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REVIEW ARTICLE

Emerging Techniques in Minimally Invasive Surgery. Pros and Cons

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Abstract New trends have emerged regarding the best minimally invasive access approaches to perform gastrointestinal surgery. However, these newer approaches are seen critically by those who demand a more strict assessment of outcomes and safety. An international panel of expert gathered at the 2014 American College of Surgeons Meeting with the goal of providing an evidence-based understanding of the real value of these approaches in gastrointestinal surgery. The panel has compared the efficacy and safety of most established approaches to gastrointestinal diseases to those of new treatment modalities: peroral esophageal myotomy vs. laparoscopic myotomy for achalasia, transgastric vs. transvaginal approach, and single-incision vs. multi-port access minimally invasive surgery. The panel found that (1) the outcome of these new approaches was not superior to that of established surgical procedures; (2) the new approaches are generally performed in few highly specialized centers; and (3) transgastric and transvaginal approaches might be safe and feasible in very experienced hands, but cost, training, operative time, and tools seem to limit their application for the treatment of common procedures such as cholecystectomy and appendectomy. Because the expected advantages of new approaches have yet to be proven in controlled trials, new approaches should be considered for adoption into practice only after thorough analyses of their efficacy and effectiveness and appropriate training.

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Introduction

In recent years, new approaches such as single port and natural orifice (natural orifice transluminal endoscopic surgery (NOTES)) procedures have emerged to further decrease the physiologic impact of minimally invasive surgery. However, those demanding a more strict assessment of outcomes and safety see these new procedures critically, claiming that cosmesis, reduced discomfort, and increased costs are not offset by improved results and better safety. In addition, these newer approaches have brought a unique cadre of complications that makes them suitable only in very specialized centers and less feasible and useful to most surgeons.

The goal of this paper is to provide an evidence-based understanding of the real value of these approaches in gastrointestinal surgery today. To achieve this goal, an international panel of experts gathered at the 2014 American College of Surgeons Meeting and compared the efficacy and safety of most established approaches to gastrointestinal diseases to those of new treatment modalities: laparoscopic myotomy for achalasia vs. peroral esophageal myotomy (POEM), laparoscopic cholecystectomy vs. transgastric (TG) vs. transvaginal (TV) approach, and single-incision vs. multiport access laparoscopic surgery.

Esophageal Achalasia: Laparoscopic Heller Myotomy (Dr. Patti)

In 1991, Pellegrini et al. performed the first thoracoscopic myotomy for achalasia.[1] Even though the initial results showed that the approach was feasible, safe, and gave good relief of dysphagia, the technique evolved to a laparoscopic approach with a fundoplication after the realization that abnormal reflux was present in about 60 % of patients.[2] The laparoscopic approach also allowed a longer myotomy onto the gastric wall, further decreasing the risk of persistent or recurrent dysphagia.[3] In the past few years, high-quality evidence has emerged, which provides the basis for the current surgical treatment. Richards et al. conducted a prospective randomized clinical trial comparing 21 patients treated by laparoscopic Heller myotomy (LHM) alone and 22 by LHM and Dor fundoplication. While relief of dysphagia was similar in the two groups, pathologic reflux was present in 47.6 % of patients after LHM alone and in 9.1 % after LHM and Dor fundoplication.[4] Rawlings et al. reported in 2012 the results of a multi-center, prospective, randomized controlled trial comparing Dor vs. Toupet fundoplication after LHM. Relief of dysphagia and esophageal acid exposure was similar in the two groups,[5] suggesting that either type of partial fundoplication was appropriate. Conversely, a randomized trial showed that a total fundoplication should not be performed, as it is associated with a high rate of recurrent dysphagia.[6]

LHM with partial fundoplication is today the preferred treatment modality for achalasia in most centers.[7] Dysphagia is improved in about 80 to 90 % of patients 10 years after this operation.[8,9] Recently, POEM has been introduced by Inoue et al. in Japan.[10] At a mean follow-up of 5 months, none of 17 patients had recurrent dysphagia while one patient developed grade B esophagitis. The resting LES pressure decreased from a mean of 52.4 to 19.9 mmHg. In 2012, Swanstrom et al. published the outcome of 18 patients treated with POEM.[11] The authors reported three intraoperative complications (two gastric and one esophageal perforations), which were all repaired endoscopically. At a mean follow-up of 11.4 months, dysphagia was relieved in all patients with a drop of the median Eckardt score from 6 to 0. Post-operative upper endoscopy showed esophagitis in 28 % of patients, and pH monitoring showed pathological reflux in 46 % of cases. In 2013, von Renteln et al. reported the results of a prospective trial of 70 patients undergoing POEM in FIVE centers in Europe and North America.[12] At 12-month follow-up, 82 % of patients had remission of dysphagia while 18 % had already recurrent dysphagia. Symptoms of reflux were reported by 37 % of patients, and an upper endoscopy revealed esophagitis in 42 % of patients. No Ph monitoring was performed.

Few nonrandomized and retrospective studies comparing POEM and LHM have been published. Hungness et al. reported the short-term outcomes in 18 patients undergoing POEM and in 55 patients treated by LHM.[13] Post-POEM upper endoscopy showed esophagitis in 33 % of patients. Treatment success, defined as Eckardt score ≤3 after POEM, was achieved in 89 % of patients at median 6-month follow-up. Bhayani et al. compared 64 patients undergoing LHM to 37 who had POEM.[14] LES resting pressure was lower after LHM than after POEM (7.1 vs. 16 mmHg); abnormal acid exposure by 24-h pH monitoring was observed in 39 % of patients after POEM and in 32 % of patients after LHM, and at 6-month follow-up, 29 % of LHM patients reported dysphagia to solids compared to none of the POEM patients.

Based on this limited evidence, POEM seems to be a promising new procedure. The following concerns, however, should be taken into consideration before this technique becomes the treatment modality of choice: (1) POEM requires advanced technical skills; (2)perforation of the esophagus or stomach has occurred in all the published studies, and this event can be potentially fatal; (3) even though a decrease in LES pressure has been documented, the mean post-procedure

LES pressure remains between 15 and 20 mmHg, higher than then 10-mmHg cutoff which is a predictor of long-term failure;[15] (4) the experience with POEM replicates the problem of a high incidence of gastroesophageal reflux encountered after LHM without a fundoplication; (5) while in case of recurrent dysphagia after LHM, pneumatic dilatation or a redo myotomy has proven to be very effective,[8,16] it is unclear how safe and effective it is after POEM; and (5) the success rate of POEM is 100 % in some studies,[10,14] but only 82 to 89 % in others after a very short follow-up.[12,13] These results raise issues about advising patients to have POEM instead of LHM as primary treatment modality. A LHM has been shown to improve dysphagia in about 80 to 90 % of patients 10 years after the operation.[8,9] For POEM, only short-term follow-up, between 6 and 12 months, is available. Therefore, randomized controlled clinical trials comparing POEM to LHM and POEM to pneumatic dilatation are needed before endorsing the use of POEM as the treatment of choice.

Esophageal Achalasia: POEM (Dr. DeMeester)

In 2007, Pasricha et al. described an endoscopic technique to divide the circular fibers of the LES.[16] Since Inoue's first procedure in 2008, there have been numerous POEM procedures performed worldwide.[7] While most are done for achalasia, the indications have expanded to treat esophageal spasm or delayed gastric emptying and to remove benign esophageal tumors.[17–19] Nevertheless, based on early results of POEM, a few conclusions can be drawn.

POEM is safe, even during the learning curve, as there has been not a single death documented after POEM.[20,21] Capnoperitoneum occurs commonly, but decompression is necessary in only 5–10 % of patients. Bleeding from large submucosal vessels while creating the submucosal tunnel can be problematic, but it can be controlled with bipolar forceps, and with experience, it is much easier avoided. Delayed bleeding occurs rarely, although in some cases, reexploration of the tunnel has been required.[22] Another occasional source of morbidity is the mucosal closure, and a leak into the submucosal tunnel should prompt reexploration. The most serious complication has been a contained esophageal perforation at the level of the gastroesophageal junction.[13] Treatment consisted of endoscopic and laparoscopic evaluation of the area with placement of drains. Overall, POEM has a remarkably little morbidity, although most cases are done in centers with great experience in the treatment of esophageal disorders.

POEM results in significant improvement in dysphagia. In a series of 20 patients, the median Eckardt score at 1 month after POEM was 1, down from 6 pre-POEM, and over half of the patients had complete resolution of dysphagia. These results persisted with longer follow-up: at 18 months, the median Eckardt score was 0, most patients had no dysphagia, and all were satisfied with the results. The median emptying at 5 min by timed barium swallow had improved from 48 to 100 % at 6 months post-POEM.[11] Similarly, in an international, multi-institution series of 70 patients, the median Eckardt score had dropped from 7 to 1 at 3 months and success was achieved in 97 % of patients. At 12 months after POEM, sustained success was present in 82 % of patients, and the mean Eckardt score was 1.7 in 51 patients followed-up.[12]

Any procedure that opens up the LES improves esophageal emptying but leads to reflux. In the series by Swanstrom et al., 44 % of patients reported heartburn after POEM, and all were taking acid suppression medications. Erosive esophagitis was seen in 28 %, and 46 % of patients had increased esophageal acid exposure.[11] In the international series, 37 % of patients had reflux symptoms and 42 % had erosive esophagitis 12 months after POEM.[12]

Compared to a LHM with partial fundoplication, POEM has been shown to have a similar outcome in two retrospective comparative studies.[13,14] In the series by Hungness et al., operative times were shorter with POEM, but complications and the median length of stay were similar. In the series by Bhayani et al., the median operative time and hospital stay were shorter for POEM, but complications were similar. The post-operative Eckardt scores were lower after POEM, and all patients had relief of dysphagia compared to 97 % after LHM and partial fundoplication. Heartburn, regurgitation, and chest pain were similar; the absolute and relative decreases in LES resting pressures were similar, although the resting pressure was higher after POEM, and the frequency of increased acid exposure was at about 35 % for each procedure.

In summary, POEM has largely been performed mostly in international centers with an interest and experience in esophageal disorders. In this setting, the procedure has been safe and able to palliate symptoms in the short-term. Longer follow-up and randomized and prospective trials are needed to define the role of POEM in the treatment algorithm of esophageal achalasia.

Transgastric Route in Gastrointestinal Surgery (Dr. Hungness)

The SAGES/ASGE NOTES White Paper in 2005 focused the attention of NOTES on several areas for what was thought initially as only TG: access, gastric closure, prevention of infection, suturing and anastomotic devices, maintaining spatial orientation, development of a multi-tasking platform, managing complications and hemorrhage, physiologic untoward events, and training.[22] Early studies revealed that TG procedures were feasible yet very difficult, time-consuming, and dependent on industry's development of tools and platforms.

Overall, the number of TG cases performed worldwide is much less than transvaginal (TV). The main reasons are ease

of TV access and closure and direct access to the upper abdomen without needing retroflexion as in the case of TG cholecystectomy and the use of conventional rigid laparoscopic equipment. Auyang et al. reported that of the first 432 NOTES cases, only 58 were TG with at least one additional transabdominal port.[23] The recent Euro-NOTES and German NOTES studies confirmed low TG utilization with 7.5 and 1.3 % rates, respectively.[24,25] There are minimal and conflicting data regarding infection after the TG approach. The Ohio State group reported minimal gastric contamination of peritoneal aspirates and no clinical infection. PPI use did increase peritoneal contamination but had no clinical relevance.[26] In contrast, Kaehler et al. found a 13 % intrabdominal abscess rate following TG appendectomy in 15 patients.[27]

TG cholecystectomy was initially thought to be the primary target for NOTES. Early clinical experience, however, revealed significant technical difficulties. In 2009, Auyang et al. described a TG hybrid technique in four patients utilizing balloon dilation and a specialized locking overtube that stabilizes the endoscopic instruments in retroflexion.[28] Nevertheless, cases lasted up to 4 h. More concerning was the report of gallbladder specimens getting stuck at the cricopharyngeus muscle resulting in at least one esophageal perforation. In 2013, Arrezo et al. reported that of 423 NOTES cholecystectomies performed, only 12 were TG. Compared with TV, TG had an increased operative time but similar complication rates.[24] Today, most centers have abandoned TG cholecystectomy.

TG access to the appendix seems instead more feasible. Arezzo et al. described 33 NOTES appendectomies, 86 % of which performed with a TG hybrid approach.[24] Gastric closure with a commercially available clip resulted in a 96 % closure rate. The only failure required laparoscopic suturing to close the gastrotomy. The mean operative time was 100 min compared to 59 min for the TV approach. The complication rate was 18 % (one minor, four major). The major complications consisted of two conversions to laparotomy due to extensive serosal injury to the cecum and two abscesses in the pouch of Douglas, which were explored laparoscopically to ensure that the gastric and appendiceal stump was secure. Therefore, TG appendectomy appears to be feasible, however, with a low acceptance rate and potentially high infection rates.

TG approaches have created excitement over the past decade. The reality, however, is that although clinical feasibility has been established, more complications and no clear advantage have been established. Therefore, laparoscopic technique to cholecystectomy and appendectomy still remains the standard of care.

Operative Access: Transvaginal Route in Gastrointestinal Surgery (Dr. Perretta)

The TV access was chosen for the first human NOTES cholecystectomy because of the benefits of an established method of access and closure of the entry point, direct line of vision toward the gallbladder, and the ability to introduce rigid laparoscopic instruments that could assist in different steps of the procedure.[29–31] Since then, TV procedures have used rigid in-line instruments or a flexible platform. However, the majority of procedures in Europe have been performed by a rigid hybrid technique either by a modified TEM instrumentation or using laparoscopic rigid instrumentation as described by Zornig in 2007.[32] Zornig's technique became popular, as it relies on known laparoscopic skills and instrumentation. The popularity of this technique was recently highlighted in a report from the German Society of General and Visceral Surgery with over 488 NOTES cholecystectomies, almost all performed with the Zornig's technique.[25]

TV access has a strong track record of safety in gynecology and, not surprisingly, has been the leading access for NOTES. With the goal of tracking the evolution of new techniques, a global European NOTES activity registry was created among ten centers. An independent nationwide German registry was also established as an outcome database to allow the monitoring and safe introduction of NOTES.[25] According to these registries, TV NOTES have low complication rate, minimal post-operative pain, and short recovery time. Different centers performing NOTES have adapted the techniques according to their own expertise and comfort level. In general, enlarged uterus, adhesions from prior pelvic surgery, history of endometriosis or pelvic inflammatory disease, and previous C-section are the main contraindications.

As of today, there have been 1582 published cases of TV procedures with an overall complication rate of 7.5 %. The International Multicenter Trial on NOTES (IMTN)[24] and the German Registry D-NOTES[25] reported good clinical results of TV NOTES. In the IMTN Study, the complication rate was 6.9 %. Complications requiring intervention were as follows: intraoperative bleeding, bowel injury (recognized and treated intraoperatively), and biliary leak from the cystic duct. No cases of infection following TV NOTES were reported. Biliary leaks occurred in two patients due to inefficient cystic duct closure. The German D-NOTES group reported 551 cases of TV NOTES, with a 3.1 % complication rate and a conversion rate to laparoscopic and open surgery of 4.9 %. Complications included the following: rectal and bladder injury and vaginal bleeding. One pelvic abscess after cholecystectomy required laparoscopic drainage.

Infection is rare in the TV NOTES literature. The risk of infection associated with a vaginal hysterectomy is as low as 3.9 %,[25] whereas only two infections occurred among 1077 NOTES cases.[25,33] One patient developed an abscess in the pouch of Douglas after a hybrid TV cholecystectomy; another patient developed an abscess in the right lower quadrant after a TV appendectomy for gangrenous appendicitis. Therefore, the concern of an infectious complication due to the TV access is not justified. Moreover, rectal injury associated with

culdoscopy using a Veress needle–trocar system has an overall incidence of 0.65%.[34] Only two cases of rectal injury have been described; one was successfully treated nonoperatively, and the other was closed transrectally.[25] These injuries seem to occur more often with a pure TV access and less often when a hybrid access is performed to visualize the vagina from the umbilical port. The German D-NOTES registry describes three bladder injuries. One injury required intraoperative laparoscopic repair, and two were managed with an indwelling catheter. The frequency of urinary tract infections is comparable to the rate of urinary tract infections after vaginal hysterectomies (0.68%).[35] There has been only one case of dyspareunia after TV NOTES.[36] In addition, female sexual function is not impaired after TV procedures, although data in the gynecologic literature is controversial.[37–39] Vaginal bleeding is a rare, self-limited event.

TV approach has proven its feasibility and safety in a large clinical experience in very specialized centers. However, as for the TG approach, there seems to be no advantage to the more traditional and well-established laparoscopic approach.

Multi-Port Laparoscopic Access (Dr. Soper)

The first application of laparoscopy in general surgery was that of a cholecystectomy, which rapidly became the gold standard of treatment for gallstones.[40] Laparoscopic surgery differs from traditional "open" surgery in many ways: (1) a satisfactory pneumo-peritoneum must be established, (2) someone other than the surgeon controls the laparoscopic view, which is usually two-dimensional and highly magnified, (3) the surgeon views a video screen not the operative field, and (4) the laparoscopic ports act as fulcra, so the instruments move in a direction opposite that of the surgeon's hands. As a result, there is a "learning curve" that was initially manifested by a higher rate of bile duct injuries, particularly early in the adoption of this technique.[41] However, some principles of open surgery are maintained with traditional multi-port operations: the ability to provide adequate traction and counter traction, triangulation of the operative field, and instruments entering the field off-axis from the visualization.

Despite the increased incidence of bile duct injury with laparoscopic cholecystectomy, many surgeons rapidly adopted this technique. Individuals requiring cholecystectomy began to demand that the operation be done laparoscopically, and thus, randomized prospective trials were initially challenging to organize. In 1992, the NIH consensus conference "Gallstones and Laparoscopic Cholecystectomy" determined that laparoscopic cholecystectomy "provides a safe and effective treatment for patients with symptomatic cholelithiasis" and that "the outcome of laparoscopic cholecystectomy is influenced greatly by the training, experience, skill, and judgment of the surgeon performing the procedure."[42] Also in 1992 was the first of several small prospective randomized trials comparing laparoscopic to open cholecystectomy.[43] These trials demonstrated that the laparoscopic approach was associated with less pain, shorter hospitalization, and more rapid return to full activity.

Over the ensuing two decades, other abdominal operations were described using laparoscopic techniques: appendectomy, colectomy, gastrectomy, fundoplication, etc.[44] Common to all of these reports was a description of an early learning curve as surgeons worked out the unique aspects of exposure, retraction, and manipulation using these novel methods. With each of these operations, studies have confirmed that the results of laparoscopy are generally better than those of open operations due to less pain and fewer complications.[45] Multi-port laparoscopy has thus "set the bar" quite high for clinical outcomes. Nevertheless, surgeons continue to try new approaches to further decrease the surgical insult to patients. These include the use of smaller instruments and thus smaller incisions, while maintaining the ability to triangulate within the operative field and to view the target "off line" from the laparoscopic instruments. There are a few small prospective randomized trials, suggesting that "needle-scopic" (using 2- or 3-mm-diameter instrumentation) may lead to slightly less pain and improved cosmetic appearance compared to traditional 5- to 10-mm laparoscopic ports.[46]

More recently, laparoscopic operations have been performed using multiple instruments placed through a single skin incision. A number of devices have been designed to allow simultaneous insertion of multiple instruments. The single-incision approach is limited; however, because the instruments are placed in line with the endoscope, triangulation of tissue is more difficult, the ability to retract tissue may be diminished, and the hand pieces of the instruments often clash outside the body, rendering the technique more difficult in the average surgeon's hands. Concerns have therefore been raised about the safety of this technique. However, relatively large clinical series have been published using these single-incision techniques with good clinical outcomes. Several prospective randomized trials have been published comparing single-incision versus multi-port access for cholecystectomy, appendectomy, and other procedures.[47–49] Most show that single-incision access takes longer and does not significantly decrease pain or enhance post-operative recuperation. Up to this time, no study has definitively proven the advantage of fewer incisions compared to multi-port surgery, other than the potential for improved cosmetic appearance. In fact, one large prospective randomized trial of single-incision versus multi-port cholecystectomy with long-term follow-up revealed that the cosmetic results were somewhat improved with the single-incision access, but this approach led to a significantly increased risk of subsequent incisional hernias.[50]

In summary, clinical results of multi-port laparoscopy have set the bar high for comparison with other minimally invasive techniques. The use of smaller/fewer incisions may lead to cosmetic advantages, but clinical outcomes are not superior to those of multi-port laparoscopy.

Operative Access: Single-Incision Route in Gastrointestinal Surgery (Dr. Rosemurgy)

The term laparo-endoscopic single-site (LESS) surgery describes single-site laparoscopy, and it was introduced by a consortium in 2010.[51]

Cholecystectomy is an ideal operation to hone LESS surgery skills. It is a common operation, and it does not involve any reconstruction. Its learning curve is definable and short.[52,53] The technique of LESS cholecystectomy has become standardized, and proficiency can be attained after about 25 operations.[54] While there are some concerns related to the cost due to the use of single multi-trocar ports, the approach offers other cost savings, such as with instrumentation. Similarly, LESS cholecystectomy provides other opportunities, like utilization of epidural anesthesia, with cost savings and patient satisfaction (e.g., reduction in post-operative pain).[55]

The LESS approach for the treatment of GERD started in 2008. The learning curve was not very long.[56] The fundamentals of the operation are the same whether the approach is with conventional multi-port laparoscopy or LESS surgery, and thereby, outcomes have shown to be similar. Early in our experience, we compared the course and outcome after LESS fundoplication to those after conventional multi-portlaparoscopy.[57] We found that while the LESS approach required more time, there were no differences between the approaches in term of outcomes.

LESS Heller myotomy gives a "scarless" alternative while providing palliation indistinguishable from multi-port laparoscopy.[58] As with LESS fundoplications, and other LESS operations, the learning curve with LESS Heller myotomy and anterior fundoplication is definable and short.[59] As expected, symptom relief is similar to that of multi-port laparoscopy, but with better cosmesis, recovery, and patient satisfaction with the LESS approach.[58,59]

LESS surgery gives equal access to all quadrants of the abdomen and pelvis. Thus, the approach lends itself very well to colectomy. Unfortunately, laparoscopy is applied for a minority of colectomies and the LESS approach is uncommonly utilized in patients undergoing laparoscopic operations. However, there are a burgeoning number of reports supporting LESS colectomy.[60,61] A randomized trial comparing LESS colectomy to conventional laparoscopic colectomy documented safety with lower pain scores and shorter length of stay with LESS colectomy.[61] For distal pancreatectomy with or without splenectomy, the LESS approach requires an extraction site and this is usually placed at the lateral axillary line to avoid a scar visible from the front. The extraction site can also be within the pubic hairline or transvaginal, if the patient so wishes. The operation is as safe and fast as with a conventional laparoscopic or robotic approach, and the cosmetic outcome and recovery is superior to either.

In summary, LESS surgery is safe in very experienced hands and has a unique cosmetic advantage, and clinical outcomes are similar to those of multi-port laparoscopy.

Conclusions

A few decades ago, patients requiring cholecystectomy began to demand that the operation be done laparoscopically. Since then, multi-port laparoscopy has become accessible to the general population with results that set the standards. Nevertheless, surgeons have rightly continued to push new approaches to further decrease the surgical trauma. The real value of these approaches is unclear, however. The panel recognized that the outcome of these approaches is not superior to multi-port laparoscopy. Some of the newer approaches, like POEM, still need to be validated with clinical trials and longer follow-up before being endorsed as the standard of care for the treatment of achalasia. TG and TV approaches might be as safe and feasible as multi-port laparoscopy in very experienced hands, but cost, training, operative time, and tools seem to limit their application. The panel also acknowledged that these approaches are generally performed only in few specialized centers. As a consequence, these approaches are less accessible to the general population, as the majority of surgeons in the community may choose not to adopt the newer techniques. In fact, one of the limiting factors to a wider application of some of these approaches is that surgeons may require a specific training and different tools to reliably address new challenges. Finally, the panel recognized that considerations of safety and training must also be considered prior to introduction of newer approaches to clinical practice.

In the 1990s, laparoscopic surgery just "happened." Courses in specialized centers where minimally invasive techniques were perfected mushroomed and surgeons flocked to learn the new approaches. At that time, hospitals required no specific training experience for these new procedures, no proficiency assessment prior to their clinical use, and no minimal practice volume to justify their adoption. There was also no discussion of performing these operations under an Institutional Review Board or to subject the surgeons to focused performance practice evaluation. Today, these issues variably persist with no clear practice guidelines. The panel agreed that innovations should be carefully tested prior to dissemination and that should be accompanied by training requirements geared to achieve proficiency and by methods to evaluate their

safe adoption in clinical practice. Nevertheless, some progress has made in the past years, compared to the 1990s. In fact, while the Joint Commission in 2008 clearly mandated a detailed evaluation of professional performance as part of an "ongoing" or "periodic" process of granting and maintaining practice privileges in all medical centers, who and how should specifically regulate the safe introduction of innovation in clinical gastrointestinal surgery is still unclear.

Laparoscopy has been a revolution in surgery because it has allowed performing the same operation done open with minimal incisions, whereas the newer techniques allow performing the same operation done "laparoscopically" with just fewer/smaller incisions, in the abdomen or in hollow viscera. It follows that the clinical outcomes of newer techniques are in a few best hands nonsuperior to the standard of care to date. Consequently, reasonableness would dictate a careful consideration for further adoption by the average gastrointestinal surgeon. The consequence of this logic is proved by the rapid disappearance of TG and TV approaches from clinical practice, at least in the USA. On the other hand, when confronted about embracing and disseminating innovative techniques as POEM, which might really have the best potential application in clinical practice, physicians—potential adopters—and the public—potential subjects—remain protected by the rigorous techniques of the scientific method, which is used universally to validate new knowledge objectively and which should be used to validate these newer techniques. An example of this reasoning is given by the vast knowledge gained in the treatment of achalasia that has been derived from randomized trials and studies with appropriately long follow-up published in recent years. The result is that the surgical treatment of achalasia today is codified and backed up by strong evidence.

To sum up, without question, innovation should be always pursued, although with reasonableness, and within the constraints of the scientific method.

References

1. Pellegrini C, Wetter LA, Patti M, et al. Thoracoscopic esophagomyotomy. Initial experience with a new approach for the treatment of achalasia. Ann Surg 1992;Sept:216(3):291-6.
2. Patti MG, Pellegrini CA, Horgan S, et al. Minimally invasive surgery for achalasia: An 8-year experience with 168 patients. Ann Surg 1999;230:587-94
3. Oelschlager BK, Chang L, Pellegrini CA. Improved outcome after extended gastric myotomy for achalasia. Arch Surg 2003;138:494-7
4. Richards WO, Torquati A, Holzman MD, et al. Heller myotomy versus Heller myotomy with Dor fundoplication for achalasia. A prospective randomized double-blind clinical trial. Ann Surg 2004;240:405-15
5. Rawlings A, Soper NJ, Oelschlager B, et al. Laparoscopic Dor versus Toupet fundoplication following Heller myotomy for achalasia: results of a multicenter, prospective, randomized-controlled trial. Surg Endosc 2012;26:18-26
6. Rebecchi F, Giaccone C, Farinella E, et al. Randomized controlled trial of laparoscopic Heller myotomy plus Dor fundoplication versus Nissen fundoplication for achalasia. Ann Surg 2008;248:1023-30
7. Patti MG, Herbella FA. Fundoplication after laparoscopic Heller myotomy for esophageal achalasia: What type? J Gastrointest Surg 2010;14:1453-8
8. Zaninotto G, Costantini M, Rizzetto C, et al. Four hundred laparoscopic myotomies for esophageal achalasia. A single center experience. Ann Surg 2008;248:986-93
9. Cowgill SM, Villadolid D, Boyle R, et al. Laparoscopic Heller myotomy for achalasia: results after 10 years. Surg Endosc 2009;23:2644-9
10. Inoue H, Minami H, Kobayashi Y, et al. Peroral endoscopic myotomy (POEM) for esophageal achalasia. Endoscopy 2010;42:265-71
11. Swanstrom LL, Kurian A, Dunst CM, et al. Long-term outcomes of an endoscopic myotomy for achalasia. The POEM procedure. Ann Surg 2012;256:659-67
12. Von Renteln D, Fuchs KH, Fockens P, et al. Peroral endoscopic myotomy for the treatment of achalasia: An international prospective multicenter study. Gastroenterology 2013;145:309-11
13. Hungness ES, Teitelbaum EN, Santos BF, et al. Comparison of perioperative outcomes between peroral esophageal myotomy (POEM) and laparoscopic Heller myotomy. J Gastrointest Surg 2013;17:228-35
14. Bhayani NJ, Kurian AA, Dunst CM, et al. A comparative study on comprehensive, objective outcomes of laparoscopic Heller myotomy with per-oral endoscopic myotomy (POEM) for achalasia. Ann Surg 2014;259:1098-103
15. Eckardt VF, Gockel I, Bernhard G. Pneumatic dilation for achalasia: late results of a prospective follow up investigation. Gut 2004;53:629-33
16. Pasricha PJ, Hawari R, Ahmed I, et al. Submucosal endoscopic esophageal myotomy: a novel experimental approach for the treatment of achalasia. Endoscopy 2007;39:761-4
17. Inoue H, Ikeda H, Hosoya T, et al. Submucosal endoscopic tumor resection for subepithelial tumors in the esophagus and cardia. Endoscopy 2012;44:225-30
18. Shiwaku H, Inoue H, Beppu R, et al. Successful treatment of diffuse esophageal spasm by peroral endoscopic myotomy. Gastrointest Endosc. 2013;77:149-50
19. Khashab MA, Stein E, Clarke JO, et al. Gastric peroral endoscopic myotomy for refractory gastroparesis: first human endoscopic pyloromyotomy (with video). Gastrointest Endosc. 2013;78:764-8
20. Kurian AA, Dunst CM, Sharata A, et al. Peroral endoscopic esophageal myotomy: defining the learning curve. Gastrointest Endosc. 2013;77:719-25
21. Teitelbaum EN, Soper NJ, Arafat FO, et al. Analysis of a learning curve and predictors of intraoperative difficulty for peroral esophageal myotomy. J Gastrointest Surg 2014;18:92-8
22. Rattner D and Kalloo A, ASGE/SAGES working group. ASGE/SAGES working group on natural orifice translumenal endoscopic surgery. Surg Endosc 2006;20:329-33
23. Auyang ED, Santos BF, Enter D, et al. Natural Orifice Translumenal Endoscopic Surgery (NOTES™): A Technical Review. Surg Endosc. 2011;25:10:3135-48
24. Arezzo A, Zornig C, Mofid H, et al. The EURO-NOTES clinical registry for natural orifice transluminal endoscopic surgery: a 2-year activity report. Surg Endosc 2013;27:3073-84

25. Lehmann KS, Zornig C, Artl G, et al. Natural orifice transluminal endoscopic surgery in Germany: Data from the German NOTES registry. Chirurg in press 2014.
26. Memark VC, Anderson JB, Nau PN, et al. Transgastric endoscopic peritoneoscopy does not lead to increased risk of infectious complications. Surg Endosc 2011;25:2186-91
27. Kaehler G, Schoenberg MB, Kienle P, et al. Transgastric appendectomy. Br J Surg. 2013;100(7):911-5
28. Auyang ED, Hungness ES, Vaziri K, et al. Human Notes Cholecystectomy: Transgastric Hybrid Technique. J Gastrointest Surg, 2009;13(6):1149-50
29. Von Ott D. Die Beleuchtung der Bauchhohle (Ventroskopie) als Methodebei Vaginaler Coeliotomie. Abl Gynakol 1902;231:817-23
30. Paldi E, Timor-Tritsch I, Abramovici H, Peretz BA. Operative culdoscopy. Br J Obstet Gynaecol 1975;82:318-320
31. Decker A, Cherry TH. Culdoscopy—A new method in the diagnosis of pelvic disease—preliminary report. Am J Surg 1944; 64:40-44
32. Zornig C, Emmermann A, von Waldenfels HA, Felixmuller C. [Colpotomy for specimen removal in laparoscopic surgery]. Chirurg 1994;65:883-5
33. Zorron R, Palanivelu C, GalvaoNeto MP, et al. International Multicenter Trial on clinical natural orifice surgery—NOTES IMTN study: preliminary results of 362 patients. Surg Innov 2010;17:142-58
34. Gordts S, Watrelot A, Campo R, Brosens I. Risk and outcome of bowel injury during transvaginal pelvic endoscopy. Fertil Steril 2001;76:1238-41
35. Brummer TH, Jalkanen J, Fraser J, et al. FINHYST, a prospective study of 5279 hysterectomies: complications and their risk factors. Hum Reprod 2011;26:1741-51
36. Palanivelu C, Rajan PS, Rangarajan M, et al. NOTES: Transvaginal endoscopic cholecystectomy in humans-preliminary report of a case series. Am J Gastro 2009;104:843-7
37. Wood SG, Solomon D, Panait L, Bell RL, et al. Transvaginal Cholecystectomy: Effect on Quality of Life and Female Sexual Function. JAMA Surg. 2013;148(5):435-8
38. El-Toukhy TA, Hefni M, Davies A, Mahadevan S. The effect of different types of hysterectomy on urinary and sexual functions: a prospective study. J Obstet Gynaecol 2004;24:420-5
39. Roussis NP, Waltrous L, Kerr A, et al. Sexual response in the patient after hysterectomy: total abdominal versus supracervical versus vaginal procedure. Am J ObstetGynaecol 2004;190:1427-28
40. Soper NJ, Stockman PT, Dunnegan DL, et al. Laparoscopic cholecystectomy: the new "gold standard"? Arch Surg 1992;127:917-21
41. Anonymous. Prospective analysis of 1,518 laparoscopic cholecystectomies: The Southern Surgeons Club. NEJM 1991;324:1073-8
42. Anonymous. NIH Consensus Development Panel on Gallstones and Laparoscopic Cholecystectomy. JAMA 1993;269:1018-9
43. Barkun JS, Barkun AN, Sanpalis JS, et al. Randomized control trial of laparoscopic vs. mini cholecystectomy: the McGill gallstone treatment group. Lancet 1992;340:1116-9
44. The Clinical Outcomes of Surgical Therapy Study Group. A comparison of laparoscopically assisted and open colectomy for colon cancer. NEJM 2004;350:2050-9
45. Vinuela EF, Gonen M, Brennan MF, Strong VE. Laparoscopic vs. open distal gastrectomy for gastric cancer: a meta-analysis of randomized trials and high-quality nonrandomized studies. Ann Surg 2012;255:446-56
46. Cheah WK, Lenzi JE, So JBY, et al. Randomized trial of needlescopic vs. laparoscopic cholecystectomy. Br J Surg 2001;88:45-7
47. Chen WTL, Chang SC, Chiang HC, et al. Single-incision laparoscopic vs. conventional laparoscopic right hemicolectomy: a comparison of short-term surgical results. Surg Endosc 2011;25:1887-92
48. Trastulli S, Cirocchi R, Desiderio J, et al. Systematic review and meta-analysis of randomized clinical trials comparing single-incision vs. conventional laparoscopic cholecystectomy. Br J Surg 2013;100:191-208
49. St Peter J, Adibe OO, Juang D, et al. Single incision vs. standard three port laparoscopic appendectomy: a prospective randomized trial. Ann Surg 2011;254:586-90
50. Marks JM, Phillips MS, Tacchino R, et al. Single incision laparoscopic cholecystectomy is associated with improved cosmesis scoring at the cost of significantly higher hernia rates: one year results of a prospective randomized multi-center single blinded trial of traditional multi-port laparoscopic cholecystectomy vs. single incision laparoscopic cholecystectomy. J Am Coll Surg 2013; 216:1037-47
51. Gill I, Advincula A, Aron M, et al. Consensus statement of the consortium for laparoendoscopic single site surgery. Surg Endosc. 2010;24:762-8
52. Hernandez J, Ross S, Morton C, et al. The learning curve of laparoendoscopic single site (LESS) cholecystectomy: definable, short, safe. J Am Coll of Surg. 2010;211:652-7
53. Ross S, Rosemurgy A, Albrink M, et al. Consensus statement of the consortium for LESS cholecystectomy. Surg Endosc. 2012;26:2711-6
54. Hernandez JM, Morton CA, Ross SB, et al. Laparoendoscopic single site cholecystectomy: the first 100 patients. Am Surg. 2009; 5:681-85
55. Ross SB, Managar D, Karlnoski R, et al. Laparo-endoscopic single site (LESS) cholecystectomy with epidural vs. general anesthesia. Surg Endosc. 2013; 27:1810-9
56. Ross SB, Choung E, Teta AF, et al. The learning curve of laparoendoscopic single-Site (LESS) fundoplication: definable, short, and safe. JSLS 2013;17:376-84
57. Ross S, Roddenbery A, Luberice K, et al. Laparoendoscopic single site (LESS) conventional laparoscopic fundoplication for GERD: is there a difference? Surg Endosc. 2013;27:538-47
58. Barry L, Ross S, Dahal S, et al. Laparoendoscopic single-site Heller myotomy with anterior fundoplication for achalasia. Surg Endosc. 2011;25:1766-74
59. Ross SB, Luberice K, Kurian TJ, et al. Defining the learning curve of laparoendoscopic single-site Heller myotomy. Am Surg. 2013;79: 837-44
60. Boni L, Dionigi G, Cassinotti E, et al. Single incision laparoscopic right colectomy. Surg Endosc. 2010; 24:3233-6.
61. Poon JT, Cheung CW, Fan JK, et al. Single-incision versus conventional laparoscopic colectomy for colonic neoplasm: randomized controlled trial. Surg Endosc. 2012;26:2729-34