Current Evidence in Gastrointestinal Surgery: Natural Orifice Translumenal Endoscopic Surgery (NOTES)

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Abstract

Background Natural orifice translumenal endoscopic surgery (NOTES) is a technique that uses transvisceral access to perform surgical procedures entirely through a natural orifice. Despite the increasing awareness of NOTES, there remain obstacles to its technical feasibility and widespread acceptance. Furthermore, with the paucity of high-level supporting evidence, NOTES currently remains an experimental technique.

Objective This article reviews the goals, applications, technical and practical challenges, and future direction of NOTES in gastrointestinal surgery.

Keywords Natural orifice translumenal endoscopic surgery (NOTES) · Minimally invasive surgery

Abbreviations

ASGE	American Society for Gastrointestinal Endoscopy
MA-NOS	Minilaparoscopic-assisted natural orifice surgery
NOTES	Natural orifice translumenal endoscopic surgery
NOSE	Natural Orifice Specimen Extraction
NOSCAR	Natural Orifice Surgery Consortium For Assessment And Research
PROGRESSS	Perirectal oncologic gateway for retroperitoneal endoscopic single-site surgery
SAGES	Society of American Gastrointestinal and Endoscopic Surgeons
TAMIS	Transanal minimally invasive surgery
TEM	Transanal endoscopic microsurgery

Background

Natural orifice translumenal endoscopic surgery (NOTES) was heralded as a paradigm shift in minimally invasive surgery. In

NOTES, procedures may be performed through transvaginal, transgastric, transrectal, or transesophageal approaches. NOTES was originally described by Kalloo et al. in 2004 as a peroral transgastric approach to access the peritoneal cavity for a liver biopsy in a porcine model.¹ The initial report attracted widespread interest from both surgeons and gastroenterologist worldwide. Within a year, Reddy and Rao reported the first human transgastric appendectomy at the Annual Conference of the Society of Gastrointestinal Endoscopy of India.² Numerous investigators followed suit, using NOTES in animal models to perform a variety of intraperitoneal procedures, including cholecystectomy, colectomy, and distal pancreatectomy.^{3–7} By 2007, Swanstrom et al. reported the first successful human NOTES procedure— a transgastric cholecystectomy.⁸

Goals

The goal of NOTES was to provide a technology for potentially scar-free surgery and abolishment of incision-related complications, such as wound infections, incisional hernias, postoperative pain, and adhesions.⁹ Patient and surgeon desire for a surgical technique that provided reduced recovery time, physical pain, and scarring over available minimally invasive approaches provided momentum for NOTES research and expansion.¹⁰ Wound infections are reported to occur in 2–25 % of surgical procedure and have a significant impact on patient outcomes and health-care expenditures.^{11–13} While minimally invasive surgery decreased the incisional

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hernia rate dramatically, NOTES introduced the ability to eliminate all incisions and subsequent incisional hernias (Fig. 1).¹⁴

Application of NOTES

NOTES has been extensively applied and tested in animal and cadaver models. Since the first description, more than 2,000 reports of NOTES across all surgical specialties have been described. A PubMed© search of NOTES from 2004 to the present yielded over 600 publications, with more than half published in general surgery journals (50.9 %).¹⁵ The transgastric, transrectal, transcolonic, transanal, transvesical, and transesophageal approaches have been feasible for a variety of procedures, including cholecystectomy, hepatectomy, splenectomy, nephrectomy, gastrojejunostomy, gastric sleeve resection, tubal ligation, distal pancreatectomy, and colectomy. However, most published studies remain clinical series (43.9 %) and experimental animal reports (48 %), with the articles focusing primarily on cholecystectomy, access creation/closure, and peritoneoscopy.¹⁵

With the abundance of safety and feasibility studies, the question remains why NOTES has not progressed further into clinical practice. In humans, only about 43 reports covering 432 NOTES cases have been reported.¹⁶ Cholecystectomy (84 %) and appendectomy (7 %) were the most popular procedures reported. Meta-analysis and single-center studies of NOTES procedures in human patients found that cholecystectomy, intestinal cancers, renal cancers, appendectomy, mediastinoscopy, and peritoneoscopy were all feasible with NOTES with low postoperative complication rates, no visible scars, and lower analgesia requirements.^{16–20} However, the technical complications encountered demonstrated the need of developing endoscopic instruments to safely facilitate each approach.¹⁷

To encourage NOTES research and outline areas to further the human application of NOTES, the collaborative

Natural Orifice Surgery Consortium For Assessment And Research (NOSCAR) working group was formed from the SAGES and the ASGE.¹⁰

Technical Challenges

NOSCAR identified unresolved technical issues in NOTES, including how to access the peritoneal cavity, viscerotomy closure, suturing/anastomotic devices, spatial orientation, developing a multitasking operating platform, managing complications, and effective training.¹⁰ There is no “best practice” to access the peritoneal cavity. Current major routes described in all reports include transgastric (52.5 %), transcolonic (12.3 %), transvesical (12.5 %), transvaginal (10.5 %), and combined (12.3 %).¹⁵ In human subjects, the main access routes were transvaginal (84 %), transgastric (13 %), transesophageal (4 %), and transrectal (<1 %).¹⁶ The transgastric approach uses endoscopic balloon dilatation, sphincterotome, or needle knife cautery to create and dilate a hole on the anterior stomach wall for introduction of the operating platform. However, there is a risk of injuring surrounding organs blood vessels during the blind puncture, as well as devastating consequences from a leak. There have been entry assists described in animal models, including endoscopic ultrasound or invaginating the gastric wall to distract from surrounding organs, but the efficacy in human subjects is not described.^{21–23}

The transvaginal approach has been successfully used in the diagnosis of endometriosis, adhesions, and ectopic pregnancy. It has the advantage over other access methods that the incision can be achieved under direct visualization without an intra-abdominal scope.¹⁶ However, this approach requires working deep in the pelvis and is only applicable in 50 % of the population. Further, there is the risk of injuries to the rectum, ureters, bladder, and colon while obtaining access or closing the posterior vaginal wall given its proximity to these structures.¹⁶ With the transvesical approach, the major limitation is working against the long male urethra. Both the transvaginal and transvesical approaches have a potential reduction in morbidity compared to transgastric access. The transrectal approach, facilitated with a stable transanal endoscopic microsurgery (TEM) platform or performed through direct transrectal trocar insertion, allows direct access to upper quadrants without retroflexion and permits removal of large specimens and the use of operating anosopes for secure closure.^{24–26} However, there is a risk of closure leak and need for better NOTES instrumentation before widespread clinical application. Further research is underway with the PROGRESSS study.²⁷ Each approach has its pros and cons, and all require development of best practices and improved instrumentation.

Studies on safer alternatives for access are underway. Elmunzer et al. evaluated the utility of sonographic guidance

Fig. 1 Minimally invasive scale of surgical procedures

for safe intraperitoneal access during the initial NOTES puncture.²⁸ In a porcine feasibility study, 32 sonographic-guided access procedures were performed through the antrum, posterior stomach wall, or rectum, of which 16 used sonographic guidance for safe intraperitoneal access by avoiding extraluminal organs and vessels during the initial puncture and 16 using standard NOTES blind puncture to evaluate potential complications. All 16 blind NOTES access procedures had clinically catastrophic complications, while only three sonographic-guided procedures had complications. Thus, sonographic guidance significantly decreased complications during access and may be a promising addition to developing safe standards for peritoneal access.

The optimal visceral closure technique after NOTES is also under development. A closure device must create a full-thickness, tension-free closure. The ideal tool must also be easy to use, applicable to multiple organs, reproducible, reliable, and safe. Current options include clips, endoscopic tubes, T fasteners, endoscopic suturing devices, and novel closure devices, such as the Spiderman. It is necessary that the closure device provides a nearly 100 % secure closure of the enterotomy site, as a leak rate of even 1 % would be unacceptable with the low leak rates of laparoscopy.²⁹ To date, viscerotomy closure has not been achieved reliably in humans, and the subsequent risk of peritoneal infection remains a valid concern.³⁰

The tissue apposition system (TAS) may be a promising device for endoscopic suturing. In human subjects, TAS was feasible as an alternative to laparoscopic colectomy for endoscopically unresectable polyps. The device could be expanded to facilitate closure of larger defects from NOTES procedures.³¹

The current NOTES instruments and endoscopes are another technical limitation. A variety of laparoscopic instruments exist for hybrid NOTES with a transabdominal port, but flexible endoscopic instrumentation is much more limited. The available tools limit visualization, successful completion of the procedure compared to laparoscopy, and evolution of NOTES.³² There is also no standardization of the available endoscopes or instruments. The choice of endoscope and dissection tools utilized differs greatly between pure NOTES, hybrid procedures, and access routes, with wide variation even within the same procedure and access method.^{16,33} Current research on developing instruments to aid performing pure NOTES is underway.^{34,35} For further incorporation into humans, fundamental steps and elements present in all procedures, as well as practical and technical challenges, will need to be resolved.

NOTES also introduces ergonomic challenges to surgeons. With no standardization in technique, ergonomic studies of NOTES cholecystectomy have shown that surgeons were uniquely limited in visualization, tissue manipulation, and in the ability to independently perform tasks, requiring collaboration to safely complete NOTES procedures.³⁶

The small number of procedures precludes an accurate estimate of the actual complication rates or analysis of

contributing factors. Thus, it remains to be determined whether complications associated with NOTES are a result of an early learning curve or inherent procedure and likely to occur at unacceptable rates even after ascension up the learning curve.¹⁶ Standardization in technique and reporting, as well as large-scale prospective trials, is necessary for proper analysis of outcomes and complications.

Practical Challenges

Developing a training platform and training providers to teach and use NOTES is another technical hurdle. For NOTES to become a common surgical approach, multiple training platforms are needed for success. Options for success include a hands-on training experience in a simulated environment, close monitoring of surgeon performance with both thermal imaging and motion tracking to ensure proper technique and confirm procedural competence, and mentoring through their initial procedures.^{37–39} Combining advanced imaging technologies with proficiency-based virtual reality simulation is a feasible alternative to animal testing once the safety and efficacy parameters of NOTES are established.⁴⁰ In a study on training techniques with currently available instruments for transgastric procedures, technical limitations impacted learning, with problems encountered including intraesophageal friction, lack of platform stability, lack of precision in tissue retraction, and lack of independence of endoscopic vision; the technical problems were more limiting than procedural or medical knowledge.⁴¹

Steep learning curves are encountered when attempting to introduce NOTES into training programs, despite the availability of experienced NOTES investigators.⁴² While education remains in development, studies have shown that most surgeons desired training in NOTES, and almost all would perform NOTES if further research showed demonstrable benefits. Building on existing platforms may aid learning and teaching. TEM has been described as the ideal NOTES platform for endoscopic access of the peritoneal cavity through the anus.²⁵ Using the combination of established TEM and NOTES principles, colorectal resections could be performed through smaller or no abdominal incisions. Trunzo and Delaney used the combination to perform a novel proctectomy technique in a porcine model.⁴³ The circumferential rectal sleeve resection was safe and feasible using TEM with flexible endoscopic assistance. After extensive cadaver and animal lab experience, NOTES transanal endoscopic rectosigmoid resection with total mesorectal excision using the TEM platform and laparoscopic assistance was also shown to be safe and oncologically sound in a human rectal cancer patient.^{24,25} Based on these experiences, marrying techniques could further education, case complexity, and spread clinical application of NOTES.

Both surgeon and public attitude toward NOTES have influenced its adaption. While patients desire improved cosmesis and less pain, major concerns about infection, incisional hernias, dyspareunia, and postoperative sexuality and fertility, especially with the transvaginal approach, outweigh advantages of NOTES.^{44–48} Studies show that patients would consider NOTES only if there was no additional risk, pain, operative time, or cost over laparoscopy.⁴⁹ Interestingly, procedure-related risks, pain, and recovery time were more important to patients than cosmesis in the choice of approach.^{49,50} Surgeons' acceptance of NOTES, both for their patients and their own care, is still lacking. In a survey of over 350 surgeons comparing NOTES to laparoscopy for cholecystectomy, NOTES was reported as riskier and requiring greater skill. Only 24 % would undergo a NOTES cholecystectomy themselves, finding it too new and riskier than laparoscopy. As the risk of having a complication was paramount, the majority (88 %) required data showing improved outcomes over laparoscopy to adapt NOTES.⁵¹

Future Direction

Variations in NOTES have been implemented to increase use of the technique. While pure NOTES uses only an endoscope, hybrid NOTES uses both an endoscope and a laparoscope, facilitating an additional view, intraoperative traction of organs, and the familiar laparoscopic techniques, which can help the transition to NOTES.^{52,53} Minilaparoscopy-assisted natural orifice surgery (MA-NOS) uses the principles of laparoscopic surgery for transrectal colorectal resections.^{54–56} In preliminary studies, MA-NOS has been safe and feasible and may aid safe progression to pure NOTES for providers experienced in laparoscopic surgery. Natural orifice specimen extraction (NOSE) has been used for transanal and transvaginal specimen extraction during laparoscopic colorectal surgery.⁵⁷ In 179 anterior resections in rectal cancer patients, Franklin et al. found NOSE safe, feasible, and valuable in reducing incisional complication risks while maintaining proper oncologic principles.⁵⁸ Therefore, it may be a bridge towards NOTES.⁵⁹ Transanal minimally invasive surgery (TAMIS), a hybrid of TEM and single-port laparoscopy, was developed and proven as an efficacious tool for resection of malignant and benign rectal lesions.⁶⁰ Since development, the range of procedures successfully approached through a TAMIS approach have grown.^{61,62} and techniques combining endoscopic visualization with TAMIS to facilitate intraluminal articulation and visualization have been reported.⁶³ These techniques show the evolution in minimally invasive surgery.

The cost–benefit analysis of this emerging technology is also an issue that deserves consideration in the current health-care market. There are increased costs associated with the development and learning acquisition of any new technique.

Once providers are efficient in NOTES, the procedure has the potential to reduce length of stay, postoperative complications, readmissions, and their associated health-care costs.

Conclusions

The potential for NOTES technology is endless. However, with the current literature and application, no conclusions can be drawn about the overall safety, efficacy, or superiority of NOTES in surgery.¹⁵ To assure that the technology is effective and efficient, the future of NOTES requires careful laboratory investigation with subsequent IRB-approved clinical trials. Appropriate equipment development and standardized methods of visceral entry and closure would aid acceptance of NOTES. Finally, standardized training programs and short-term cost and outcome analysis would help the new technology integrate into clinical application. Current needs for success are clinical trial, cost–benefit analysis, and standardized training programs. Additional research detailing long-term outcomes, safety, feasibility, and superiority over current minimally invasive techniques in human subjects is needed to further the clinical adaption of NOTES initially set forth by the NOSCAR committee.

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2. The transvisceral access approach with the highest morbidity is:
 - a. Transvaginal
 - b. Transvesical
 - c. Transgastric**
 - d. Transanal
3. The first animal NOTES procedure described in the literature was:
 - a. Transgastric liver biopsy**
 - b. Transgastric cholecystectomy
 - c. Transvaginal appendectomy
 - d. Transvaginal colectomy
4. The first human NOTES procedure described in the literature was:
 - a. Transrectal cholecystectomy
 - b. Transgastric cholecystectomy**
 - c. Transvaginal appendectomy
 - d. Transrectal appendectomy
5. Feasibility studies of NOTES have shown all of the following except:
 - a. No visible scars
 - b. Lower analgesia requirements
 - c. Low postoperative complication rates
 - d. Appropriate endoscopic instruments are available to safely facilitate each approach**
6. The most commonly described access route for NOTES in human is:
 - a. Transvaginal**
 - b. Transvesical
 - c. Transgastric
 - d. Transanal
7. Which is true regarding technical challenges to viscerotomy closure in NOTES?
 - a. The transvaginal approach risks injury to surrounding structures when closing the posterior vaginal wall**
 - b. The transvesical approach is prohibitive in females due to their long urethra
 - c. The transrectal approach has eliminated the risk of closure leak and subsequent peritonitis.
 - d. Best practices for closure have been published by NOSCAR
8. Practical challenges to increase utilization of NOTES include:
 - a. Improving surgeon attitude
 - b. Improving public attitude
 - c. Developing a training platform to train providers to teach and use NOTES
 - d. All of the above**

CME/MOC Questions – 8 multiple choice (A-D)

1. All of the following are validated options for transgastric peritoneal entry in human patients except:
 - a. Endoscopic balloon dilatation
 - b. Sphincterotome
 - c. Needle knife cautery
 - d. EMR-cap myotomy**