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Natural Orifice Translumenal Endoscopic Surgery (NOTES): Emerging Trends and Specifications for a Virtual Simulator

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Abstract

Introduction and study aim—A virtual translumenal endoscopic surgical trainer (VTEST™) is being developed to accelerate the development of Natural Orifice Translumenal Endoscopic Surgery (NOTES) procedures and devices in a safe and risk-free environment. For a rapidly developing field such as NOTES, a needs analysis must be conducted regularly to discover emerging research trends and areas of potential high impact for a virtual simulator. This paper presents a survey-based study which follows a similar study conducted by this group in 2011 [1].

Methods—A 32-point questionnaire was distributed at the 2012 National Orifice Surgery Consortium for Assessment and Research (NOSCAR) annual meeting. This data was subsequently augmented by an identical online survey, targeted at the members of the American Society for Gastrointestinal Endoscopy (ASGE) and the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES), and analyzed.

Results—28 NOTES experts participated in the 2012 study. Cholecystectomy (CE) procedure remained the most commonly performed NOTES technique, with 18 positive responses (64%). In contrast to 2011, the popularity of the NOTES appendectomy (AE) was significantly lower, with only 2 (7%) instances (CE vs AE, $p < 0.001$), while the number of POEM (Peroral Endoscopic Myotomy, PE) cases had increased significantly, with 11 (39%) positive responses respectively (PE vs AE, $p=0.013$). Strong preference towards hybrid rather than pure NOTES techniques (82% vs 11%, $p<0.001$) was also expressed. Other responses were similar to those in the 2011 study,

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with the VTEST™ utility in developing and testing new techniques and instruments ranked particularly high.

Conclusion—Based on the results of this study, a decision was made to focus exclusively on the transvaginal hybrid NOTES cholecystectomy procedure, including both rigid and flexible scope techniques. The importance of developing a virtual NOTES simulator was reaffirmed, with POEM identified as a promising candidate for future simulator development.

Keywords

NOTES; POEM; Natural orifice surgery; Transvaginal; Virtual reality; Simulator

Introduction

NOTES is an emerging surgical paradigm, being viewed as a potential alternative to laparoscopic surgery, where internal organs are accessed by perforating the viscera (stomach, colon or vagina) using a flexible endoscope inserted through natural orifices such as the mouth, anus or vagina, without making any incisions on the surface of the body [2]. The feasibility and safety of a per-oral transgastric endoscopic approach to the peritoneal cavity was demonstrated in 2004 [3]. Such “scarless” procedures not only lead to better cosmetic results but also enhance the prospects of decreased wound infections and incisional hernia, as well as operative stress, postoperative immobility, and pain [4]. To realize the full potential of NOTES a working group called the Natural Orifice Surgery Consortium for Assessment and Research (NOSCAR) was formed in 2005. In a corresponding white paper, members from the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) and the American Society for Gastrointestinal Endoscopy (ASGE), have identified eight fundamental problems that had to be resolved in order to make NOTES a commonly accepted and a widely utilized procedure [5]. One of these problems was the urgent need for effective training platforms that are able to reduce poor outcomes of the early NOTES procedures, which, in turn, could lead to premature regulatory restrictions.

Effective NOTES training is complicated by the fact that a multidisciplinary team is often needed in order to perform the procedure [6]. While pure NOTES procedures utilize flexible scopes exclusively and with no assistance via traditional laparoscopic intervention, the hybrid NOTES approach does indeed rely on laparoscopic assistance and can utilize either flexible and/or rigid scopes. Therefore, expertise in both the traditional laparoscopic techniques and interventional gastroenterology needs to be honed during NOTES training. All of the commonly available NOTES training methods rely on trainers that require constant replenishment of the materials, and/or have complex institutional approval procedures (porcine models, cadavers, ex-vivo model-based simulators) [7, 8]. Furthermore, the trainees’ performance evaluation is often subjective and is primarily based on his or her perceived ‘mastery’, as observed by the participating test experts. Commercial virtual reality (VR) – based simulators remedy these problems, as they do not rely on disposable test materials that require replenishment. Moreover, the simulators themselves often have built-in automatic performance measurement metrics. They are, therefore, frequently encountered in the training labs specializing in traditional laparoscopic and endoscopic procedures [9–11].

Despite the well-established success of using VR-based simulators for both laparoscopic surgery and gastrointestinal endoscopy training, no VR simulators existed for NOTES training until very recently. Recognizing the potential of such a simulator, the National Institutes of Health (NIH) have funded a multi-year research project, led by researchers from the Rensselaer Polytechnic Institute (RPI) closely working with the medical experts at Beth Israel Deaconess Medical Center, and Cambridge Health Alliance. The focus of the project is to develop a high-fidelity VR-based NOTES simulator [1].

The bulk of the critical design parameters of the simulator were established via a structured needs analysis study, undertaken at the 2011 NOSCAR meeting, where a 30-point questionnaire was distributed among the attending NOTES experts. The questionnaire was focused on the specific NOTES procedures that were prevalent within the NOTES community at the time, as well as the specific details of such procedures, including the tools utilized, access and closure methods, etc. [1]. As a result, 22 responses were received and analyzed. Initially, the VR-NOTES simulator was targeted at the appendectomy procedure exclusively, utilizing either the transgastric or the transvaginal approach. However, cholecystectomy was selected as the most widely performed procedure according to the survey results. Upon a follow-up investigation it was judged that human and animal trials also supported this conclusion [12–14]. Furthermore, transvaginal access was preferred over the transgastric and the transrectal routes, most likely due to the risk of intestinal contents leakage with the former [15], and susceptibility of the latter to contamination from fecal bacteria [16]. Therefore, despite the initial intent of the project to focus solely on appendectomy-specific models and training methods, the project's scope was expanded to also include the NOTES cholecystectomy procedure, with both the transgastric and the transvaginal approaches.

A thorough task analysis was undertaken prior to the development of a simulator in order to determine the key tasks of the NOTES procedures to be modeled within the VR-NOTES simulator. A hierarchical task analysis (HTA) model was developed as a result [17]. This model was then utilized as the basis for creation of the Virtual Translumenal Endoscopic Surgery Trainer (VTEST™) - the first virtual reality simulator for the NOTES cholecystectomy procedure performed using a hybrid procedure using a rigid endoscope [18]. However, for a rapidly changing field such as NOTES, a needs analysis must be performed at regular intervals of time to ensure continued clinical relevance of the simulator and discover emerging trends in NOTES research. We therefore performed a follow-up survey-based study at the 2012 NOSCAR meeting, the results of which are presented here.

Materials and methods

This protocol qualified for an exemption when reviewed by the Rensselaer Polytechnic Institute (RPI) institutional review board. A 32-point questionnaire was distributed at the 2012 annual Natural Orifice Surgery Consortium for Assessment and Research (NOSCAR) meeting held in Chicago, IL. The questionnaire covered a variety of topics, including background and experience of the participants (Table 1); procedure, approach, and preferences (Table 2); instruments and tool preferences (Table 3); and preferences on the VR-NOTES simulator (Table 4). The VR-NOTES simulator was being specifically targeted

at the transvaginal hybrid NOTES cholecystectomy; however, additional questions specifically focusing on the current trends in the NOTES community were included. The questionnaires were collected for analysis at the end of the 2012 NOSCART meeting (12 responses). In order to reach a wider audience, the paper questionnaire was subsequently augmented with an identical online survey, targeted at the members of the ASGE and SAGES (18 responses). The SPSS 18.0 statistical software package (IBM Inc.) and Wilcoxon ranked-sum test were used in the analysis.

Results

The expert group was composed of the NOSCART participants, as well as the individuals who had completed the online survey (2 online participants representing industry were excluded from the expert group). Of the 28 NOTES experts who had completed the questionnaire, 19 (68 %) were general surgeons, 7 (25 %) were gastroenterologists, and 2 (7 %) were gynecologists. The clinical experience of the participants ranged from less than 5 years to more than 25 years (Fig. 1).

The most popular subjects for hybrid NOTES procedures performed by the participants were on pigs (23 responses, 82%), followed by humans (19, 68 %), cadavers (11, 39 %), dogs (3, 11 %), and ex-vivo simulators (2, 7 %) (Fig. 2). For the pure (non-hybrid) procedures, the majority were performed on pigs (19 responses, 68 %), followed by humans (17, 61 %), cadavers (7, 25 %), a dog (1, 4 %), and an ex-vivo simulator (1, 4 %) (Fig. 3).

The cumulative NOTES experience of the participating experts is presented in Figure 4 (some of the experts had only pure NOTES or only hybrid NOTES experience).

Cholecystectomy was the most common procedure performed on live human patients, with 18 surveyed individuals reporting this experience (64 %), followed by peroral endoscopic myotomy (POEM) (11 individuals, 39 %), transgastric peritoneoscopy (7 individuals, 25 %), appendectomy (2 individuals, 7 %), and one instance each of nephrectomy and tubal ligation (Fig. 5).

For NOTES cholecystectomy, the most preferred method of performing the surgery was via a hybrid procedure with rigid tools (46 %), followed by a hybrid procedure using flexible tools (36 %). Pure NOTES procedure with either flexible or rigid tools was given preference only in 11 % of the responses (Fig. 6).

The preferred gallbladder retraction method for NOTES cholecystectomy using either flexible or rigid tools was with the aid of 2–3mm instruments (14 responses, 50 %), followed by transabdominal sutures (6 responses, 21%), with the rest of the surveyed individuals indicating no preference. For training in NOTES cholecystectomy, the majority of the participants have selected live animal as the preferred method (21 responses, 75 %); observation of a live case as the second most popular option (16 responses, 57 %); VR simulator with realistic interface and force feedback (12 responses, 43%); cadaver and proctor (11 responses, 39 %); the least popular option was the ex-vivo box trainer (6 responses, 21 %) (Fig. 7).

The majority of the surveyed individuals had no preference regarding the brand of endoscope for the VR-NOTES simulator (82 %), as long as it provided two channels (57 %), as opposed to three (32 %) or some other number of channels (11 %). The ability of the VR-NOTES simulator to work with prototype devices was universally deemed useful (96 %). Most of the participants chose the needle knife as the preferred transluminal access method (86 %), followed by access/closure device (82 %), tunnel/submucosal flap technique (79 %), guide wire (68 %), balloon (64 %), hydrodissection (50 %), manual incision (32 %), and trocar insertion (29 %). When presented with the choice of achieving hemostasis, most of the participants chose endoclips (79 %), followed by bipolar cautery and suturing device (both 71 %), coagrasper (50 %), monopolar cautery (46%), ultrasonic energy and argon plasma coagulation (both 29 %), multipolar coagulation probe (21 %), and radiofrequency (11 %). With regards to the methods of specimen retrieval in the VR-NOTES simulator, the presented choices of retrieval net and rat-tooth/alligator forceps had approximately the same preference levels (61% and 57%, respectively), followed closely by basket and snare (50% and 46%, respectively), while the endocatch bag (7 %) and laparoscopic specimen retrieval bag (4 %) options were deemed much less popular. Most of the participants chose the suturing device as the preferred method of transluminal closure in the VR-NOTES simulator (82 %), followed by endoclips (71 %), over-the-scope clip (61 %), stapling device (54%), access/closure device (43 %), T-tags (36 %), and manual closure (14 %). In order to verify the integrity of closure of the gastrotomy, air leak test was the most popular choice (68 %), followed by visual inspection (46 %), and fluid leak test (32 %).

Table 5 depicts the mean and standard deviations from the responses for the five-point Likert scale questions. All of the questions were scored highly, with an averages score of 3.88. Some of the highest scores were associated with importance of the proposed capabilities of a virtual NOTES trainer in developing and testing new techniques and instruments. The haptic (force feedback) features of the simulator were also deemed important. The procedure-specific capabilities of the simulator (vaginal wall closure, placement of the specimen in a bag), on the other hand, were ranked quite low.

Discussion

According to the results of the 2012 NOSCAR Summit questionnaire, cholecystectomy (CE) remained the most popular NOTES technique, with 64% of the participants having performed the procedure in their lifetime. However, the popularity of the NOTES appendectomy (AE) was surprisingly low, with only 7% (2 participants) listing the experience (CE vs AE, $p < 0.001$). Furthermore, there was a significant surge in the number of POEM (Per Oral Endoscopic Myotomy, PE) and transgastric peritoneoscopy (TP) cases performed by the NOTES experts, with 11 (39 %) and 7 (25 %) positive responses respectively, as depicted in Figure 8 (PE vs AE, $p = 0.013$; TP vs AE, $p = 0.096$).

Furthermore, according to the 2012 questionnaire, POEM (PE) could eventually become a mainstream clinical procedure, as it was selected as the best indicator for NOTES to eventually become the standard of care versus the cholecystectomy (CE) (CE vs PE, $p = 0.225$). Interestingly, the 2011 survey results indicated the cholecystectomy and the

appendectomy procedures to have approximately the same level of importance with regards to the standard of care indicator, with no such indication for POEM (Fig. 9).

The sharp increase in the interest in POEM can be attributed to some unique characteristics of this procedure. It is a less invasive endoscopic treatment for symptomatic esophageal achalasia - a chronic progressive benign disease with severe morbidity and difficult management [19]. International experience of POEM is also rapidly growing, with a recent study detailing a POEM treatment trial in Europe, where 22 patients were treated with greater than 90% of the cases resulting in short-term relief [20]. In another study, 28 cases of POEM-based achalasia treatment were investigated, where esophagogram and manometry studies were done before and after the procedure, and subjective symptom score and Eckardt score were assessed before and 3 months after POEM [21]. POEM was successfully done in all of these cases, with no incidences of any severe complications such as perforation and mediastinitis. According to these results, POEM could be a curative standard treatment of choice for esophageal achalasia.

However, the low incidence of achalasia (0.3%–1% per 100,000 population) is often quoted. With potential for serious complications related to the technically demanding POEM procedure, training in this procedure is challenging. Furthermore, there are other ethical and training issues associated with human trials to be addressed. Therefore, there is a growing urgency in the need for novel POEM training approaches, required to decrease the learning curve. The porcine model is often quoted as the most appropriate animal model for training in POEM due to its anatomy being similar to that of humans [22]. However, this training approach retains the usual drawbacks of the other physical NOTES trainers, including the need for constant replenishment of the training materials, onerous IACUC approval process and lack of objective assessment. An alternative to live animal models are ex-vivo simulation models. Porcine ex-vivo specimens allow the performance of POEM in a tissue model without the ethical concerns of live animals, although the training materials still need to be replenished. The group of Matthes et al recently completed an ex-vivo study assessing the learning curve of POEM novices in an ex-vivo porcine box trainer (unpublished data).

The superior potential of a VR-based POEM simulator can be fully realized in this case. Any future works on a virtual POEM trainer, would have to proceed at a brisk pace, given the rapid increase in the adoption of this technique evidenced in this study. To verify this claim, a quick search on the National Center for Biotechnology Information (NCBI) PubMed website for the number of NOTES and POEM publications over the past nine years was conducted. It was found that the number of POEM-specific publications has been rising exponentially, particularly after 2011 (Fig. 10). What is also interesting to note is the number of publications in the area of NOTES peaked in 2010 and is currently on the decline. This could be due to multiple causes, including frustration with existing tools, need for dexterous robotic NOTES platforms, regulatory hurdles, lack of patient interest and the need for standardized procedures and training, some of which are summarized in the second NOSCAR whitepaper [6].

With regards to the rest of the 2012 NOSCAR summit questionnaire - most of the other responses have remained at the levels similar to those in the initial 2011 study, with some of

the highest scores still being associated with the importance of the proposed capabilities of a virtual NOTES trainer in developing and testing new techniques and instruments. There was, however, a very strong tendency among the surveyed individuals to gravitate towards the hybrid NOTES methods, using either flexible or rigid instruments, rather than pure NOTES techniques (82% vs 11%, $p < 0.001$). This is in sharp contrast to the 2011 survey results, as indicated in Figure 11.

Therefore, a decision was made to focus the VTEST™ development exclusively on the hybrid version of the transvaginal NOTES cholecystectomy procedure, utilizing rigid and flexible scopes. Overall, however, the general consensus that the VR-based NOTES simulator/trainer with a highly realistic interface and a haptic (force feedback) capability would be a valuable tool in the emerging field of NOTES remains valid. The comments and suggestions brought up in the 2012 questionnaire will be used to guide its further development.

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Figure 1.
Number of years of clinical practice of the participants

Figure 2.
Number of hybrid NOTES procedures

Figure 3.
Number of pure NOTES procedures

Figure 4.
Cumulative NOTES experience

Figure 5.
NOTES procedures performed on live human subjects

Figure 6.
Preferred approach for NOTES cholecystectomy

Figure 7.
Preferred environment for training in NOTES cholecystectomy

Figure 8.
Comparison of the NOTES procedures performed on live human subjects

Figure 9.
NOTES standard of care indicator

Figure 10.
NOTES and POEM publication trends

Figure 11.
Pure vs hybrid NOTES procedure preferences

Table 1

Background and experience section of the questionnaire

Question no.	Questions on background and experience
1	I am (Surgeon, Gastroenterologist, Other specialty)
2	I have been in clinical practice for ____ years
3	Did you participate and filled in a questionnaire at the 2011 NOSCART meeting?
4	How many hybrid NOTES procedures have you performed on the following subjects? (porcine, human subjects, cadaver, other species)
5	How many pure (non-hybrid) NOTES procedures have you performed on the following subjects? (porcine, human subjects, cadaver, other species)
6	Which procedures have you performed with NOTES using live human subjects? (appendectomy, cholecystectomy, nephrectomy, tubal ligation, sigmoidectomy or colectomy, lung biopsy, POEM, transgastric peritoneoscopy, other procedures)
7	Which is the single best indication for NOTES to eventually become standard of care?

Table 2

NOTES procedure, approach, and preference section of the questionnaire

Question no.	Questions on NOTES procedure, approach, and preference in the simulator
8	For NOTES cholecystectomy, which approach do you prefer? (hybrid NOTES using flexible instruments, hybrid NOTES using rigid instruments, pure NOTES using flexible instruments, pure NOTES using rigid instruments)
9	For NOTES cholecystectomy using rigid instruments, how do you retract the gall bladder? (transabdominal sutures, 2–3 mm instruments (Minilap, etc.), other)
10	For NOTES cholecystectomy using flexible scope, how do you retract the gall bladder? (transabdominal sutures, 2–3 mm instruments (Minilap, etc.), other)
11	For training in NOTES cholecystectomy, which of these environments do you prefer? (live animal, cadaver, box trainer, observe live case, proctor, VR Simulator with realistic interface and force feedback)
12	Rate the importance of a realistic interface with force feedback (haptics) for the NOTES simulator (Likert scale 1 (not important) - 5 (very important))
13	Rate the importance of feeling torque forces while navigating the endoscope. (Likert scale 1 (not important) - 5 (very important))
14	Rate the importance of feeling force while manipulation of instruments (forceps, snare) through endoscopic channels. (Likert scale 1 (not important) - 5 (very important))
15	Rate the importance of feeling forces while navigating the rigid scope. (Likert scale 1 (not important) - 5 (very important))

Table 3

NOTES instruments and tools preference section of the questionnaire

Question no.	Questions on instruments and tools preference
16	Which flexible endoscope brand and type do you use for NOTES? (Olympus, Pentax, Storz, Fujinon, other)
17	Which rigid endoscope brand and type do you use for NOTES? (Olympus, Pentax, Storz, Fujinon, other)
18	For the purpose of the VR-NOTES simulator, do you have preference in the brand of the endoscope? (yes, no)
19	How many number of channels do you prefer in VR-NOTES (1, 2, 3, more than 3 channels)
20	Should the VR-NOTES simulator be capable of working with prototype devices? (yes, no)
21	The proposed simulator would allow the use of several types of tools and methods to achieve transluminal access for both the approaches. Which of these from the given list would be useful for testing in the simulator? (needle knife, balloon, guide wire, hydro-dissection, tunnel/submucosal flap technique, access/closure device, manual incision, trocar insertion, other)
22	To achieve hemostasis, which of the following tools would you like to see as a choice in the final simulator? (endoclips, bipolar cautery forceps, monopolar cautery forceps, multipolar coagulation probe, coagrasper, suturing device, ultrasonic energy, RF energy, argon plasma coagulation, other)
23	Which of these methods of retrieval of the specimen (ex. gall bladder) do you want as a choice in the final simulator? (snare, rat tooth/alligator forceps, basket, retrieval nets, other)
24	Which of these methods of transluminal closure do you want as a choice in the final simulator? (endoclips, T-tags, stapling device, suturing device, access/closure device, over-the-scope clip, manual closure, other)
25	The unique feature of the VR simulator is that it can precisely report the integrity of the closure of gastrotomy. In addition to that would you prefer more traditional methods of testing? (visual inspection, air leak test, fluid leak test, other)

Table 4

Rating on the preferences in the VR-NOTES simulator section of the questionnaire

Question no.	Questions on rating on the preferences in the VR-NOTES simulator
26	In the initial VR-NOTES simulator, rate how important is it to include the vaginal wall closure. (Likert scale 1 (not important) - 5 (very important))
27	Rate the importance of the specimen being placed in a bag during retrieval of the organ. (Likert scale 1 (not important) - 5 (very important))
28	The VR-NOTES simulator could be capable of providing multiple views to identify the global position of the endoscope (flexures of the endoscope tube as well as the angulated tip). For example, one such view could be the view of endoscope from outside the body with transparent internal organs. Such views might help to find the best spatial orientation of the flexible endoscope to reach the target (gallbladder in this case). Rate the importance of this functionality in the initial VR- NOTES simulator. (Likert scale 1 (not important) - 5 (very important))
29	In the VR-NOTES simulator, multiple endoscopic/laparoscopic views could be shown in the same screen to learn/train operating in triangulation. Rate the importance of this functionality in the initial VR-NOTES simulator. (Likert scale 1 (not important) - 5 (very important))
30	The ultimate goal of the VR-NOTES simulator is to become a testbed for developing and training in new procedures for NOTES in a virtual reality environment. Rate the importance of such a VR testbed for developing new procedures for NOTES. (Likert scale 1 (not important) - 5 (very important))
31	Rate the importance of VR-NOTES simulator for training in NOTES cholecystectomy. (Likert scale 1 (not important) - 5 (very important))
32	In the VR-NOTES simulator, various new instrument designs can be tested even before they are fabricated for their effectiveness. Rate the importance of designing/testing new instruments for the NOTES procedure in the VR-NOTES simulator. (Likert scale 1 (not important) - 5 (very important))

Table 5

Likert scale questionnaire responses

Question	Mean $\pm$ SD
Importance of realistic interface and force feedback	3.92 $\pm$ 0.89
Importance of feeling torque while navigating the scope	4.19 $\pm$ 0.92
Importance of feeling forces while manipulating the instruments	4.08 $\pm$ 1.00
Importance of feeling forces while navigating the scope	3.48 $\pm$ 1.10
Importance of including vaginal wall closure	3.04 $\pm$ 1.22
Importance of specimen being placed in a bag during retrieval	3.42 $\pm$ 1.04
Importance of having multiple views to identify the global position of the endoscope	4.04 $\pm$ 0.74
Importance of multiple endoscopic/laparoscopic views to learn/train in triangulation	3.96 $\pm$ 0.81
Importance of VR testbed for training and developing in new procedures for NOTES	4.15 $\pm$ 0.77
Importance of VR-NOTES simulator for training in NOTES cholecystectomy	4.08 $\pm$ 0.78
Importance of designing/testing new instruments for the NOTES procedure in VR-NOTES	4.31 $\pm$ 0.67