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NOTES in Europe: summary of the working group reports of the 2012 EURO-NOTES meeting

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ABSTRACT

The sixth EURO-NOTES workshop (4 – 6 October 2012, Prague, Czech Republic) focused on enabling intensive scientific dialogue and interaction between surgeons, gastroenterologists, and engineers/industry representatives and discussion of the state of the practice and development of natural orifice transluminal endoscopic surgery (NOTES) in Europe. In accordance with previous meetings, five working groups were formed. In 2012, emphasis was put on specific indications for NOTES and interventional endoscopy. Each group was assigned an important indication related to ongoing research in NOTES and interventional endoscopy: cholecystectomy and appendectomy, therapy of colorectal diseases, therapy of adenocarcinoma and neoplasia in the upper gastrointestinal tract, treating obesity, and new therapeutic approaches for achalasia. This review summarizes consensus statements of the working groups.

Introduction

Since 2007, The European Association for Endoscopic Surgery (EAES), together with the European Society of Gastrointestinal Endoscopy (ESGE), has been organizing and conducting annual joint workshops on natural orifice transluminal endoscopic surgery (NOTES) and interventional endoscopy. The sixth EURO-NOTES workshop took place in Prague, Czech Republic (4 – 6 October 2012).

Although the number of participants was down compared with previous years, more than 120 participants attended the meeting, demonstrating that research in NOTES is still attractive for both surgeons and gastroenterologists. The 2012 workshop was strongly influenced by new techniques in NOTES-related interventional endoscopy, such as peroral endoscopic myotomy (POEM). Furthermore, although progress has been slow, NOTES-associated surgical procedures including hybrid NOTES – cholecystectomy, NOTES – appendectomy, and colorectal procedures have recently been integrated into routine clinical medicine, as demonstrated by many publications and documented procedures in the EURO-NOTES registry. The 2012 workshop aimed to give an overview of all current research activities and ascertain future research needs. In addition, for the first time, hands-on training of luminal and transluminal procedures in live animals was available, which greatly enhanced the workshop. As in previous years, working groups with an emphasis on specific indications for NOTES and interventional endoscopy were formed: cholecystectomy/appendectomy, colorectal diseases, therapy of adenocarcinoma/neoplasia in Barrett's and in the stomach, anti-obesity, and achalasia.

Position statements from these working groups are summarized below.

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Cholecystectomy/appendectomy

Cholecystectomy has been the classical indication for NOTES. The vast majority (more than 500 cases [82 %]) of NOTES procedures listed in the Euro-NOTES registry are therefore cholecystectomies, and most of these procedures are performed via the vagina as a natural orifice with rigid laparoscopic instruments. In the only prospective randomized clinical trial, of 1-year duration, comparing the vaginal and transumbilical approaches using flexible instruments with the conventional laparoscopic

cholecystectomy [1], postoperative pain, length of hospital stay, and time off work were similar in the three groups. However, surgical time was longer among cases in which a flexible endoscope was used.

In contrast, appendectomies that have been registered in the EURO-NOTES registry account for less than 10 % of NOTES procedures. Here, a transgastric access is the preferred route.

Both transvaginal cholecystectomy and transgastric appendectomy appear to be safe with complication rates comparable to conventional laparoscopy if performed by experts with sufficient experience. However, for both indications, a pure NOTES approach with a single flexible endoscope introduced via one natural orifice is rarely performed, and transabdominal laparoscopic assistance is still considered useful to enable traction/countertraction. In addition, the common approach for NOTES – cholecystectomy is via a laparoscopic port placed transvaginally, thereby enabling various rigid instruments to be used for better traction.

It should also be noted that apart from NOTES resection, new endoscopic procedures that reduce the need for surgery are also under investigation. In particular, transgastric or transduodenal endoscopic ultrasonography (EUS)-guided drainage of the gall bladder using covered, self-expanding, modified metal stents can be minimally invasive alternatives to cholecystectomy in selected patients.

Summary statements

Current data suggest that transvaginal port laparoscopy is the preferred approach for NOTES, with complications comparable to standard transabdominal laparoscopic cholecystectomy.

A transgastric access is the theoretically preferred route for appendectomy. However, further data are necessary before the safety of such an approach can be rated in comparison to laparoscopic surgery. In addition, multitasking platforms appear desirable to aid such NOTES procedures.

For both NOTES – cholecystectomy and NOTES – appendectomy, single-shot antibiotic administration is recommended.

New concepts of endoscopic gastro-/duodeno-biliary drainage rather than cholecystectomy appear to be promising in selected patients.

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Colorectal diseases

Access routes for NOTES include the vagina, the stomach, the esophagus, and the colorectum. As stated in previous workshop summaries on access and closure, access to the peritoneal cavity via the colorectum bears the highest risk for bacterial contamination. In 2010, the gastric and transvaginal approaches were therefore recommended as the preferred routes for NOTES procedures [2]. However, taking into consideration new developments in successful transanal/transrectal/transcolonic NOTES procedures, this attitude has changed. Meanwhile, colorectal clinical NOTES interventions comprise colon resections, total mesorectal rectum resections of cancers in stage T2 or T3, and retrieval of specimens. More than 20 publications on NOTES colorectal interventions in humans have been published on this topic with almost 100 patients treated by NOTES-assisted colorectal resections. Transcolonic NOTES procedures have been restricted almost completely to hybrid interventions with additional laparoscopic support. However, there have also been case reports where pure NOTES interventions without laparoscopic assistance were performed. Nevertheless, the acceptance of this access route is still low among physicians and patients. This might be related to the complexity of some procedures, with available data provided by only a few expert centers, and the continued fear of increased infection rates.

Apart from these considerations, the choice of platform is still a matter of debate. Currently, transanal endoscopic microsurgery platforms or single-port devices appear most attractive, but these are restricted to the pelvis below the promontory due to the use of laparoscopic instruments. In contrast, flexible NOTES platforms would be of

potential advantage for better access to the descending colon and hepatic flexure. However, currently available flexible endoscopic platforms and instruments show many limitations (angulation, visualization, transmission of forces, etc.).

Summary statements

At the present time, transcolonic/transrectal NOTES should be restricted to interventions where the access site is incorporated in the specimen/anastomosis (mainly left-sided colon or rectum) and thus resected within the specimen.

The indications for colorectal NOTES comprise neoplastic lesions rather than inflammatory diseases; neoadjuvant therapy is no contraindication but multivisceral resection is no indication.

Further studies are required and should focus on comparison of colorectal NOTES with other available minimally invasive procedures (single-port surgery). Endpoints evaluated should be pain, return to normal activity, leakage rate, oncological safety, infection, cosmesis, and costs.

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Therapy of adenocarcinoma/neoplasia in Barrett's esophagus and in the stomach

As mentioned above, rectal cancers even in stage T2 and T3 can be treated using a NOTES approach. This is not the case for upper gastrointestinal cancers. In general, NOTES procedures for therapy of neoplasia and early cancers have not been mentioned to date. The concept does not appear to be attractive given the potential risks of a transmural endoscopic approach without the benefits (lymph node resection!) of conventional oncological surgery. However, intraluminal endoscopic resection using endoscopic mucosal resection (EMR) or endoscopic submucosal dissection (ESD) should be considered the method of choice if the following criteria are fulfilled: mucosal adenocarcinoma of differentiated type, diameter of lesion smaller than 2 cm for elevated tumors, and diameter below 1 cm with no visible ulceration for depressed lesions. ESD as a definitive curative approach can also be discussed when intestinal-type cancers are larger than 2 cm or only the upper submucosal layer (sm1) is infiltrated ("extended criteria") [3]. For all other cases, oncological surgery still has to be considered the gold standard.

For Barrett's neoplasia, the therapeutic algorithm is quite similar to gastric cancers/intraepithelial neoplasia. Here, additional radiofrequency ablation is recommended if neoplasia is invisible or if Barrett's mucosa remains adjacent to the area of endoscopic resection [4]. A close follow-up and surveillance program should be offered to all patients undergoing endoscopic therapy.

Cancers and intraepithelial neoplasia should be distinguished from submucosal tumors. A NOTES-like procedure of full-thickness resection of the gastric wall might be reasonable for those tumors when resection en bloc is mandatory but adequate assessment of lymph nodes is not necessary.

Summary statements

Cases that meet the standard criteria do not require major surgery but allow curative endoscopic resection by EMR or ESD.

Cases that meet the extended criteria should be considered for endotherapy after interdisciplinary discussion and consensus of tumor boards.

For submucosal tumors, EMR/ESD bears a risk of incomplete resection of gastrointestinal stromal tumors and intraperitoneal tumor cell dissemination. Here, endoluminal full-thickness resection with endoscopic or laparoscopic closure or laparoscopic wedge resection under endoscopic guidance should be performed

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Anti-obesity

At the present time, current surgical procedures are quite satisfactory, with excellent clinical results. However, there are also several shortcomings of surgery. In particular, irreversibility of the respective procedure limits its use and implies careful patient

selection. Furthermore, there is a problem of wound infection in super-obese patients, highlighting potential advantages of NOTES procedures.

The working group discussed currently available procedures for treating obesity. These are traditional methods such as endoscopic placement of a gastric balloon, vertical banded gastroplasty, and bypass surgery. Newer, more experimental methods are intragastric Botox injection, endoscopic gastric plication, endoluminal duodeno-jejunal bypass or electrostimulation. However, it has to be mentioned that even in surgery, no consensus could yet be achieved upon the best technique.

Summary statements

There is a need for a “fully” endoscopic, transoral bariatric procedure.

This procedure should be effective, reversible, easy to do, safe, and cost-effective.

The most promising principles for fully endoscopic treatment include gastric pacing with endoscopic implantation devices and sleeve mechanisms.

At the present time, such a procedure will probably not completely replace standard laparoscopic bariatric surgery.

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Achalasia

Although achalasia is a rare disease, a new technique in NOTES-related interventional endoscopy – peroral endoscopic myotomy (POEM) – has gained significant interest. In contrast to pneumatic dilation or Botox injection in the lower esophageal sphincter, POEM, which is similar to Heller’s myotomy, aims at definitive cure of the disease. However, POEM is a complex procedure, and hence requires an endoscopist who is highly skilled in interventional flexible endoscopy, with previous training in animals and ongoing experience in ESD procedures. In contrast, balloon dilation is rather easy to perform. It has also been demonstrated that endoscopic pneumatic dilation appears to be as effective as laparoscopic myotomy [5]. Hence, the question arises of whether there is a real need for POEM, and which patients will benefit most from POEM compared with pneumatic dilation or laparoscopic myotomy? Furthermore, although short-term results are promising, there is still a need for long-term follow-up results after POEM.

Summary statements

POEM is a new and promising NOTES approach for the treatment of achalasia.

Short-term results obtained in a few selected patients have shown results comparable to laparoscopic myotomy.

POEM is a very complex and risky procedure; endoscopists with an interest in POEM should therefore be highly skilled, trained by specialists, and experienced in performing ESD before treating patients with this technique.

The question of which therapy is best must be addressed by randomized trials comparing pneumatic dilation, POEM, and laparoscopic myotomy (including long-term follow-up of patients).

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Conclusion

NOTES is dead? No, it is not! The summaries of all of the working group reports demonstrate that NOTES and interventional endoscopy have become clinical reality. There is still a long way to go before the procedures discussed above become everyday routine practice, but the concept per se is being continuously evaluated and modified for clinical practice. Many obstacles from previous years have been overcome. As with any “disruptive technology” [6], following the trigger of the first description of NOTES in 2004 and the subsequent years of inflated expectations (NOTES hype), it might be assumed that the trough of disillusionment has been overcome and the slope of enlightenment has just recently been reached. The next few years will show when and how the plateau of productivity will be reached. Current NOTES-associated procedures such as POEM and transanal resections will certainly help to change our current practice and firmly integrate the NOTES concept into

clinical routine. Interdisciplinary involvement is the key to such further development; EURO-NOTES 2012 was characterized by fruitful discussions among various clinicians, scientists, engineers, and industry representatives. We look forward to continuing this dialogue at EURO-NOTES 2013 in Barcelona.

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