

Patient attitudes and expectations regarding natural orifice transluminal endoscopic surgery

Lee L. Swanstrom · Eric Volckmann ·
Eric Hungness · Nathaniel J. Soper

Received: 24 April 2008 / Accepted: 16 December 2008 / Published online: 3 April 2009
© Springer Science+Business Media, LLC 2009

Abstract

Background Natural orifice transluminal endoscopic surgery (NOTES) has theoretical patient advantages. Because public attitude toward NOTES will influence its adoption, this study aimed to assess patients' opinions regarding the NOTES procedure.

Methods For this study, 192 patients were surveyed. Both NOTES and laparoscopic surgery (LS) are described together with an example case. Presurgical patients rated the importance of various aspects of surgical procedures and their preference for cholecystectomy via NOTES or LS.

Results Complication risks, recovery time, and postoperative pain were considered more important than cosmesis, cost, length of hospital stay, or anesthesia type ($p < 0.001$). In the self-reports, 56% of the respondents preferred NOTES for their cholecystectomy and 44% chose LS. The patients perceived NOTES as having less pain, cost, risk of complications, and recovery time but requiring more surgical skill than open surgery or LS ($p < 0.04$). College-educated patients were more likely to choose NOTES, whereas patients 70 years of age or older and those who had undergone previous flexible endoscopy were less likely to select NOTES ($p < 0.04$). Although 80% of the patients choosing NOTES still preferred it even if it carried a slightly greater risk than LS, their willingness to

choose NOTES decreased as complications, cost, and hospital distance increased and as surgeon experience decreased ($p < 0.001$). This study had a limitation in that the survey population was from surgery clinics.

Conclusion A majority of the patients surveyed (56%) would choose NOTES for their cholecystectomy. The deciding characteristics of the patients were more education, youth, and no previous flexible endoscopy. Procedure-related risks, pain, and recovery time were more important than cosmesis, cost, length of hospital stay, and anesthesia type in the choice of a surgical approach. Patients were less willing to accept NOTES as risks and costs increased and as surgeon experience and availability decreased.

Keywords Cholecystectomy · GI · Endoscopy · Laparoscopy · NOTES · Patient preference · Public opinion

Wonderful is the force of public opinion! We must act and walk in all points as it prescribes; follow the traffic it bids us, realize the sum of money, the degree of "influence" it expects of us or we shall be lightly esteemed; certain mouthfuls of articulate wind will be blown at us, and this, what moral courage can front?
Thomas Carlyle, 1829.

The concept of natural orifice transluminal endoscopic surgery (NOTES) may represent a natural evolutionary convergence between developments in therapeutic flexible endoscopy and laparoscopic surgery. As it evolved, NOTES made use of multiple-channel flexible endoscopes inserted transorally, transvaginally, or per rectum for the performance of intraabdominal surgeries (retroperitoneally or intrathoracically) under a pneumoperitoneum.

L. L. Swanstrom (✉)
Division of Minimally Invasive Surgery, Legacy Health System
and Oregon Health Sciences University, 1040 NW 22nd Avenue,
Suite 560, Portland, OR 97210, USA
e-mail: lswanstrom@aol.com

E. Volckmann · E. Hungness · N. J. Soper
Department of Surgery, Northwestern University Feinberg
School of Medicine, Chicago, IL, USA

Theoretically, NOTES offers the possibility of even less invasive surgery than laparoscopy provides, with proposed benefits of no wound complications, less pain, less immunosuppression, better cosmesis, and possibly a migration of surgeries from the operating room to the outpatient endoscopy suite.

Uniquely, NOTES, which emerged as a clinical possibility in 2004 [1] and currently is riding a wave of interest, has not really been studied as a clinical practice. Currently, intense research is focused on the “practice” of NOTES with an emphasis on the development of enabling technologies, physiologic impact, and design of ideal procedures [2–6].

To date, worldwide clinical NOTES experience has been limited, with the first clinical cases in the United States occurring only in mid-2007. To date, no reports in the literature have confirmed any supposed benefit or described the incidence of complications. Widespread clinical application of NOTES will depend on the final development and approval of the required technologies in addition to laboratory and clinical documentation of patient advantages versus costs and risks.

A “wildcard” in this proposed development pathway is the reaction of the popular media and public to the concept of NOTES. In relatively recent history, the rapid introduction and dissemination of laparoscopic cholecystectomy has been driven to a large extent by public demand. Therefore, with the prospect that clinical NOTES introductions will increase in the near future, we need a better understanding of the following issues: Will the early announcements of NOTES procedures be widely reported or largely ignored in the popular press? Will the public perceive this development as a significant advance over current options or merely as a scientific novelty? Will NOTES be understood as a futuristic “incisionless” development or lumped with minimally invasive surgery or flexible endoscopy? In short, will the public pick up on the NOTES concept and start demanding it as an alternative to current procedures?

The final question is a critical one for several reasons: (1) Industry needs to know how many resources to direct toward research and development based on marketing projections. (2) Surgical and gastroenterological societies need to project the adoption rates of NOTES so they can proactively design education models and work on credentialing and reimbursement issues. (3) Surgeons in particular need to know how soon, if ever, they will need to learn and apply this approach to their practice. If there is a large demand and NOTES appears to be a desirable alternative to common surgical procedures, surgeons will need to adopt NOTES early to maintain critical practice volumes.

To understand better the impact public opinion might have on NOTES, we performed a patient opinion survey to assess public attitudes toward NOTES.

Methods

A 58-item survey instrument was created and structured to assess patient attitudes toward NOTES compared with those toward laparoscopic surgery (LS). The two approaches were described in layman’s terms, and cholecystectomy was used as a referent procedure (Appendix 1).

The study was approved by the respective institutional review boards (IRB) of Legacy and Northwestern University, and consent was obtained from the participants. The patient population identified for the survey comprised prospective surgical patients seen in two busy gastrointestinal surgical clinics (Legacy Health System, Portland, OR, and Northwestern University, Chicago, IL). The study excluded patients being seen for postsurgical visits, those requiring urgent or emergent surgery, those younger than 16 years, and those unable to read and complete the consent forms or questionnaire.

The study patients were offered the opportunity to participate in an anonymous opinion survey by the clinic staff. If patients agreed to answer the questionnaire, they were given an instruction sheet that described in general layman’s terms the concept of NOTES, the purpose of the survey, how the information would be analyzed, and the methods used to protect their anonymity. The patients were allowed to complete the questionnaire at the time or take it home and return it later.

The survey was administered to 192 sequential patients over the course of 30 days. The survey was designed and custom programmed using Microsoft Visual Studio 2005 for development of the Web site and Microsoft SQL Server 2005 for the database (Microsoft, Redmond, WA, USA) using input from the medical informatics program at Northwestern University. The resulting data were analyzed for significance using the Wilcoxon signed ranks test (SPSS 14.0; SPSS, Chicago, IL, USA).

Results

The survey was offered to 212 consecutive preoperative surgery patients and completed for 192 patients. The demographics of the responding patients are presented in Table 1.

The subjects considered the risk of experiencing a complication, the recovery time, and the amount of postoperative pain to be more important than the length of the hospital stay (LOS), anesthesia type, cosmesis, or cost (all $p < 0.001$, Wilcoxon signed ranks test) (Table 2). The patients perceived NOTES to be associated with less pain, cost, risk of complications, and recovery time but requiring more surgical skill than either open surgery or LS (all $p < 0.04$) (Table 3).

Table 1 Survey population demographics (*N* = 192)

	Response
Age (years)	Mean, 50; median, 55
Sex (%)	
Male	49
Female	51
College education (%)	79
Employed (%)	64
Previous flexible endoscopy (%)	60
Previous laparoscopic surgery (%)	52
Previous open surgery (%)	48

Table 2 Relative importance of factors in the choice of a surgical approach^a

<i>Complication risk (%)</i>	
98.4	Important/somewhat important
Mean/median	Important
Mode	Important
<i>Postoperative pain (%)</i>	
88.9	Important/somewhat important
Mean/median	Important
Mode	Important
<i>Recovery time (%)</i>	
92.6	Important/somewhat important
Mean/median	Important
Mode	Important
<i>LOS (%)</i>	
75.9	Important/somewhat important
Mean/median	Somewhat important
Mode	Important
<i>Anesthesia type (%)</i>	
71.1	Important/somewhat important
Mean/median	Somewhat important
Mode	Important
<i>Cosmesis (%)</i>	
49.5	Important/somewhat important
Mean/median	Neither important/unimportant
Mode	Somewhat important
<i>Cost of procedure (%)</i>	
59.9	Important/somewhat important
Mean/median	Somewhat important
Mode	Somewhat important

Question posed to patients: *General attitudes* When considering a surgery, please rate the following items as to their importance to you *LOS* length of hospital stay

^a Paired *t*-test for complication, risk, and pain significant versus all but cost—complication risk, recovery time, and pain significant versus cosmesis and LOS

Table 3 Procedure perceptions expressed on a scale of 1 (minimal) to 5 (extreme)

<i>Mean pain</i>	
Open	4.51
Lap	2.72
NOTES	2.11
<i>Mean cost</i>	
Open	3.67
Lap	3.3
NOTES	3.13
<i>Mean complication risk</i>	
Open	4.07
Lap	3.16
NOTES	2.76
<i>Mean length of recovery</i>	
Open	4.31
Lap	2.78
NOTES	2.16
<i>Mean skill required</i>	
Open	4.43
Lap	4.62
NOTES	4.74

Question posed to patients: “Based on the description provided to you or on your own knowledge and understanding of the surgical options explained in the introduction, please grade each option (laparoscopic surgery or NOTES) compared with a traditional ‘open’ surgery”

Lap laparoscopic, *NOTES* natural orifice transluminal endoscopic surgery

In answer to the hypothetical cholecystectomy question (i.e., “based on the information presented, if you needed to have your gallbladder removed surgically, would you choose to have it done via NOTES or laparoscopy?”), 56% of the patients reported that they would opt for a NOTES approach, whereas 44% preferred LS. The patients who would not choose NOTES reasoned that NOTES was too risky (35%), too new (35%), had no advantages over LS (22%), or simply was not appealing (36%) (Fig. 1).

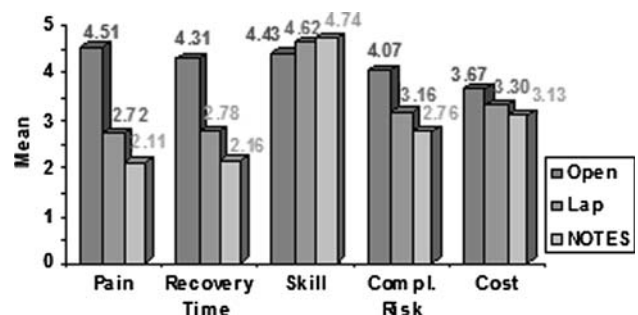


Fig. 1 Opinions regarding the relative merits of open, laparoscopic, and natural orifice transluminal endoscopic surgery (NOTES) cholecystectomy

Patients with a college education were more likely to choose NOTES. Patients 70 years old or older and those who had undergone a flexible endoscopy were less likely to select NOTES (all $p < 0.04$). Although 80% of the patients choosing NOTES still would prefer it even if it carried slightly greater risks than LS, willingness to choose NOTES decreased as the risk of complications, cost, and hospital distance increased and as surgeon experience decreased (all $p < 0.001$).

Discussion

Medical scientists and clinicians often do not consider the impact that public opinion has on how they practice. Certainly, new advances in clinical practice usually are conceived on the basis of a scientific or technologic advance, which then is evaluated scientifically through a typical process that includes technology testing, laboratory studies, and finally, carefully structured clinical outcomes testing. In spite of this, outside forces including medical economics, interspecialty politics, industry marketing, and public demand can have an enormous and sometimes overriding impact on the eventual adoption of new procedures.

Two recent illustrations showing the effect of public demand on clinical practice are particularly relevant to the discussion of the future of NOTES. In the late 1980s, laparoscopic cholecystectomy, a totally new approach for gallbladder surgery, was introduced by a small number of surgical innovators. A small minority of surgeons enthusiastically embraced the concept, whereas the vast majority did not. The majority saw little need for laparoscopic cholecystectomy, perceived a need to wait for prospective outcomes data, or condemned it as a conceptually “bad” or “pointless” idea. Indeed, early studies seemed to show that laparoscopic cholecystectomy resulted in little patient benefit (besides cosmesis) [7], increased cost to society [8], and had some potential for patient harm [9].

The public, however, with some help from the lay press, industry, and entrepreneurial marketing, perceived it differently and essentially demanded that their surgeons provide this “new,” “innovative,” and “patient-friendly” operation for them. This led to a somewhat chaotic stampede for surgical education that proved traumatic for both surgeons and patients. Currently, laparoscopic cholecystectomy is the “gold standard” throughout most of the world although its incidence of common duct injury still is two to three times higher than historical rates for open cholecystectomy [10].

A second and contrary example is that of endoluminal gastroesophageal reflux procedures. These techniques represented a low-morbidity alternative to laparoscopic or open surgery for patients who did not want long-term

pharmacologic therapy. Based on moderate clinical efficacy, they were approved by the Food and Drug Administration (FDA) in 2000. Once again, the procedures were embraced enthusiastically by a coterie of enthusiasts and marketed aggressively by industry.

Significantly, the public never expressed interest in endoluminal gastroesophageal reflux procedures, which led to a cascade effect of disinterest in practitioners taking time off to learn them, to a lack of pressure on insurers to pay for them, and subsequently, to financial failure for the device manufactures. Thus, after 6 years of their availability, companies have little interest in advancing the technologies, insurers have little reason to pay for them, and practitioners (except for a few enthusiasts) seldom practice them.

The results of the current survey show some indication that NOTES may fall more in line with the laparoscopic cholecystectomy adoption scenario. Of the patients surveyed, 56% would prefer removal their gallbladder via NOTES despite its newness. Significantly, this preference persisted even if the procedure risk was higher (80% still preferring NOTES). Perhaps most significant, 18% would elect NOTES even if the surgical risk was *much* higher, the expense was higher (91.7%), they were the first patient of their surgeon (21%), or they had to drive 25 miles to access the option (83.5%).

What is the reason for the favorable public response? The survey indicates a public presupposition that NOTES would be associated with less pain, lower cost, faster recovery, and better cosmesis. On the other hand, the minority of patients who would prefer surgery by laparoscopy explained their choice as related mostly to the newness of NOTES. It was a foreign and somewhat disturbing concept for 36.6% and therefore considered more risky by 35.4%.

It is interesting to note which patients did or did not want their operation via NOTES. It might have been expected that young college-educated patients would be more technology friendly, but it is odd that patients who had undergone a flexible endoscopy in the past would not be interested in a flexible endoscopic surgery. This disinterest may, in fact, be due to skepticism that such a low-impact, “easy” procedure could accomplish a complex surgery.

The accuracy of the public’s perception concerning NOTES might be gauged by how they compared laparoscopy with open surgery, also considering it to be less painful, costly, risky, and more cosmetic, judgments that have been demonstrated clinically [11]. The surveyed patients perceived that NOTES would require more skill on their surgeon’s part than either laparoscopic or open cholecystectomy, and 84% considered their surgeon’s level of experience a major factor in choosing any approach.

One might be tempted to write off the public's choice of NOTES as an unrealistic quest for a no-impact surgery (the "Star Trek" effect). In fact, our survey seemed to show more common sense on the part of the public as they ranked risk of complications as the most important criterion of a surgical approach, significantly more important than the length of hospital stay or cosmesis, which ranked last as a reason to choose an approach.

These results can be compared with the only other survey on this subject, published recently [12]. This was a survey of 100 patients by a gastroenterology group asking essentially the same question posed in this survey, but adding the option for vaginal or rectal removal of the gallbladder. Their results were even more strongly in favor of the NOTES approach, with 78% preferring NOTES.

Once again, the respondents were willing to accept a higher risk of complications to obtain the benefits they perceived (less pain, 99%; better cosmesis, 89%). A strong majority (92% of men and 81% of women) preferred transoral surgery to transvaginal or rectal surgery.

The possible weaknesses of this survey include the number of participants, although the study had adequate numbers to achieve statistical significance for differences between most of the response categories. The number, although relatively small, does represent a significant percentage of the patients seen in a 1-month period at two busy surgery clinics because very few patients refused the opportunity to participate in this study. Although all the patients were being seen for gastrointestinal complaints (both clinics specialize in gastrointestinal diseases), not all the patients were being seen specifically for gallbladder problems, which would have decreased the overall study numbers or prolonged data collection such that media coverage of NOTES could have biased the response.

This lack of homogeneity in the study group may have affected the results to the extent that the example of cholecystectomy may have been less relevant to some patients. In the introduction given to the patients, an effort was made to stress that cholecystectomy was used simply as an example of a surgery that might be performed by these approaches.

The study population also may not accurately represent the general public because the study patients were drawn from those being seen in a surgery clinic. Thus, they may represent a different demographic or could have been trying to second guess what they thought the surgeon would want to hear. We tried to obviate this bias by having the front office staff distribute and collect the survey with no direct involvement by the surgeons. The demographics represented were similar to those for the general urban public (age of 55 years, 50/50 male/female, 79% college educated). The one exception may have been the relatively high incidence of prior surgery, which may have influenced the patient's opinions to some degree.

Such a survey also may have a natural bias toward the choice perceived as the "newer," with the assumption that because science "progresses," something new must therefore equate with "improved" or "advanced." We tried to counter this by establishing open cholecystectomy as the baseline referent and treating laparoscopic cholecystectomy as a newer "advanced" technique together with the NOTES cholecystectomy.

Concern might be raised that the participants may have been biased in favor of NOTES due to the attending surgeons' notoriety as NOTES pioneers. This study, however, was performed before any popular press reports referring to the surgeons had appeared, so the only way for the participants to have known of this "expertise" would have been from reading the scientific literature; which seems unlikely.

Finally, our outline of possible benefits or complications for NOTES surgery was largely theoretical because no published human cases existed at the time of this study. We based our description of such complications on several inputs: our acute/survival animal and cadaver laboratory experience over the past 4 years, published and presented animal research from other centers, anecdotal reports of human cases, and universality of certain complications associated with biliary surgery, endoscopy, and gastrotomy. These same justifications were used for the IRB application for our phase 1 human trials, which were approved and started in May 2007.

Conclusions

The results of this survey indicate that the majority of patients would prefer their cholecystectomy to be performed via the NOTES approach as long as their surgeon was well trained and the inherent risks were not significantly greater than those associated with laparoscopic surgery. This is an indication that physicians should keep an eye on developments related to NOTES (particularly as training options become available) because a rapid demand for these procedures may arise once the possibility of NOTES reaches the attention of the public.

Appendix 1: the survey tool

Background

- Age:
- Sex:
- Education:
- Employment:
- Have you had surgery before?

Flexible endoscopy (e.g., colonoscopy or upper endoscopy):

Outpatient minor surgery (e.g., tonsils, plastic surgery):

Open surgery (e.g., appendectomy, lung surgery, heart surgery, abdominal surgery):

Laparoscopic surgery (e.g., tubal ligation, gallbladder surgery):

Had you heard about laparoscopic surgery before this study?

Had you heard about natural orifice transluminal endoscopic surgery (NOTES) type surgeries?

General attitudes:

When having a surgery what aspects of the procedure approach are most important?

- Cost of the procedure
- Complication risk
- Length of hospital stay
- Type of anesthesia (sedation vs general)
- Cosmetic result
- Amount of pain after surgery
- Time required for return to full activity levels

Based on the preceding description or on your own knowledge and understanding of the surgical options mentioned in the preceding scenario, please grade each option compared with an old-fashioned “open” surgery using 0 (no, none, nothing) to 5 (severe, maximum, high)

Open (traditional) surgery	Laparoscopic (“keyhole”) surgery	NOTES (flexible endoscopic surgery)
----------------------------------	--	--

Amount of pain after surgery

Cost of the procedure

Risk of having a complication (e.g., infection, organ injury, blood clot)

Length of recovery (time until return to work or normal activities)

Degree of skill needed by your surgeon to perform the procedure

If your surgeon was very experienced in one of the procedures but new to the other (yet well trained and fully credentialed in it), would that influence your choice?

NOTES vs. Laparoscopy:

Who do you think NOTES surgeries might be best for infants? children? working adults? the elderly? everyone?

If you were the one who needed the gallbladder surgery and your surgeon was fully qualified to perform either procedure, which would you prefer?

Laparoscopic surgery

NOTES surgery

If you choose laparoscopic surgery as your preferred approach:

Why did you choose laparoscopy?

- NOTES is too new.
- NOTES sounds more risky.
- I see no advantage to NOTES over laparoscopic surgery.
- It sounds more painful than laparoscopy.
- I don't like the thought of something being removed from my mouth or rectum.
- Other _____

Would you still choose NOTES as your preferred surgical approach if:

The complication rate was slightly higher (2% vs 1%)? Significantly higher (10% vs 1%)?

If you had to pay slightly more (<\$100)? Significantly more (\$100–\$1,000)? Had to pay out of pocket (\$12,000)?

If your surgeon was fully trained but you were his first patient for the procedure? 10th?, 100th?

If you had to go to another hospital in your town? To a hospital 25 miles away? To a hospital 100 miles away? To a hospital 500 miles away?

Other reasons why you chose NOTES? _____

References

1. Kalloo AN, Singh VK, Jagannath SB, Niiyama H, Hill SL, Vaughn CA, Magee CA, Kantsevov SV (2004) Flexible transgastric peritoneoscopy: a novel approach to diagnostic and therapeutic interventions in the peritoneal cavity. *Gastrointest Endosc* 60:114–117
2. Hu B, Chung SC, Sun LC, Kawashima K, Yamamoto T, Cotton PB, Gostout CJ, Hawes RH, Kalloo AN, Kantsevov SV, Pasricha PJ, Eagle Claw II (2005) A novel endosuture device that uses a curved needle for major arterial bleeding: a bench study. *Gastrointest Endosc* 62:266–270
3. Jagannath SB, Kantsevov SV, Vaughn CA, Chung SS, Cotton PB, Gostout CJ, Hawes RH, Pasricha PJ, Scorpio DG, Magee CA, Pipitone LJ, Kalloo AN (2005) Peroral transgastric endoscopic ligation of fallopian tubes with long-term survival in a porcine model. *Gastrointest Endosc* 61:449–453
4. Kantsevov SV, Jagannath SB, Niiyama H, Chung SS, Cotton PB, Gostout CJ, Hawes RH, Pasricha PJ, Magee CA, Vaughn CA,

- Barlow D, Shimonaka H, Kalloo AN (2005) Endoscopic gastrojejunostomy with survival in a porcine model. *Gastrointest Endosc* 62:287–292
5. Swanstrom LL, Kozarek R, Pasricha PJ, Gross S, Birkett D, Park PO, Saadat V, Ewers R, Swain P (2005) Development of a new access device for transgastric surgery. *J Gastrointest Surg* 9: 1129–1136
 6. Wagh MS, Merrifield BF, Thompson CC (2005) Endoscopic transgastric abdominal exploration and organ resection: initial experience in a porcine model. *Clin Gastroenterol Hepatol* 3:892–896
 7. Squirrell DM, Majeed AW, Troy G, Peacock JE, Nicholl JP, Johnson AG (1998) A randomized, prospective, blinded comparison of postoperative pain, metabolic response, and perceived health after laparoscopic and small-incision cholecystectomy. *Surgery* 123:485–495
 8. Schirmer BD, Dix J (1992) Cost effectiveness of laparoscopic cholecystectomy. *J Laparoendosc Surg* 2:145–150
 9. Peters JH, Gibbons GD, Innes JT, Nichols KE, Front ME, Roby SR, Ellison EC (1991) Complications of laparoscopic cholecystectomy. *Surgery* 110:769–777
 10. Waage A, Nilsson M (2006) Iatrogenic bile duct injury: a population-based study of 152,776 cholecystectomies in the Swedish Inpatient Registry. *Arch Surg* 141:1207–1213
 11. Archer SB, Sims MM, Giklich R, Traverso B, Laycock B, Wolfe BM, Apfelgren KN, Fitzgibbons RJ, Hunter JG (2000) Outcomes assessment and minimally invasive surgery: historical perspective and future directions. *Surg Endosc* 14:883–890
 12. Varadarajulu S, Tamhane A, Drelichman ER (2008) Patient perception of natural orifice transluminal endoscopic surgery as a technique for cholecystectomy. *Gastrointest Endosc* 67:854–860 (Epub 20 Mar 2008)