). Family planning services are within the scope of "Basic Health Services" and its purpose is not to limit the number of individuals in the family but to provide couples with help and counseling about having children (2).

Maternal and infant mortality rates are parameters that are developmental indicators and these rates are higher in developing countries compared with developed countries. A gap of less than two years between births significantly affects maternal health and increases the maternal death rate by increasing the probability of high-risk pregnancy (3, 4). In societies with higher education levels and socioeconomic status, marriage, pregnancy and fertility occur at older ages, and consequently the need for contraceptive methods increases. Using contraceptive methods prevents young- and old-age pregnancies and high fertility, and as the spacing between births increases, the number of high-risk pregnancies decreases and the maternal death rate also drops (5). Couples are being provided with the information and services needed to protect women's and children's health, and families have

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been educated effectively about fertility for the last 40 years in our country.

The total fertility rate reflects the mean number of children a woman may give birth to during her reproductive period (15-49 years of age). According to the Turkey Demographic and Health Survey, the birth rate was 2.18 in 2014, and 2.14 in 2015 (6). In other words, the mean number of children a woman might give birth to during her reproductive period is 2.14. This shows that this is above the population renewal rate of 2.1. According to these data, approximately 75% of women of reproductive age use any one of the contraceptive methods, but unfortunately, the ratio of effective method use is only approximately 50% (6). In this study, it was aimed to identify the level of contraceptive method use and factors that influenced the preference of method among women of reproductive age who lived in the central district of Meram in Konya.

Material and Methods

This study was approved by the local ethics comitte of Konya Training and Research Hospital (reference number: 2016-10-01). The study was conducted in the Women's Diseases and Birth Clinic's Family Planning Polyclinic of Konya Training and Research Hospital over a five-year period between January 2010 and December 2015, and included 10,730 women who wanted to use a contraceptive method and gave their consent to participate in the study. After their gynecologic examination was performed, the women were asked to complete a survey that identified their descriptive characteristics such as age, duration of marriage, education level, socioeconomic status and social security, and fertility characteristics such as the number of pregnancies, births and miscarriages, and also included questions about the family planning method they used.

Statistical analyses were performed using SPSS 15.0 for Windows (SPSS, Chicago, IL, USA). The data studied were recorded as mean ± standard deviation, minimum-maximum. The Chi-square test was used for statistical analysis. Statistical significance was set at $p<.05$.

Results

The distribution of the age, education level, social security status, and socioeconomic status of the women included in the study are presented in Table 1. According to this, over the five-year period, 80% of the 10,730 women were aged 20 to 40 years. In the study group, 65% of the women were high-school graduates, 88.92% had social security, and 82.84% belonged to the middle-income group.

The mean age of the women was 31.57±8.14 years, and the mean duration of marriage was 10.03±6.71 years at the end of the study. The mean number of pregnancies was identified as 2.64±1.46, the number of births was 1.92±1.01, the number of miscarriages was 1.71±0.89, and the mean number of children was 1.83±0.90 (Table 2).

The distribution of family planning methods preferred by the women evaluated within the study is presented in Table 3. The most preferred method was intrauterine device (IUD) (37.38%), and this was followed by coitus interruptus (CI) (15.74%) and oral contraceptives (OCs) (15.65%), and the least preferred method was subcutaneous implant (SI) (3.17%).

In Table 4, the family planning methods used are presented in association with education levels. Women with primary school

Table 1. The distribution of women according to the demographic features

Features	Number (n=10,730)	%
Age groups (years)		
15-19	360	3.35
20-24	1981	18.47
25-29	2889	26.93
30-34	1928	17.97
35-39	1442	13.44
40-44	1059	9.86
45-49	1071	9.98
Education level		
Primary education	2032	18.94
High school	7048	65.69
University	1650	15.37
Social security status		
Available	9541	88.92
Non-available	1189	11.29
Marital status		
Married	10,409	97.01
Single	31	2.99
Economic status		
Lower level	850	7.92
Intermediate level	8889	82.84
High level	991	9.24

Table 2. The fertility data of the women

Variables	Minimum/ Maximum	Mean ± Standard deviation
Age (years)	19-49	31.57±8.14
Duration of marriage	2-32	10.03±6.71
Number of pregnancies	0-6	2.64±1.46
Parity number	0-5	1.92±1.01
Number of miscarriages	0-4	1.71±0.89
Number of living children	0-5	1.83±0.90

level education mostly preferred IUD and CI, whereas women with high-school or university level education mostly preferred IUDs and OCs. SI was mostly preferred by women who were university graduates (p<.05).

When the birth control method preferred by the patients was assessed in accordance with the socioeconomic status, it was observed that women with low and middle-income levels preferred IUD and CI, those with better income levels preferred OCs and IUD (p<.05). SI was mostly used as a family planning method by women with middle-level income (Table 5).

Discussion

In our study, it was aimed to identify the association between education level and socioeconomic status, and the contraceptive methods preferred by interviewing 10,730 women who presented to our hospital's family planning polyclinic over five years between January 2010 and December 2015. The mean age of the women was 31.57±8.14 years, the duration of marriage was 10.03±6.71 years, the most preferred method was IUD, and the least preferred method was SI. It was identified that the use of effective modern methods, IUDs and OCs, increased as the education level and socioeconomic status of the women improved. It was identified that the use of IUDs and OCs increased as the education level and socioeconomic status of the women improved.

There are different data about the most preferred family planning methods in the existing literature. Kitapcıoğlu and Yanıkkerem (7) and Özdemir et al. (8) reported that IUDs (48.8%) were the most commonly used contraceptive method (48.8% and 50.7%), but Yıldırım et al. (9) reported condoms (39.1%) as the most commonly used contraceptive method.

In a study performed by Sak et al. (10) on the relationship between education level and contraceptive method preference, CIs (42.1%) were the most commonly used method and they identified that the use of IUDs and OCs increased as the level of education increased.

According to the data of the Turkey Demographic and Health Survey and the Institute of Population Studies, modern contraceptive methods are more preferred than conventional methods in Turkey today. The most common conventional method used was CI with a ratio of 25%, and the most common modern method used was IUD (11, 12).

The study conducted by Kaya et al. (13) with 303 women of reproductive age to demonstrate the level of contraceptive method use showed that the most common methods were CIs (23.1%), IUDs (21.5%), condoms (19.8%), and OCs (13.9%), and it was shown that the ratio of modern and effective contraceptive method use increased as the socioeconomic status improved.

Table 3. The distribution of family planning methods used by the women

Family planning methods	Number (n=10,730)	%
CI	1689	15.74
IUD	4011	37.38
OC	1679	15.65
Condom	1371	12.8
Depot progesterone	969	9.03
BTL	671	6.25
SI	340	3.17

CI: coitus interruptus; IUD: intrauterine device; OC: oral contraceptive; BTL: bilateral tubal ligation; SI: subcutaneous implant

Table 4. The distribution of the birth control methods preferred by the women with respect to education level

Education level (n=10,730)	CI (n=1689)	IUD (n=4011)	OC (n=1679)	Condom (n=1371)	DP (n=969)	BTL (n=671)	SI (n=340)	p
Primary school (n=2032) (%)	520 (25.60)	531 (26.13)	339 (16.68)	311 (15.30)	219 (10.77)	100 (4.92)	12 (0.60)	
High school (n=7048) (%)	949 (13.47)	3140 (44.55)	1090 (15.47)	870 (12.34)	541 (7.68)	349 (4.95)	109 (1.54)	<.05
University (n=1650) (%)	220 (13.33)	340 (20.60)	250 (15.15)	190 (11.51)	210 (12.73)	221 (13.40)	219 (13.28)	

CI: coitus interruptus; IUD: intrauterine device; OC: oral contraceptive; BTL: bilateral tubal ligation; SI: subcutaneous implant; DP: depot progesterone

Table 5. The distribution of birth control methods preferred by the women with respect to their socioeconomic status

Economic status (n=10,730)	CI (n=1689)	IUD (n=4011)	OC (n=1679)	Condom (n=1371)	DP (n=969)	BTL (n=671)	SI (n=340)	p
Lower level (n=850) (%)	204 (24.00)	326 (38.35)	17 (2.00)	101 (11.88)	97 (11.41)	97 (11.41)	8 (0.95)	
Intermediate level (n=8889) (%)	1471 (16.55)	3463 (38.96)	1421 (15.98)	1080 (12.45)	771 (8.68)	462 (5.19)	221 (2.49)	<.05
High level (n=991) (%)	14 (1.42)	222 (22.41)	241(24.32)	190 (19.18)	101 (10.14)	112 (11.32)	111 (11.21)	

CI: coitus interruptus; IUD: intrauterine device; OC: oral contraceptive; BTL: bilateral tubal ligation; SI: subcutaneous implant; DP: depot progesterone

In our study, the most preferred contraceptive methods were IUDs (37.38%), CIs (15.74%), OCs (15.65%), condoms (12.8%), depot progesterone (9.03%), bilateral tubal ligation (6.25%), and SIs (3.17%), respectively.

The conventional CI method was the second most common method used in our study. Although its ease of use and lack of cost appear to be the advantages of this method, which was once widely used by most societies, its chance of success is rather low in comparison with other methods because it effectiveness depends on the motivation and adjustment of couples.

IUDs are one of the preferred modern methods and its ease of use, long-lasting effect, high-reliability rates, the possibility of use during the breastfeeding period, and the fast return of fertility once the method is abandoned are among its very important advantages; conditions such as irregular menstruation are its disadvantages.

OCs are another modern and effective method with similar advantages to IUDs and have the additional advantage of not causing irregular menstruation. Its only disadvantage may be the probability of forgetting to take the pill. This negative aspect may be counteracted by motivation to some extent (14). The use of OCs was in third place with a ratio of 15.65%.

In parallel with the increase of the frequency of sexually-transmitted diseases, the use of condoms has also increased. In a study conducted by Inal (15), the rate of condom use in our country was reported as 5%, and it was reported as 11.3% in the study conducted by Çınar et al. (16). In our study, the ratio of condom use was reported as the fourth most common method used, similar to the second study.

In the study conducted by Civi and Bodur (17) in 1991 in Konya, which was performed by interviewing 265 women, it was identified that 78.9% of women were protected from pregnancy and that 79.4% of these women used an effective method. The use of modern and effective contraception methods increased up to 85% in our study.

We observed that IUDs were the most preferred method of contraception in this particular region. This might be explained to some extent with their easy access and being covered by the social security system. In Turkey, Family Health Centers provide free IUDs; their installation and all gynecologic examinations are free in these centers. In contrast, OCs are not paid for by the social security system.

The importance of informing couples must not be forgotten to ensure that contraceptive methods do not fail. Even though audiovisual media has an important role in providing information and raising awareness, health care providers must also be devoted to education and counseling. Such an education and counseling service is most accessible and appropriate during the follow-up periods before and after giving birth (18). Women are particularly inclined towards contraceptive methods during the postpartum period and more sensitive and effective efforts made by health care providers during this period would provide benefit. Our study has the largest number of patients among the related studies in the current literature. The geographic region in which the participants resided represents typical Anatolia. Therefore, the results of this study may reflect Turkey in general.

In conclusion, choosing effective and reliable contraceptive methods is directly proportional to the education level and socioeconomic status of women. To ensure that women of reproductive age have higher ratios of access to contraceptive methods in addition to raising awareness via audiovisual media, health care workers should also be more sensitive and dedicated. Achieving healthy pregnancies by means of modern and effective contraceptive methods will help drop the maternal and infant death rates, which are among the key developmental indicators. In addition, studies directed to improving education levels and socioeconomic status of women of reproductive age are also required.

Ethics Committee Approval: *Ethics committee approval was received for this study from the local ethics committee of the Konya Training and Research Hospital (No: 2016-10-01).*

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Extraperitoneal lymph node dissection in locally advanced cervical cancer; the prognostic factors associated with survival

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Abstract

Objective: Surgical staging was recently recommended for the decision of treatment in locally advanced cervical cancer. We aimed to investigate clinical outcomes as well as factors associated with overall survival (OS) in patients with locally advanced cervical cancer who had undergone extraperitoneal lymph node dissection and were managed according to their lymph node status.

Material and Methods: The medical records of 233 women with stage IIb-IVa cervical cancer who were clinically staged and underwent extraperitoneal lymph node dissection were retrospectively reviewed. Paraaortic lymph node status determined the appropriate radiotherapeutic treatment field. Surgery-related complications and clinical outcomes were evaluated.

Results: The median age of the patients was 52 years (range, 26-88 years) and the median follow-up time was 28.4 months (range, 3-141 months). Thirty-one patients had laparoscopic extraperitoneal lymph node dissection and 202 patients underwent laparotomy. The number of paraaortic lymph nodes extracted was similar for both techniques. Sixty-two (27%) of the 233 patients had paraaortic lymph node metastases. The 3-year and 5-year OS rates were 55.1% and 46.5%, respectively. The stage of disease, number of metastatic paraaortic lymph nodes, tumor type, and paraaortic lymph node status were associated with OS. In multivariate Cox regression analyses, tumor type, stage, and presence of paraaortic lymph node metastases were the independent prognostic factors of OS.

Conclusion: Paraaortic lymph node metastasis is the most important prognostic factor affecting survival. Surgery would give hints about the prognosis and treatment planning of the patient. (J Turk Ger Gynecol Assoc 2017; 18: 77-84)

Keywords: Cervical cancer, extraperitoneal, lymph node

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Introduction

Cervical cancer is a major health problem worldwide and the most common cause of cancer-related death in women from developing countries. Survival and management of cervical cancer depends on the stage of the disease, which is determined by the principles of the International Federation of Gynecology and Obstetrics (FIGO) revised in 2009 (1). Five-year survival rates achieve 88-100% in stage Ia-b disease, whereas in advanced stage, it barely reaches 50%. Treatment of early-stage disease comprises mainly surgery, whereas higher stage disease is managed using chemoradiation. Although the staging system does not include lymph node involvement, radiation therapy principles are determined according to the extension of affected lymph nodes. Inaccuracy of clinical staging, which reaches 50-56%, makes pre-treatment nodal staging and future research about the topic more important (2).

With the additional finding of lymph node involvement as the most important prognostic factor for cervical cancer, assessment of lymphatic involvement has gained greater importance. Surgical evaluation of lymph nodes is a reliable method and may be performed either transperitoneally or extraperitoneally. Surgical staging of cervical cancer has been implemented commonly since the 1990s when the extraperitoneal technique

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was discovered because the transperitoneal approach was shown to increase postradiotherapy complications and thus morbidity such as urologic and gastrointestinal problems (3, 4). Extraperitoneal lymph node dissection with chemo-radiotherapy has been investigated heavily in patients with locally advanced cervical cancer, but in developing countries with low income, it brought about many difficulties in practice. Surgical staging in order to evaluate paraaortic lymph node status was recommended in the 2015 National Comprehensive Cancer Network (NCCN) guidelines in patients with locally advanced (stage Ib2-IVa) cervical cancer (5). Treatment modalities differ in patients with positive paraaortic lymph nodes. The data of long-term outcomes are required because surgical staging is recommended and used more frequently. This retrospective study aimed to investigate clinical outcomes as well as factors associated with overall survival (OS) in patients with locally advanced cervical cancer who underwent extraperitoneal lymph node dissection and were managed according to their lymph node status.

Material and Methods

In this retrospective study, 240 patients with locally advanced stage cervical cancer who had extraperitoneal lymph node dissection in the gynecologic oncology clinic from January 1998 to January 2013 were enrolled. Data about patient characteristics, treatment, histology, stage, and follow-up were collected from medical records. The study was approved by the local ethics committee (2016/216). All patients were clinically staged preoperatively in accordance with the FIGO staging system (1). Gynecologic examination under general anesthesia (all patients), cystoscopy, proctoscopy, and ultrasonography of the kidneys when involvement was suspected, were performed. Preoperative imaging methods were not standard for all; some had computerized tomography (CT), whereas some underwent magnetic resonance imaging (MRI). None of the patients had positron emission tomography-CT (PET-CT) data.

Lymph node dissection was performed via laparotomic extraperitoneal or laparoscopic extraperitoneal approach. Laparotomy (LPT) was performed through a left paramedian incision. The retroperitoneum was exposed by rolling the peritoneum medially till the psoas muscle and iliac vessels, bifurcation of the aorta, ovarian vessels and ureters were visualized. Paraaortic lymph nodes from the level of the common iliac bifurcation up to the level of the left renal vein were resected. Grossly enlarged (>2 cm) pelvic lymph nodes were also removed to improve the effect of radiotherapy. Laparoscopy (L/S) was performed using the technique described by Querleu et al. (6). Lymph nodes were defined macroscopically metastatic if they were palpable or of visible dimensions during the operation and positive in the pathology reports. In cases in which paraaortic lymph node metastasis was seen in frozen sections, scalene lymph node dissection was additionally performed.

In cases without paraaortic metastasis, external pelvic radiotherapy (5040 cGy) with intracavitary doses of 2800 cGy was performed. If the paraaortic metastasis was positive, 4500 cGy extended field radiotherapy was applied to the level of T_{12}-L_1. Concomitant chemotherapy was added to radiotherapy after the 2000s, which consisted of weekly cisplatin regimens (40 mg/m^2 of body surface area, 25 mg/m^2 in patients receiving paraaortic radiotherapy) intravenously with amifostine in some cases. Patients with scalene node metastasis were treated with chemotherapy plus palliative radiotherapy.

Patients were followed up every 3 months for 2 years, every 6 months until the fifth year following treatment, and yearly thereafter. In every follow-up, pelvic examination, abdominal ultrasonography, complete blood count, and blood chemistry were performed. Chest X-ray was performed yearly or in case of clinical suspicion. Thoracic and/or abdominal CT was requested when needed. The period from surgery to death or last visit was defined as OS. Follow-up time was evaluated as the time between surgery and the time of the patient's last examination (death or last visit).

Statistical analysis

The analysis of data was performed using SPSS for Windows, version 11.5 (SPSS Inc.; Chicago, IL, United States). OS and lifetime span were calculated according to Kaplan-Meier analyses and the log-rank test was used to determine factors that affected survival. Three- and 5-year survival rates, and expected lifetimes with 95% confidence intervals (CI) were calculated for each variable. Prognostic numeric and ordinal variables associated with survival were determined using the univariate Cox's proportional hazards model. Hazards ratio with 95% CI and Wald statistics for each variable were calculated. Multivariate Cox's regression analysis was used for the analysis of effects of risk factors that were found to affect survival. Variables with p values less than 0.25 were included in the multivariate analysis as risk factors. Statistical significance was considered at $p<.05$.

Results

When patients with follow-up less than 3 months (n=7) were excluded, the data of 233 patients were evaluated. The median age of the patients at the time of diagnosis was 52 years (range, 26-88 years). The median follow-up time was 28.4 months (range, 3-141 months). According to the FIGO clinical staging system, 183 (78.5%) patients were stage IIb, 8 (3.4%) were stage IIIa, 38 (16.3%) were stage IIIb, and 4 (1.7%) patients were stage IVa. The most common tumor type was squamous cell carcinoma (88.4%), followed by adenocarcinoma (6%) and

adenosquamous carcinoma (1.7%). Tumor grade was valid in 82 patients and 72% of the tumors were grade 2. The cervical lesion was >4 cm in 142 (60.9%) patients and ≤4 cm in 91 (39.1%) patients. Extraperitoneal lymph node dissection was performed via L/S in 31(13.3%) patients and LPT in 202 (86.7%). Eight (25.8%) of the 31 patients who had L/S underwent LPT because of pneumoperitoneum failure.

The median paraaortic node yield was similar for both LPT and L/S groups [LPT group: 10 (2-33); L/S group: 13.5 (1-27), p=0.409]. Sixty-two of the 233 patients (27%) had paraaortic lymph node metastases. Metastases were microscopic in 36 patients, macroscopic but <2 cm in 20, and ≥2 cm in 6 patients. According to the operation notes, 57 (28%; n=57/202) patients in the LPT group had palpable paraaortic nodes. Twenty-nine (51%) of the patients with palpable paraaortic lymph nodes had paraaortic metastasis. The relation between palpable lymph nodes and metastasis was statistically significant (p<.001). Scalene lymph node dissection was performed in 55 patients, 9 (3.9%; n=9/55) of whom had metastases.

Major vascular injury [inferior vena cava (n=5), renal vein (n=2), inferior mesenteric artery (n=1)] occurred in 8 patients intraoperatively; all but one during LPT. Subcutaneous emphysema was seen in one patient during L/S. Postoperative complications were observed in 6.9% (n=16/233) of patients, all of which occurred after the LPT. The most common complication was wound disruption (n=10/16), followed by wound infection (n=2/16). The other complications were evisceration, deep vein thrombosis, hematoma formation in the wound, and subcutaneous fluid collection, one for each patient.

Preoperative MRI and CT of the lower abdomen were performed in 95 (41%) and 43 (18%) patients, respectively. MRI revealed pathologic-appearing lymph nodes in 8 patients who had metastatic nodes (n=8/20, sensitivity 40%), whereas none had pathologic findings in CT.

One hundred seventeen (50%) patients died in the follow-up period. The 3-year OS rate was 55.1% and the 5-year OS rate was 46.5%. Kaplan-Meier analysis of the survival of all patients is shown in Figure 1. Univariate analyses of categorical variables associated with OS are listed in Table 1.

In the univariate analysis, stage of disease, number of metastatic paraaortic lymph nodes, tumor type, and paraaortic lymph node status were associated with OS (p<.001, p<.001, p=.039, and p<.001) (Table 1 and 2). OS worsened as the stage and number of metastatic paraaortic lymph nodes increased. Regarding the tumor type, the presence of adenocarcinoma affected OS negatively when compared with squamous cell carcinoma (Figure 2). The OS of patients with paraaortic lymph node metastases were significantly lower than that of patients without metastases (Figure 3). Scalene lymph node metastasis was not found associated with OS in the univariate analyses (p=.712).

In the multivariate Cox regression analysis, tumor type, stage, and presence of microscopic and macroscopic paraaortic metastases were independent prognostic factors of OS (Table 3). Prognosis worsened in the presence of adenocarcinoma, microscopic and macroscopic metastases, and advanced stages. The most important independent prognostic factor of survival was the presence of a macroscopic metastatic lymph node (Table 3).

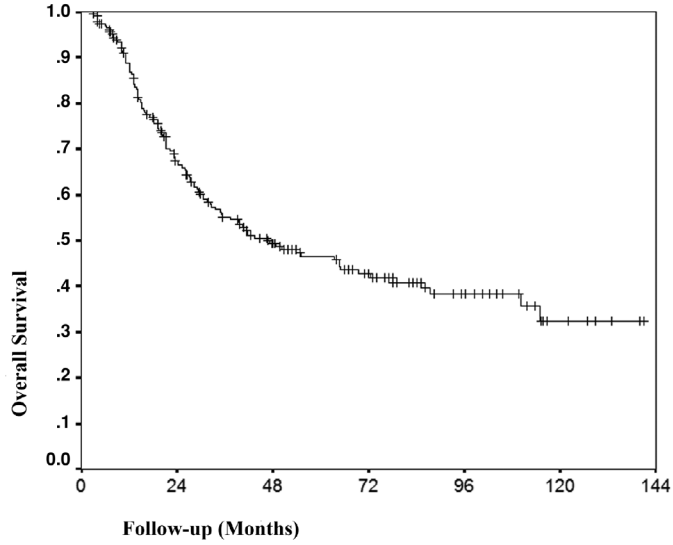

Figure 1. Kaplan-Meier analysis of cumulative survival rate of all patients

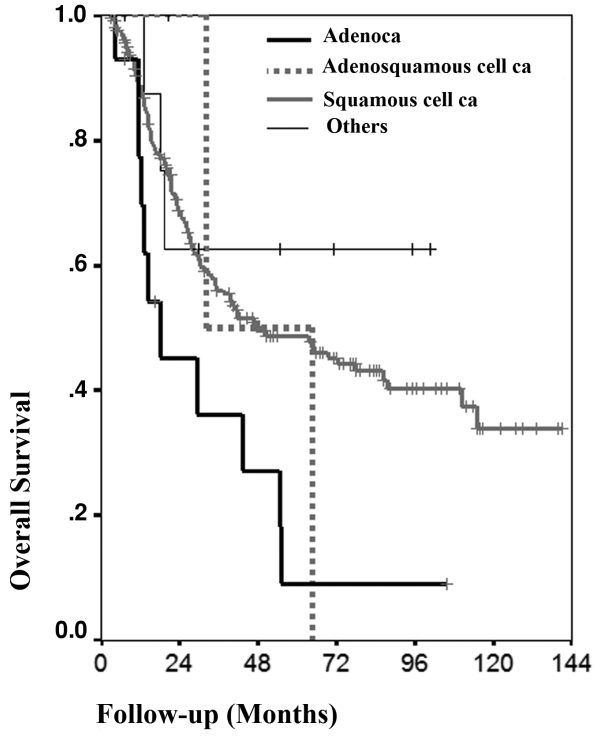

Figure 2. Kaplan-Meier analysis of cumulative survival rate according to histologic types

Table 1. Univariate Kaplan-Meier survival analysis results of categorical variables that may affect overall survival

Variables	Overall survival (%)		Lifetime span (month) (95% confidence interval (minimum-maximum)	Log-rank	p value
	3 Years	5 Years			
Histology				8.360	**.039**
Adenocancer†‡	36.1	9.0	32.7 (16.5-48.9)		
Squamous cell cancer†	56.1	48.7	72.6 (63.8-81.4)		
Adenosquamous cell cancer	50.0	50.0	48.5 (16.7-80.2)		
Other‡	62.5	62.5	69.1 (41.1-97.2)		
Cervical tumor size				0.63	.427
>4 cm	52.3	45.1	68.2 (57.9-78.4)		
≤4 cm	59.7	48.4	74.0 (60.1-87.9)		
Grade				3.55	.170
I	70.7	56.6	79.6 (51.2-107.9)		
II	57.4	53.3	78.3 (62.2-94.5)		
III	35.0	35.0	55.6 (15.0-96.3)		
Lymph node dissection				0.12	.732
LPT	55.4	47.0	71.3 (62.5-80.1)		
L/S	53.4	44.5	46.8 (36.2-57.5)		
Palpable paraaortic lymph node				0.95	.331
Absent	55.4	47.8	72.6 (63.0-82.2)		
Present	53.9	42.3	61.6 (46.7-76.5)		
Paraaortic LN status				32.66	**<.001**
Microscopic metastases#	42.2	21.7	35.9 (25.1-46.8)		
Macroscopic metastases¶	29.7	-	24.0 (17.3-30.8)		
>2 cm LN metastases§	33.3	33.3	28.3 (4.8-51.8)		
No metastases#¶§	61.1	54.9	81.2 (71.7-90.8)		
Paraaortic LN status				28.66	**<.001**
Metastases (-)	61.1	54.9	81.2 (71.7-90.8)		
Metastases (+)	37.3	15.5	30.9 (24.1-37.7)		
Scalene LN dissection				18.71	**<.001**
(-)	59.1	52.4	78.5 (69.2-87.9)		
(+)	41.9	19.6	32.9 (25.1-40.7)		
Scalene LN metastases				0.14	.712
(-)	37.7	23.6	33.4 (22.9-43.9)		
(+)	55.6	14.8	35.3 (21.9-48.7)		
Intraoperative complication				6.52	**.011**
(-)	55.8	47.4	72.5 (64.0-81.0)		
(+)	37.5	25.0	31.5 (15.1-47.8)		
Reversal to laparotomy				0.91	.339
(-)	55.8	50.2	49.9 (37.6-62.2)		
(+)	46.9	23.4	30.7 (18.8-42.6)		
Postoperative complication				0.42	.515
(-)	54.6	46.2	69.7 (61.2-78.2)		
(+)	63.6	53.0	70.2 (45.2-95.2)		

Table 1. Continued

Variables	Overall survival (%)		Lifetime span (month) (95% confidence interval (minimum-maximum)	Log-rank	p value
	3 Years	5 Years			
Pathological paraaortic LN in MRI				1.00	.317
(-)	48.5	44.7	66.2 (52.3-80.0)		
(+)	41.9	29.9	52.9 (27.5-78.4)		
Pathological paraaortic LN in CT				23.87	**<.001**
(-)	52.1	46.2	62.9 (48.3-77.6)		
(+)	-	-	12.1 (10.2-14.1)		
Overall	55.1	46.5	70.5 (62.3-78.8)	-	-

†Difference between adenocarcinoma and squamous cell carcinoma groups was statistically significant (p=.007).
‡Difference between adenocarcinoma and others was statistically significant (p=.034).
#Difference between microscopic metastatic group and group without metastases was statistically significant (p<.001)
¶Difference between macroscopic metastatic group and group without metastases was statistically significant (p<.001)
§Difference between >2 cm lymph node metastatic group and group without metastases was statistically significant (p=.002)
LPT: laparotomy; L/S: laparoscopy; LN: lymph node; CT: computerized tomography; MRI: magnetic resonance imaging

Table 2. Results of univariate Cox regression analyses of numerical and ordinal variables that may be associated with survival

Variables	HR 95% confidence interval (minimum-maximum)	Wald	p value
Age at diagnosis	1.012 (0.992-1.033)	1.310	.252
Stage	1.411 (1.166-1.708)	12.529	**<.001**
Paraaortic lymph node number	1.006 (0.973-1.040)	0.137	.711
Metastatic paraaortic lymph node number	1.061 (1.025-1.099)	11.143	**<.001**
HR: hazard ratio			

Table 3. Evaluation of all factors that may be associated with overall survival with multivariate Cox hazards regression analyses

Variables	HR 95% confidence interval (minimum-maximum)	Wald	p value
Adenocarcinoma	4.307 (1.005-18.458)	3.868	**.049**
Squamous cell carcinoma	1.326 (0.373-4.711)	0.191	.662
Adenosquamous cell carcinoma	0.769 (0.093-6.394)	0.059	.808
Microscopic metastases	5.511 (1.325-22.921)	5.509	**.019**
Macroscopic metastases	13.238 (2.231-78.532)	8.086	**.004**
>2 cm lymph node metastases	5.538 (0.408-75.096)	1.656	.198
Scalene lymph node dissection	0.340 (0.073-1.589)	1.881	.170
Intraoperative complication	1.717 (0.460-6.405)	0.648	.421
Paraaortic radiotherapy + chemotherapy	0.973 (0.434-2.184)	0.004	.947
Brachytherapy + chemotherapy	0.538 (0.111-2.619)	0.589	.443
Radiotherapy + brachytherapy	1.465 (0.689-3.113)	0.986	.321
Stage	1.343 (1.083-1.666)	7.213	**.007**
Metastatic paraaortic lymph node number	0.978 (0.907-1.055)	0.336	.562
HR: hazard ratio			

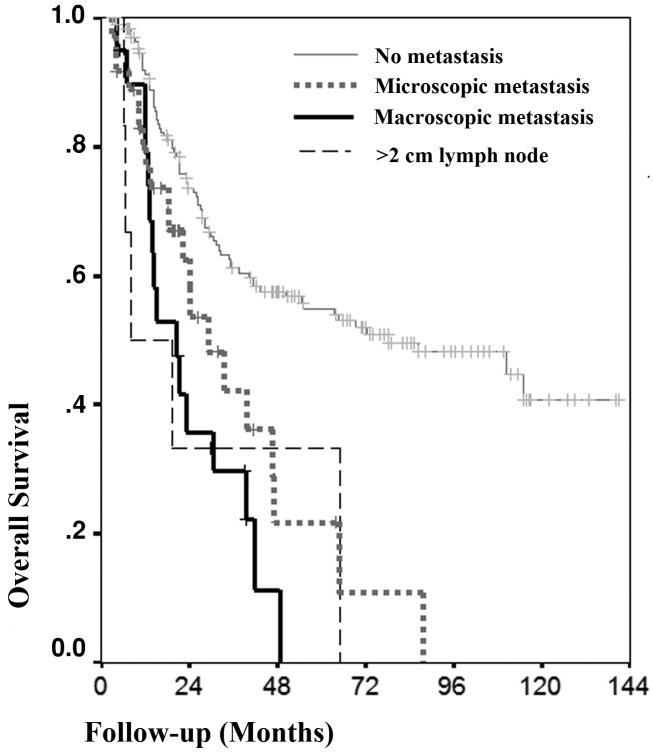

Figure 3. Kaplan-Meier analysis of cumulative survival rate according to paraaortic lymph node status

Discussion

Based on the finding of better prognosis in patients who underwent surgical exclusion of paraaortic lymph node involvement compared with radiologically determined lymph node involvement, the importance of lymph node status affecting prognosis in locally advanced cervical cancer is emphasized in the current staging system of cervical cancer (7). Paraaortic metastasis (accepted as distant metastases, M1) upgrades the stage to IVb (FIGO staging), which previously did not exist in the clinical staging system (1). The NCCN 2015 guidelines recommend using surgical staging of patients with cervical cancer because the FIGO staging system does not include regional nodal metastasis and lymphovascular space invasion, which alters the treatment choice and success in both early-stage and advanced-stage disease (5). The amount of the radiation therapy is very critical depending on the paraaortic lymph node involvement. Concurrent chemoradiation using cisplatin-based chemotherapy is the most recent alternative, which is believed to increase survival rates (30-50% decrease in the risk of death compared with radiotherapy alone) (5).

Although there are many reports arguing the definite diagnostic procedure for nodal metastases, none of the imaging methods have been found superior to surgery (8). In addition to the limitation of detecting microscopic metastases, imaging methods are problematic regarding cost in low-income countries. Even PET-CT has not been considered satisfying for detecting real metastatic lymph nodes (sensitivity 36%) (9). We detected only 40% of the metastatic nodes using MRI and none with CT, but the low number of patients who underwent these imaging studies (95 patients had MRI, 43 patients had CT) may have decreased the sensitivity value.

Among the surgical techniques, which are more accurate way of detecting paraaortic metastases, transperitoneal or extraperitoneal lymph node dissection methods have been defined. The extraperitoneal approach was shown as superior to the transperitoneal technique with decreased bowel complications following radiotherapy (10). The extraperitoneal route, when performed laparoscopically, had additional advantages in reducing surgery- related problems and minimizing the time before radiotherapy (11). Wound complications were a problem in the LPT group in our study.

Laparoscopic extraperitoneal lymph node dissection has been performed since 1997 (12). In our series, only 31 patients were staged laparoscopically and OS did not differ compared with the group that underwent LPT. The number of removed paraaortic lymph nodes did not differ in either technique.

In our study, both intraoperative and postoperative complication rates were similar in LPT and L/S. The intraoperative complication rate in L/S was 6.5% in this study, which is close to the 5.7% rate reported in Querleu et al.'s study (13). Also, for the left paramedian incision group, intraoperative complications were observed in 3.4% patients, which may be acceptable. Postoperative complications consisted mostly of wound-related problems, which were not observed after L/S, favoring the laparoscopic technique.

Paraaortic involvement rates in the literature vary from 20% to 50% in locally advanced cervical cancer (14, 15). We found 27% paraaortic node involvement, which is comparable with reported results. Although clinical staging does not include lymph node metastasis, recurrence rates increased from 29% to 56% when metastases were detected (16). Also, survival rates vary greatly for the same stage when nodal involvement exists. Five-year survival was reported as 20-25% in patients with microscopic paraaortic lymph node metastasis in a study by Heaps and Berek (17), which is very close to our 5-year survival rates in the microscopic metastatic group. The authors argued for the benefits of extended field radiotherapy with chemotherapy in these patients who have no chance of survival without treatment. Sonoda et al. (18) reported a mean survival of 38.6 months in patients without paraaortic metastases and 26.5 months for metastatic patients with bulky tumors, but the follow-up period was much shorter. The five-year OS in our study was 15.5% and 54.9%, respectively, in the groups with and without paraaortic metastases.

Another important issue thought to be associated with survival is the extent of metastases. We found that OS did not differ significantly when the paraaortic nodal involvement was macroscopic or microscopic. Interestingly, Leblanc et al. (16) reported that OS was similar in patients who were node-negative and patients with microscopic nodal disease who received extended field (chemo) radiotherapy. This was not the only study showing poor prognosis in patients with macroscopic paraaortic metastases compared with microscopic metastases (14, 19, 20). Some authors reported the advantages of removing metastatic nodes (7, 15), but with the current findings, debulking may not be definitively associated with survival.

In the univariate analysis, stage of disease, number of metastatic paraaortic lymph nodes, tumor type, and paraaortic lymph node status were found associated with OS. Leblanc et al. (16) determined that tumor size greater than 5 cm was associated with poor prognosis, but we did not find tumor size as a prognostic factor. In the multivariate Cox regression analysis, tumor type, stage, presence of microscopic and macroscopic paraaortic metastases were independent prognostic factors of OS. Regarding tumor type, there are conflicting data in the literature. Turan et al. (21) reported that tumor type, grade, tumor size, and parametrial invasion did not affect survival except lymphovascular space invasion in stage Ib cervical cancer. Unlike previous studies that reported no significant prognostic difference between squamous cell carcinoma and adenocarcinoma type (22, 23), we found that adenocarcinoma of the cervix worsened the prognosis and decreased survival of patients.

There are few studies about scalene nodal metastases in cervical cancer. In the present study, no survival difference was detected between patients with positive and negative metastatic scalene lymph nodes who had scalene lymph node dissection. Scalene node involvement means disseminated disease necessitating palliative treatment, but the current results showed that the actual prognostic factor was paraaortic nodal status. Supporting this, both paraaortic metastases and scalene metastases are considered as stage IVb in the surgical staging system (5).

One of the limitations of this study was the retrospective design. Detailed radiotherapy data and post-radiotherapy complication rates were missing because subsequent treatment of some patients including radiotherapy had been completed in different centers.

Despite the limitations, this retrospective study has a good number of patients. Extraperitoneal lymph node dissection in patients with locally advanced cervical cancer has been investigated for years and has been shown to have a significant prognostic effect (7). There is an ongoing phase III trial aiming to determine as to whether laparoscopic surgical staging improves survival, which we believe will guide management choices in the future (24). Once more, we showed that paraaortic lymph node metastasis was the most important prognostic factor affecting the survival of the patients. The most striking result is that surgery gives clues about the prognosis of the patient better than the clinical stage. Surgical staging aids in planning adjuvant therapy, prevents unjustifiable extended field radiotherapy and further complications, and thus decreases morbidity. Treatment plans of patients with locally advanced cervical cancer should be performed according to the results of lymphadenectomy, which is applicable for every patient. Extraperitoneal lymphadenectomy might contribute to improvement of survival.

Ethics Committee Approval: *Ethics committee approval was received for this study from the Local Ethics Committee of Etlik Zübeyde Hanım Womens Health Teaching and Research Hospital (No: 2016/216).*

Informed Consent: *Informed consent was not obtained since the study was retrospective.*

Peer-review: *Externally peer-reviewed.*

Author Contributions: *Concept – M.F.K., N.B., R.Ö.; Design – M.K., G.K., G.T., A.T.T.; Supervision – M.F.K., M.C.Y., A.T.T., M.C.Y.; Materials – N.B.,G.K., I.Ü., R.Ö.; Data Collection and/or Processing – M.K., N.B.,T.T., G.T.; Analysis and/or Interpretation – M.C.Y., M.K., A.T.T., I.Ü.; Literature Review – G.K., N.B., R.O., A.T.T.; Writer – M.F.K., M.K., G.K., A.T.T, I.Ü.; Critical Review – M.F.K., A.T.T., N.B., R.Ö., M.C.Y.*

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Frequency of nodular goiter and autoimmune thyroid disease and association of these disorders with insulin resistance in polycystic ovary syndrome

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Abstract

Objective: Polycystic ovary syndrome (PCOS) is a frequent endocrine disease in women. Nodular goiter and autoimmune thyroid disease (AITD) are endocrinologic abnormalities that have high prevalence. The purpose of our study was to detect the prevalence of AITD and nodular goiter in patients with PCOS and investigate whether PCOS-related hormones and metabolic factors affect these thyroid disorders.

Material and Methods: Ninety-seven women with PCOS and 71 healthy female volunteers were recruited into the study. Serum-free thyroxine, thyroid-stimulating hormone, anti-thyroperoxidase antibody and anti-thyroglobulin antibody levels were evaluated. Thyroid volume (TV) was calculated using ultrasonography.

Results: The body mass index (BMI), Waist/Hip ratio, homeostasis model assessment insulin resistance (HOMA-IR), fasting blood glucose, triglyceride and low-density lipoproteins, and fasting insulin were significantly higher in the PCOS group ($p<.05$). The control group had significantly higher serum high density lipoprotein cholesterol results ($p=.005$). The mean TV was 11.4±4.7 mL in the PCOS group and 9.9±2.8 mL in the controls ($p=.022$). Twenty-nine patients with PCOS (29/97; 29.9%) had thyroid nodules, whereas only eleven control subjects had thyroid nodules (11/71; 15.5%) ($p=.043$). The frequency of AITD was significantly higher in the PCOS group ($p=.001$). A statistically significant relationship was found between TV and age, fasting glucose, HOMA-IR, BMI, and fasting insulin ($p<.05$). Participants with thyroid nodules were older and had higher fasting glucose, BMI, fasting insulin, and HOMA-IR values compared with those without thyroid nodules ($p<.05$).

Conclusion: We demonstrated that TV and frequency of nodular goiter were increased in patients with PCOS. This result was related with insulin resistance. Therefore, we recommend that patients with PCOS must be investigated for the development of nodular goiter and AITD. (J Turk Ger Gynecol Assoc 2017; 18: 85-9)

Keywords: Polycystic ovary syndrome, autoimmune thyroid disease, nodular goiter, insulin resistance

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Introduction

Polycystic ovary syndrome (PCOS) is a frequent endocrine disease with a prevalence of 5-10% in women at reproductive age (1). Hyperandrogenism, menstrual irregularities, infertility, and obesity are main features of this syndrome. Patients with PCOS have increased risk of metabolic syndrome, cardiovascular disease, insulin resistance, type 2 diabetes mellitus (type 2 DM), and endometrial carcinoma (2-6).

Nodular goiter and autoimmune thyroid disease (AITD) are both frequently seen disorders in endocrine practice (7). Autopsy and ultrasonography (USG) series showed that thyroid nodules had a high prevalence (19-50%) in the general population (8, 9). In women, the most common cause of hypothyroidism is AITD, which affects 5-20% of the young female population. The interaction of genetic and hormonal factors are important in the etiology of AITD (10, 11).

Although iodine deficiency, female sex and age are well-known risk factors for nodular goiter, the exact pathogenesis remains to be illuminated. The potential relation between insulin resistance and thyroid nodules was reported by Rezzonico et al. (12, 13), and insulin resistance was also accepted as a

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risk factor for cancer development. Patients with PCOS have increased risk of insulin resistance. The purpose of this study was to determine the prevalence of AITD and nodular goiter in patients with PCOS and investigate whether there was an effect of PCOS-related hormones and metabolic factors on these thyroid disorders.

Material and Methods

Ninety-seven patients who were diagnosed as having PCOS between August 2015 and September 2016 in our hospital at the Department of Endocrinology and Metabolism outpatient clinic in accordance with the 2003 Rotterdam criteria were recruited to the study (14). Seventy-one age-matched healthy female volunteers were recruited to the study as a control group. The exclusion criteria were chronic systemic disease, and using drugs that could affect insulin sensitivity and lipid parameters. The study protocol was approved by the Ethics Department and all participants gave informed consent.

Anthropometric measurement, physical examination, and biochemical screening were made in all patients and controls. We obtained fasting blood samples from all participants during the 2^{nd}-5^{th} days of the menstrual cycle. Hormonal and metabolic variables of all participants were assessed. Insulin resistance was calculated using the homoeostasis model assessment formula (15). Body mass index (BMI) and Waist/Hip ratio (WHR) were determined.

Chemiluminescent microparticle immunoassays (Abbott, Architect i2000, Abbott Laboratories Diagnostics Division, IL, USA) were used to measure thyroid-stimulating hormone (TSH) and free thyroxine (fT_4), free triiodothyronine (fT_3). Chemiluminescent competitive immunoassays (Advia centaur XP, Siemens, Tarrytown, USA) were used to measure the anti-thyroglobulin antibody (anti-Tg Ab) and anti-thyroperoxidase antibody (anti-TPO Ab). The lower and upper limits were as follows: fT_3: 2.5-3.9 pg/mL; fT_4: 0.58-1.60 ng/dL; TSH: 0.38-5.33 μIU/mL; anti-Tg Ab: 0-60 IU/mL; anti-TPO Ab:0-57 IU/mL.

Thyroid USG was performed with a high-resolution ultrasound machine (Hitachi, Japan; EUB 7000) that had a 6-14 megahertz linear transducer. Only one operator performed all the measurements. Lesions over 3 mm (diameter) on USG were considered as nodules. The elliptical shape volume formula (0.479 x length x width x height) was used to calculate the volume of each thyroid lobe, and total thyroid volume (TV) was calculated by adding the right and left lobe volumes.

Statistical analysis

The SPSS statistical software (version 17; SPSS, Chicago, IL, USA) was used to perform the statistical analysis. Fisher's exact test or Chi-square test were used to analyze categorical variables. Normality of the variables was tested using the Kolmogorov-Smirnov test. The Mann-Whitney U test and independent samples t-test were to compare groups. Data are expressed as mean ± standard deviation or median with interquartile range as appropriate. Continuous variables were evaluated using Pearson's correlation coefficient, and Spearman's rho correlation coefficient test was used to evaluate non-normally distributed variables. P values less than 0.05 were considered statistically significant.

Results

The study included 97 patients with PCOS (mean age, 24.1±6.0 years) and 71 controls (mean age, 24.4±4.5 years). Table 1 represents the general characteristics of the patients and controls. There were no significant differences in terms of age and total cholesterol levels between the groups (p>.05). The BMI, WHR, triglyceride (TG), low density lipoprotein cholesterol,

Table 1. The clinical and biochemical data of patients with polycystic ovary syndrome and controls

Variable	PCOS (n=97)	Controls (n=71)	p
Age, years	24.1±6.0	24.4±4.5	.759
BMI, kg/m^2	27.5±6.0	23.4±5.0	**<.001**
Waist/Hip ratio	0.84±0.09	0.75±0.06	**<.001**
Fasting glucose, mg/dL	85.6±8.9	80.2±8.9	**<.001**
Fasting insulin, μ-IU/mL	15.8±7.1	11.4±5.2	**<.001**
HOMA-IR	3.4±1.7	2.2±1.2	**<.001**
Total cholesterol, mg/dL	177.9±30.6	169.3±26.1	.060
Triglyceride, mg/dL	112.5±64.3	89.6±44.5	.023
HDL-C, mg/dL	53.1±13.3	59.5±15.1	**.005**
LDL-C, mg/dL	104.6±24.0	87.4±18.2	**<.001**

PCOS: polycystic ovary syndrome; BMI: body mass index; HOMA-IR: homeostasis model assessment insulin resistance index; LDL-C: low density lipoprotein cholesterol; HDL-C: high density lipoprotein cholesterol
Values are shown as mean ± standard deviation

fasting blood glucose, fasting insulin and homeostasis model assessment insulin resistance (HOMA-IR) were significantly higher in patients with PCOS than in the control group (p<0.001, p<0.001, p=0.023, p<0.001, p<0.001, p<0.001, p<0.001, respectively). High density lipoprotein cholesterol was significantly higher in the control group (p=0.005).

The TSH and fT_4 levels were similar in both groups. Table 2 represents the thyroid examination of the patients and controls. The mean TV was 11.4±4.7 mL in patients with PCOS and 9.9±2.8 mL in healthy controls (p=.022). In the PCOS group and controls, thyroid nodules were detected in 29/97 (29.9%) and 11/71 (15.5%), respectively (p=.043). The number of patients with PCOS who had a single nodule was 23 and multiple nodules was 6. In contrast, 6 control subjects had a single nodule and 5 had multiple nodules.

Patients with PCOS had higher a prevalence of positive anti-Tg Ab than controls (16.5% vs. 5.6%) (p=.051). The prevalence of subjects with positive anti-TPO Ab among the patient and control groups was 32.0% and 15.5%, respectively. It was significantly higher in patients with PCOS (p=.019). The frequency of AITD was significantly higher in patients with PCOS [PCOS, 39/97 (40.2%); and controls, 11/71 (15.5%); p=.001] when we consider either thyroid heterogeneity and/or positivity of autoantibodies as AITD.

There were statistically significant relationships between TV and age, BMI, fasting glucose, HOMA-IR, and fasting insulin (Table 3, Figure 1). The correlation between anti-TG Ab, anti-TPO Ab and TSH levels were also statistically significant (r=0.466, p<.001; r=0.218, p=.005, respectively).

The participants were divided into two groups according to the existence of thyroid nodules. Participants with thyroid nodules were older and had higher fasting glucose, fasting insulin, HOMA-IR, and BMI compared with those without thyroid nodules (Table 4). TSH, fT_4, anti-Tg Ab, anti-TPO Ab, and total TV were similar both groups.

Table 2. Thyroid test results of the patients with polycystic ovary syndrome and controls

Variable	PCOS (n=97)	Controls (n=71)	p
TV, mL	11.4±4.7	9.9±2.8	**.022**
Thyroid nodule	29 (29.9%)	11 (15.5%)	**.043**
Anti-Tg Ab positive	16 (16.5%)	4 (5.6%)	.051
Anti-Tg Ab negative	81 (83.5%)	67 (94.4%)	
Anti-TPO Ab positive	31 (32%)	11 (15.5%)	**.019**
Anti-TPO Ab negative	66 (68%)	60 (84.5%)	
AITD	39 (40.2%)	11 (15.5%)	**.001**
TSH, μIU/mL	2.4±1.2	2.0±1.0	.243
fT_4, ng/dL	1.1±0.2	1.1±0.1	.905

PCOS: polycystic ovary syndrome; TSH: thyroid-stimulating hormone; fT_4: free thyroxine; Anti-Tg Ab: anti-thyroglobulin antibody; Anti-TPO Ab: anti-thyroperoxidase antibody; TV: thyroid volume; AITD: autoimmune thyroid disease
Values are shown as mean ± standard deviation

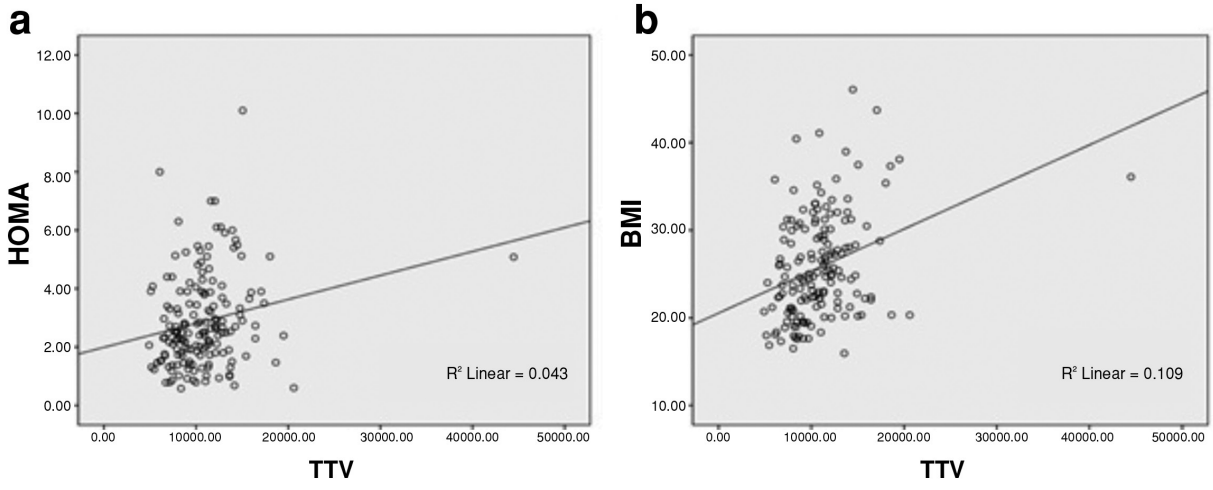

Figure 1. Thyroid volume was correlated with (a) homeostasis model assessment insulin resistance and (b) body mass index

Table 3. The correlation of thyroid volume with other parameters

Variable	r	p
Age (years)	0.172	**.026**
BMI (kg/m^2)	0.330	**<.001**
Fasting glucose	0.195	**.012**
Fasting insulin	0.212	**.006**
HOMA-IR	0.208	**.007**

BMI: body mass index; HOMA-IR: homeostasis model assessment insulin resistance index
r, Pearson's correlation coefficient

Table 4. Comparison of clinical and biochemical data in participants with and without thyroid nodules

Variable	Thyroid nodule (+)	Thyroid nodule (-)	p
Age, years	27.0±6.4	23.4±4.8	**.001**
BMI, kg/m^2	29.1±6.4	24.8±5.4	**<.001**
Fasting glucose, mg/dL	87.0±10.8	82.2±8.4	**.005**
Fasting insulin, μ-IU/mL	16.6±6.4	13.1±6.6	**.004**
HOMA-IR	3.5±1.6	2.7±1.5	**.002**

BMI: body mass index; HOMA-IR: homeostasis model assessment insulin resistance index
Values are shown as mean ± standard deviation

Discussion

Our study showed that nodule frequency and TV were significantly higher in patients with PCOS. A positive correlation was detected between TV and age, BMI, fasting glucose, fasting insulin, and HOMA-IR. Additionally, participants with thyroid nodules were older and had higher BMI, fasting glucose, fasting insulin, and HOMA-IR compared with those without thyroid nodules.

Duran et al. (16) investigated the nodular goiter prevalence in patients with PCOS. They reported that patients and controls had similar TV and nodule frequency. In their study, age and TV had a positive correlation. However, two different studies demonstrated that thyroid disorders had a high prevalence rate among young patients with PCOS compared with age-matched controls (17, 18).

TSH has important roles in the differentiation and growth of thyroid cells (19). In our study, serum TSH levels were normal and not different between patients and controls. In addition, TSH levels were similar between participants with- and without thyroid nodules. Therefore, TSH cannot be the only factor in the pathogenesis of nodule formation. Rezzonico et al. (12) reported the mitogenic effect of insulin on thyroid cell cultures. Other studies confirmed the relationship between thyroid nodule and insulin resistance (20). The reduction of thyroid nodule volume after amelioration of insulin resistance with metformin proved this causal relationship (21).

Patients with PCOS frequently have hyperinsulinemia and insulin resistance (14). We detected higher fasting insulin and HOMA-IR values in patients with thyroid nodules. The characteristic features of insulin resistance are hyperinsulinemia and impaired biologic response to insulin within target tissues (22, 23). It has been also shown that thyroid cancer cells have insulin receptors (24, 25). In light of our study results, we recommend USG evaluation for the presence of thyroid nodules in patients with PCOS with insulin resistance.

The association between AITD with PCOS is an another important topic. Kachuei et al. (26) and Janssen et al. (27) reported that the prevalence of autoimmune thyroiditis in PCOS was high (28, 29). We also detected statistically significantly high levels of anti-Tg and anti-TPO in patients with PCOS. The prevalence of positive anti-TPO Ab and anti-TgAb was higher in the PCOS group than in controls. Also the AITD's frequency was significantly higher in patients with PCOS. Calvar et al. (28) demonstrated that young patients with PCOS had a high rate of AITD and this result was associated with high levels of fasting insulin and HOMA-IR. However, no correlation was established between autoantibody positivity and metabolic parameters such as BMI, insulin, and HOMA-IR.

In conclusion, we showed that insulin resistance was an important risk factor for increased TV and nodule formation. Patients with PCOS frequently have a thyroid disorder. Thyroid hormones are usually checked during the investigation of patients with PCOS; however, as a result of our study, serum thyroid autoantibodies and presence of thyroid nodule should also be investigated in these patients. The major limitation of our study is the determination of participants' glucose status only by measuring fasting glucose and HOMA index. However, the Clinical Practice Guidelines of the Endocrine Society recommend using an oral glucose tolerance test (OGTT) to screen for impaired glucose tolerance and type 2 diabetes (29). Further studies should be designed with large numbers of participants using OGTT.

Ethics Committee Approval: *Ethics committee approval was received for this study from the ethics committee of Dışkapı Yıldırım Beyazıt Training and Research Hospital.*

Informed Consent: *Written informed consent was obtained from patients who participated in this study.*

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S.H., E.T.; Data Collection and/or Processing – M.K., S.H., Ş.A.; Analysis and/or Interpretation - M.K., M.S.A., E.Ç.; Literature Review – M.K., Ş.A., İ.Ü.; Writer - M.K., E.Ç.; Critical Review – M.K., M.S.A.,E.Ç.

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Maternal and perinatal characteristics of small-for-gestational-age newborns: Ten-year experience of a single center

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Abstract

Objective: To analyze the maternal and perinatal characteristics of small-for-gestational-age (SGA) newborns compared with appropriate-for-gestational-age (AGA) newborns in singleton pregnancies managed at our hospital between January 2006 and December 2015.

Material and Methods: The study (n=456) and control (n=4925) groups included pregnancies resulting in SGA and AGA newborns, respectively. Additionally, two SGA subgroups were defined according to abnormal (n=34) and normal (n=57) Doppler findings. Maternal demographic features; intracytoplasmic sperm injection (ICSI) pregnancies; gestational age at delivery; birth weight; major congenital anomalies, karyotype abnormalities, and genetic syndromes; maternal and obstetric problems such as hypertensive disorders, diabetes, oligohydramnios, preterm birth; admission to the neonatal intensive care unit (NICU), and perinatal mortality were recorded, and the two groups were compared with respect to these parameters.

Results: Mean maternal age, parity, gestational age at delivery, and birthweight were significantly lower; the frequencies of ICSI pregnancies, hypertensive disorders, oligohydramnios, preterm delivery, major congenital anomalies, karyotype abnormalities and genetic syndromes, admission to the NICU and perinatal mortality were significantly higher in the study group ($p<0.05$). None of the study parameters were significantly different between the two SGA subgroups ($p>0.05$).

Conclusion: The association of SGA with ICSI pregnancies, hypertensive disorders, oligohydramnios, preterm delivery, congenital/chromosomal anomalies, NICU admission and perinatal mortality may be important in perinatal care. Clinical suspicion of SGA necessitates appropriate monitorization and management. Although obstetric outcomes were not significantly different between the two SGA subgroups with abnormal and normal Doppler findings in this study, this finding must be evaluated with caution due to the small sizes. (J Turk Ger Gynecol Assoc 2017; 18: 90-5)

Keywords: Small for gestational age, risk factors, obstetric outcome

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Introduction

Small for gestational age (SGA) newborns are defined as birthweight <10th percentile according to the gestational age (1). Although constitutional factors such as female sex, ethnicity, parity or maternal body mass index, might be the cause in most SGA newborns, various maternal, fetal or placental disorders may play role in the remainder. This latter group encompasses newborns with intrauterine growth restriction (IUGR), or in other words, fetal growth restriction (FGR) (2). Not all, but some cases of pathologic SGA may be differentiated from constitutional cases according to the presence of ultrasonographic findings such as declining fetal growth curve, oligohydramnios, abnormal Doppler indices, biometric measurements <3rd percentile, as well as abnormal fetal anatomy (3). Nevertheless, several studies indicate that, SGA as a whole group, is associated with an increased risk of both neonatal morbidity, including respiratory distress syndrome, intraventricular hemorrhage, seizure, sepsis and perinatal mortality (4). Thus, the management of SGA fetuses and newborns differ from those that are appropriate for gestational age (AGA) due to the increased risk of perinatal and

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neonatal adverse outcomes. The effects of SGA are observed in the immediate neonatal period and in infancy, childhood, and adulthood. Long-term adverse outcomes such as neurocognitive impairment, obesity, type 2 diabetes mellitus, hypertension, and cardiovascular diseases are more frequently emphasized in recent studies (5, 6).

The aim of this study was to analyze the maternal and perinatal characteristics of small-for-gestational age-newborns compared with appropriate-for-gestational-age newborns in singleton pregnancies managed at our hospital between January 2006 and December 2015. The data obtained in this study may recall attention to the early suspicion and management of SGA in daily obstetric practice.

Material and Methods

This study was approved by the Institutional Review Board and Ethics Committee of Başkent University. Başkent University Ankara Hospital delivery records and patients' files between January 2006 and December 2015 were retrospectively analyzed to determine SGA and AGA newborns. Only singletons were evaluated (n=5757) excluding twin and triplet pregnancies. SGA was defined as birthweight $<10^{th}$ percentile and AGA was defined as birthweight between the 10^{th} and 90^{th} percentiles with respect to gestational age (7). The study group included 456 SGA newborns and the control group comprised 4925 AGA newborns. Maternal demographic features; intracytoplasmic sperm injection (ICSI) pregnancies; advanced maternal age; gestational age at delivery; birth weight; major congenital anomalies, karyotype abnormalities and genetic syndromes; maternal and obstetric problems such as hypertensive disorders, diabetes, oligohydramnios, preterm birth; admission to the neonatal intensive care unit (NICU), and perinatal mortality were recorded and the two groups were compared with respect to these parameters. Maternal age ≥35 years at birth was accepted as advanced maternal age. Chronic hypertension, gestational hypertension, preeclampsia, eclampsia, and superimposed preeclampsia were considered as maternal hypertensive disorders. Maternal diabetes included pregestational and gestational diabetes. When the deepest single pocket of amniotic fluid was measured as <2 cm at the second or third trimester ultrasonography, it was accepted as oligohydramnios. Preterm birth was defined as deliveries less than 37 gestational weeks. Perinatal mortality included intrauterine, intrapartum, and neonatal deaths within the postpartum first 28 days.

Doppler ultrasonography examinations of the study group including SGA newborns were also evaluated; however, we were not able to obtain the examination results of most of the cases because of the retrospective design of the study, and due to the renewal of the electronic recording system of the hospital. Thus, two subgroups were defined as abnormal and normal Doppler findings including 34 and 57 cases, respectively. Doppler examinations were accepted as abnormal when at least one of the following findings were present at any gestational age ≥24 weeks: umbilical artery (UA) S/D ratio $>95^{th}$ percentile; pulsatility index (PI) $>95^{th}$ percentile; absent or reversed end-diastolic flow (AREDF) in the UA; absent or reversed a-wave in ductus venosus (DV); and cerebroplacental ratio (CPR) was defined as middle cerebral artery (MCA) PI/UA PI $<5^{th}$ percentile. The maternal and perinatal characteristics mentioned before were compared between the two SGA subgroups with abnormal and normal Doppler findings.

Statistical analysis was performed using SPSS for Windows, version 22.0. Mann-Whitney U, χ^2, and Fisher's exact tests were used where appropriate. A p value of <.05 was considered statistically significant.

Results

The frequency of the SGA newborns among singletons was 7.92% (456/5757) between January 2006 and December 2015 at Başkent University Hospital.

The mean maternal age, parity, gestational age at delivery and birth weight were significantly lower in the study group with SGA compared with the control group (30.61±5.25 vs. 31.11±4.63; 0.41±0.66 vs. 0.49±0.68; 37.01±3.42 vs. 38.04±2.37 and 2310.45±605.66 vs. 3222.91±502.11, respectively, (p<.05). There was no significant difference between the study and the control groups with respect to gravidity (p>.05) (Table 1).

Table 1. Demographic features of the study and control groups

	Study group (SGA) n=456 Mean ± SD (range)	**Control group (AGA) n=4925 Mean ± SD (range)**	**p**
Maternal age (years)	30.61±5.25 (18-58)	31.11±4.63 (16-49)	<.05
Gravidity	1.75±1.07 (1-9)	1.83±1.07 (0-11)	>.05
Parity	0.41±0.66 (0-5)	0.49±0.68 (0-8)	<.05
Gestational age at delivery (weeks)	37.01±3.42 (20-42)	38.04±2.37 (20-42)	<.05
Birth weight (grams)	2310.45±605.66 (240-2920)	3222.91±502.11(310-4090)	<.05
Mann-Whitney U test SD: standard deviation; SGA: small for gestational age; AGA: appropriate for gestational age			

When the two groups were compared with respect to risk factors for SGA and obstetric outcomes, it was observed that the rates of ICSI pregnancies, hypertensive disorders, oligohydramnios, preterm delivery, major congenital anomaly/ chromosomal anomaly/syndrome were significantly higher in the study group (12.3% vs. 8%; 12.9% vs. 3.6%; 12.3% vs. 3.1%; 22.6% vs. 10.6% and 8.8% vs. 4.2%, respectively, p<.05). NICU admission and perinatal mortality were also significantly more frequent in the study group (26.7% vs. 8.4% and 5.3% vs. 1.2%, respectively, p<.05) (Table 2). Perinatal mortality was due to intrauterine exitus, anomaly-related mortality, and prematurity-related mortality in 25%, 33.3%, and 41.7% of cases in the study group, whereas it was 15%, 58.3%, and 26.7% in the control group, respectively. There were no significant differences between the study and control groups with respect to advanced maternal age and diabetes (p>.05) (Table 2).

In the subgroup analyses of SGA newborns with abnormal and normal Doppler findings, there were no significant differences in the mean maternal age, gravidity, parity, gestational age at delivery, and birth weight (p>.05) (Table 3).

The rates of risk factors and adverse obstetric outcomes, including ICSI pregnancies, hypertensive disorders, oligohydramnios, preterm delivery, major congenital anomaly/ chromosomal anomaly/ syndrome, NICU admission, and perinatal mortality, did not significantly differ between the two SGA subgroups with abnormal and normal Doppler findings (p>.05) (Table 4).

Discussion

Whether the topic is 'small for gestational age' or 'fetal growth restriction' the complexity of the definitions must be kept in mind while reviewing the literature. SGA is accepted as birthweight <10th percentile according to the gestational age using a population-based reference. The diagnosis of SGA would be more accurate if population-based birthweight standards were determined with healthy mothers without risk factors for FGR. Some studies in the literature used their own birthweight nomograms, whereas others, as in this study, used a different population-based nomogram (2, 4, 8). There are various single-center studies from Turkey that evaluated

Table 2. Risk factors for small-for-gestational-age newborns and obstetric outcomes in the study and control groups

	Study group (SGA) Rate (%)	Control group (AGA) Rate (%)	p
Advanced maternal age	99/456 (21.7)	1139/4925 (23.1)	>.05
ICSI pregnancies	56/456 (12.3)	393/4925 (8)	<.05
Hypertensive disorders	59/456 (12.9)	178/4925 (3.6)	<.05
Diabetes	35/456 (7.7)	349/4925 (7)	>.05
Oligohydramnios	56/456 (12.3)	154/4925 (3.1)	<.05
Preterm delivery	103/456 (22.6)	524/4925 (10.6)	<.05
Major congenital anomaly/chromosomal anomaly/syndrome	40/456 (8.8)	206/4925 (4.2)	<.05
NICU admission	122/456 (26.7)	411/4925 (8.4)	<.05
Perinatal mortality	24/456 (5.3)	60/4925 (1.2)	<.05

χ^2 test
SGA: small for gestational age; AGA: appropriate for gestational age; NICU: neonatal intensive care unit; ICSI: intracytoplasmic sperm injection

Table 3. Demographic features of small-for-gestational-age newborns with abnormal and normal Doppler findings

	Abnormal Doppler n=34 Mean ± SD (range)	Normal Doppler n=57 Mean ± SD (range)	p
Maternal age (years)	31.03±5.22 (20-39)	30.7±5.37 (18-47)	>.05
Gravidity	1.59±0.98 (1-5)	1.67±0.89 (1-4)	>.05
Parity	0.32±0.63 (0-2)	0.33±0.63 (0-3)	>.05
Gestational age at delivery (weeks)	36.5±2.98 (29-40)	37.37±2.61 (27-41)	>.05
Birth weight (grams)	2148.68±612.96 (680-2890)	2362.44±464.27 (605-2920)	>.05

Mann-Whitney U test
SD: standard deviation; SGA: small for gestational age

birthweight distribution, which probably cannot be generalized to the whole Turkish population (9, 10). Therefore, although it is a limitation of this study, we selected a population-based reference from the United States of America, which was determined to be the most powerful and most contemporary of the growth curves available (7).

The frequency of SGA newborns ranges widely from 3.5% to 17.9% in several studies in the literature due the different definitions and references used (2, 11). The rate of SGA newborns in our study appeared as 7.92%.

The current study aimed to compare the maternal and perinatal characteristics of the SGA newborns with those of AGA newborns in a single center within a ten-year period. By definition, the SGA group may include both constitutionally small but healthy newborns and those who are pathologically small; however, regarding the perinatal outcome, these two groups of SGA babies may differ from each other (12). On the other hand, the AGA group may also include both normal babies and babies who are unable to reach their biologic growth potential. Even though both SGA and AGA groups may include disordered babies, this proportion is expected to be much smaller in the AGA group, and reports in the literature agree in that perinatal morbidity and mortality rates in SGA newborns are higher (13, 14). Perinatal mortality was 5.3% (24/456) in the SGA group in our study, and it was significantly higher when compared with the 1.2% (60/4925) in the AGA group (Table 2). Perinatal morbidity such as sepsis, respiratory distress syndrome, bronchopulmonary dysplasia, intraventricular hemorrhage, necrotizing enterocolitis, retinopathy of prematurity, hypoxic ischemic encephalopathy, hypoglycemia, hyperbilirubinemia, and polycythemia might be observed more commonly in SGA newborns (15). In our retrospective data, we were not able to analyze the perinatal morbidity in the study and control groups in detail; however, the frequency of NICU admission was significantly higher in the SGA group, and this may indirectly reflect a higher morbidity rate.

Risk factors for SGA may be listed as follows: constitutionally small mothers; poor maternal nutrition; maternal and fetal infections; congenital malformations; chromosomal aneuploidies; inherited syndromes; tobacco, alcohol or illegal drug use; vascular disease; pregestational diabetes; chronic hypoxia; anemia; placental and cord abnormalities; and infertility (16).

In our study, the rates of ICSI pregnancies and major congenital anomalies/chromosomal anomalies/syndromes were significantly higher in the SGA group compared with the AGA group, in accordance with the literature (16-18). Zhu et al. (18) and Valenzuela-Alcaraz et al. (19) reported an increased incidence of SGA infants in women with a history of infertility with or without infertility treatment, and Valenzuela-Alcaraz et al. (19) also described a preferential association of SGA with treated infertility, either by ovulation induction or ICSI. We were not able to compare the study and control groups with respect to this parameter because the history of infertility was not recorded in our data; thus, we can only say that ICSI is a risk factor for SGA, either by itself or due to the history of infertility, not specified in our study.

Regarding maternal age, some studies defined young age and some defined advanced age as risk factors for SGA, whereas others failed to find any association (2). In our study, mean maternal age and parity were significantly lower in the SGA group and advanced maternal age did not appear to be a risk factor. It is generally accepted that nulliparity increases the risk of SGA infants when compared with multiparity, which may be considered as in accordance with our study (20, 21); however, conflicting results have also been reported (2).

In this study, the rate of hypertensive disorders was significantly higher in the SGA group compared with the AGA group, which is consistent with the results of various studies in the

Table 4. Risk factors and obstetric outcomes of the small-for-gestational-age newborns with abnormal and normal Doppler findings

	Abnormal Doppler n=34 Rate (%)	Normal Doppler n=57 Rate (%)	p
ICSI newborns	7/34 (20.5)	13/57 (22.8)	>.05
Hypertensive disorders	7/34 (20.5)	8/57 (14.0)	>.05
Diabetes mellitus	6/34 (17.7)	5/57 (8.7)	>.05
Oligohydramnios	5/34 (14.7)	11/57 (19.2)	>.05
Preterm delivery	12/34 (35.2)	10/57 (17.5)	>.05
Major congenital anomaly/chromosomal anomaly/syndrome	7/34 (20.5)	9/57 (15.7)	>.05
NICU admission	15/34 (44.1)	17/57 (29.8)	>.05
Perinatal mortality	1/34 (2.9)	2/57 (3.5)	>.05

NICU: neonatal intensive care unit; ICSI: intracytoplasmic sperm injection

literature (22-24). Another comorbidity evaluated in our study was diabetes, including both pregestational and gestational diabetes, and the rate did not differ significantly between the study and control groups. In the literature, it is reported that diabetes with vasculopathy was associated with increased SGA (25). Also, Langer et al. (26) suggested that a relationship existed between the level of glycemic control and neonatal weight, which means that poor glycemic control is associated with large-for-gestational-age babies, whereas stringent glycemic control is associated with SGA babies.

The rate of oligohydramnios was significantly higher in the SGA group in our study; although we did not separately evaluate the subgroup with placental insufficiency as the underlying etiology, it is known that oligohydramnios mostly accompanies in this circumstance (27).

The preterm delivery rate in our study was significantly higher in the SGA group (22.6%) compared with the AGA group, although not classified as iatrogenic or spontaneous. It is well known that SGA is one of the most common indications for medical intervention resulting in preterm birth (28). FGR has also been recognized as a cause in spontaneous preterm labor and suggests a fetal role (29). Placental insufficiency and inadequate perfusion of the fetus might result in fetal distress and premature activation of the hypothalamo-pituitary-adrenal axis.

Abnormal Doppler indices may be useful to differentiate fetuses with pathologic growth restriction due to placental insufficiency, from those that are constitutionally small but normal. For subgroup analyses, we were able to document the Doppler studies of only 91 SGA newborns out of 456. When we analyzed the subgroups of SGA with abnormal (n=34) and normal (n=57) Doppler indices, there were no significant differences with respect to the study parameters, namely: maternal demographic features and rates of ICSI pregnancies, hypertensive disorders, oligohydramnios, preterm delivery, major congenital anomaly/chromosomal anomaly/syndrome, NICU admission, and perinatal mortality. Therefore, according to our results, abnormal Doppler findings were not significantly more common in SGA newborns with adverse outcomes such as preterm delivery, major congenital anomaly/chromosomal anomaly/syndrome, NICU admission or perinatal mortality. However, this finding must be evaluated with caution due to the small sizes of the subgroups. One other limitation of our study is that we were not able to analyze and compare the obstetric outcomes according to each Doppler abnormality separately, again because of the small sample size. Unterscheider et al. (30) reported that Doppler interrogation of the UA and MCA remained the most useful tool in identifying fetuses at risk of adverse perinatal outcome, capturing 88% of all adverse outcomes; however, management of SGA fetuses is more complex and Doppler indices, biophysical profile scoring, amniotic fluid volume, and maternal health status might be in consideration.

The present study could not give any results about specific morbidities and long-term health outcomes of SGA newborns. As we had to analyze the data retrospectively. We were not able to document and evaluate all risk factors including tobacco, alcohol or illegal drug use; previous SGA child; weight gain during pregnancy; body mass index; socioeconomic status, and numbers of prenatal visits.

In conclusion, the definition, management, and timing of delivery of SGA fetuses are still under debate. This study aimed to determine risk factors associated with SGA that might either be known preconceptionally or in the earlier weeks of gestation, or be recognized during antenatal follow-up, as well as the possible adverse outcomes awaiting SGA newborns. ICSI pregnancies and mothers with known hypertensive disorders might be followed-up more closely with respect to the increased risk of SGA. In the case of SGA, oligohydramnios, gestational hypertensive disorders, major congenital or chromosomal anomalies or syndromes can be more commonly encountered and these clinical conditions might already be present before the appearance of abnormal biometric measurements and Doppler findings, or might be diagnosed later. More detailed anatomic screening of fetuses with SGA may provide to identify the anomalies; on the other hand, oligohydramnios or hypertension may be clues for recognizing SGA. According to the results of our study, regarding perinatal outcomes of SGA newborns, preterm birth, NICU admission and perinatal mortality risks are increased; therefore, the delivery of these fetuses must be planned at appropriate centers.

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The possible role of the da Vinci robot for patients with vulval carcinoma undergoing inguinal lymph node dissection

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Abstract

Inguinal lymph node dissection represents the gold standard of treatment for patients with vulval carcinoma. The application of minimally invasive techniques, such as robotics, in the surgical treatment of gynecologic cancer, reduced the rate of postoperative complications, which has an important impact on the quality of patients' life. Robotic inguinal lymph node dissection is a safe and oncologically effective but expensive and time-consuming approach in patients with penile cancer or melanoma. However, it is related with less postoperative complications, especially less lymphocele or lymphedema rates, and can improve the patients' quality of life while minimizing cost for health systems. The introduction of robot- assisted inguinal lymph node dissection in the treatment of vulval carcinoma may be identified as a provisional option for the gynecologic oncologist. Our intention was to present a brief review/commentary on the possible use of a robot-assisted technique on inguinal lymphadenectomy for patients with vulval cancer. (J Turk Ger Gynecol Assoc 2017; 18: 96-8)

Keywords: Da Vinci, vulval cancer, lymphadenectomy, robotics

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Introduction

The gold standard of vulval cancer management includes radical vulvectomy or wide local excision to achieve removal of the primary tumor followed by inguinal lymphadenectomy. Historically, Basset (1) in 1912 was the first to describe better survival rates of up to 74% in patients who had radical vulvectomy with an inguinal and pelvic lymphadenectomy (butterfly technique). Later, Taussig (2) used a less aggressive approach with separate incisions for the groin dissection and the vulvar excision with equally good results. However, such an approach was not widely accepted until 1981 when Hacker et al. (3) reported his study showing that the 5-year survival rate was 97%. Nowadays, the Royal College of Obstetricians and Gynecologists guidelines suggest wide local excision of the vulval tumor, followed by inguinal lymph node dissection performed using a triple-incision approach to minimize postoperative complications (4).

Inguinal lymph node dissection in women with vulval carcinoma is related with high postoperative complication rates e.g. lymphocyst, skin flap necrosis, and lymphedema or even up to 50% of wound infections (5). These morbidity rates are mainly related to the traditional open approach, and for this reason, some surgeons tried to develop minimally invasive techniques for inguinal lymph node dissection (6). Bishoff et al. (7) were the first to present a minimally invasive endoscopic approach for the groin node dissection. Josephson et al. (8) reported the first case of robotic inguinal lymphadenectomy. The main advantages of the robotic approach compared with laparoscopy include comfort for the surgeon, and a 3D approach with high magnification and instruments with a higher degree of freedom, especially in the limited working space of the groin (9).

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The aim of our manuscript was to present the robotic approach as a provisional option for patients with vulval cancer undergoing groin node dissection. Our intention was to present a brief review/commentary on the possible use of a robot-assisted technique on inguinal lymphadenectomy for patients with vulval cancer. The technique, advantages, and surgical challenges are discussed based on similar experience of other surgical specialties (e.g. urology, plastic surgery).

Technique

- Positioning the patient in a low lithotomy
- Bladder catheterization
- Surgical landmarks recognized
- Preparation of the surgical field with iodine solution
- Robot is located at 45° to the left side of the patient
- Assistant sits contralateral to the robot on the right side of the patient
- Femoral triangle is identified and a 2-cm incision is performed about 3 cm below its inferior aspect
- Scarpa's fascia is identified and after blunt-finger dissection, the scope is used to create a superficial subcutaneous flap by sweeping the lens under the fascia
- Pneumoperitoneum up to 15-20 mm Hg pressure
- Three robotic trocars are used (two 8-mm and one 10-mm trocar)
- Bipolar Maryland and monopolar scissors are the main instruments used
- The boundaries of the dissection are similar to the open approach
- Surgical specimens removed in a laparoscopic bag
- Saphenofemoral junction is exposed after opening the fascia lata and deep pelvic lymph node dissection can also be performed if necessary
- Hemostasis checked
- Suction drains are placed bilaterally
- Trocar incisions are closed in standard fashion

Discussion

There is not enough evidence regarding the role of the da Vinci robot (Intuitive Surgical, Sunnyvale, USA) in groin node dissection. The approach has never been used for patients with vulval cancer; however, it has been used in patients with melanoma or penile cancer (6, 8, 10-12). We present the possible advantages of such an approach in patients with vulval cancer based on the experience from other specialties or the videoscopic technique (13-15). The evidence from videoscopic groin node dissections suggests that the postoperative complication rates are lower compared with the open approach. More specifically, Lu et al. (16) performed a laparoscopic groin node dissection in 15 patients with vulvar cancer. The authors showed that only one patient with diabetes developed a wound infection. The rate of skin-related postoperative complications was 20% and the rate of cellulitis was 10%, which was significantly lower compared with the open technique (16). Similarly, another study presented the results of patients with penile cancer who were treated robotically with no surgical site complications (6). Kharadjian et al. (11) revealed that none of the 26 patients who underwent robotic groin node dissection developed any lymphocele or lymphedema, which implies that the risk of developing such complications is minimized. This can obviously be related to improved postoperative quality of life and body image, while it minimizes the cost of postoperative care for health systems. However, such early findings with such short follow-up, albeit encouraging, should be further clarified with randomized controlled trials.

Current data from patients with melanoma or penile cancer who underwent robotic groin node dissection suggest that it is safe and oncologically effective, and the morbidity rates seem to be lower compared with open surgery. The above mentioned are supportive for the future use of minimally invasive techniques in groin node dissections in patients with vulval cancer. The main advantages of the procedure include lower postoperative morbidity, shorter hospital stay, less time for recovery, less postoperative pain, and better cosmetic appearance. Regarding the nodal yield of the new approach, two studies showed comparable results to the traditional open approach (7.1 vs. 7.2, respectively, with 1.6 vs. 1.8 positive nodes respectively) (8, 13). On the other hand, longer surgical time is essential for the minimally invasive approach, which can obviously increase the operation cost, but this could be improved in parallel to the learning curve of each individual surgeon.

Local recurrence rates after six years of follow-up can reach 6.6% in the robotic versus 7.7% in the open approach (13). Tobias-Machado et al. (17) showed that there was no local or systemic recurrence during a mean follow-up of 31.93 months in patients who underwent laparoscopic groin node dissection. For all the above reasons, Kharadjian et al. (11) concluded that the robotic method maintained consistency with oncologic principles in patients with penile cancer.

Several limitations can be found in such a newly developed approach. The retrospective nature of the available studies is one of them. Prospective randomized controlled trials are necessary to clarify the morbidity rates and advantages of this new approach. The main objections that could be raised include cost and learning curve; however, the long-term benefits of robotic inguinal lymph node dissection must be weighed against the cost of the da Vinci robot. Nevertheless, the robot-assisted

technique could be proved cost-effective in centres with large series of patients (18). Moreover, the risk of port site metastasis should also be clarified in the future. Iavazzo and Gkegkes (19) showed that the port site metastasis rate in patients who had robotic operations for other gynecologic cancers was an extremely rare entity and was related to various factors, among which was the improper manipulation of the removed tumor. To date, no port site metastasis has been reported in the literature for patients who underwent robotic groin node dissection.

However, such a time-consuming minimally invasive approach in a closed field might be challenged by traditional surgeons. Gyneoncologists with expertise in robotic surgery and familiarity with groin node dissection should perform such operations in order to achieve similar oncologic outcomes to the traditional technique, including lymph node count and survival. Optimization of patient selection can further clarify the reported surgical outcomes such as operative time, nodal yield, morbidity, five-year survival, and recurrence rates. Naldini et al. (20) suggested that a multicenter prospective randomized study would clarify whether the minimally invasive approach for patients with vulval cancer could replace the standard open approach used for groin node dissection.

Conclusion

By learning from other specialties' experience, we can see that robotic groin dissection is safe and oncologically effective, but expensive and a time-consuming approach in patients with penile cancer or melanoma. The fact that it is related with fewer postoperative complications, especially less lymphocele or lymphedema, could lead to improvements in patients' quality of life and minimize cost for health systems. For these reasons, in our opinion such an approach should also be applied in patients with vulval cancer, even though, in order to reach safe conclusions, randomized trials should be performed.

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What is your diagnosis?

A para1 woman aged 27 years presented with a 5-month history of heaviness and abdominal distension. The distension had gradually increased over time. There was no history of fever or weight loss. Bowel and urinary habits were normal. Her menstrual cycles were regular. She underwent a cesarean delivery 1 year previously. Intraoperative notes showed an 11x9x8-cm fundal fibroid, her ovaries were normal. The cesarean section was uneventful and myomectomy was not attempted at that time. The post-operative period was uneventful.

When she visited our outpatient department, she was carrying ultrasonography (USG) and magnetic resonance imaging (MRI) reports, which were suggestive of a dermoid cyst or mucinous ovarian tumor. Her hemoglobin was 9.3 gm/dL, the total leukocyte count (TLC) was 6000 cells/mm^3, and markers for ovarian tumor such as Ca-125 were negative. The MRI films are shown in Figure 1.

On general physical examination, the patient was maintaining good health. Her vitals were stable. In her abdominal examination, a healed cesarean Pfannenstiel scar was seen, there was a cystic mass filling the whole abdomen, the lower limit could not be reached, and mobility was restricted. The abdomen was not tender. In the vaginal examination, the uterus was bulky and the same mass was felt through the anterior fornix.

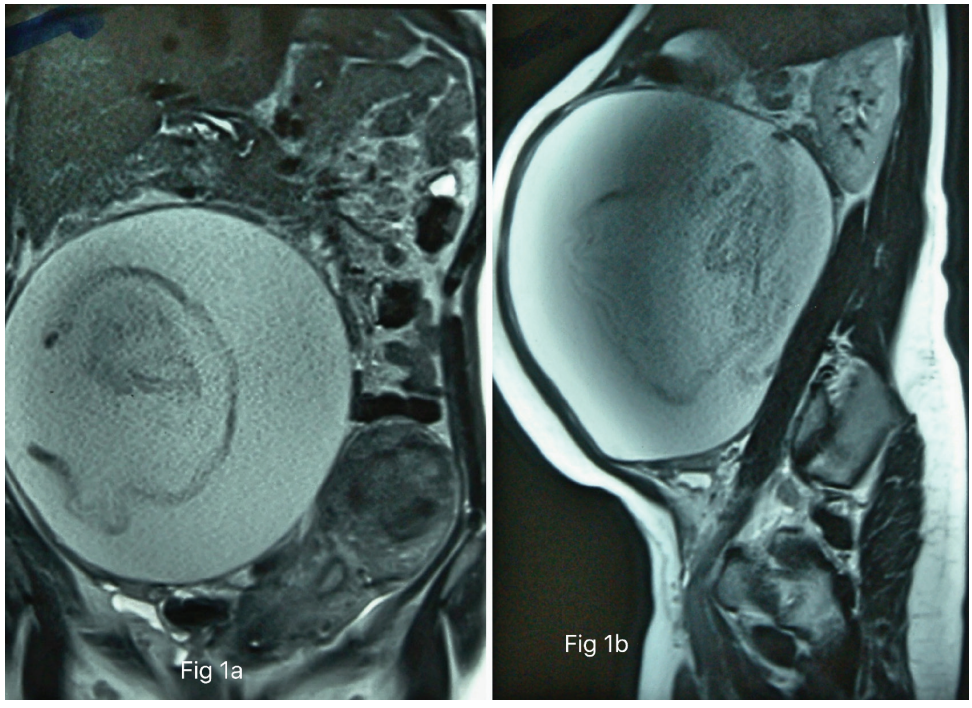

Figure 1. T1-weighted magnetic resonance imaging images (a) Coronal section (b) Sagittal section

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Answer

The plan was unilateral ovariotomy and staging if the mass appeared malignant because imaging showed tumor confined to one ovary and the patient was P1L1. The possibility of malignancy and the treatment plan of optimal cytoreduction in the event of extra-ovarian disease was explained to the patient and husband prior to surgery. On opening the abdomen, a thick-walled cyst extending up to xiphisternum was encountered. There were flimsy adhesions with the omentum. The content of the cyst (pus) was aspirated with a 21-gauge needle. A stab incision was made and 5 liters of pus was drained. The incision was increased and a whole sponge was found and removed from inside (Figure 2). Further mobilization revealed that bowel formed the posterior wall. Both ovaries were seen separately. There was a subserous fibroid 10x8 cm in size. This was an encysted collection of pus around the sponge, which had been retained in the right paracolic gutter at the time of cesarean section. The abscess wall was removed, the part that involved the bowel was left. A wide bore drain was kept in place for 48 hrs. Myomectomy was not performed because the fibroid was subserous and asymptomatic and there was pus. The pus culture was sterile. The patient received broad spectrum antibiotics (piperacillin + tazobactam and metronidazole) intravenous for 7 days. Postoperative recovery was uneventful and the patient was discharged on day 7 in a stable condition.

Retrospectively, when we took the history again, the patient recalled that she had fever during the post-cesarean period, which settled after a course of antibiotics. Reviewing the MRI images, the strand-like structure was actually the sponge in the abscess. Probably a simpler investigation such as X-ray of the abdomen would have picked up the diagnosis. We did not suspect a retained surgical item because the patient did not initially report a history of fever in the postoperative period.

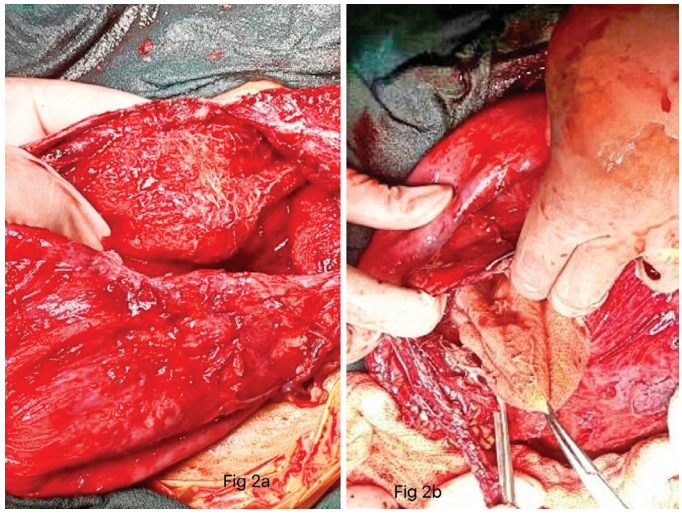

Figure 2. Intraoperative findings (a) A pseudocyst wall that contained 5 liters of pus with retained sponge in situ (b) A retained surgical sponge (held with artery forceps)

Retained surgical items (RSI) are a preventable cause of patient morbidity and sometimes mortality. It is included in the 27 "never events" released by the National Quality Forum in the United States of America (1). In a systematic review, authors reported 1.32 RSI events per 10,000 surgical procedures (2). Gawande et al. (3) reported 8 risk factors for RSI, which included emergency operation, unexpected change in operation, more than one surgical team involved, change in nursing staff during procedure, body mass index (BMI), volume of blood loss, female sex, and surgical counts. Out of these risk factors, emergency surgery, unplanned change in the operation, and BMI were found as statistically significant.

Sponges are the most common RSI (68%) (4). Retained surgical sponges are known as gossypiboma, which consists of two words: gossypium (cotton) and boma (place of concealment). A retained sponge may lead to two types of reaction. The first is an acute inflammatory reaction, which may present as infection or formation of an abscess surrounding the retained sponge. The other type of reaction is an aseptic fibrous reaction, which includes formation of adhesion and granuloma surrounding the retained sponge, eventually presenting as a mass (5). Wan et al. (6) performed a systemic literature review of retained surgical sponges from 1963 to 2008, including 254 cases. The most common location was the abdomen (56%), followed by the pelvis (18%). Out of 254 cases, 42% presented with pain/irritation followed by palpable mass (27%), fever (12%), and obstruction (9%); 6% of cases were asymptomatic. The most commonly used diagnostic modality was computed tomography (CT) (61%) and X-ray (35%). USG was used in (34%), and MRI was performed in 20% cases. These cases were at high risk for complications such as capsule formation (51%), adhesions (31%), abscess (24%), and fistula formation (20%) (6). Our patient presented with an abscess, possibly secondary to infection in an exudative reaction due to the sponge. What is unusual, however, is a delayed presentation and no symptoms of fever and pain.

In a series of 8 cases by Chopra et al. (7), five patients presented after abdominal hysterectomy, two patients had a history of lower (uterine) segment cesarean section (LSCS) and another one had a history of ovarian cystectomy. The presentation varied among the patients and included fever, abdominal pain, intestinal fistula, pus discharge from the abdominal wound, and a palpable lump in the abdomen.

Palpable masses in the abdomen/pelvis may be confused with soft tissue tumors based in that location (8). Patients usually present weeks to years after primary surgery and the longest duration reported in the literature was 35 years after Billroth I gastrectomy in a male (9).

Often misdiagnosed preoperatively, a high index of suspicion and imaging studies can help in making the diagnosis. Abdominal X-ray is the first-line investigation and CT is the confirmatory imaging test. MRI has no diagnostic use in such cases because the radiopaque marker is neither magnetic nor paramagnetic, hence not visible on MRI (5).

The usual treatment of an RSI is surgical removal through an open or laparoscopic approach (10).

To emphasize, prevention is always better than cure. To decrease the incidence of RSI, a few new technologies have been developed such as radio-frequency chip identification by barcode scanner (11), computer-assisted counting of sponges using barcodes (12), and a data-matrix–coded sponge counting system in addition to standard manual counting protocols (13). Where these facilities are not available, accurate sponge counts once before surgery, twice after surgery, and better communication between members of the surgical team are mandatory to avoid such unnecessary complications. The diagnosis of RSI should be kept in mind in any postoperative patient who presents with pain, infection or palpable mass.

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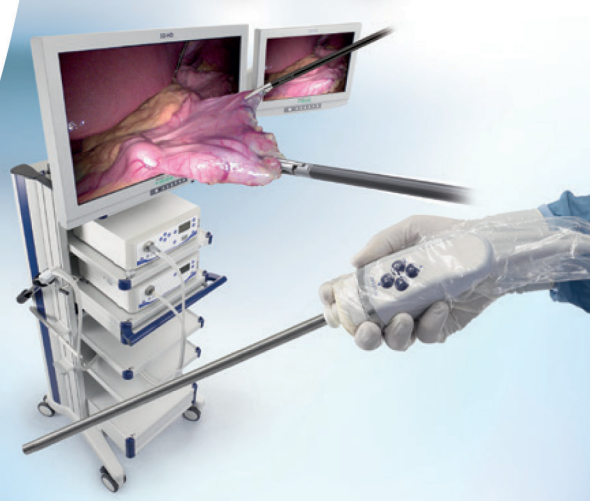

5th SEERSS 1st GynoOncoMIS and Robotic Surgery Congress Abstracts

Oral Presentation

OP-01

Robotic-assisted sacrohysteropexy for pelvic organ prolapse: Initial experience and literature review

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Objective: To declare our initial results of robotic-assisted sacrohysteropexy for pelvic organ prolapse and compare with the present literature.

Material and Methods: The results of 15 patients with apical vault prolapse those underwent robotic-assisted sacrohysteropexy were included.

Results: The mean gravidy was 3.87±1.62 (range 1-8) and the mean parity was 3.25±1.61 (range 1-8). The mean age of the study population was 50.94±5.1 (range 43-61) years. The mean duration of surgical procedure was 163.13±43.77 (range 120-270) minutes. The mean postoperative hospital stay was 3.81±0.98 (range 2-5) days. There was no identified failure of the surgeries after 6 months follow up.

Conclusion: According to recent data, the robotic-assisted sacrohysteropexy surgery had shorter operating time (120.2 min), less operative bleeding (50 mL; mean hemoglobin drop 1.4 g/dL), and fewer postoperative symptoms. Patients' overall satisfaction and required reoperation due to postoperative complications were the same with open sacrohysteropexy technic. As a initial reports of our department, we also have observed better patients postoperative satisfaction results with the literature. By improvement in experience, we will have shorter operation durations.

Keywords: Pelvic organ prolapse, robotic surgery, sacrohysteropexy

OP-02

Technique of robotic hysterectomy: TIPS and TRICKS

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Robotic hysterectomy has been popularly preferred after 2005 FDA gave confirmation for operation (1). Compared with laparoscopy it has same results, equal intraoperative and short term postoperative outcomes so that is widely accepted as an alternative surgical approach in appropriately selected gynecologic patients. Main advantages are the wrist-like motion of the robotic arms, allowing difficult movements deep in the pelvis, a three-dimensional view, lower blood loss (even <60 mL), fewer wound complications, fewer urinary tract injuries, minimal rates of conversion to open, reduction of tremor interference, a reduced lenght of hospital stay (same day discharge) and a faster return to normal activities, improved quality of life, surgeons' fatigue is minimized and decreased learning curve for intracorporeal suturing (2). However the economic feasibility of robotic surgery still remains as another obstacle to be solved. Our aim is to explain the surgical techniques of robotic hysterectomy. The standardization of the technique using tips and tricks and recognition of critical anatomical landmarks can shorten the leaning curve in such a way that the surgeon can achieve cost effective use of the equipment.

Keywords: Robotics, hysterectomy, minimal invasive surgery

OP-03

Laparoscopic single port surgery (SPLS) for management of ruptured ovarian ectopic pregnancy

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Objective: Ovarian pregnancy is a rare entity but incidence is on rise (1/2100-1/7000 pregnancies) often overlooked and associated with higher maternal morbidity and mortality. The aim of this presentation is to assess the management of ruptured ovarian ectopic pregnancy that is a life threatening gynecological emergency.

Case: 28 year-old G3P2 woman presented with lower abdomial pain. Tachycardia (108 bpm), blood pressure 90/60 mmHg, with abdominal guarding and the presence of cervical excitation were noted on examination. Transvaginal sonography showed only significant intraabdominal bleeding. Haemoglobin was 8,8 and b-hCG was 17232. Ruptured ectopic pregnancy was diagnosed and immediately SPLS was performed. Unilateral salpingooophorectomy was performed on the left side.

Discussion: Spiegelberg described diagnostic criteria (1878) for ovarian pregnancy; the fallopian tubes, including fimbria, must be intact and seperate from the ovary; the gestatinal sac must occupy the normal position of the ovary; the ovary must be attached to the uterus through the uteroo-ovarian ligament and there must be ovarian tissue attached to the pregnancy in the specimen. Our case fulfills all of these criteria. Ovarian pregnancy had been treated by ipsilateral oophorectomy, but the trend has been shifted toward conservative surgery such as cystectomy or wedge resection performed at either laparotomy or laparoscopy. Management options like medical therapy have been tried with various success rate. In our case oopherectomy had to be resorted because of uncontrolled hemorrhage.

Conclusion: Practitioners should be aware of non-tubal pregnancies to aid more efficient diagnosis, optimise management and increase patient safety. As more innovations of surgical instruments occur, the technical challenges of the procedure will be reduced and it is likely that single port gynecologic surgery will be adopted even further.

Keywords: Ectopic pregnancy, SPLS, laparoscopic

OP-04

Results of surgery for women with apical vaginal prolapse during robotic surgery adoptation process

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Objective: We evaluated patients underwent surgery for apical vaginal prolapse from July 2015 to November 2016. First year efficacy and safety of laparoscopic/robot assisted sacrocolpopexy compared with vaginal surgery (SSF and colpocleisis).

Material and Methods: We performed 11 robotic, 12 laparoscopic SCP and 15 vaginal operation (5 colpocleisis, 10 SSF). Robotic assisted patients were younger, had lower parity and ASA grade, had lower stage of prolapse compared to vaginal surgery group but not LS group.

Results: Duration of operation is less in patients in the vaginal surgery group (65±24) compared with the LS group (160±40) and robotic surgery group (254±65 min). Intraoperative blood loss and length of hospital stay is similar in all groups. But complications were more common in laparoscopic and robotic surgery groups. Anatomic cure wasn't different between robotic and LS group, but one women developed recurrent apical prolapse in SSF group. Symptomatic cure was high for all groups. Mesh exposure occurred in one robotic SHP patient.

Conclusion: Laparoscopic/robotic SCP and vaginal procedures had similar short term cure rates and high satisfaction. Higher recurrence rate in vaginal approach and higher thromboembolic events in endoscopic surgery take in account during determining type of surgery.

Keywords: Uterine prolapse, apical prolapse, sacrocolpopexy, robotic surgery

Table 1. Baseline characteristics

Mean ± SD median (IQR)	Robot assisted n=11	Laparoscopic n=12	Vaginal n=15	p value
Age	55.6±7.3	62.9±5.7	69.6±8.2	0.021
Parity	3 (2)	3 (3)	4 (3)	0.123
BMI	27.2±3.4	25.8±2.8	26.8±5.0	0.307
ASA grade	1 (1)	2 (0.5)	2 (2)	0.087
Prior gynecologic operation Colporrhaphy TAH Abdominal SCP VH	 1 2 1 -	 - 2 - 2	 2 2 1 1	
POP_Q stage	3 (0)	3 (1)	4 (1)	0.053
Point C	3.6±1.2	3.0±1.4	3.6±2.0	0.580

Table 2. Peri-post operative findings

Finding	Robot assisted n=11	Laparoscopic n=12	Vaginal n=15
Length of stay (day)	3 (2)	3 (0)	2 (0)
Length of procedure (min)	254±65	160±40	65±24
Change in Hct	-4.5±2.6	-5.0±1.7	-4.9±2.4
Types of surgery	SCP=9 SHP=2	SCP=9 SHP=1 Lateral suspension=2	SSF=10 Colpocleisis=5
Conversions LS-SCP to lateral suspension	0	2	0
Concomitant procedures Colporrhaphy TOT Anterior vaginal mesh Adhesyolysis Vaginal hysterectomy	 2 2 - 2 -	 3 1 - 1 1	 4 3 3 - 2
Complications Embolism Cuff cellulitus Bladder perforation Mesh erosion	1 (pulmonary) 2 - 1	1 (venous) - - -	- - 1 -
Postoperative findings POP-Q points C Aa Ab De novo SUI Apical prolapsus Anatomic cure Symptomatic cure	n=8 -7 (2) -1 (1.7) -1 (1.7) 1 - 6/8 (85.7%) n=10 9 (90%)	n=8 -7 (2) -1 (1) -2 (2.7) 2 - 8/8 (100%) n=9 8/9 (88.9%)	n=2 -6 and +3 -2 and +3 -1 and +4 1 1 ½ n=8 7/8 (87.5%)

OP-05

Cystoscopic evaluation of ureteral patency and bladder with indigo carmine vital dye

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Objective: Ureteral injuries is not common but could be life threatening injuries in gynecological surgeries. Detecting injury intraoperatively is very important. Because, indigo carmine has been using for several years as a vital dye for detecting ureteral injuries at the meantime of the gynecological and laparoscopical surgeries. As a routine, we have been performing intraoperative cystoscopy in vaginal, abdominal and laparascopic surgeries if necessesary. We want to present our experience with indigo carmine vital dye for ureteral patency and bladder consistency in urogynecological surgeries.

Material and Methods: This was a retrospective study of all women who underwent cystoscopic evaluation of ureteral patency at the time of urogynecological surgery from 2013 January to 2016 january at a tertiary care referral center. We investigated patients who received indigo carmine vital dye for detecting possible ureteral injuries intraoperatively in vaginal, laparascopic or abdominal surgeries.

Results: 250 patient was included into the study. Two patients had delayed indigo carmine ureteral pass and supposed ureteral kinking and one patient had not visible ureteral patency with indigo carmine. There was no allergic reaction and there was no complication because of indigo carmine. All these patients were evaluated intraoperatively.

Conclusion: Intraoperative cystoscopy with indigo carmine vital dye is an easy way to detect ureteral patency easily with low cost and without complication.

Keywords: Cystoscopy, indigo carmine, laparoscopy, vaginal surgery

OP-06

Single-port laparoscopy for treatment of concomitant adnexal masses and cholecystectomy or appendectomy

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Objective: To report our experience treating adnexal masses concomitant with appendectomy or cholecystectomy using a combination of the SILS TM port and straight non-roticulating laparoscopic instruments.

Material and Methods: The study included 9 women with symptomatic and persistent adnexal masses with appendicitis or cholecystitis. Removal of adnexal masses and performed appendectomy or cholecystectomy via single-incision laparoscopic surgery using a combination of the SILSTM port and straight non-roticulating laparoscopic instruments.

Results: Six patients had symptomatic complex adnexial masses and 3 patients had symptomatic myoma uteri. In 2 of the patients had myoma uteri, appendectomy (hysterectomy+BSO+appendectomy) were performed concomitantly and in 1 of patients had myoma uteri cholecystectomy (hysterectomy+BSO+cholecystectomy) were performed concomitatly. In 4 of the patients had symptomatic adnexal masses appendectomy (hysterectomy+bso or uso or cystectomy+appendectomy) were performed concomitantly and in 2 of patients had complex adnexial masses cholecystectomy (hysterectomy+USO or USO+cholecystectomy) were performed concomitatly. Mean age of the patients was 47.1 years and mean duration of surgery was 128 min. All patients were treated using straight, non-roticulating laparoscopic instruments. Mean tumor diameter was 5.5 cm (range: 3-9 cm) at patients with adnexial masses. All patient pathology reports were benign. None of the patients converted to laparotomy. All patients were discharged on postoperative d 1. None of the patients required readmission to hospital. Post surgery all patients reported that they were satisfied with their incision and cosmetic results.

Conclusion: SILS with classical laparoscopic instrument is more cost effective than standard SILS and can result in better aesthetic result, improve the time of recovery, and less postoperative pain than classical laparoscopy for the treatment of adnexal masses concomitant appendectomy or cholecystectomy.

Keywords: Single port, single incision laparoscopic surgery, cholecystectomy, adnexal mass, appendectomy

Table 1. Characteristics of the patients

Patients no	Age (Years)	Type of adnexal masses	Concomitant operation	Type of operation	Pathology
1	44	Myoma uteri	Appendectomy	Myomectomy + appendectomy	Myoma uteri, appendicitis
2	66	4 cm complex ovarian cysts	Cholecystectomy	USO + cholecystectomy	Mucinous cystadenoma + cholecystitis
3	48	Myoma uteri	Appendectomy	Hysterectomy + BSO + appendectomy	Myoma uteri, appendicitis
4	30	6 cm complex ovarian cysts	Appendectomy	USO + appendectomy	Mucinous cystadenoma + appendicitis
5	54	Myoma uteri + Ovarian cysts	Cholecystectomy	Hysterectomy + BSO + cholecystectomy	Myoma uteri, cholecystitis
6	45	9 cm ovarian cysts	Cholecystectomy	USO + Cholecystectomy	Torsione cysts + cholecystitis
7	48	6 cm ovarian cysts	Appendectomy	Hysterectomy + BSO + appendectomy	Mature cystic teratome, appendicitis
8	63	Myoma uteri + Ovarian cysts	Cholecystectomy	Hysterectomy + USO + cholecystectomy	Myoma uteri, cholecystitis
9	26	Ovarian cysts	Appendectomy	Cystectomy + appendectomy	Appendicitis

OP-07

Laparoscopic management of an ovarian torsion in a woman with 7 weeks' gestation

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Objective: Ovarian torsion (OT) is one of the most common gynecologic surgical emergencies. All age groups can be affected, but ovarian stimulation, as found during early pregnancy or infertility treatment, is a major risk factor. Diagnosing OT in early pregnancy can be challenging. Patients frequently present with abdominal pain and non-specific symptoms. Missed diagnosis of OT could lead not only to ovarian necrosis and sepsis, but also threaten the pregnancy. The objective of this article is to present a case of OT in early pregnancy and its laparoscopic management.

Case: A 40-year-old woman at 7 weeks gestational age presented to the Emergency Department (ED) with 2 h duration of abdominal pain, nausea, and vomiting. The patient was not on ovarian stimulation treatments. A bedside ED ultrasound showed an enlarged edematous right ovary with a large cyst, but without flow on color Doppler. The patient underwent emergent laparoscopic surgery. Right ovarian cystectomy was performed without using any energy modalities after detorsion of the right ovary. She was placed on progesterone therapy upon hospital discharge and eventually delivered a healthy term infant.

Conclusion: Laparoscopic surgery can be safely performed in pregnant patients for ovarian torsion, in first trimester.

Keywords: Adnexal mass, ovarian torsion, ultrasonography, pregnancy

OP-08

An initial experience with Da Vinci XI® robotic-assisted system

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Objective: Major improvements in endoscopic surgery in gynecology over the last 40 years have changed the management of gynecologic procedures. In 1998, the first robotic procedures were performed in gynecology. Since then, several studies have been published about robotic hysterectomy demonstrating the feasibility and safety of this new procedure. We present herein an initial experience with robotic-assisted surgeries for benign and malign gynecological diseases.

Material and Methods: Between May 2015 and November 2016, 26 procedures were performed with support of the Da Vinci XI® robotic system. Demographic and perioperative findings of the patients were collected from robotic surgery form of our clinic.

Results: Twenty-two patients underwent operations for benign and 2 for malignant lesions. The median age of patients was 49 years (range 29-69 years) and median BMI was 26.4 kg/m^2 (19.5-35.5 kg/m^2). Procedure time (174 vs 64 minutes, $p<.0001$) and total operating time was 190 min (120-430 min) and consol time 20 min (15-30 min). Estimated blood loss was 50 mL (15-210 mL). Change in hemoglobin (Hb) was 1.6 gr/dL (0.8-3.8 gr/dL) and length of hospital stay was 2 days (2-8 days). Intra-operative data of the patients are summarized in Table 2. No intraoperative complication was observed and conversion to an open procedure was not necessary in any patient.

Conclusion: We present our initial experience with robot-assisted surgery. Robot-assisted gynecologic surgery is associated with longer operating time but decreased blood loss, and tolerable complication rates.

Keywords: Robotic surgery, gynecology, initial experience

Table 1. Patient characteristics

Case	Age (years)	Parity	BMI	Medical history	Prior abdominal surgery
1	47	3	24.4	None	None
2	48	2	27.3	None	Cesarean
3	50	5	27.5	DM	None
4	50	4	27.2	DM+HT	None
5	36	2	21.4	None	None
6	47	2	19.5	None	Cesarean
7	53	2	22	HT	Unilateral salpingooophorectomy
8	54	2	23.4	HT	None
9	48	3	30.4	None	None
10	69	3	28.1	DM+HT	Abdominal hysterectomy + salpingooophorectomy
11	33	3	28	None	Cesarean
12	50	2	25.5	None	None
13	50	2	26.6	HT	None
14	63	3	35.5	HT	Appendectomy
15	47	4	26.3	HT	None
16	53	2	33.6	DM	Cholecystectomy
17	51	2	28.8	None	None
18	46	2	23.3	None	None
19	40	4	24.8	None	Cesarean
20	65	1	24.4	HT	Cholecystectomy
21	52	1	33.6	HT	Cesarean
22	35	3	22.5	None	None
23	39	0	24.9	None	Appendectomy
24	29	0	21.5	None	None
25	46	3	29	None	None
26	50	3	34.1	None	None

Table 2. Operative outcomes of patients

Case	Diagnosis	Procedure	Total operation time (skin to skin) (min)	Blood loss (mL)	Change in Hb (g/dL)	Length of stay (day)
1	Uterine desensus	Hysterectomy + salpingooophorectomy+sacrocolpopexy	170	180	2.9	2
2	Ovarian cyst	Hysterectomy + salpingooophorectomy	140	25	0.8	2
3	Myoma	Hysterectomy + salpingooophorectomy	190	70	1.8	2
4	Myoma	Hysterectomy + salpingooophorectomy	130	40	1.1	3
5	Myoma	Myomectomy	160	75	1.8	2
6	Myoma	Hysterectomy + salpingooophorectomy	190	210	3.8	2
7	Uterine desensus	Hysterectomy + unilateral salpingooophorectomy + sacrocolpopexy	220	50	1.1	2
8	Myoma	Hysterectomy + salpingooophorectomy	130	50	0.8	3
9	Myoma	Hysterectomy + salpingooophorectomy	120	110	2	4
10	Desensus	Sacrocolpopexy	220	40	1	8
11	Cervical cancer	Pelvic lymphadenectomy + bilateral ovarian transposition + bilateral salpingectomy	270	90	1.6	5
12	Myoma	Hysterectomy + salpingooophorectomy	220	130	2.6	2
13	Myoma	Hysterectomy + salpingooophorectomy	220	20	0.8	3
14	Uterine desensus	Hysterectomy + salpingooophorectomy+sacrocolpopexy	250	85	2.1	3

Table 2. Continued

Case	Diagnosis	Procedure	Total operation time (skin to skin) (min)	Blood loss (mL)	Change in Hb (g/dL)	Length of stay (day)
15	Uterine desensus	Sacrouteropexy	140	15	1.2	3
16	Myoma	Hysterectomy + salpingooophorectomy	240	140	2.8	2
17	Myoma	Hysterectomy + salpingooophorectomy	120	50	1.8	2
18	Myoma	Hysterectomy + salpingooophorectomy	190	35	1.8	2
19	Myoma	Hysterectomy	170	100	2.9	2
20	Uterine desensus	Hysterectomy + salpingooophorectomy + sacrocolpopexy	240	15	0.9	4
21	Uterine desensus	Sacrouteropexy	170	50	1.6	2
22	Cervical cancer	Hysterectomy + pelvic lymphadenectomy + bilateral ovarian transposition	430	100	1	7
23	Myoma	Myomectomy	140	95	1.8	2
24	Sex reassignment surgery (female-to-male)	Hysterectomy + salpingooophorectomy	150	15	0.8	2
25	Myoma	Hysterectomy + salpingooophorectomy	240	20	1.1	5
26	Uterine desensus	Hysterectomy + salpingooophorectomy + sacrocolpopexy	220	20	1.3	2

OP-09

Laparoscopic approach to adnexal masses

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About 5% of women are admitted to the surgery due to adnexal masses (1). 4-24% of the adnexal masses diagnosed in the premenopausal period and 39-63% in the postmenopausal period were reported as malignant (2). Patients with adnexal masses can be evaluated preoperatively with clinical findings, comorbidities and laboratory results, and different approaches can be made. In this presentation, we will describe the approach to different medical and operative difficulty levels on three different patients who were diagnosed with adnexal mass.

Keywords: Adnexal mass, laparoscopy, gynecology

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OP-10

Laparoscopic hysterectomy: As a surgical approach for women with benign gynaecological conditions

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Case: A 49-year-old multiparous woman presented with abnormal uterine bleeding (G4P3). In examination, uterus was founded 10w sizes and palpable 4x5 cm leiomyoma at posterior side. In ultrasound scanning, uterus size was 12x6 cm, endometrial line regular 4mm, bilateral adnexes was normal. Laparoscopic hysterectomy and bilateral salpingoophorectomy has been planned and performed. Pathological evaluation revealed leiomyoma uteri and benign endometrial changes.
Results: Hysterectomy is one of the most frequently performed the gynaecologic surgical procedure and can be carried out vaginally, abdominally, laparoscopically, or with robot-assisted laparoscopy. The most common indications for hysterectomy are symptomatic uterine leiomyomas (40.7%), endometriosis (17.7%), and uterine prolapse (14.5%). Abdominal hysterectomy is performed in 66% of cases, vaginal hysterectomy in 22% of cases, and laparoscopic hysterectomy in 12% of cases (1). Although vaginal hysterectomy is offered as the safest and most cost-effective route by which to remove the uterus, laparoscopic hysterectomies have greatly increased within the last few decades and even exceed the number of vaginal hysterectomies. Laparoscopic hysterectomy is particularly useful in patients with limited vaginal access, a fixed immobile uterus, and in those women who desire supracervical hysterectomy (2, 3).

Keywords: Hysterectomy, benign gynaecological disease, laparoscopic hysterectomy

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OP-11

Mini-laparoscopy setting in total laparoscopic hysterectomy: Single institution experience

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Objective: To evaluate the feasibility of mini-laparoscopy (M-LPS) by using percutaneous endoscopic instrument in total laparoscopic hysterectomy (TLH).

Material and Methods: Prospective observational study. Tertiary-care university-based teaching hospital and academic affiliated private hospital. Twenty-one women who underwent mini-laparoscopic hysterectomy, between December 2015 and November 2016. M-LPS was performed through one optical transumbilical 5-mm trocar, one 5-mm ancillary port on the right side, one 3-mm ancillary port on left and one 2-mm percutaneous endoscopic instrument (MiniGrip® Handle, Teleflex Inc. Wayne, USA) (Figure 1). A 5-mm 0-degree endoscope, 3 mm laparoscopic instruments and integrated bipolar and ultrasonic technology (Thunderbeat, Olympus Medical Systems Corp, Tokyo, Japan) were used. All operations were performed by the same surgeon.

Results: A total of 21 patients were included. The median age was 50 years (range, 41-56 years); body-mass index was 29 kg/m^2 (range, 25-33 kg/m^2), and uterine weight was 250 gr (range, 80-290 gr). Of the 21 patients, 15 had uterine myomas; 4 had endometrial hyperplasia; and 2 had adnexal mass. The median operating time was 110 minutes (range, 80-185 min), and estimated blood loss was 85 mL (range, 60-180 mL). Conversion to laparotomy and blood transfusion was not required. Recovery of gastrointestinal activity and spontaneous urination started at median 18 hours (range, 12-24 hour) and 6 hours (range, 4-8 hour), respectively. The median amount of carbondioxide usage is 250 mL (range, 100-400 mL). Intra- and postoperative complications were not observed.

Conclusion: Mini-laparoscopy by using percutaneous instrument is feasible and nearly "scar-free" procedure that promotes quick recovery and acceptable operation time with minimal blood loss and excellent post-operative pain scores.

Keywords: Mini-laparoscopy, percutaneus instrument, hysterectomy

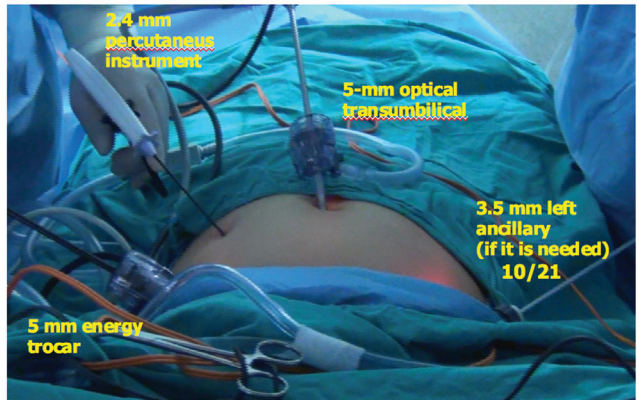

Figure 1. Configuration of trochars

Table 1. Patient characteristics

Patient characteristics

	TLH* (n=21)
Age, years	50 (41-56)
BMI, kg/m^2	29 (25-33)
Uterine weight, grams	250 (80-290)
Operation time, minutes	110 (80-185)
Estimated blood loss, mL	85 (60-180)
Indication of hysterectomy, n(%)	
Uterine fibroids	15 (71)
Endometrial hyperplasia	4 (19)
Adnexal mass	2 (10)

* data are given as median (range) or No.(%), as approriate

OP-12

Safety and efficacy comparison of two different uterine manipulators in total laparoscopic hysterectomy

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Objective: To evaluate the safety and efficacy of two different uterine manipulators in total laparoscopic hysterectomy (TLH).

Material and Methods: One-hundred and twenty-five women who underwent TLH, between January 2014 and January 2016 in tertiary-care university-based teaching hospital and private hospital. All operations were performed by two expert endoscopic surgeons using one of the following two uterine manipulators: (1) Clermont-Ferrand (CF) (Karl Storz, Gmbh and Co, Tuttlingen, Germany) and VECTEC (VT) (VECTEC, Hauterive, France). Lateral movement and elevation of the uterus, visualization of the vaginal fornix, difficulty of insertion, maintenance of pneumoperitoneum and handling were evaluated using visual analog scale (VAS) and graded as either good, fair or poor. Number of insertion attempts, need for switching to an alternative uterine manipulator, and colpotomy time were recorded. The data were re-analyzed by re-watching un-edited videos of the operations and reviewing special laparoscopic hysterectomy files.

Results: A total of 125 patients were included. The CF was used in 62 patients, and the VT was used in 63. The baseline characteristics of two groups were comparable (Table 1). There were no differences in surgery related outcomes between two groups (Table 2). Compared with the CF group, the VT group had better visualization for vaginal fornices ($p<0.001$) and maintenance of pneumoperitoneum ($p<0.001$). On logistic regression analysis, lateral movement and elevation of the uterus between two groups were not significant, after adjusting for uterine weight (adjusted p value=0.27). Re-attempt for placement or need for switching to an alternative instrument was not required in any of the groups. As an intraoperative complication, two patients (1.2) had uterine perforation during placement of VT.

Conclusion: VT is associated with better visualization and pneumoperitoneum maintenance while other parameters were similar for both uterine manipulators.

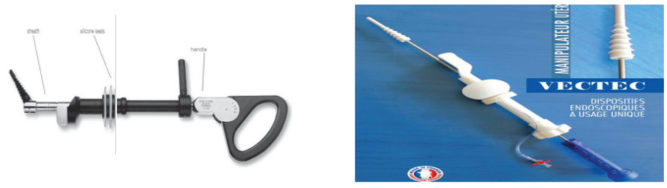
Keywords: Laparoscopy, total hysterectomy, uterine manipulators

Table 1. Qualitative assessment

Qualitative assessment of the use of uterine manipulators

Visualization of vaginal fornices , %				
Poor	0	0	<0.001	0.008
Fair	18	0		
Good	82	100		
Handling, %				
Poor	0	0	0.07	
Fair	8	19		
Good	92	81		
Placement of uterine manipulator, %				
Poor	18	2	0.002	<0.001
Fair	13	29		0.001
Good	69	69		
Requirement for additional tool, %	73	6	<0.001	
Uterine trauma, %	0	2	0.24	
Adequate pneomoperitoneum, %				
Poor	22	0	<0.001	
Fair	68	3		
Good	10	97		

data are given as median (range) or No.(%), as approriate



Clermont-Ferrand (CF) (Karl Storz, Gmbh and Co, Tuttlingen, Germany

VECTEC (VT) (VECTEC, Hauterive, France)

Figure 1. Uterine manipulators

OP-13

Multimodality approach is essential for reversible paraneoplastic limbic encephalitis caused by ovarian teratoma with autoantibodies to NMDAR (N-methyl-D-aspartate receptor)

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Objective: Paraneoplastic encephalitis (PLE) associated with various tumors and in only 3-4% it is associated with ovarian teratomas derived from the primordial germ cells of the ovary. The pathogenesis of PLE is incompletely understood, but it is believed to be associated with antibody and T-cell responses against the expression of shared epitopes in the nervous system and the tumors. So resection of the tumour appears significant in achieving sustained neurological recovery. PLE can even lead to death when treatment for the occult tumor is delayed or inappropriate. This case report emphasizes the crucial role of the gynecologist in these remote nonmetastatic complications of a PLE associated with teratoma in a multimodality approach.

Case: A 33 year-old woman who presented with 15 days of mental and behavior change. Physical and neurological examination revealed no cause for these symptoms; extensive metabolic and imaging studies were normal, serum anti-neuronal antibodies were negative and an EEG done was unremarkable. CSF examination was within normal range and MRI scans of the brain was suspicious for limbic encephalitis. Immunological characterisation of her serum and CSF demonstrated the presence of anti-NMDA receptor autoantibodies. CT scan of her pelvis revealed a 2 cm unilateral left ovarian mass. The gynecologic oncologist was consulted to exclude ovarian pathology as origin of this possible paraneoplastic syndrome. Diagnostic laparoscopic surgery was planned for our patient, but she had died unexpectedly before surgery.

Conclusion: In the rare case a teratoma is associated with PE most women are not aware of having gynecological pathology just like in our patient. Therefore the psychiatrist, neurologist as well as the

gynecologist ought to be aware of these paraneoplastic syndromes. Further reports may be helpful to determine ideal treatment modalities.

Keywords: Paraneoplastic encephalitis, NMDAR, ovarian teratoma

OP-14

Metastatic epithelioid trophoblastic tumor: Case report

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Objective: Epithelioid trophoblastic tumor (ETT) is an extremely infrequent tumor, seen mostly in the reproductive age. ETT is one of the most curable gynecologic malignancies; however, its correct diagnosis requires a high level of suspicion. Elevated serum b-human chorionic gonadotropin (hCG) may give a useful clue to the clinical diagnosis of ETT, genetic fingerprinting and immunohistochemistry (to recognize dual cell population, keratin pearls, intercellular bridges, Ki-67 labelling index, inhibin, hCG, hPL, CK-18) are potentially valuable tools to confirm the diagnosis of ETT. This is critical for the appropriate treatment and complete excision is the cornerstone of the treatment due to the apparent relative chemoresistance of ETT.

Case: We describe a 73 year old G6P6 postmenopausal patient with ETT who was initially misinterpreted and treated as metastatic squamous carcinoma of unknown origin which was characterized by the patient's advanced age at the time of diagnosis and the longest latency period between the prior gestational event and the diagnosis of ETT. ETT may present as metastatic disease in up to %35 of patients, like as in our case who presented to our hospital complaining of inguinal mass. Inguinal biopsy specimens simulated keratinizing squamous cell carcinoma. Serum hCG level was not determined preoperatively. She was treated with concurrent intravenous carboplatin/taxol salvage therapy. After an unsuccessful treatment excisional procedure was done to inguinal mass. The final pathology report showed ETT. EMA/CO (etoposide, methotrexate and actinomycin/cyclophosphamide and vincristine) was administered. However no further treatment was given because the patient refused.

Conclusion: Accurate differential diagnosis would properly guide therapy and change prognosis. Both gynecologists and pathologists should be alert to the potential misdiagnosis of squamous cell carcinoma and avoidance of undertreatment and overtreatment are emphasized.

Keywords: Epithelioid trophoblastic tumor, squamous cell carcinom of cervix, gestational trophoblastic disease

OP-15

Laparoscopic myomectomy versus robotic myomectomy: A comparison for bleeding and operation time

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Objective: Comparison of laparoscopic myomectomy (LM) and robotic assisted LM (RALM) in terms of the operation time and the estimated blood loss.

Material and Methods: The medical records of the patients who underwent LM or RALM between June 2014 and January 2016 at Acıbadem University Maslak Hospital, in the Department of Gynecology were extracted from the hospital's database. Total 44 RALM and 38 LM patients have met the criteria. Of total 44 RALM cases, 17 were operated with da Vinci (Intuitive Surgical, Inc., Sunnyvale, C) Si platform, and 27 with da Vinci Xi platform. For all robotic cases, patient card was docked centrally, and three robotic arms and smoke evacuator were used. For LM cases, a 10 mm 00 scope and 3 ancillary ports were inserted. We utilised the integrated ultrasonic and bipolar energy instrument to perform uterine incision and myoma enucleation. In all cases, myomas were removed with the help of 12 mm automatic power morcellator.

Results: The means of EBL for LM and RALM groups were 165 30 cc and 178 69 cc, respectively. The difference in EBL between LM and RALM was not statistically significant (p=0.22). The operation times' means were 130 45 min for LM and 176 51 min for RALM. A significantly higher operation time was determined in RALM group compared with LM (p=0.000).

Conclusion: Although robotic assisted myomectomy increases feasibility of suturing and provides better visualisation of the operative field when compared with conventional laparoscopy, some disadvantages such as longer operation time and higher costs are still being challenges. In our study, the mean operation time was significantly longer in RALM group, whereas EBL were comparable between the groups. Even though previous studies have shown similar results in terms of longer operation times with RALM, some studies claimed no difference between RALM and LM. Further studies are needed to evaluate early surgical outcomes of RALM and LM.

Keywords: Robotic myomectomy, laparoscopic myomectomy, estimated blood loss

Table 1. Charecteristics of groups and early surgical parameters

	LM (n=38)	RALM (n=44)	p
Age	36.2±6.5	36.5±5.8	0.20
BMI (kg/m^2)	22.6±2.7	22.9±2.5	0.52
Myoma size (cm)	6.5±1.5	7.2±1.8	0.10
EBL (cc)	165.6±30	178±69	0.22
Operation time (min)	130±45	176±51	0.00

OP-16

Laparoscopic detection of sentinel lymph node in obese patient with endometrial cancer: A case report

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Objective: Endometrial cancer (EC) is the most common gynecological malignancy in Turkey, with an estimated 4427 new cases in 2015. The role of comprehensive surgical staging in early stage of EC remains controversial. Complete systemic pelvic and para-aortic lymphadenectomy may not result in additional survival outcome benefit, and may produce additional morbidity. Laparoscopic SLN mapping provide the prognostic information while avoiding the morbidity associated with a complete lymphadenectomy. We report our experience of laparoscopic SNL detection in obese patient with EC.

Case: A 56-year-old woman with well-differentiated EC. MRI of the pelvis showed a 3×2 cm lesion in the endometrial cavity with superficial myometrial invasion without any enlarged pelvic or paraaortic nodes. The patient's height, weight and BMI were 1.62 cm, 98 kg, 37.3 kg/sqm, respectively. Four mL blue dye (1 mL per injection) was injected into the cervix at 3,6,9 and 12 o'clock positions to identify sentinel lymph nodes before the procedure. After complete inspection of peritoneal cavity and collecting pelvic washings, she underwent laparoscopic pelvic SLN detection plus extrafascial total hysterectomy and bilateral salpingo-oophorectomy. SNL, stained with blue color, was observed in the upper part of the left obturator fossa and removal of the identified node was achieved through meticulous dissection. SNL was not found on the right pelvic area and total right pelvic lymphadenectomy was performed followed by TLH-BSO. The operative time was 110 min, and the estimated blood loss was 150 mL. No postoperative complications were registered, and the patient was discharged 30 h after surgery. The SLN ultra staging exam was negative, and the final pathology showed FIGO stage 1A G1 EC with a 6/25-mm myometrial invasion.

Conclusion: Laparoscopic SLN detection plus TLH-BSO is a feasible procedure with minimal surgical trauma in obese patients with early EC.

Keywords: Endometrial cancer, sentinel lymph node, laparoscopic

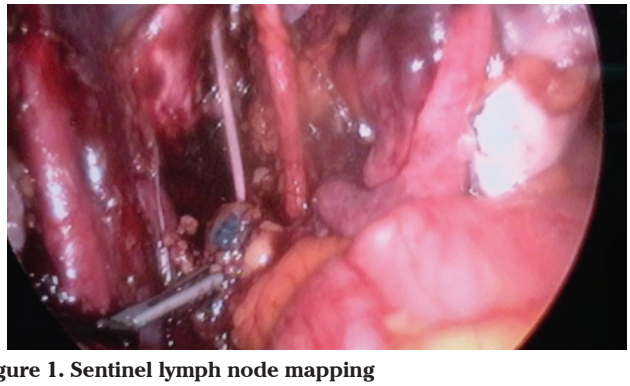

Figure 1. Sentinel lymph node mapping
SNL, stained with blue color, is observed in the upper part of the left obturator fossa

OP-17

Laparoscopic approach for adnexal masses

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We will present as a video form.

Keywords: Laparoscopy, adnex, mass

OP-18

Single port laparoscopic hysterectomy

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Keywords: Laparoscopy, hysterectomy, single port

OP-19

Minimal invasive and uterus preserving surgery for uterine prolapse-laparoscopic sacrohysteropexy

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Numerous methods have been discussed in literature for the treatment of apical prolapse of uterus via the abdominal, vaginal or laparoscopic approach. With recent advances in laparoscopic surgery, uterine suspension via the laparoscopic technique has become more popular. There are variations in practice of laparoscopic uterine suspension and the best surgical technique is not yet to be decided. In this report, we present a case of 47-year old women presented with symptomatic, POP [pelvic organ prolapse quantification system (POP-Q)] - stage II uterine prolapse and a history of vaginal prolapse surgery. Under general aneaesthesia, the peritoneum over the sacral promontory was incised and extended inferiorly along the right lateral aspect of the rectum. A non-absorbable synthetic type one monofilament, polypropylene mesh (Ethicon Inc., Somerville, NJ) wrapped around the cervix either through openings in the broad ligaments. The front arms of mesh were sutured

to the anterior aspest of cervix with 2.0 absorbable polyglactin 910 violet blalded sutures (Vicryl; Ethicon Inc., Somerville, NJ) and the sum up of two arms (continuing with body of mesh) was sutured to the posterior cervix at the level of uterosacral ligaments. After folding the mesh through the retroperitoneal tunnel without tension, the head of the mesh was attached to sacral promontorium by using 3-5, 5 mm helical fasteners (Protack; United States Surgical, Tyco Healthcare, Norwark, CT). In conclusion, the peritoneum over the mesh closed using the 2.0 absorbable polydiaxonone knotless tissue device (Stratafix; Ethicon Inc., Somerville, NJ). At third-months follow-up, she was POP stage 0 and had no symptoms. Minimal invasive approach, preservation of the uterus and vaginal lenght, and reinforcing the natural uterine support are the main advantages of laparoscopic sacrocolpopexy and so it might be considered as a good alternative for patient with uterine prolapse.

Keywords: Sacrohysteropexy, uterus, prolapse

Figure 1. Sacrocolpopexy-postoperative third month

OP-20

Safe cystectomy technique

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Objective: To make the cyst excision procedure used in routine endoscopic surgery more safe.

Material and Methods: In the complicated cyst we routinely performed laparoscopic surgery to define the manipulation of the ovary in a safe bag to prevent the spread.

Results: Although we routinely perform this procedure in endoscopic surgery, we can prevent the loss of time for chemical peritonitis and peritoneal lavage due to the dissemination of the cyst content in cases like dermoid cyst, although we can not change the disease state in case of an unexpected malignancy.

Keywords: Complicated cyct, cystectomy, safety, chemical peritonitis

OP-21

Laparoscopic hysterectomy plus sacrocolpopexy

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Objective: Describe to laparoscopic hysterectomy plus sacropexy is a valid option women presenting with genital prolapse.

Material and Methods: We performed firstly laparoscopic hysterectomy after sacrocolpopexy for vaginal vault prolapse using a permanent polypropylene Y- mesh. Standard operative technique for sacrocolpopexy was used. Three sutures were placed on the anterior leaflet of the mesh, and three sutures were placed posteriorly. Two sutures were placed in the presacral ligament. Mesh was retroperitonealized with a running 2-0 monocryl suture.

Results: Traditional laparoscopichysterectomy plus sacrocolpopexy should be considered a primary therapy for total uterine prolapse for patients without fertility expectancy.

Keywords: Laparoscopic sacrocolpopexy, hysterectomy, uterine prolapse

OP-22

Laparoscopic myomectomy clamping uterine artery for giant myoma

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Division of Gynecologic Oncology, Başkent University Faculty of Medicine, Adana, Turkey

Objective: We describe an alternative tecnique for giant myoma.

Material and Methods: We performed clamping bilaterally uterine arteries for giant myoma on laparoscopic surgery.

Results: With this technique, hemorrhage can be reduced to ensure adequate monitoring of the surgical field and reduced patient blood transfusion requirements.

Keywords: Uterine artery clamping, laparoscopic myomectomy, tecnique

OP-23

How to pass the needle through the loop of undirectional barbed suture in an easier and faster way?

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The purpose of this educational video article is to demonstrate the easier and faster passing of the needle through loop of unidirectional barbed suture.

Keywords: Barbed suture, undirectional, laparoscopy

OP-24

An alternative colpotomy technique at total laparoscopic hysterectomy

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Objective: The purpose of this video article is to demonstrate an alternative colpotomy technique that enables maximal protection of the cervical ring, helps to prevent the ureteral injury by distancing, and avoids shortening of the vagina at total laparoscopic hysterectomy.

Design: Step-by-step explanation of the alternative colpotomy technique using educational video setting: University-affiliated private hospital.

Interventions: The operation was performed under general anesthesia in dorsal lithotomy position. A malleable Sims uterine curette was inserted into the cavity to manipulate the uterus until it was replaced with a uterine manipulator before starting the colpotomy. The abdominal cavity was insufflated, and a 5 mm primary trocar was placed through the umbilicus. A 30-degree telescope was used for visualization of the peritoneal cavity. A 2,4 mm percutaneous instrument (MINILAP® SYSTEM WITH MINIGRIP® HANDLE) to the upper right quadrant, a 3 mm port to the left lower quadrant, and a 5 mm port to the right lower quadrant were placed. Round ligaments were cut, and retroperitoneal space was opened. Bilateral ureters were exposed and identified by the gentle and careful dissection along the posterior leaflet of the broad ligament. The uterovesical fold was dissected from the anterior wall of the uterus to clarify the colpotomy area. After that, the infundibulopelvic ligament was grasped, coagulated and transected on both sides. Before coagulation and transection of the uterine arteries, the safety of ureters was confirmed again. Uterine arteries were grasped and coagulated, and then cut bilaterally. After the uterine artery transection, a VECTEC surgical uterine manipulator (VECTEC, Hauterive, France) was inserted into the vagina in place of the sharp curette. The plastic rotating blade of uterine manipulator was strongly pushed forward into the anterior vaginal fornix. Colpotomy incision was started from the uppermost middle point of an anterior vagina, and extended to both sides with a monopolar L-hook electrocautery at 40 watts cutting mode. Then the manipulator's blade was maneuvered into the right lateral fornix, and THUNDERBEAT platform (Olympus Medical Systems Corp, Tokyo, Japan) was chosen as the modality of energy for the transection of the rest of the vagina. After rotating the blade of manipulator into the lateral fornix, it was pushed forward delineating the connection between vagina and cervix and then retracted backward to give place to THUNDERBEAT. One jaw of THUNDERBEAT was inserted into the fornix. The vagina was cut from the uppermost part leaving cardinal ligaments maximally on the vaginal side. At the posterior part of colpotomy, the vaginal wall was cut from the uppermost part of uterosacral ligaments, as well.

Finally, the left lateral fornix was cut by the same principles, and colpotomy was completed circumferentially. By using the manipulator's blade, at the uppermost margin of the vagina, ureters remained apart from the transection area, uterosacral and cardinal ligaments were protected, and the vaginal length was preserved maximally. After the detachment of uterus, the specimen was removed vaginally. The vaginal cuff was closed by using unidirectional barbed suture. Our technique is included 7 steps: (1) After transecting the uterine arteries, there is no need to cut more paracervical tissue (2) push the anatomical rotating blade of uterine manipulator strongly forward into the anterior vaginal fornix while forcing the manipulator's shaft cranially (3) start the colpotomy incision from the uppermost margin of anterior cervicovaginal junction (4) rotate the blade to the lateral fornix (5) push the blade again to the cranial direction in order to expose the attachment of lateral vaginal wall to the cervix (6) retract the blade gently to give place to the energy device in transecting vagina (7) cut carefully above the manipulator's blade.

Conclusion: In our technique, colpotomy starts immediately after the transection of the bilateral uterine artery. In the absence of unnecessary paracervical tissue dissection below this level, the possibility of ureteral injury could be minimized, and the sacrouterine and cardinal ligaments could be maximally preserved.

Colpotomy is carefully performed above the blade of uterine manipulator after accessing the anterior vaginal fornix. Transection of cervicovaginal connection from the uppermost part warrants maximal preservation of the cervical ring. A detachment of vagina above cervical ring can be accomplished via effective uterine manipulation. Stretching tissues by applying enormous pressure on uterine manipulator are pivotal for exposure of vaginal fornices that allows easy transection of the uppermost vagina. Maximal preservation of paracervical ligaments with this technique preserve the apical support of vagina, and avoids shortening of vaginal length. The technique also minimizes the ureteral injury by distancing.

Keywords: Colpotomy, uterine support preservation, laparoscopy

5th SEERSS 1st GynoOncoMIS and Robotic Surgery Congress Abstracts

Video Presentation

VP-01

Laparoscopic type III radical hysterectomy

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We will present as a video form.

Keywords: Radical, hysterectomy, laparoscopy

VP-02

Laparoscopic pelvic and paraaortic lymphadenectomy treatment of endometrial cancer

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We will present as a video form.

Keywords: Laparoscopy, lymphadenectomy, endometrial cancer

VP-03

Robotic excision of deep pelvic endometriotic nodule

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Thirty years old lady presented with history of left flank pain. Patient seen by urologist and MRI showed left renal pelvis hydronephrosis with dilatation of ureter. Cystoscopy done biopsy collected and pathology showed endometriosis. Therefore, patient refered to our department for further management.

Keywords: Deep infiltrative endometriotic nodule, robotic, renal hydronephrosis

VP-04

Robotic resection of bulky conglomerate of pelvic lymph nodes in a cervical cancer patient

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Objective: We aimed to present a video demonstration of robotic resection of bulky pelvic lymph nodes incidentally found during lymphadenectomy for early stage cervical cancer.

Material and Methods: A brief video presentation of a radical surgery that we performed using daVinci® XI robotic system in a patient with endocervical adenocancer.

Results: A 31-year-old woman admitted to our clinic with a cervical cancer screening test results of positive HPV test (type 16) and negative cytology. Colposcopy revealed major findings including dense acetowhite epithelium inside the transformation zone extending into endocervical canal more than 5 mm. Histopathological examination of endocervical curettage was consistent with adenocarcinoma in situ. She underwent cold-knife cone biopsy which revealed a diagnosis of endocervical adenocancer with a depth of stromal invasion of 4 mm and horizontal spread of 6 mm, positive LVSI and negative cone margins. A definitive surgery consisting of modified radical hysterectomy, pelvic lymphadenectomy and bilateral ovarian transposition was planned. Surgery was initiated with the performance of right pelvic lymphadenectomy. During the dissection, a 3x3 cm conglomerate of bulky hypogastric lymph nodes, densely attached to the ureter, hypogastric artery and external iliac vein, was detected. LNs was resected with fine and blunt dissection using monopolar scissors. No complication was observed. Frozen section examination revealed a positive result for LN metastasis. Radical hysterectomy was abondened and the operation was terminated following bilateral ovarian transposition was carried out.

Conclusion: Bulky lymph node metastasis can occur in cervical cancer even in case of lack of deep stromal invasion. Robotic surgery may enhance dissection capability of surgeon in cases with densely adherent tumor.

Keywords: Cervical cancer, robotic surgery, bulky lymph node metastasis

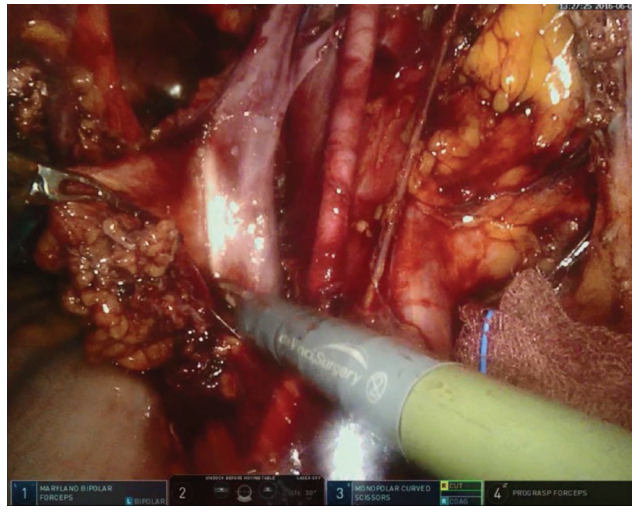

Figure 1. Right hypogastric bulky lymph node

VP-05

Laparoscopic blinded endometrial cavity resection for Robert's uterus

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Robert's uterus is a rare Müllerian duct anomaly characterized by a blind endometrial cavity and an asymmetrical uterine septum. A 15 year old virgin patient presented to the gynecology clinic with a history of progressively increasing colicky lower abdominal pain and dismenorhea. The patient underwent laparoscopic surgery and no indentations could be visualized on the fundus or outer border of the uterus during exploration. However the right fallopian tube appeared agenetic and the right side of the uterus appeared distended due to menstrual blood retention. The left fallopian tube appeared normal and the patient was diagnosed with Robert's uterus. The blind endometrial cavity was excised totally with harmonic scapel. The patient was discharged on the first postoperative day without any complications. Upon follow-up the patient reported that her dismenorhea symptoms had resolved totally. The aim during treatment is to either provide a communication between the blind cavity and the patent hemicavity or to excize the blind cavity totally. This can be carried out by laparotomy, laparoscopy or hysteroscopy. The total excision of of the blind cavity by laparoscopy is a safe and effective treatment modality which does not adversely affect the hemiuterus or its blood supply.

Keywords: Robert's uterus, endometrectomy, laparoscopy

VP-06

Laparoscopic obturator nerve repair: A video presentation

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Objective: To demonstrate epineural repairment of iatrogenically injured obturator nerve during pelvic lymphadenecetomy.

Material and Methods: A surgical video presentation of laparoscopic repairment of an iatrogenically transected obturator nerve with an ultrasonic energy device. Case: A 50 year-old woman who had diagnosis of endometrial adenocarcinoma was referred to Acıbadem Maslak Hospital for laparoscopic staging surgery. She had no significant previous medical and surgical history. During right pelvic lymphadenectomy, obturator nerve was transected totally via ultrasonic energy device. After completion of lymphadenectomy, proximal and distal ends of the right obuturator nerve were identified. A 3.0 poliglactin u-suture was placed to the edges of the nerve, and epineural end-to-end enclosing was completed.

Results: Patient had no motor or sensory loss of function clinically. She was discharged postoperative day two. During 3 month follow ups, she had no complaint related with obturator nerve.

Conclusion: Obturator nerve is a land mark for pelvic lymphadenectomy in gynecologic cancer surgery. During pelvic lymphadenectomy obturator nerve is at risk of injury. Transection of obturator nerve can be made with sharp dissection or with an electro/ultrasonic surgical device. As a result of the obturator nerve transection, weakness in the adduction of thigh, sensory loss or pain of the medial thigh can be seen clinically. After transection, immediate repair of the nerve should be considered. To prevent functional loss and to restore anatomy, epineural end to end coaptation is considered preferable method. As in our case, repairing obturator nerve immediately after injury usually produces favorable results.

Keywords: Laparoscopy, obturator nerve, nerve repair

VP-07

A simple new method for laparoscopic sacrocervicopexy

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Objective: We are demonstrating a new technique for laparoscopic sacrocervicopexy for uterine prolapse in this video abstract.

Material and Methods: The first part is the vaginal procedure. We use a polipropylene macroporous T-shaped mesh to fix it to the cervix. We dissect anterior and posterior of the cervix like in the mcdonald cerclage operation and place the head of the mesh around the cervix with suturing non-absorbable 2.0 prolene sutures. After that tail of the T-shaped mesh is passed with the clamps between the sacrouterine ligamants from rectouterine space to the abdomen. In the second part we perform laparoscopy. We dissect the peritoneum and rectum down and take the mesh from vagina. We use laparoscopic tacker with stainless steel tack to fix the mesh in tension free manner to the sacrum and anterior longitudinal ligament. After that we close the peritoneum with polyglactine 2.0 sutures and finish the operation.

Results: We perform this operation on 42 patient from 2010-2016 in our tertiary referral university teaching hospital. Mean age of the patients is 36.7 years old. After 1 year follow-up; all of the patients but one have sufficent vagina in pelvic examination. Average C point lifting was 6.1 cm. Thirty-one patients reported satisfied sexual intercourse. Three patients reported disparunia. Seven of 42 patients who had symptoms of stress or urge incontinence preoperatively, didn't undergo any concomitant continence surgery. Four of these patients reported subjective improvement of their incontinence after one year. There was only one complication which is a mesh erosion and excised laparoscopically.

Conclusion: This method can be an alternative to the traditional vaginal methods and classical laparoscopic sacrocervicopexy. Although it has not long term results and there is not enough patients who undergone this operation, the technique can be considered as a simple, easier and feasible surgical method.

Keywords: Sacrocervicopexy, laparoscopy, urogynecology, new method

VP-08

Transvaginal extraction for myoma retrieval by using CCL vaginal extractor without power morcellation in robotic surgery

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A 34 years old woman was admitted with lower abdominal pain and infertility. Multiple myomas were found on pelvic examination and transvaginal sonography. Robotic myomectomy was suggested to preserve the uterus. At the end of the surgery, CCL vaginal extractor (manufactured by STORZ) was used to remove the myomas without power morcellation. The purpose of this video article is to demonstrate the transvaginal retrieval method during robotic myomectomy.

Keywords: Robotic surgery, transvaginal extraction, myoma

VP-09

Laparoscopic Hysterectomy for Intraligamentary Myoma

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A case of a 54 year-old patient with abdominal pain. The gynecologic ultrasonography revealed 95 mm *844 mm solid mass on left adnex. Ca 125 and other tumor markers were normal. Laparoscopic hysterectomy and bilateral salpingo oophorectomy was performed. Permanent pathology: degenerative myoma.

Keywords: Myoma, laparoscopy, broad ligament

VP-10

Step by step bag morcellation in laparoscopic myomectomy

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The Morsafe tissue isolator bag has been designed and is specifically indicated for morcellation and as a result offers significant features and benefits that cannot be duplicated by other non-indicated bags being considered. Morsafe, with its unique two port design, offers the surgeon superior visibility during the surgery. It also contains a special ring in the bag opening to allow the surgeon ultimate control of the bag opening and easy access to the interior of the bag during surgery. The aim of this video is to demonstrate the each step of bag morcellation during laparoscopy. This video is included inserting the isolation bag into the abdomen, where tissue slated for removal was placed within the bag. The surgeon then pulled the opening of the bag to the exterior of the abdomen, inflated the bag, and fragmented the tissue within the bag to contain and remove it. After each procedure, the surgeon visually inspected the isolation bag for tears, as well as the abdominal and peritoneal cavities for tissue pieces left behind. At the end, Versator tissue morcellator can morcellate large tissue quickly, efficiently and safely.

Keywords: Laparoscopy, myomectomy, bag morcellation

VP-11

Laparoscopic versus robotic hysterectomy

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We will present as a video form.

Keywords: Laparoscopy, robot, hysterectomy

VP-12

The presentation of 2 cases which have been operated due to the testicular feminization

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The presentation of 2 cases which have been operated due to the testicular feminization;

Case 1: H.B. 18 years old. She was diagnosed with 17-hydroxlase insufficiency due to the homozygote mutation in *CYP17* gene. Since the patient's karyotype is 46,XY and there is a risk of malignancy, her gonads were removed from the inguinal canal bilaterally with laparotomy.

Case 2: A.D. 16 years old. L/S gonadectomy case presentation due to the testicular feminization. Her gonads were removed from the abdomen in which the ovaries were placed via laparoscopy. The size of uterus were observed as 4x3 cm.

Keywords: testicular feminization, gonadectomy, 17-hydroxlase insufficiency

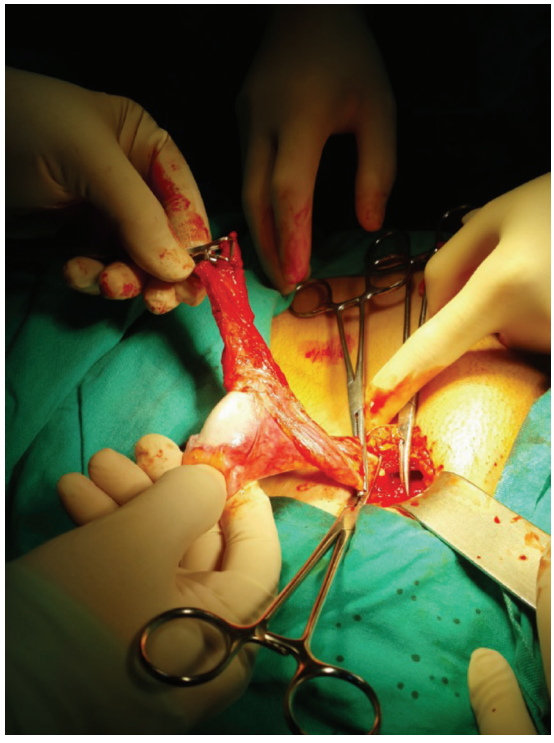

Figure 1. Gonadectomy from inguinal canal

Figure 2. Testicular feminisation, patient

VP-13

Single port robotic assisted laparoscopic hysterectomy: A video presentation

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Objective: To demonstrate single port robotic hysterectomy.

Material and Methods: A surgical video presentation of single port robotic assisted (RASS) laparoscopic hysterectomy. Operation time was defined as the time from intubation to the end of extubation. Setup time was defined as the time from first incision to the end of the docking of the robotic arms. Estimated blood loss (EBL) was calculated from the difference between irrigation and suction fluid volumes. Case: A 53-year-old woman who had 8 months of medical treatment for resistant uterine bleeding underwent RASS laparoscopic hysterectomy. She had no significant medical or operative history.

Results: Operation time was 160 min, EBL was 30ml and no perioperative complication occurred. The patient was discharged the day after surgery. No significant pathology was revealed by histopathological examination.

Conclusion: Minimal invasive procedures improve perioperative outcomes in gynecologic procedures (1). Evidence shows single port laparoscopic hysterectomy has comparable operative outcomes compared with traditional laparoscopy and also better cosmetics and less port site complications (2, 3). Following the

single port laparoscopic procedures, RASS surgery is the very last promising procedure for gynecologic minimal invasive surgery. And also RASS hysterectomy has comparable outcomes compared with classic multi-port hysterectomy (4). RASS surgery brings some advantages (greater dexterity, better visualisation, less instrument crowding or more triangulation) to single site laparoscopic surgery, however there are several limitations such as nonarticulated instruments, limited electrosurgical options, instrument clashing and higher costs. RASS may find a broader application area in gynecologic surgeries in near future if these technical challenges can be overcome.

Keywords: Single port robot, single site, hysterectomy

VP-14

Laparoscopic hysterectomy in bulky uterus

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We will present as a video form.

Keywords: Laparoscopy, bulky, difficult

VP-15

Laparoscopic bulky lymphadenectomy

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We will present as a video form.

Keywords: Lapharoscopy, lympadenectomy, bulky lymph node

VP-16

Robotic repair of central cystocele with vaginal sacroplexy suspention

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A 63 years old lady presented with swelling of anterior vaginal wall. Patient examined and diagnosed to have grade 3 central cystocele. Therefore, patient posted for robotic repair.

Keywords: Central cystocele, sacroplexy, robotic

VP-17

Laparoscopic management of incidental obturator nerve injury during pelvic lymphadenectomy

Mert Göl

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Minimal invasive surgery is now accepted in endometrial cancer as the main type of surgery as prognosis of the patients and harvested lymph nodes count do not decrease compared to laparotomy. Furthermore, in cervical cancer and even in early stage of ovarian cancer minimal invasive surgery has promising results.

In this video we present a patient with endometrial cancer 1B Grade 3 who underwent laparoscopic pelvic and paraaortic lymphadenectomy. We present here important anatomical landmarks to be aware of during dissection to avoid complications. Furthermore here we present some tips to visualise anatomical planes clearly to faciliate the surgery.

Keywords: Laparoscopy, pelvic, paraaortic, lymh node

VP-18

Morcellation of large and multiple myomas in a safety compartment

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Objective: To explain the details of the Safe Compartment Technique (SCT) developed to prevent dissemination resulting from morcellation used to remove huge and multiple myomas during laparoscopic surgery.

Material and Methods: The SCT we routinely perform during myomectomy.

Results: The technique was successfully performed in all cases The mean time it took to create the safe compartment was found to be 4±1 minutes.

Keywords: Myoma, safety, morcelaltion

VP-19

Deep pelvic endometriosis with infitrating ureter

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Objective: We aim to detailed laparoscopic deep endometriosis surgery.

Material and Methods: We performed laparoscopic pelvic deep endometriosis surgery with ureter dissection.

Results: Laparoscopic management of deep pelvic endometriosis with minimal complications.

Keywords: Deep endometriosis, laparoscopic surgery, infiltrating ureter

VP-20

Step by step laparoscopic sacrocolpopexy

Gonca Çoban, Songül Alemdaroğlu, Seda Yüksel Şimşek, Hakan Kalaycı, Hüsnü Çelik

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Objective: Describe to laparoscopic sacropexy is a valid option women presenting with genital prolapse.

Material and Methods: We performed laparoscopic sacrocolpopexy for total uterine prolapse saving uterus, using a permanent polypropylene Y-mesh standard operative technique for sacrocolpopexy was used. Two-three sutures were placed on the anterior vesico-cervical fasia. Two sutures were placed in the presacral ligament. Mesh was retroperitonealized with a running 2-0 monocryl suture.

Results: Traditional laparoscopic sacrocolpopexy should be considered a primary therapy for vaginal vault prolapse.

Keywords: Laparoscopic, sacrocolpopexy, total uterine prolapse

VP-21

Laparoendoscopic single site hysterectomy

Gökhan Demirayak, Çağlar Helvacıoğlu, Cihan Comba, Hüseyin Cengiz, Cihan Kaya, İsa Aykut Özdemir

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The aim of this presentation is to show a laparoendoscopic single-site (LESS) hysterectomy case. Currently, most gynecological surgeries, including radical ones, can be performed via laparoendoscopic single-site surgery. 54 years old woman with cervical intraepithelial neoplasia 3 (CIN 3) was operated by using this technique. LESS hysterectomy is safe and feasible technique.

Keywords: Laparoendoscopic single site hysterectomy, single port hysterectomy, single port access total laparoscopic hysterectomy (SPA-TLH)

VP-22

Laparoscopic resection of bladder endometriosis

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A 33-year-old woman was referred to us with urinary storage symptoms and severe pelvic pain. She had Gravida 2 with Cesarean sections. On Pelvic MRI, 2x3 cm suspected endometriotic lesion was detected over the fundal part of bladder. Laparascopic surgery was planned and sacro-uterine nodul excision, endometrioma cyst excision and partial bladder excision was performed. During the postoperative period, folet catheter was kept 7 days after surgery, and spontan urination was started at 8 hours after removing of foley. Patient were followed-up at least 3 months after surgey without any complication.

Keywords: Laparoscopy, endometriosis, bladder resection

VP-23

Laparoscopic dermoid cyst excision in an endobag

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This video presentation demonstrates removal of a dermoid cyst inside the same bag without any spillage. Dermoid cyst excision in a bag seems to be a feasible method to prevent intraperitoneal spillage and to reduce the operative time.

Keywords: Dermoid cyst, mature cystic teratom, bag

VP-24

Preservation of uterine support in robot-assisted total laparoscopic hysterectomy

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For the robotic surgical procedure we used the 3-arm Robot da Vinci Si system (Intuitive Surgical Inc., Sunnyvale, CA), with side docking. The 4 trocars were placed above the level of the umbilicus with 8 cm from each other, with the trocar for the camera as highest above the umbilicus. We used as robotic instruments for arm 1 the bipolar fenestrated forceps and for arm 2 the unipolar scissor, besides the 3D camera in the central robot arm. The patients' legs were put in boot-type leg holders, and the patients were placed in 25-30° trendelenburg. The abdominal cavity was insufflated with CO2 to a maximum of 15 mmHg. Round ligaments were cut, and retroperitoneal space was opened. Bilateral ureters were exposed and identified by the gentle and careful dissection along the posterior leaflet of the broad ligament. The uterovesical fold was dissected from the anterior wall of the uterus to clarify the colpotomy area. After that, the infundibulopelvic ligament was grasped, coagulated and transected on both sides. Before coagulation and transection of the uterine arteries, the safety of ureters was confirmed again. Uterine arteries were grasped and coagulated, and then cut bilaterally by using Ligasure 5-mm Blunt Tip LF1537 with the Force Triad generator. After the uterine artery transection, a Clermont-Ferrand surgical uterine manipulator (Storz, Germany) was inserted into the vagina in place of the sharp curette. The plastic rotating blade of uterine manipulator was strongly pushed forward into the anterior vaginal fornix. Colpotomy incision was started from the uppermost middle point of an anterior vagina, and extended to both sides with a monopolar. The vagina was cut from the uppermost part leaving cardinal ligaments maximally on the vaginal side. By using the manipulator's blade, at the uppermost margin of the vagina, ureters remained apart from the transection area, uterosacral and cardinal ligaments were protected, and the vaginal length was preserved maximally.

Keywords: Robotic hysterectomy, uterine manipulator, cardinal ligament

VP-25

Laparoscopic sacrocolpopexy: Modus operandi

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Sacrocolpopexy is a surgical technique used to treat vaginal vault or uterine prolapse. The objectives of the procedure are to reduce prolapse and to restore the anatomy and function of the vagina. During the procedure, the apex of the vagina/fundus of the uterus or stump of the cervix is lifted back up to its natural position by attaching a synthetic mesh from the top and back of the vagina to the sacral promontory. The mesh provides the vagina with the right amount of support to keep it in the correct position. We want to present our approach and our modus operandi.

Keywords: Laparoscopy, sacrocolpopexy, pelvic organ prolapse

VP-26

Learning ovarian dermoid cyst excision: Easy or difficult?

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Objective: In this video abstract we define a simple,easy and effective technique of dissecting the dermoid cyst after iatrogenic rupture.

Material and Methods: If a perforation occurs in laparoscopy, we suture the ruptured site of the cyst with poliglactin 2.0 sutures. So that we can close cyst wall and stop leaking fluid to the abdomen. Most of the cases, one suture is sufficient. After aspirating and cleaning spilled fluid f the cyst, we find another cleavage plan from another clear place of the dermoid cyst. Performing careful and meticulous dissection, we extract dermoid cyst in an endoscopic bag and suture ovarian incision with 2.0 polyglactine sutures.

Results: We use this method especially in laparoscopic trainings. All of the laparoscopic trainings and operations are perfomed under supervision of an advanced pelvic surgeon in our gynecologic laparo-endoscopy unit. If a resident or an assistant doctor rupture while dissecting dermoid cyst, the supervisor pelvic surgeon suture perforated site and begin dissecting with another anatomic plan. If it recurs in second operation of the trainee, then he/she proceed with suturing under supervision.

Conclusion: This is a very simple but effective and easy technique for dermoid cyst excision in laparoscopic learning curve. Laparoscopic suturing may be difficult for beginners in laparoscopy but we believe that these operations are very suitable for suture learning. Because hemorrhage risk is very low and suturing site is not in a hard place in contrast to laparoscopic myomectomies or hysterectomies.

Keywords: Dermoid cyst, laparoscopy, resident training

VP-27

Robotic surgery for large myoma

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We will present as a video form.

Keywords: Robot, large, myomectomy

VP-28

Laparoscopic ureter dissection

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We will present as video form.

Keywords: Laparoscopy, ureter, dissection

VP-29

Robotic excision of deep pelvic lymph node metastasis

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Patient was diagnosed with ovarian caner. PET/CT showed recurrence of the disease deep in pelvic lymph node. Therefore, the procedure performed.

Keywords: Metastasis, pelvic lymph node, robotic

VP-30

Laparoscopic myomectomy and prophylactic abdominal cerclage operation

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A 34 year-old patient married for 10 years admitted to the hospital with history of uterine fibroids and one painless second trimestr pregnancy loss that was related to cervical insufficiency. She had no significant uterine abnormality in hysterosalpigography and had ovulation induction for treatment of infertility. Admission examination revealed 6 cm fibroid in the anterior wall of uterus. She was scheduled for laparoscopic myomectomy, informed about cervical insufficiency and the risk of recurrent second trimestr losses. Prophylactic laparoscopic abdominal cerclage operation was recommended. She preferred an abdominal cerclage operation at the time of myomectomy. Patient underwent laparoscopic surgery. After removal of 6 cm myoma, myometrium and serosa were approximated by using 2-0 barbed sutures. The vesicouterine peritoneum was opened and dissected off the lower uterine segment, exposing the uterine vessels anteriorly on both sides. A 5-mm nonabsorbable Mersilene polyester suture was placed by passing each needle medial to the uterine vessels from posterior to anterior at the level of the internal cervical os bilaterally. The landmarks for this placement is a distance of 1.5 cm superior and 1 cm lateral to the insertion of the uterosacral ligament on the posterior uterus. The myoma retrieved with power tissue morcellation. Patient got pregnant after ovulation induction treatment 8 months after surgery and delivered a healty baby at term.

Keywords: Abdominalcerclage, laparoscopy, habituelabortus, prophylacticcerclage

VP-31

Laparoscopic radical hysterectomy

Hüsnü Çelik, Gonca Çoban, Songül Alemdaroğlu

Department of Gynecologic Oncology, Başkent University Faculty of Medicine, Adana, Turkey

Objective: We describe laparoskopic radical hysterectomy.

Material and Methods: We performed laparoskopic radical hysterectomy for stage Ib1 squamous cell cervical cancer.

Conclusion: The laparoscopic approach, but the magnified visual field in laparoscopy may enable fine manipulation, especially for preserving autonomic nerve tracts for cervical cancer surgery.

Keywords: Laparoscopic, radical hysterectomy, cervical cancer

VP-32

Laparoscopic radical trachelectomy

Hüsnü Çelik, Gonca Çoban, Songül Alemdaroğlu, Pınar Aytaç Çağlar

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Objective: We aim to define laparoscopic radical trachelectomy with pelvic lymphadenectomy.

Material and Methods: We operated 37 years old patient, stage Ib1 and who desire fertility.

Results: Laparoscopic radical trachelectomy and pelvic lymphadenectomy should be offered as an alternative treatment for women with early stage cervical cancer who want to preserve their fertility.

Keywords: Laparoscopic radical trachelectomy, pelvic lymphadenectomy, fertility

VP-33

Laparoscopic paraaortic lymphadenectomy

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Objective: We aim to descibe laparoscopic paraaortic lymphadenectomy.

Material and Methods: We performed to laparoscopic paraaortic lymphadenectomy level of renal vein.

Results: Laparoscopic paraaortic lymphadenectomy is feasible and safety method for gynecologic oncology patients.

Keywords: Laparoscopic, paraaortic, lymphadenectomy

VP-34

Laparoscopic hysterectomy without ultra energy modality

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Objective: We aim to describe laparoscopic hysterectomy without ultra energy modality.

Material and Methods: We performed laparoscopic hysterectomy with routine bipolar energy with the same practicality by the same same steps.

Results: We couldn't find any difficulty from the new generation energy modalities.

Keywords: Laparoscopic hysterectomy, energy modality, bipolar

VP-35

Accurate identification and removal of invisible symptomatic deep intramural myomas by endoscopic ultrasound guidance

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Objective: To describe the application of endoscopic ultrasound for identifying and accurate localization of symptomatic deep intramural myomas that are not visible to the naked eye or palpable by a laparoscopic probe.

Material and Methods: Description of the technique in an educational video. University affiliated private hospital.

Results: Intraoperative endoscopic ultrasound (IEU) can be utilized to localize deep intramural myomas that do not protrude from the serosa and thus aid in making an accurate incision that will facilitate their removal. IEU transducer has an adjustable head, which is able to move 90-degree in four directions. The technique for searching myomas is sliding the head systematically across the anterior, fundal and posterior walls of the uterus, both in top - down and side-to-side directions. The endometrial echo is used as an anatomical landmark to provide the optimal orientation of scanning array. In some cases myomas may be located at equal distance from the anterior, posterior and fundal surfaces (Video). At this time, if the surgeon cannot determine the closest serosal surface to the myoma, correct orientation can be achieved with the help of a blunt laparoscopic instrument. The instrument pushes the uterine serosa next to the transducer's head. This creates an indentation on the myometrium just above the myoma providing the evaluation of the distance between the myoma and the serosal surface (Video). The technique should be repeated for all surfaces to choose the appropriate one in the closest proximity with the myoma. The approval of the local institutional review board was obtained for this study.

Conclusion: The use of the IEU with the above mentioned technique aids in accurate identification and removal of deep intramural myomas.

Keywords: Deep intramural myomas, intraoperative ultrasonography, endoscopy

VP-36

The utility of percutaneus endoscopic instrument in total laparoscopic hysterectomy

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A 49 years old woman was admitted with irregular menstrual bleeding. Myometrial or adnexial lesions were not found on transvaginal ultrasonography. Endometrial biopsy was revealed out endometrial hyperplasia with complex atypia. Laparoscopic hysterectomy + bilateral adnexectomy was suggested. Procedure was performed under general anesthesia in dorsolithotomy position. After veress needle insertion, the abdominal cavity was insufflated with carbondioxide and pneumoperitoneum was obtained. M-LPS was performed through one optical transumbilical 5-mm trocar, one 5-mm ancillary port on the right side, one 3-mm ancillary port on left and one 2-mm percutaneous endoscopic instrument. A 5-mm 0-degree endoscope, 3 mm laparoscopic instruments and integrated bipolar and ultrasonic technology (Thunderbeat, Olympus Medical Systems Corp, Tokyo, Japan) were used. Vaginal cuff was closed by using 2/0 V-loc suture. Intraoperative and postoperative complication was not seen. Final pathology reported no evidence of cancer.

Keywords: Percutaneous endoscopy, laparoscopy, hysterectomy

VP-37

Laparoscopic retroperitoneal paraaortic lymph node dissection

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We will present as a video form.

Keywords: Laporoscopy, retroperitoneal, lymh node dissection

VP-38

A difficult laparoscopic hysterectomy in the case of densely attached uterus to the anterior abdominal wall

Barış Kaya

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Objective: To present a laparoscopic hysterectomy in the case of uterus densely attached to the anterior abdominal wall.

Material and Methods: A 46- year- old woman suffering from severe menorrhagia who had 5.9 gr/dL Hb, is planned for total laparoscopic hysterectomy after 4 units of blood transfusion. She had a bowel surgery and a C-Section in her history. A uterine manipulator (VCare®, ConMed Endosurgery, Utica, NY) was fixed to the cervix in a lithotomy position under general anesthesia. Direct entry from the Palmer's point was preferred and 10 mm 0 degree rigid laparoscope placed 4 cm above the umbilicus via 12 mm trocar, followed by a 5 mm trocar placement in right lateral side (1 cm above the umblical level) after providing pnomoperitoneum with CO_2. The uterus was 18w gestation week in size and densely attached to the anterior abdominal wall. Dens adhesions were lysed with bipolar coagulation and cut with laparoscopic scissors carefully which allowed mobilizing the uterus. Then the ligamentum ovari proprium, round ligament, uterine arteries, broad, cardinal and uterosacral ligaments were dissected and cut with a 5 mm LigaSure™ (Covidien, Mansfield, MA) respectively. After removing uterus, vaginal cuff was closed with Vicryl by laparoscopic suturing technique.

Results: The left subcostal area is preferred initial access point in our case to avoid possible entry complications. Severe adhesions may cause; difficulty in finding free space for port placement, limit the traction and visualization, bleeding from the surface of the visceral organs or bowel and urinary tract injury. In our case, densely attached uterus mobilized with meticulous dissection and obeying the laparoscopic surgical rules strictly.

Conclusion: Choosing Palmer's point for access and the right trocar placements in big uterus, traction and counter-traction, working on the right anatomic planes and patience of the surgeon are the key elements for a successful procedure without conversion to open laparotomy.

Keywords: Laparoscopic hysterectomy, dens adhesion, previous surgery

VP-39

Robotic myomectomy, cystectomy and pregnancy: Case report

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Objective: Reproductive surgery preserves, enhances or restores fertility. The minimal access surgery offers many benefits in relation to open surgery.

Case: A 33-year-old female patient, with primary infertility of six years of evolution in who uterine myomatosis with six centimeter right entometrioma and four centimeter dermoid cyst was diagnosed and robotic surgery was indicated.

Conclusion: The advantages of robotic surgery are: lower blood loss, hospital stay and postoperative pain and faster reinstatement to normal activities, in addition to a promising reproductive outcome for the patient.

Keywords: Fertility, myomectomy, robotic surgery

CONGRESS CALENDER

INTERNATIONAL MEETINGS

(for detailed International Meeting please go website: http://www.medical.theconferencewebsite.com/conferences/obstetrics-and-gynaecology)

July 2-5, 2017	**The 33rd Annual Meeting of ESHRE, Geneva, Switzerland** https://www.eshre.eu/annual-meeting
September 21-24, 2017	**The 19th World Congress on Gestational Trophoblastic Diseases, İstanbul, Turkey** www.worldcongressgtd2017istanbul.com
October 4-8, 2017	**IVF 19th World Congress on In Vitro Fertilization in conjunction with VI. Society of Reproductive Medicine and Surgery Congress, Antalya, Turkey** http://www.isivf2017.com
October 18-21, 2017	**26th ESGE/7. Ulusal JED Kongresi, Antalya, Turkey** http://jed2017.org
October 26-29, 2017	**13rd World Congress of Perinatal Medicine, Belgrade, Serbia** http://www.wcpm2017.com
October 28-November 1, 2017	**3rd Annual Meeting of the ASRM, San Antonio, USA** http://scientific.asrmcongress.org
April 27-May 01, 2018	**XII. Turkish German Gynecologic Congress, Kyrenia, TRNC** www.tajev2018.org

NATIONAL MEETINGS

September 28-October 1, 2017	**16. Perinatoloji Kongresi, Muğla** http://www.perinatoloji2017.org
October 5-8, 2017	**5. Ulusal İşlevsel Ürolojik ve Kadın Ürolojisi Kongresi, Antalya** http://islevseluroloji2017.org/
November 2-4, 2017	**Türkiye Maternal Fetal Tıp Derneği Ultrasonografi Kursu, İstanbul** http://www.tmftpultrason2017.org

JTGGA CME/CPD CREDITING

Answer form for the article titled *"The possible role of the da Vinci robot for patients with vulval carcinoma undergoing inguinal lymph node dissection"* within the scope of CME/CPD

1. **Which of the following is considered the gold standard of vulval cancer management?**
   a) Radical vulvectomy or wide local excision plus inguinal lymphadenectomy (triple incision technique).
   b) Radical vulvectomy or wide local excision plus inguinal lymphadenectomy and pelvic lymphadenectomy.
   c) Radical vulvectomy or wide local excision plus inguinal lymphadenectomy (butterfly technique).
   d) Radical vulvectomy or wide local excision followed by sentinel lymph node technique
   e) Radical vulvectomy or wide local excision followed by robotic lymphadenectomy

2. **Which of the following complications is not related to inguinal lymphadenectomy?**
   a) Lymphocyst
   b) Lymphedema
   c) Skin flap necrosis
   d) Urinary incontinence
   e) Wound infection

3. **Which of the following is not an advantage of robotic approach?**
   a) Comfort for the surgeon
   b) Shorter surgical time
   c) 3D approach
   d) High magnification
   e) Instruments with a higher degree of freedom

4. **Which of the following is false regarding the role of minimal invasive approach for inguinal lymphadenectomy?**
   a) Shorter hospital stay
   b) Shorter recovery period
   c) Equally safe and oncologically effective
   d) Lower morbidity rates
   e) Less postoperative pain

5. **Which of the following is not true regarding the steps of robotic inguinal lymphadenectomy?**
   a) Femoral triangle is identified and a 2-cm incision is performed about 3 cm below its inferior aspect
   b) Scarpa's fascia is identified and after blunt-finger dissection, the scope is used to create a superficial subcutaneous flap by sweeping the lens under the fascia
   c) Pneumoperitoneum up to 5-10 mm Hg pressure
   d) Bipolar Maryland and monopolar scissors are the main instruments used
   e) Saphenofemoral junction is exposed after opening the fascia lata and deep pelvic lymph node dissection can also be performed if necessary

6. **Which of the following is not correct?**
   a) Prospective randomized controlled trials are necessary to clarify the morbidity rates and advantages of robotic inguinal lymphadenectomy for vulval cancer patients
   b) The main disadvantage is the high cost
   c) Objections could be raised regarding the learning curve
   d) The risk of port site metastasis is not clear
   e) Robotic approach at the moment is cost effective for the health systems

JTGGA CME/CPD CREDITING

Questions on the article titled *"The possible role of the da Vinci robot for patients with vulval carcinoma undergoing inguinal lymph node dissection"* within the scope of CME/CPD

1st Question	A	B	C	D	E
2nd Question	A	B	C	D	E
3rd Question	A	B	C	D	E
4th Question	A	B	C	D	E
5th Question	A	B	C	D	E
6th Question	A	B	C	D	E

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JTGGA MANUSCRIPT 2017/2

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Güç ve güvenle birleşen güzellik...

DİENİLLE KÜB ÖZETİ: ÜRÜN ADI: DİENİLLE 2 mg/0,03 mg Film Kaplı Tablet. **FORMÜL:** 2 mg dienogest/0,03 mg etinilestradiol (Her bir film kaplı tablet). **FARMAKOLOJİ:** ATC kodu: G03FA15. DİENİLLE dienogest (progestojen) ve etinilestradiol (östrojen) içeren, antiandrojenik etkili bir kombine oral kontraseptif (KOK)'tir. **ENDİKASYONLAR:** Hormonal kontrasepsiyon. **KULLANIM ŞEKLİ VE DOZU:** Tabletler her gün aynı zamanda ve birbirini izleyen 21 gün boyunca alınır. Bir önceki ay hormonal kontraseptif kullanımı yoksa, tabletler kanamanın ilk günü alınmaya başlanmalıdır. Bir sonraki pakete 7 günlük tabletsiz aradan sonra devam edilir, genellikle ara kanama bu dönemde meydana gelir. Tipik olarak kanama, son hapı aldıktan 2-3 gün sonra başlar ve bir sonraki paketten ilk tablet alınana kadar devam edebilir. **UYGULAMA ŞEKLİ:** Oral. **KONTRENDİKASYONLAR:** İçeriğindeki maddelerden herhangi birine karşı aşırı duyarlılık; venöz tromboz veya pozitif hasta öyküsü; arteriyel tromboz veya pozitif hasta öyküsü veya prodromal olayların varlığı; arteriyel tromboz için ciddi ya da birçok risk faktörünün varlığı, venöz veya arteriyel trombozun kalıtsal veya edinilen yatkınlığının göstergesi olabilecek biyokimyasal faktörler, ağır karaciğer hastalığı veya pozitif hasta öyküsü (karaciğer fonksiyon değerleri normale dönmemişse), karaciğer tümörü veya pozitif hasta öyküsü; steroid bağımlı tümörler; tanı konulmamış vajinal kanama; fokal nörolojik belirtili migren öyküsü; geçmişte yaşanan pankreatit veya ağır hipertrigliseridemi; ağır veya akut böbrek yetmezliği. **ÖZEL KULLANİM UYARILARI VE ÖNLEMLERİ:** DİENİLLE kullanımından önce olası dolaşım bozukluğu risklerine karşı KOK tedavisi dikkatlice tartışılmalıdır. Herhangi bir KOK kullanımı, kullanılmadığı durum ile karşılaştırıldığında venöz tromboemboli riski artar. Bazı epidemiyolojik çalışmalarda uzun süre KOK kullanımının servikal kanser riskinde artışa neden olabileceği bildirilmiştir, ancak bu bulguların KOK kullanımının hangi etkilerine bağlı olabileceği halen tartışılmaktadır. Kendisinde ya da aile öyküsünde hipertrigliseridemi olan kadınlarda, KOK kullanımı sonucu pankreatit riski artabilir. **İLAÇ ETKİLEŞİMLERİ VE GEÇİMSİZLİKLER:** Herhangi bir geçimsizlik yoktur. Diğer ilaçlar ile arasındaki etkileşmeler ara kanamaya ve/veya kontraseptif potansiyel kaybına yol açabilirler. Bu etkiler karaciğer enzim indüksiyonunu arttıran hidantoin, barbitüratlar, primidon, karbamazepin ve rifampisin durumunda gösterilmiş olup; rifabutin, efavirenz, nevirapin, okskarbazepin, topiramat, felbamat, ritonavir, nelvinafir, griseofulvin ve St. John's wort içeren bitkisel ilaçlar için geçerlidir. **GEBELİK VE EMZİRME:** Gebelik döneminde kontrendikedir. Kullanımı sırasında gebelik meydana gelirse kullanım durdurulmalıdır. Emzirme döneminde kullanılmaması tavsiye edilir. **ARAÇ VE MAKİNE KULLANIMI:** Herhangi bir etkisi bulunmamaktadır. **İSTENMEYEN ETKİLER:** KOK kullanan kadınlarda venöz ve arteriyel tromboemboli riski vardır. Sigara, hipertansiyon, kan pıhtılaşması ve lipid metabolizması bozuklukları, ağır obezite, varis, gelişmiş flebit ile tromboz gibi faktörler venöz ve arteriyel tromboemboli riskini artırabilir. **RAF ÖMRÜ VE SAKLAMA KOŞULLARI:** 36 ay-25°C'nin altındaki oda sıcaklığında saklayınız. **TİCARİ TAKDİM ŞEKLİ:** PVC/PVDC-Alu blisterde, 21 film kaplı tablet. **FİYATI:** 34,28 TL (Şubat 2017 itibariyle). **ÜRETİM YERİ:** Laboratorios Leon Farma S.A.La Vallina s/n. Poligono Industrial Navatejera 24008, Leon İSPANYA. **RUHSAT SAHİBİ:** Exeltis İlaç San. ve Tic. A.Ş. Kültür Mah. Nisbetiye Cad. No:56 Akmerkez B Blok Kat: 6 D: 574 Etiler, Beşiktaş/İstanbul. **RUHSAT TARİH/NO:** 16.02.2015-2015/136.

DROSPERA KÜB ÖZETİ: ÜRÜN ADI: DROSPERA 3 mg/0,02 mg film kaplı tablet. **FORMÜL:** 3 mg drospirenon ve 0,02 mg etinilestradiol içeren 24 adet aktif ve 4 adet plasebo beyaz film kaplı tablet. **FARMAKOLOJİ:** ATC kodu: G03AA12. DROSPERA drospirenon (progestojen) ve etinilestradiol (östrojen) içeren, antimineralokortikoid ve antiandrojenik etkili bir kombine oral kontraseptif (KOK)'tir. **ENDİKASYONLAR:** Kontrasepsiyon, hormona bağlı su tutulması ve buna bağlı belirtilerin gözlendiği durumlar, orta derecede akne vulgaris ve premenstruel disforik bozukluk semptomlarının tedavisi. **KULLANIM ŞEKLİ VE DOZU:** Tabletler gösterilen sırayla, her gün yaklaşık aynı zamanda, bir miktar su ile ve birbirini izleyen 28 gün boyunca alınır. Bir önceki ay hormonal kontraseptif kullanımı yoksa, tabletler kanamanın ilk günü alınmaya başlanmalıdır. Tablete 2. ile 5. günler arasında başlanması da kabul edilebilir, bu durumda tablet alımına başlanması itibariyle yedi gün boyunca ilave bir koruma yöntemi kullanılmalıdır.Bir sonraki pakete önceki kutudaki son tablet alımının ertesi günü başlanır. Çekilme kanaması genellikle plasebo tablet alımına başlanmasından 2-3 gün sonra başlar ve bir sonraki pakete başlandığında devam edebilir. Doğru şekilde kullanıldıklarında başarısızlık oranı yılda yaklaşık % 1 kadar olup, bu oran hap alımı unutulduğunda veya doğru alınmadığında artabilir. **UYGULAMA ŞEKLİ:** Oral. **KONTRENDİKASYONLAR:** Venöz veya arteriyel trombotik/tromboembolik olayların veya serebrovasküler bir olayın varlığı ya da öyküsü, bir tromboz prodromunun varlığı veya öyküsü, venöz veya arteriyel tromboz için ciddi ya da birçok risk faktörünün varlığı, fokal nörolojik belirtili migren öyküsü, ağır karaciğer hastalığı (karaciğer fonksiyon değerleri normale dönmemişse) varlığı, ağır veya akut böbrek yetmezliği, karaciğer tümörü varlığı veya öyküsü, steroid bağımlı tümörler, tanı konulmamış vajinal kanama, bilinen gebelik veya gebelik şüphesi, içeriğindeki maddelerden herhangi birine karşı aşırı duyarlılık, pankreatit ya da ağır hipertrigliseridemi öyküsü. **ÖZEL KULLANIM UYARILARI VE ÖNLEMLERİ:** KOK kullanımı ile ender olarak ortaya çıkan arteriyel ve venöz trombotik/tromboembolik hastalıkların risk artışı arasında ilişki bildirilmiştir. Venöz tromboembolizm riski kullanımın ilk yılında en yüksek olup, bir KOK'a başlarken ya da aynı veya farklı bir KOK'a tekrar başlarken (4 hafta ya da daha uzun aradan sonra) mevcuttur. Servikal kanser için en önemli risk faktörü süregelen human papilloma virus (HPV) enfeksiyonudur. Bazı epidemiyolojik çalışmalarda, uzun süre KOK kullanımının servikal kanser riskinde artışa neden olabileceği bildirilmiştir; ancak bu bulguların KOK kullanımının hangi etkilerine bağlı olabileceği halen tartışılmaktadır. Risk faktörlerinin veya bu durumlardan herhangi birinin ilk kez ortaya çıkması ya da artması halinde hemen doktora başvurulmalıdır. Tedavinin devamlılığı hakkındaki karar doktor vermelidir. **İLAÇ ETKİLEŞİMLERİ VE GEÇİMSİZLİKLER:** Herhangi bir geçimsizlik yoktur. Oral kontraseptifler ve diğer ilaçlar (HİV proteaz inhibitörleri ve antibiyotikler gibi) arasındaki etkileşmeler ara kanamaya ve/veya kontraseptif başarısızlığa yol açabilirler. Antibiyotik tedavisi (rifampisin ve griseofulvin dışında) alan kadınlar, ilacın sonlanmasını takiben 7 gün boyunca bariyer yöntemi kullanmalıdırlar. **GEBELİK VE EMZİRME:** Gebelik döneminde kontrendikedir. Kullanımı sırasında gebelik meydana gelirse kullanımı durdurulmalıdır. Emzirme döneminde genellikle önerilmemelidir. **ARAÇ VE MAKİNE KULLANIMI:** Herhangi bir etkisi bulunmamaktadır. **İSTENMEYEN ETKİLER:** Oral kontraseptif olarak ya da orta düzeyli akne vulgaris tedavisinde kullanıldığında en sık bildirilen advers reaksiyonlar bulantı, memelerde ağrı, öngörülmeyen uterin kanarna ve daha ileri belirtilmemiş genital sistem kanamasıdır.Bu etkiler kadınların > %3'ünde gözlemlenir. PMDD tedavisi için kullanıldığında en sık bildirilen advers reaksiyonlar; bulantı, memelerde ağrı ve öngörülmeyen uterin kanama. Bu etkiler kullanıcıların > %10'unda gözlemlenir. Ciddi advers olaylar arteryel ve venöz tromboembolizmdir. **RAF ÖMRÜ VE SAKLAMA KOŞULLARI:** 36 ay-25°C'nin altındaki oda sıcaklığında saklayınız. **TİCARİ TAKDİM ŞEKLİ:** PVC/PVDC-Alu blisterde, 24 aktif ve 4 plasebo film kaplı tablet. **FİYATI:** 27,06 TL (Şubat 2017 itibariyle). **RUHSAT SAHİBİ:** Exeltis İlaç San. ve Tic. A.Ş. Kültür Mah. Nisbetiye Cad. No:56 Akmerkez B Blok Kat: 6 D: 574 Etiler, Beşiktaş/İstanbul. **ÜRETİM YERİ:** Laboratorios Leon Farma S.A.La Vallina s/n. Poligono Industrial Navatejera 24008, Leon İSPANYA. **RUHSAT TARİH/NO:** 24.02.2015-2015/208.

DROSETİL KÜB ÖZETİ: ÜRÜN ADI: DROSETİL 3 mg/0,03 mg Film Kaplı Tablet. **FORMÜL:** 3 mg drospirenon/0,03 mg etinilestradiol (Her bir film kaplı tablet) **FARMAKOLOJİ:** ATC kodu: G03AA12. DROSETİL drospirenon (progestojen) ve etinilestradiol (östrojen) içeren, antimineralokortikoid ve antiandrojenik etkili bir kombine oral kontraseptif (KOK)'tir. **ENDİKASYONLAR:** Kontrasepsiyon, hormona bağlı su tutulması ile ilişkili belirtiler, akne ve sebore tedavisi. **KULLANIM ŞEKLİ VE DOZU:** Tabletler gösterilen sırayla, her gün yaklaşık aynı zamanda, bir miktar suyla ve birbirini izleyen 21 gün boyunca alınır. Bir önceki ay hormonal kontraseptif kullanımı yoksa, tablet alımına kanamanın ilk günü başlanmalıdır. Tabletlere 2. ile 5. günler arasında başlanması da kabul edilebilir, bu durumda tablet alımına başlanması itibariyle yedi gün boyunca ilave bir koruma yöntemi kullanılmalıdır. Bir sonraki pakete 7 günlük, sıklıkla çekilme kanamasının izlendiği ve tablet alınmayan dönemi takiben geçilir. Bu kanama, genellikle son tabletin alınmasını takiben 2.-3. gün başlar ve bir sonraki pakete başlandığında devam edebilir. KOK'lar doğru şekilde kullanıldıklarında başarısızlık oranı yılda yaklaşık % 1 olup, ilaç unutulduğunda ya da yanlış kullanıldığında oran artabilir. **UYGULAMA ŞEKLİ:** Oral. **KONTRENDİKASYONLAR:** Venöz veya arteriyel trombotik/tromboembolik olayların veya serebrovasküler bir olayın varlığı ya da öyküsü, bir tromboz prodromunun varlığı veya öyküsü, venöz veya arteriyel tromboz için ciddi ya da birçok risk faktörünün varlığı, fokal nörolojik belirtili migren öyküsü, ağır karaciğer hastalığı (karaciğer fonksiyon değerleri normale dönmemişse) varlığı, ağır veya akut böbrek yetmezliği, karaciğer tümörü varlığı veya öyküsü, steroid bağımlı tümörler, tanı konulmamış vajinal kanama, bilinen gebelik veya gebelik şüphesi, içeriğindeki maddelerden herhangi birine karşı aşırı duyarlılık. **ÖZEL KULLANIM UYARILARI VE ÖNLEMLERİ:** KOK kullanımı ile ender olarak ortaya çıkan arteriyel ve venöz trombotik/tromboembolik hastalıkların risk artışı arasında ilişki bildirilmiştir. Venöz tromboembolizm riski kullanımın ilk yılında en yüksek olup, bir KOK'a başlarken ya da aynı veya farklı bir KOK'a tekrar başlarken (4 hafta ya da daha uzun aradan sonra) mevcuttur. Servikal kanser için en önemli risk faktörü süregelen human papilloma virus (HPV) enfeksiyonudur. Bazı epidemiyolojik çalışmalarda, uzun süre KOK kullanımının servikal kanser riskinde artışa neden olabileceği bildirilmiştir; ancak bu bulguların KOK kullanımının hangi etkilerine bağlı olabileceği halen tartışılmaktadır. Risk faktörlerinin veya bu durumlardan herhangi birinin ilk kez ortaya çıkması ya da artması halinde hemen doktora başvurulmalıdır. Tedavinin devamlılığı hakkındaki karar doktor vermelidir. **İLAÇ ETKİLEŞİMLERİ VE GEÇİMSİZLİKLER:** Herhangi bir geçimsizlik yoktur. Oral kontraseptifler ve diğer ilaçlar (enzim indükleyiciler ve antibiyotikler gibi) arasındaki etkileşmeler, ara kanamaya ve/veya kontraseptif başarısızlığa yol açabilirler. Antibiyotik tedavisi (rifampisin ve griseofulvin dışında) alan kadınlar, ilacın sonlanmasını takiben 7 gün boyunca bariyer yöntemi kullanmalıdırlar. **GEBELİK VE EMZİRME:** Gebelik döneminde kontrendikedir. Kullanımı sırasında gebelik meydana gelirse kullanım durdurulmalıdır. Emzirme döneminde genellikle önerilmemelidir. **ARAÇ VE MAKİNE KULLANIMI:** Herhangi bir etkisi bulunmamaktadır. **İSTENMEYEN ETKİLER:** KOK kullanan kadınlarda venöz ve arteriyel tromboemboli riski vardır. Sigara, hipertansiyon, kan pıhtılaşması ve lipid metabolizması bozuklukları, ağır obezite, varis, gelişmiş flebit ile tromboz gibi bazı faktörler venöz ve arteriyel tromboemboli riskini artırabilir. **RAF ÖMRÜ VE SAKLAMA KOŞULLARI:** 36 ay-25°C'nin altındaki oda sıcaklığında saklayınız. **TİCARİ TAKDİM ŞEKLİ:** PVC/PVDC-Alu blisterde, 21 film kaplı tablet. **FİYATI:** 24,92 TL (Şubat 2017 itibariyle) **ÜRETİM YERİ:** Laboratorios Leon Farma S.A.La Vallina s/n. Poligono Industrial Navatejera 24008, Leon İSPANYA. **RUHSAT SAHİBİ:** Exeltis İlaç San. ve Tic. A.Ş. Kültür Mah. Nisbetiye Cad. No:56 Akmerkez B Blok Kat: 6 D: 574 Etiler, Beşiktaş/İstanbul. **RUHSAT TARİH/NO:** 24.02.2015-2015/205.
REÇETE İLE SATILIR.

Daha geniş bilgi için firmamıza başvurunuz. Tel: 0 212 365 93 30, infoTR@exeltis.com . Herhangi bir şüpheli advers reaksiyon ile karşılaşılması halinde TÜFAM'a bildiriniz. (www.titck.gov.tr; e-posta:tufam@titck.gov.tr) Tel:0 800 314 00 08; Faks: 0 312 218 35 99.

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