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CONSENSUS STATEMENT

Euro-NOTES Status Paper: from the concept to clinical practice

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Abstract
Background The concept of natural orifice transluminal endoscopic surgery (NOTES) consists of the reduction of access trauma by using a natural orifice access to the intra-abdominal cavity. This could possibly lead to less post-operative pain, quicker recovery from surgery, fewer postoperative complications, fewer wound infections, and fewer long-term problems such as hernias. The Euro-NOTES Foundation has organized yearly meetings to work on this concept to bring it safely into clinical practice. The aim of this Euro-NOTES status update is to assess the yearly scientific working group reports and provide an overview on the current clinical practice of NOTES procedures.
Methods After the Euro-NOTES meeting 2011 in Frankfurt, Germany, an analysis was started regarding the most important topics of the European working groups. All prospectively documented information was gathered from Euro-NOTES and D-NOTES working groups from 2007 to 2011. The top five topics were analyzed.
Results The statements of the working group activities demonstrate the growing information and changing insights. The most important selected topics were infection issue, peritoneal access, education and training, platforms and new technology, closure, suture, and anastomosis. The focus on research topics changed over time. The principle of hybrid access has overcome the technical and safety limitations of pure NOTES. Currently the following NOTES access routes are established for several indications: transvaginal access for cholecystectomy, appendectomy and colon resections; transesophageal access for myotomy; transgastric access for full-thickness small-tumor resections; and transanal/transcolonic access for rectal and colon resections.
Conclusions NOTES and hybrid NOTES techniques have emerged for all natural orifices and were introduced into clinical practice with a good safety record. There are different indications for different natural orifices. Each technique has been optimized for the purpose of finding a safe and realistic solution to perform the procedure according to the specific indication.

Keywords Hybrid NOTES · Interventional endoscopy · NOTES · Transanal surgery · Transesophageal surgery · Transgastric surgery · Transvaginal surgery

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Natural orifice transluminal endoscopic surgery (NOTES) emerged in the early 2000s as a logical development of ideas originating from interventional endoscopists and gastroenterologists with "surgical spirit" to move the limits of flexible endoscopy further. The process was supported by gastrointestinal surgeons with the motivation to expand the possibilities of minimal access surgery. Following the groundbreaking initiative of the Natural Orifice Surgery Consortium for Assessment and Research (NOSCAR) as a joint effort of the Society of American Gastrointestinal Endoscopists and Surgeons (SAGES) and the American Society of Gastrointestinal Endoscopy (ASGE), the Euro-NOTES Foundation was created in Europe by a joint effort of the European Association of Endoscopic Surgery (EAES) and the European Society of Gastrointestinal Endoscopy (ESGE) in early 2007 [1].

After the initial hype of ideas and fantasies of performing intra-abdominal surgery via flexible endoscopes, followed by a more critical phase of reflections and after 5 years of intensive work in many dedicated centers, the concept of NOTES has become a clinical reality [2]. This has happened despite the early disappointment of many resulting from the complex problems and technical limitations of NOTES procedures. The tremendous work of the early experiments and the training sessions for endoscopic and laparoscopic skills adapted to the special NOTES techniques were supported by several large Euro-NOTES grants provided by industry. Eventually this work resulted in the careful step into early clinical work in dedicated centers [3–10].

The aim of this Euro-NOTES status update is to assess this work and evaluate the yearly scientific working group reports, as well as provide an overview on the current clinical practice of NOTES procedures.

The concept of NOTES

The principle of minimal access surgery is the reduction of access size and access trauma, aiming for a shorter patient recovery, improved postoperative well-being, better cosmesis, less inhibiting postoperative restrictions (thus getting the patient quickly back to full physical and psychological abilities), and possibly improved long-term outcome. The latter could be achieved by fewer wound infections and fewer incisional hernias over time. The advantage of the concept of minimal access surgery over conventional open surgery has been clearly shown in the past decades [11, 12]. The improvements in patient care 20 years ago with the advent of minimal access surgery were not only caused by the reduction of abdominal incisions, but also by conceptional changes that came along with rethinking perioperative care [13].

The concept of NOTES follows that line of thinking. It moves the reduction of access trauma one step further by using a natural orifice as an access route to the intra-abdominal cavity. Further minimizing access trauma at the abdominal or thoracic wall could possibly lead to less postoperative pain, improved and quicker recovery from surgery, fewer postoperative complications, fewer wound infections, and fewer long-term problems such as hernias.

The publication of these ideas triggered a controversial discussion. It was feared that using a natural orifice and creating a transluminal opening could increase the risk for infections and complications such as peritonitis, as observed during the introduction of laparoscopic surgery [1, 2, 14, 15]. Therefore, a careful assessment of these concerns, as well as an assessment of techniques and an even more careful introduction into clinical practice, were necessary.

In 2005, NOSCAR established working groups and published a white paper in 2006 [1]. In this white paper, the basic important challenges of NOTES research were discussed and possible solutions were proposed. Since 2007, the Euro-NOTES Foundation has organized yearly working groups among researchers to discuss important issues concerning NOTES. This information was documented in published reports. In addition, in Europe, several activities on a national level were realized, such as the working groups of the D-NOTES initiative (Deutschland-NOTES, a German group for investigating NOTES). As a consequence, yearly prospective documentation is available to evaluate the progress of research and to track the burning issues in NOTES research, from the initial experimental setup until now, when NOTES techniques have made their way into clinical practice.

Methods

After the Euro-NOTES meeting in Frankfurt in September 2011, an analysis was started regarding the different issues that were discussed in the respective European working groups over the years. This was performed in relation to NOSCAR's 2006 white paper, which defined the basis of the NOTES concept and summarized the challenges and tasks to solve the problems [1, 2]. Therefore, prospectively documented information was gathered from Euro-NOTES and D-NOTES working groups for the years 2007 to 2011.

Table 1 lists the challenges and important topics of the initial NOSCAR meeting and white paper [1]. Table 2 provides an overview on the European working groups [16–20].

First, the chosen topics of the working groups in the past years were identified and summarized to determine the most important topics each year and to assess their

Table 1 Important challenges and questions

Peritoneal access
Gastric closure
Prevention of infections
Suturing and anastomotic devices
Maintain spatial orientation
Development of a multitasking platform
Management of intraperitoneal complications and hemorrhage
Physiologic untoward events caused by NOTES
Training

NOTES natural orifice transluminal endoscopic surgery, *NOSCAR* Natural Orifice Surgery Consortium for Assessment and Research

As established by the NOSCAR group during their initial working meeting and publication [1, 2]

changing importance over the years. It also became clear what topics persisted over the years and which topic were only of temporary interest.

Second, the working groups' final statements and messages on these topics were extracted and compared. We focused on assessing the changes in interpretation over the years regarding a given topic.

Third, the current status of the working group results of the Frankfurt Euro-NOTES 2011 meeting were analyzed and summarized to demonstrate the current status of clinical practice of the NOTES procedures, together with the review of current literature up through 2012.

Results

Table 3 provides an overview of the chosen topics of the published European working groups in the few past years [16–20]. The infection issue was the most frequent selected topic in the working groups over 5 years; this topic was chosen seven times.

The topics on peritoneal access, platforms/new technologies, and education/training were chosen on five

Table 2 Overview of European working groups, 2007–2011

Meeting	Years	Group	Coordinator
Gothenburg, Sweden	2007	Euro-NOTES	PO Park, M Bergstrom
Hamburg, Germany	2008	D-NOTES	KH Fuchs [16]
Brussels, Belgium	2008	Euro-NOTES	J Deviere
Munich, Germany	2009	D-NOTES	A Meining, H Feussner [17]
Mannheim, Germany	2010	D-NOTES	G Kaehler [18]
Rome, Italy	2010	Euro-NOTES	G Costamagna, A Meining [19]
Kiel, Germany	2011	D-NOTES	A Fritscher-Ravens [20]
Frankfurt, Germany	2011	Euro-NOTES	KH Fuchs

Table 3 Overview of working group topics

Topic	NOSCAR 2005	EN 07	DN 08	EN 08	DN 09	DN 10	EN 10	DN 11	EN 11	Total
Peritoneal access[a]	X	X				X	X	X	X	5
Closure	X	X		X			X	X		4
Infection	X	X	X	X	X	X	X	X		7
Suture/anastomosis	X	X	X	X	X					4
Spatial orientation	X									0
Platforms/new technology	X				X	X	X	X	X	5
Complications	X									0
Education + training	X	X	X		X		X	X		5
Structure, organization, interdisciplinarity			X		X	X	X			4
Indications		X								1
Triangulations		X		X						2
NOTES research		X		X						2
Bariatrics				X						1
Associated techniques				X			X			2
Visualization								X		1

NOTES natural orifice transluminal endoscopic surgery, *EN* Euro-NOTES, *DN* D-NOTES

[a] In recent years, this topic was split into different access techniques, such as transvaginal, transoral, transanal/transcolonic

occasions. (Peritoneal access was also chosen yearly in the beginning, then temporary dropped.) Starting in 2010, this topic reappeared, but now it was more differentiated, usually by possible access route: transoral, transgastric, transvaginal, and transanal/transcolonic. The topics platforms/new technology and education/training were, over the years, two of the major focused themes for NOTES research.

Suture/anastomosis and gut closure, as well as organization and interdisciplinarity, were topics chosen each on four occasions at the eight possible working group conferences. Topics such as complications and "other" (related to unexpected problems and events, as established in the NOSCAR list) were never chosen as working group topics in Europe.

In the beginning, the transgastric route was one of the most favored techniques, in part because the thought behind the route and its development were strongly influenced by gastroenterologists [1, 3, 4]. Quickly, however, surgeons and urologists enlarged the spectrum of access routes [1, 5, 7, 21]. As a consequence, the focus of the research work changed over time.

Another major topic was the improvement and further development of flexible endoscopic technology, which resulted in the development of multifunctional platforms [22]. At the time, it was thought that these platforms would enable or at least facilitate NOTES.

NOSCAR's initial list consisted of several topic related to complications and problems. The topics around complications never made it back onto a list of working group topics, thus indicating that this did not play a major role in the development of early experimental research and early clinical work.

Topics that were chosen only once or twice in the past 5 years were triangulation, clinical indications, NOTES research management, and special technical aspects such as visualization.

Focusing on the statements of the past years, the most striking result is the changing importance of the issue of infection on the clinical introduction of NOTES and hybrid NOTES techniques. In several statements in the early years, 2007–2008, infectious problems were feared when the transesophageal and transcolonic approaches were used, but more recently, the working group statements summarize the increasing clinical role of these transluminal techniques and their low complication rate.

Another important result from the analysis of statements of the working groups is the early request for new platforms so that NOTES-associated techniques could be introduced to clinical practice. In recent years, several transluminal techniques such as peroral endoscopic myotomy (POEM) and transanal techniques were reported to be clinically introduced using new conceptual ideas and applications rather than new sophisticated platform technology.

Analysis of the current literature on the clinical applications of NOTES and hybrid NOTES techniques regarding the risk of infection is provided in Table 4. The overview demonstrates the clinical experience of more than 1300 cases with a low incidence of infections for all

Table 4 Risk of infection during NOTES and hybrid NOTES procedures

Route	Study	Years	Procedure	*n*	Infection rate
Transesophageal	Inoue [26]	2010	POEM	17	0
	Zhou [27]	2011	POEM	42	0
	von Renteln [28]	2012	POEM	17	0
	Ren [29]	2012	POEM	119	0
	Eleftheriadis [30]	2012	POEM	200	0.5 %
Transgastric	Narula [24]	2009	Peritoneoscopy	10	0
	Dallemagne [31]	2010	Cholecystectomy	11	0
	Nikfarjam [32]	2010	Peritoneoscopy	9	11 %
	Zheng [33]	2011	Peritoneoscopy	5	0
Transvaginal	Lehmann [34]	2010	Cholecystectomy Appendectomy	551	3 (0.5 %)
	Zorron [35]	2010	Cholecystectomy Other	362	1 %
	Zornig [36]	2011	Cholecystectomy	100	1 (1 %)
Transanal/transcolonic	Sylla [37]	2010	Rectal resection	1	0
	Lacy [38]	2011	Rectal resection	1	0
	Telem [39]	2012	Rectal resection	4	0
	Fuchs [40]	2012	Colon resections	15	0

NOTES natural orifice transluminal endoscopic surgery, *POEM* peroral endoscopic myotomy

Table 5 Results of transvaginal NOTES procedures

Study	Years	Procedure	*n*	Complications	Access problems	Successful completion rate (no. of trocars)
Zornig [51]	2009	TV CE	68	1 pelvic abscess with reintervention	3 adhesions	96 % (1)
Zorron [35]	2010	Registry	362	Minor: 5.8 %		95 %
		TV CE		Major: 3.0 %		
Lehmann [34]	2010	Registry	551	4.9 %	7 patients	96 %
		TV CE	488	3.3 %		95 %
		TV colon	14	0		71 %
Zornig [36]	2011	TV CE	100	Minor: 0	0	100 % (1)
				Major: 1		
				Abscess		
Linke [57]	2013	TV CE + colon resection	106			

NOTES natural orifice transluminal endoscopic surgery, *TV* transvaginal, *CE* cholecystectomy

Table 6 Results of transesophageal procedures (POEM)

Study	Years	*n*	Complications	Access problems	Success rate (%)
Inoue [26]	2010	17	0	0	100
Zhou [27]	2011	42	0	0	97
Swanström [59]	2011	5	0	0	100
von Renteln [28]	2011	16	0	0	94
Costamagna [60]	2012	11	0	0	100
Ren [29]	2012	119	50 %	0	98
Eleftheriadis [30]	2012	200	1 %	0	98

POEM peroral endoscopic myotomy

transluminal procedures such as transesophageal, transgastric, transvaginal, and transanal/transcolonic approaches, ranging from 0.5 % to 11 %.

Regarding the differentiation of various access routes, analyses of published data are provided in Tables 5, 6, 7, and 8. The most frequently clinically used access route is the vagina (Table 5). Transvaginal hybrid NOTES operations can be completed without conversion in more than 90 % of the attempted cases, while the complication rate is reported as below 5 %.

The transesophageal route (used mostly for POEM) was established as a safe therapeutic option for the treatment of achalasia. Results are listed in Table 6. On the basis of the current literature, access problems and complications are low after proper training.

The transgastric approach is of only limited clinical value despite its early clinical introduction in 2007; documented experience remains limited. Table 7 provides an overview of the indications and results for the transgastric route.

The results on clinical applications of the transanal/transcolonic route are listed in Table 8. There are reports on transanal techniques for rectal resections and transcolonic techniques for colonic resections in both benign and malignant colorectal disease.

In summary, the results of the working group reports and the current literature indicate that safe introduction of NOTES and hybrid NOTES techniques was possible for all transluminal routes. Although the most common access route is the vagina, selective indications have emerged for each of the different access techniques, including cholecystectomy and colorectal resection via the transvaginal approach, esophageal myotomy via the transesophageal approach, staging and small tumor resection via the transgastric approach, and colorectal resections via the transanal/transcolonic approach.

Discussion

Prevention of infection

The most frequently chosen topic for a working group was infection. For decades, the penetration of the gut wall has been considered to be a major negative event and an acute complication during endoscopy. Similarly, in abdominal

Table 7 Results of transgastric NOTES procedures

Study	Years	Procedure	*n*	Complications	Access problems	Successful completion (no. of trocars)
Narula [24]	2009	TG peritoneoscopy	10	0	0	100 % (1)
Dallemagne [64]	2009	TG cholecystectomy	5	0	0	100 % (1)
Salinas [61]	2010	TG cholecystectomy	27	Morbidity 18 %, mortality 0	0	100 % (1)
Nikfarjam [32]	2010	TG peritoneoscopy	9	1 infection at gastrotomy site	0	100 % (1)
Nau [25]	2011	TG peritoneoscopy	40	0	0	100 % (1)
Zheng [33]	2011	TG peritoneoscopy	5	0	0	100 % (1)
Dotai [62]	2012	TG sleeve gastrectomy and large organ extraction	28	7.1 %	14 %	100 % (1)
Perry [63]	2012	TG peritoneoscopy in obese patients	10	0	20 %	80 % (1)

NOTES natural orifice transluminal endoscopic surgery, *TG* transgastric

Table 8 Results of transanal/transcolonic NOTES procedures

Study	Years	Procedure	*n*	Complications	Access problems	Successful completion (no. of trocars)
Sylla [37]	2010	Transanal rectal resection	1	0	0	96 % (2)
Lacy [38]	2011	Transanal rectal resection	1	0	0	100 % (3)
Telem [39]	2012	Transanal rectal resection	4	0	0	100 % (3)
Fuchs [40]	2012	Transanal colon resection	15	6.6 %	6.6 %	93 % (3)
Lacy [73]	2012	Transanal deep anterior rectal resections	3	0	0	– (4)

NOTES natural orifice transluminal endoscopic surgery

and thoracic surgery, opening the gut is avoided to limit the risk of complications. This fear was thus stimulating critical voices during the introduction of transluminal techniques. Because infection seemed to be a major obstacle of NOTES as it worked its way into clinical practice, several studies addressing this issue were performed, and infection was evaluated with great caution [1, 6, 23–25].

Important information regarding the transgastric approach came from Narula et al., demonstrating a rise in bacterial contamination parameters of the peritoneal cavity after opening the stomach; however, no severe complications from infections were observed. The infection rate in experimental series ranged between 0 and 16 % [6]. By 2010, several analyses were performed assessing the danger of infection and the risk of subsequent complications in the transgastric, transvaginal, transcolonic, and transesophageal routes. As a consequence, Euro-NOTES recommendations in the working groups regarding infection were summarized and published [19]. Endoscopes must undergo high-level disinfection in a commercial washing machine, and sterile end effector instruments at the tissue level must be used. In addition, the procedure should be performed under routine sterile conditions with gowns, drapes, and gloves to minimize contamination. Infection is prevented by intravenous antibiotic prophylaxis before surgery [19, 20]. The acid environment of the stomach must be preserved by discontinuing proton pump inhibitor therapy a week before surgery, if applicable. Also, during the procedures, sterile fluids and tube connections must be used.

Current clinical evaluation and evidence after 5 years of experimental and clinical practice indicate that infection is no longer a major concern, and the frequency of infectious NOTES complications is rather low (<3 %) [26–40]. The danger of infection was overestimated in the beginning of NOTES research, which is quite understandable. Still, comparative prospective trials are lacking. Despite this, infection rate may obviously be kept low by limiting contamination. This can be accomplished by disinfecting the pharynx, esophagus and stomach, and bowel, as well as providing an adequate antibiotic prophylaxis, which is routine practice in gastrointestinal surgery. A number of studies on clinical experience indicate that the disinfection of flexible endoscopes to be used in the mediastinum or

abdominal cavity seems to be sufficient in limiting contamination and thus preventing infection.

Peritoneal access

In the beginning of NOTES, the transgastric route was favored because its theory and development were strongly influenced by gastroenterologists [1, 3, 4]. Several transgastric access techniques, such as the PEG-related technique, the puncture and dilatation technique, and the more surgical direct gastrotomy technique with a needle knife, were investigated. With time, other disciplines became involved, and access routes via the vagina, colon, and urethra were developed and assessed experimentally [1, 3–5, 7–10, 17, 21, 36]. After controversial discussions of which route was the best and the safest, many expected an optimal route to emerge from various research efforts. Today, experimental and clinical experience indicates that there is a place for all these routes for different indications and procedures. In the meantime, several closure techniques have been successfully established for the different approaches. All routes—transesophageal, transgastric, transvaginal, and transanal/transcolonic—are well established in clinical practice.

The principle of hybrid techniques has overcome some of the limitations that inhibited the clinical breakthrough of NOTES. In hybrid procedures, transabdominal trocars are used in limited numbers and in a small size to facilitate, assist, and enable the maneuvers through the natural orifice via graspers for better retraction, exposure, and delivery of rigid energy devices. Despite the fact that transabdominal instruments will somewhat limit the possible positive effects of NOTES, hybrid procedures increase usually patient safety by facilitating the use of well-known and safe laparoscopic techniques.

The transvaginal route was established in operative gynecology a century ago [41], and transvaginal endoscopy or culdoscopy were first performed many decades ago [42–44]. The transvaginal route was used in the early days of laparoscopy for specimen retrieval [45, 46]. The advantage of the transvaginal access is the possibility of the use of rigid laparoscopic instruments, which surgeons are familiar with.

The concept of hybrid transvaginal cholecystectomy is comprehensible to surgeons and can be introduced in clinical practice, although it has a steep learning curve [47–51]. As with many hybrid techniques, primary abdominal access is performed via a safe standard laparoscopic approach with establishment of a capnoperitoneum and a transumbilical camera trocar, preferably of 5 mm. This allows for a safe introduction of larger access via the vagina with several trocars and/or other instruments. The technical maneuvers to dissect and remove the gallbladder are similar to established laparoscopy. In addition to cholecystectomy, transvaginal appendectomy and colon resections were also introduced into clinical practice, with a good safety record [52–55]. Although discussions focused on possible adverse effects of postoperative dyspareunia, the transvaginal technique has a good safety record and is well established [34–36, 53, 55–57].

Several working groups recommended that transvaginal NOTES procedures should be initially performed in cooperation with gynecologists, until surgeons gained enough experience to perform this technique safely [34, 36]. Usually guidelines advise performing 10 to 15 procedures to become experienced. Perioperative antibiotic prophylaxis with cephalosporin should be provided, and a preoperative gynecologic examination is advised [34, 36].

Contraindications for transvaginal access are rectovaginal endometriosis, pregnancy, and malignomas of the cervix and vagina. Previous gynecologic operations can cause severe adhesions. Therefore, it is advisable to use extra precautions, such as a preliminary capnoperitoneum and intraperitoneal visual control, when penetrating the vagina. It is advised to perform a suture closing of the access route of the posterior vaginal wall. Also, a gynecologic postoperative assessment is advised.

The first comparative trials have been published demonstrating the possible advantage of these NOTES and hybrid procedures over classic laparoscopic cholecystectomy regarding the cosmetic result [36].

The transesophageal route, which is the most frequently used in POEM, has also been evaluated for mediastinal work [27–30, 58–60]. Even though in the initial description of POEM it is claimed that the longitudinal muscle layer is not divided, clinical experience has demonstrated that in many POEM cases, the longitudinal muscle layer, which is rather thin compared to the circular layer, is often penetrated partially by the pressure of the endoscope in the dissection tunnel once the circular muscle layer has been divided [27, 29]. Thus, POEM may also be classified under the transesophageal access route. Currently, several clinical indications are evaluated for the POEM techniques, including achalasia, diffuse esophageal spasm and other spastic motility disorders, and mediastinal explorations.

For the treatment of achalasia, POEM is on its way to being an established therapeutic option to other alternatives such as endoscopic dilation and laparoscopic myotomy. Approximately 800 procedures have been performed worldwide by now. The complication rate is low, and the success rate is high enough to justify randomized comparative trials versus the established surgical techniques of laparoscopic myotomy.

A second indication for the transesophageal approach is exploration for mediastinal disease such as abscesses as well as collecting lymph nodes. Clinical experience is limited, and at this point, no recommendation regarding the latter indication can be provided.

The prerequisite for the transesophageal and transgastric approaches is a team experienced in endoscopic and laparoscopic procedures. The endoscopes must undergo high-level disinfection, antibiotic prophylaxis with cephalosporins must be provided, and the procedure must be performed under strict rules to prevent contamination and infection.

The transgastric route, which was initially thought to be the ideal way to enter the abdomen, has been tested for several indications, including peritoneal exploration, appendectomy, cholecystectomy, ovarian tube ligation, small bowel tumor resection, and gastric tumor resection [1–6, 10]. Despite the tremendous effort of many teams to establish appendectomy, cholecystectomy, and staging peritoneoscopy in clinical practice, they are currently not well established in clinical practice. One reason for this may be the technical limitations of flexible endoscopy in the abdominal cavity. The problem is the lack of strength of retraction, the lack of precision in movement, and the poor steering abilities of the flexible scope [2, 7, 10, 19]. In addition, several multitasking platforms were developed by industry but never reached the quality required for a commercially available product [22, 31]. As a consequence, the transgastric route and associated techniques are currently used for full-thickness gastric wall resections and other indications [6, 61–63]. In Europe, few studies were performed with cholecystectomy, staging peritoneoscopy, and appendectomy [19, 20, 31, 50]. Transgastric cholecystectomy was quite time-consuming and seemed to be technically very demanding compared to the transvaginal cholecystectomy [31, 34, 64]. Transgastric appendectomy is under trial evaluation.

The transanal/transcolonic technique was initially considered problematic because of the infection issue and the bacterial load of the colon. A large clinical experience existed for transanal endoscopic procedures, created as transanal endoscopic microsurgery (TEM) by Gerhard Buess in the early 1980s [65, 66]. From this experience came the information that infection should not be a major problem in transanal procedures. Experimentally, an enormous effort was put forth to test the feasibility of transcolonic procedures [67–70]. Initially, the approach from the lower abdomen seemed to be advantageous, especially for upper gastrointestinal procedures such as cholecystectomy and fundoplication. However, in the clinical setting, a necessary bowel preparation for a cholecystectomy or fundoplication would not be acceptable. Therefore, these ideas never made it to a clinical test.

The groundbreaking ideas came from Denk et al., who enlarged the vision of TEM by using the transanal route for complete rectal resection, initially tested in cadavers [69]. The most important idea behind the transanal/transcolonic route is the use of the anastomotic site as the access into the peritoneal cavity [38, 40, 69–72]. As a consequence, because no additional opening in the gut is necessary, there is no additional risk of the access site infection and complications other than the risk of the anastomosis [40, 73]. With completion of anastomosis, access via the natural orifice is also closed.

The latter idea was improved by hybrid technology that used transabdominal minilaparoscopy and rigid small-size energy devices for safe dissection. These led to the introduction of transanal hybrid colon resections, creating a compromise between the concept of NOTES (access via a natural orifice) and the experience of the safe technique of minilaparoscopic dissection to complete the resection of the bowel and perform the anastomosis. This made it possible to perform transanal/transcolonic colorectal resections in clinical practice [37–40, 73].

Today, we differentiate the transanal approach using the principle of the original TEM technique to dissect the lower rectum and perform colorectal resections and rectal anastomosis, and the use of the transanal approach to pass deeper into the abdominal cavity and use a transcolonic approach at the anastomotic site at the rectosigmoid level to perform colon resections.

Transanal/transcolonic hybrid NOTES procedures are increasingly performed in Europe, even though this approach was initially considered to be a dangerous application because of the issues of contamination and infection of the colon. On the basis of the long-term clinical experiences of TEM, and on the basis of the conceptional modifications that were made in the past years for using the anastomotic site as natural orifice into the abdominal cavity, transanal hybrid colon resections and transanal hybrid rectal resections were judged by the working groups to be the most promising development in NOTES today.

Education and training

Because NOTES procedures require both capabilities in interventional endoscopy and advanced laparoscopic surgery, many speculations emerged regarding the future role of surgeons and gastroenterologists or endoscopists performing these procedures [1, 2, 18, 19, 21]. It was even thought that in the future, a digestivist would need to learn both techniques from both disciplines. Working groups focusing on this subject even established a list of training requirements for NOTES surgeons and endoscopists [17–19]. With more experimental and clinical experience, however, it became clear that NOTES and hybrid NOTES procedures required a long training phase as well as extensive clinical and technical experience; these were necessary to perform NOTES procedures safely in the abdominal or thoracic cavity [2, 19, 20]. These techniques

cannot be learned in workshops or courses in a few weeks [21]. In addition, the initial euphoria about the idea of interdisciplinary cooperation between gastroenterologists and GI surgeons to perform NOTES together remained an illusion, with only a few exceptions [2, 19, 20].

There is no doubt that these new techniques should be taught in a preclinical setting, and extensive experimental work is needed before taking these techniques to the patient [2, 19, 20]. The safe performance of these procedures requires more experience and a higher mental workload than traditional minimal invasive surgery [74]. Interventional endoscopy and advanced laparoscopy must be well established before involving NOTES techniques. The prerequisites for clinical introduction of an innovative procedure such as NOTES procedures in clinical practice have been outlined in detail by EAES consensus recommendations [75].

Today, these techniques have been introduced in only a few dedicated centers worldwide that have surgeons with the necessary experience, which was usually established by an exhaustive training program in both flexible endoscopy and laparoscopy.

Intestinal closure

Great concern was expressed regarding safe closure of the gut; there was initially a substantial fear of possible complications, just as in the infection issue. Several prototypes of suturing devices were developed by industry and experimentally evaluated [16–20]. Unfortunately, some of the promising tools, such as flexible stapling devices, were withdrawn from the market. Some start-up companies with interesting products went out of business. Other developments, such as the over-the-scope clip, have emerged, creating valuable instruments that play a well-established role in clinical practice [76, 77]. Some suture devices and preliminary platforms were used successfully in selective centers. The multitasking platforms, which were initially thought to become the solution for safe access and closure as well as for anastomotic techniques, did not reach the clinical level [22].

As a consequence, safe closure is possible today via all access routes with rather simple technical and new conceptional means. In the esophagus, clinical evidence has demonstrated that mucosal clips are sufficient for closing esophagotomies when secured and associated with the tunnel technique [30]. Over-the-scope clips and endoscopic suture devices are used in clinical practice for limited gastrotomies [77]. Direct surgical closure and suture is well established in transvaginal procedures [34–36]. For the transanal/transcolonic approach, as an example of conceptional improvement, the access site is safely closed by completing a colorectal anastomosis [38–40].

Suturing and anastomosis

Suturing and anastomotic techniques were often discussed in European working groups. Initially, hope was focused on an endoscopic suturing device that could be advanced via a natural orifice in the abdominal cavity, making safe closure and anastomoses possible [1, 16, 17]. Industry has developed several endoscopic suturing devices and furthermore has heavily invested in several multitasking platforms [19, 20, 22]. These useful new tools may be used for suturing and creating an anastomosis [22]. Unfortunately, the financial crisis has slowed these developments. Some of these tools are used in dedicated centers, but clinical use is still very limited.

Conceptional developments and changes, mainly hybrid solutions, have made it possible to apply the NOTES concept to abdominal surgery and endoscopy using suture and anastomotic techniques. The hybrid concept permits safe conventional laparoscopic stapling and suture techniques. These solutions will soon be used to test the advantages and disadvantages of the concept of NOTES. However, for pure NOTES surgery, a need remains for effective endoscopic suturing devices.

Platforms and new technologies

Multitasking platforms to perform pure NOTES procedures via flexible endoscopy in the abdominal or thoracic cavity, as envisioned in the original idea of NOTES, are still lacking [1]. Whether robot technology, 3D vision, and improvements in optical correctness, motion scaling, and other features can be accomplished in these future tools and at the same time be transformed into a clinically available, reasonably priced product cannot yet be judged. Several working groups have established basic requirements for platform applications [18–20].

Optimal multitasking platforms should have changeable effectors, image guidance, the possibility of traction and countertraction, and sufficient triangulation, while having steerable stability to increase precision in maneuvers [19]. Today, these features are still not available in clinical practice.

Current studies of clinical application of NOTES and hybrid NOTES procedures

At the Euro-NOTES meeting in Frankfurt in September 2011, working groups were established for each access route. These groups discussed the available literature and the newest clinical experience.

The transesophageal NOTES technique has emerged to a dependable clinical level [26–30]. POEM is becoming an

established therapeutic option for the treatment of achalasia. The complication rate is low, as shown in Table 6, and the success rate is high enough to justify randomized comparative trials versus the established surgical techniques of laparoscopic myotomy. A European multicenter study is currently on the way.

For the transesophageal approach, indications include explorations of mediastinal disease and collection of lymph nodes. The lack of clinical experience means that recommendations cannot yet be provided for lymph node collection.

Transesophageal and a transgastric approaches require surgical teams experienced in endoscopic and laparoscopic procedures. Endoscopes must be disinfected, antibiotic prophylaxis with cephalosporins must be provided, and steps must be taken to prevent contamination and infection [19].

For the transgastric technique, there is no real "killer application," such as myotomy, for the esophagus. A limited gastrotomy can be safely closed with over-the-scope clip technology. If there is a larger opening in the gastric wall after resection of a gastric wall tumor, either endoscopic suturing devices or hybrid technology with laparoscopic stapling closure is necessary. In Asia, gastric wall tumors are more frequent. Therefore, a growing experience exists in Japan, Korea, and China on these rendezvous procedures between endoscopic and laparoscopic techniques.

Transvaginal procedures are well established worldwide, with an experience of several thousand cases. The safety record of published series is remarkable—less than 3 % (Table 5). The first comparative trials have been published demonstrating the possible advantages of these hybrid NOTES procedures over classic laparoscopic cholecystectomy regarding the cosmetic result [36].

In Europe, transanal/transcolonic hybrid NOTES procedures are increasingly being performed, despite initial fears of contamination and colon infection. The working groups judged the transanal hybrid colon and rectal resections to be the most promising developments in NOTES today. Two different indications have emerged within the last year. Transanal resections for rectal cancer can be performed directly in the TEM-based technique using more advanced technology [37–39, 73]. Dissection is performed in combination transanally and transabdominally in the hybrid technique. The anastomosis is performed transanally with a stapler or with hand-sewn sutures. A second option is a transanal hybrid colon resection that uses the upper rectum as a natural orifice at the anastomotic site. The dissection is performed via transabdominal instruments, and resection, anastomosis, and closure are achieved via the transanal approach [40].

In conclusion, NOTES—and more frequently hybrid NOTES—techniques have emerged for all natural orifices. Interestingly, different indications require utilizing different natural orifices. Each technique has been optimized for the purpose of finding a safe and realistic way to perform the procedure according to the specific indication. Each approach has been established clinically and has a good safety record. Further research will be conducted to prove their advantages. The most valuable result is the low complication rate that could be realized during the introduction of NOTES and associated techniques in clinical practice. NOTES techniques will thus remain in the clinical arena and will, we hope, help advance endoscopy and minimal access surgery for the benefit of patients.

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