Natural Orifice Surgery (NOS)-the next step in the evolution of minimally invasive surgery

Doğal Açıklık Cerrahisi (DAC)-minimal invaziv cerrahinin evriminde bir sonraki adım

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Abstract

Endoscopy, which was introduced in the 20th century, changed the outcome of surgery by reducing the need for analgesia and shortening hospital stay. Any new surgical method should improve safety and outcome. At the beginning of the 21st century, the use of natural orifice surgery is a promising progress. The transgastric and transdouglas approaches are currently being investigated and evaluated. The transgastric approach still has a long way to go due to objective problems such as infections, stomach acidity, and the optimal way to ensure the safe closure of gastrotomy. The transdouglas approach, however, is already starting to establish itself and it seems that with the construction of designated instruments it will prevail in the 21st century.

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Özet

Yirminci yüzyılda kullanıma sunulan endoskopi, analjezi ihtiyacını azaltarak ve hastanede yatış süresini kısaltarak cerrahinin akibetini değiştirdi. Yeni herhangi bir cerrahi metodun güvenliliği ve akibeti iyileştirmesi gerekir. Yirmi birinci yüzyılın başında, doğal açıklık cerrahisinin kullanımı umut verici bir ilerlemedir. Transgastrik ve transdouglas yaklaşımlar halen araştırılmakta ve değerlendirilmektedir. Enfeksiyonlar, mide asiditesi ve gastrostominin güvenli kapatılmasının optimal yolu gibi objektif problemlerden dolayı transgastrik yaklaşımın önünde hala uzun bir yol vardır. Bununla birlikte, transdouglas yaklaşım halihazırda kendini kabul ettirmeye başlamıştır ve tasarlanmış enstrümanların yapımıyla birlikte 21. yüzyılda yaygınlaşacak gibi görünmektedir. (J Turkish-German Gynecol Assoc 2012; 13: 56-60)

Anahtar kelimeler: Endoskopi, doğal açıklık cerrahisi

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Introduction

Endoscopic surgery achieved high standards during the 20th century as proved by reducing morbidity, improving recovery and shortening hospital stay. Although endoscopic procedures are less invasive than open surgery, they still require several incisions for port placements and incision enlargement for specimen retrieval (1). Most of the discomfort and complications associated with open and endoscopic surgery are caused by the abdominal incisions: The longer they are, the stronger the pain intensity and the higher the risk for wound infection and herniation (2). Despite the high standards of endoscopy already achieved, it seems that surgery can be made safe and efficient by using various natural orifices such as the mouth or the vagina as an access to the abdominal cavity. This natural orifice surgery (NOS) concept seems to be the next step in the evolution of minimally invasive surgery and may further reduce the invasiveness of surgical procedures by eliminating abdominal wall incisions and their implications, such as the afore mentioned postoperative abdominal pain, wound infection, and herniation (3, 4). This and other potential benefits of this approach have been proposed and debated, and are the driving force for extensive research in this emerging discipline.

Several areas were recognized as being potential barriers to the further development of the NOS concept. These include the creation of safe access and closure of the incision of the abdominal cavity, and the development of devices to facilitate these interventions (5). The transvaginal and transgastric approaches were the common routes used for the first NOS applications in human.

The access to the abdomen

While the American NOSCAR (Natural Orifice Surgery Consortium for Assessment and Research) working group decided to concentrate on the transgastric approach (6), many researchers focused on the use of the transvaginal route in women because the pouch of Douglas offers an easy and safe access into the peritoneal cavity (7). This was also the preferred route for some innovative surgeons to perform cholecystectomies or appendectomies using hybrid techniques (8-11). The NOSCAR group as well as other authors promoted the transgastric access, which turned out to be a technical challenge, because current flexible endoscopes

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and instruments are quite restricted in design and too unstable when introduced into the peritoneal cavity (12).

Transgastric approach

The transgastric access remains an appealing approach because it is more universally available than the transvaginal one and may be also more appealing to patients. This approach is feasible but associated with several problems: stomach acidity, problems which might arise from iatrogenic penetration of the stomach, the bacteriological contamination of the instruments introduced through the mouth and oesophagus, and the limitations involved with the limited diameter of the instruments in use due to the oesophageal diameter. Furthermore, several technical challenges inherent to the transgastric approach exist, including the creation of a gastrotomy, maintaining the necessary pneumoperitoneum, manipulating abdominal organs, retrieving specimens, and safe closure of the wall of the stomach.

Transgastric access into the peritoneal cavity

Several transgastric access procedures within the stomach have been described using the needle-knife method, sphincterotome and balloon dilatation. The procedure itself begins with the use of a standard single-channel endoscope for gastroscopy and placement of an overtube. The stomach is then disinfected, although the exact clinical benefit of thus reducing the bacterial load has not been studied or quantified; however, this step seems logical to maintain sterility in the abdominal cavity (13).
Various techniques for gastrotomy have been reported, with the most common location for the incision being the anterior gastric wall. Wagh et al. initially used endoscopic ultrasound (EUS) to mark the location of the gastrotomy, but this technique was abandoned after initial experiments found it not particularly useful. A percutaneous endoscopic gastrostomy (PEG) technique has also been described to help prevent damage to adjacent structures (13).
In their original report, Kalloo et al. described the following gastrotomy technique (14): A forward-viewing endoscope (GIF-160; Olympus America Corp., Melville, N.Y.) is inserted into the stomach. Access to the peritoneal cavity is made by using a needle-knife (KD-10Q-1.A; Olympus) to create an initial 2-mm incision in the anterior wall of the stomach. A flexible-tip guidewire (Jagwire 5658; Microvasive Endoscopy, Boston Scientific Corp., Natick, Mass.) is then advanced through the incision into the peritoneal cavity under fluoroscopic guidance. The incision is enlarged, either by extending it with a pull-type sphincterotome (210Q-0720; Olympus) to 20 mm or by dilation with an 8-mm dilation balloon (CRE esophageal balloon 5838; Microvasive) which is inserted over the guidewire. The endoscope is then advanced into the abdominal cavity, which is insufflated to lift the anterior abdominal wall and to expose the abdominal viscera (14).

Pneumoperitoneum

The transgastric insufflation is even more complex, not just because of the lack of the hand guided feedback but also due to the different anatomical considerations. When the abdominal wall is insufflated during laparoscopy, it is elevated, but when an incision is made transgastrically there is no direct way to make sure that there is a safe space beyond and there is no way to control the presence of intestinal loops just behind the incision. Hybrid manoeuvres are of course possible. A Verres needle can be introduced prior to stomach penetration, but without an optical device inserted into the peritoneal cavity prior to the penetration, safety cannot be guaranteed.
The pneumoperitoneum is currently maintained out of convenience with simple insufflation via the endoscope, because there is no readily available pressure regulated insufflator for NOS adapted to the flexible endoscopic system.

Closure of the gastric incision

Ensuring adequate closure of the gastric incision seems to be the most crucial part of transgastric surgery and is regarded as the biggest challenge in the passage from preclinical studies to human application. A leak from the stomach could lead to significant complications; hence, a reliable closure with minimal risk of leak must be achieved. At present there is no evaluated way of providing the optimal closure of the stomach that is needed for an endoscopic transluminal approach. Contemporary closure techniques described include endoscopic suturing, tissue opposition and clipping, and PEG tube closure (5).
Endoclips are the accessory most commonly used for gastric closure; however, endoclips are primarily designed for haemostasis and not for approximating edges of incisions (13).
Various sophisticated devices are being developed to ensure closure. Examples include prototype devices, e.g. the Stringer Device (LSI Solutions, Victor, NY) (15), the Eagle Claw (Olympus America, Inc., Center Valley, PA) (16, 17), the NDO Plicator (NDO Surgical, Mansfield, MA, USA) (18), and the three-channel device based on ShapeLock technology (USGI Medical, Inc., San Clemente, CA) (12, 19).
The Stringer Device is a prototype incision and closure device that was used by Fong et al. to assess the transcolonic approach as a means of accessing and systematically exploring the abdominal cavity in a pig survival study design (15). After advancing the hand-activated device under visualization to the desired incision site, a purse string suture is deployed around the planned incision site using an integrated dual metal ring mechanism. This is followed by the creation of a 20 mm incision with a blade mechanism at the tip of the device. For closure, a suction mechanism brings the tissue into a chamber at the tip of the device. Two needles (single arrows) pass through the tissue to engage a single-stranded suture with metal rings in the distal tip to create a purse string (2-0 polypropylene).
The Eagle Claw was developed by Olympus Medical Systems in collaboration with the Apollo Group (16, 17). It was originally described for endoscopic control of major arterial bleeding. A major problem with endoscopic suturing devices has been that the placed sutures were often too superficial to allow good approximation and permanent healing. This was due to the superficial bites that suction capsules could achieve and also because suturing could not be performed under direct vision.

The Eagle Claw that can be mounted alongside a standard endoscope uses large curved needles and allows suturing under direct vision. The introduction of an opposable jaw allows the new suturing device to grasp the tissue sufficiently r to achieve full-thickness sutures. The grasping forceps function also allows placing of sutures more precisely (16, 17).

The NDO Plicator is a reusable endoscopic tissue-plicating device designed to handle gastroesophageal reflux disease (GERD) by reducing the inner diameter of the gastroesophageal junction with sutured, full-thickness, tissue plications. The device consists of two articulating jaws and a retractable tissue grasper that accommodates a thin endoscope which is passed through a channel in the device. Single-use suture implants are preloaded on the jaws of the device prior to wire-guided access into the stomach. Once the stomach is intubated by the Plicator, the access wire is exchanged for a thin endoscope, which provides visualization. For treatment of GERD, the NDO device is then retroflexed to 180° for grasping, opposing, and plicating tissue with an implant. The implant consists of two expanded polytetrafluoroethylene (ePTFE) pledgets bound to form a U-stitch with pretied 2-0 polypropylene sutures and two titanium retention bridges. Clinical studies have demonstrated improvement in GERD symptoms for patients undergoing NDO plication at the gastroesophageal junction (18).

The Transport platform scope (Transport, USGI Medical, San Capistrano, CA, USA) has 7-, 6-, and two 4 mm working channels, which has allowed the creation of 5-mm graspers with 2.5 cm jaws similar to those of laparoscopic tools. Such graspers enable retraction of organs and large ''bites'' of tissue to allow approximation and closure (12, 19).

Altogether, the transgastric access seems to be complicated for the surgeon and risky for the patient. The most significant concern associated with an endoscopic transluminal approach is secure closure of the wall of the organ that is traversed in order to gain access to the abdominal cavity. Although some preclinical studies have addressed the efficacy of gastrotomy closure, the relatively low number of experimental subjects leaves these studies inadequately empowered to derive meaningful comparisons between closure techniques. A study comparing the best viscerotomy closure practice between multiple endoscopic clips and a proprietary device would require hundreds of operations to show minor differences between them. Moreover, the reports of pigs surviving NOTES without any viscerotomy closure raise the question as to whether the pig is an optimal model to study closure techniques (20). An endoluminal method of determining closure security at the end of a transgastric procedure remains an unresolved issue. Nonetheless, all above mentioned methods should make access and closure via the stomach or colon nearly as safe as the transdouglas route. Should these challenges be solved, training programmes will have to be developed, preferably using designed simulators before- and if - it becomes mainstream therapy.

Transdouglas approach

The transdouglas access has been used for more than 100 years by gynaecologists for diagnostic and therapeutic purposes, thus being well established and accepted. Opening and closure of the vaginal wall is safe and is done from the outside under vision by using standard surgical techniques. In every vaginal hysterectomy, with or without prolapse, the opening of the pouch of Douglas is carried out easily by cutting the vaginal wall transversally about 1-2 cm above the external os and then lifting the posterior aspect of the cervix with a tooth tennaculum, identifying the pelvic peritoneum between the sacro-uterine ligament, pulling it with surgical forceps, cutting it with round scissors, inserting the scissors into the peritoneal cavity, and pulling the widely opened scissors out using both hands (21). This method has been proved to be safe, does not require insufflation prior to the manoeuvre, and can be done under epidural and/or spinal anaesthesia.

It is well-known that the vaginal wall repairs itself without leaving any visible scars and without causing long-term dysfunction. Even if closure of the access site at the apex of the vagina were to fail, there would be little if any clinical significance. The extremely low risk of hernia is evidenced by the fact that many gynaecologists do not routinely suture the posterior colpotomy when performed during pelvic operations. Furthermore, experience of gynaecologists performing transvaginal hysterectomy has demonstrated safety in regards to rarity of pelvic infection (22).

The advantages of the transvaginal approach are as follows:

1) The easy and relatively non-traumatic entry into the abdominal cavity;
2) The possible wide diameter of the inserted instruments;
3) When performing vaginal hysterectomy the pouch of Douglas can be opened under vision, and the traditional 15 mmHg pressure is not needed. For some procedures much lower intra-abdominal pressure is needed, therefore these procedures can be performed with epidural anaesthesia;
4) The vaginal wall lining repairs without leaving scars and without any long-term discomfort or dysfunction;
5) Large specimens can be retrieved.
6) Optimal ergonomics: the transdouglas approach can be performed while the surgeon is seated comfortably.

For all these reasons the transdouglas approach seems actually to be the preferred route for NOS procedures by many authors, since it does not necessitate any sophisticated devices for opening and closure of the posterior colpotomy. It is easy for the surgeon and safe for the patient.

Clinical application of NOS

We believe that due to the relatively uncomplicated entry into the abdomen and its safety, the use of the pouch of Douglas will become more prevalent during the 21st century when adapted instruments have been introduced. Various abdominal operations have already been done using the transdouglas route.

In recent years, the pouch of Douglas has also been used as an entry for infertility evaluation and treatment using the so-called fertiloscope (23).

I In 2001, a preliminary report on culdo-laparoscopy was published (24), and in 2003 a procedure of a combined transvaginal hysterectomy and hybrid cholecystectomy in an 81-year-old woman was reported (25). Later, other hybrid transvaginal cholecystectomies were reported in Brazil (9), the United States (10), and France (11).

The transdouglas approach for urological, gynaecological and surgical indications is establishing itself gradually, not just because of the relatively uncomplicated access but also due to the relatively wide diameter of the entry, which enables the usage of wide instruments and easy retrieval of specimens. In our own study, which was conducted in order to estimate the potential usage of the pouch of Douglas, the mean diameter was measured to be 2.6 cm with a range of 2.0-3.4 cm (26). This was an anatomical study, but it seems that in living patients the elasticity of the pouch of Douglas is even higher. These results are important when instruments are being designed which could be used without causing damage to the pelvic floor due to over-stretching.

The feasibility of hybrid transdouglas nephrectomy combined with mini-laparotomy has already been evaluated in five patients (27). Although the average operation time was long (120 minutes), the blood loss was minimal and all the reported operations performed were uneventful.

Recently, with accumulated experience, more sophisticated transvaginal procedures are being done, like hybrid hemicolectomy (28) or nephrectomy (29, 27), and even a combined abdominal and transvaginal sleeve gastrectomy in morbidly obese women has been reported, although in six of them a conversion (to laparoscopy) became necessary (30). Different gynaecological procedures such as the removal of uterine fibroids are routinely done transvaginally (31, 32). Apart from all these reported studies, cholecystectomy nowadays is the most widely performed NOS procedure, mostly due to its easiness, its history as an initial target for minimally invasive surgery, and the fact that laparoscopy is a ready fallback (33). However, it is widely felt that removing the gallbladder is not the ideal target for widespread NOS adoption. This is due to the already minimally invasive nature of the laparoscopic gold standard. There is consensus, however, that cholecystectomy is a worthwhile model for the initial exploration of the potential of NOS.

The largest experience with NOS procedures has been in Germany, where well over 1500 transvaginal cholecystectomies have been performed. A report on 551 cases of natural orifice transluminal endoscopic surgery from the German NOTES registry was recently published (34). From South America, reports are emerging concerning a large and diverse experience with transvaginal cholecystectomy, in particular, approaching a clinical norm in several centers (33).

Transvaginal hybrid NOS is a safe method with a low complication rate, even in old or obese patients. It can be performed with rigid endoscopes and conventional trocars, which seem to be favorable for surgeons, as both instruments are common in surgical practice (34).

The future of NOS

At the time when reports concerning surgical procedures are emerging from all over the world, it becomes clear that, in order to avoid hybrid operations, the introduction of designed instruments is necessary, which will provide the safety and perfection of the surgery. These instruments should contain optics, irrigation and suction, coagulation, triangulation, and stability.

Special instruments which provide stability and enable suturing or coagulation must be designed in order to perform single port transdouglas procedures with safety.

Today's challenge is to secure optimal vision, stability and accuracy, which is difficult and needs a high degree specialization.

When performing operations according to evidence-based methods with the same steps and sequence, the matched outcome variability should not deviate significantly. However, when operating in a location that is far away from the entry point without optimized instruments, different individual skills might lead to variation concerning the operative and postoperative outcome (bleeding, damage to neighbouring organs, febrile morbidity, and hospital stay).

The conditio-sine-qua-non of secure standardized performance of single port or hybrid procedures is the adapted optimized tools.

Any new surgical method should provide benefits when compared to the previously existing ones. The benefits of the transgastric approach still have to be evaluated. However, the transdouglas approach is a very promising one which, even with the existing instrumentations, has already proved its benefits. When designed instruments are introduced (7), it seems that the transdouglas approach will become the state of the art for abdominal operations in women in the 21st century.

Conflict of interest

No conflict of interest was declared by the authors.

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