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Patient Perception of Natural Orifice Transluminal Endoscopic Surgery in an Endoscopy Screening Program in Korea

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Purpose: Natural orifice transluminal endoscopic surgery (NOTES) is a new method of accessing intracavitary organs in order to minimize pain by avoiding incisions in the body wall. The aim of this study is to determine patients' acceptance of NOTES in Korea and to compare their views about laparoscopic surgery and NOTES for benign and malignant diseases. **Materials and Methods:** The target number of total subjects was calculated to be 540. The subjects were classified into 18 sub-groups based on age groups, gender, and history of prior surgery. The questionnaire elicited information about demographic characteristics, medical check-ups, diseases, endoscopic and surgical histories, marital status and childbirth, the acceptance of NOTES, and the preferred routes for NOTES. In addition, the subjects chose laparoscopic surgery or NOTES for a hypothetical cholecystectomy and rectal cancer surgery, and responded to questions regarding the acceptable complication rate of NOTES, the appropriate cost of NOTES, and the reason(s) why they did not select NOTES. **Results:** 486 of 540 patients (90.0%) who agreed to participate in this study completed the questionnaire. NOTES was preferred by the following patients: elderly; a history of treatment due to a disease; having regular check-ups; and a history of an endoscopic procedure ($p < 0.05$). The most preferred route for NOTES was the stomach (67.1%). Eighty-four percent of the patients choosing NOTES responded that the complication rate of the new surgical method should be the same or lower than laparoscopic surgery. Vague anxiety over a new surgical method was the most common reason why NOTES was not selected in benign and malignant diseases (64% and 73%), respectively. **Conclusion:** Patients appear to be interested in the potential benefits of NOTES and would embrace it if their concerns about safety are met. We believe that qualified surgical endoscopists can meet these safety concerns, and that NOTES development has the potential to flourish.

Key Words: NOTES, endoscopy, surgery, patient perception, survey

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INTRODUCTION

Natural orifice transluminal endoscopic surgery (NOTES) is a new method of accessing intracavitary organs in order to minimize pain by avoiding incisions in the

body wall.¹ A key concept in the development of NOTES was the use of a standard flexible endoscope to access the abdominal cavity via a gastrotomy, much as done for endoscopic pancreatic cyst-gastrostomies. As the NOTES movement progressed, it was appreciated that other natural orifices, such as the anus, the urethra, and the vagina could also serve as portals of entry.

As with most novel surgical methods, providers and patients' opinions on NOTES vary. Many surgeons question if this new surgical method will be accepted in the years to come and are interested in the perception of NOTES among patients. Although the perceptions of NOTES by patients have been studied in some countries,²⁻⁷ most were in Western countries. No study has been conducted in countries where a national endoscopic screening program for gastric cancer is actively utilized, such as Korea and Japan. Widespread familiarity with endoscopy by patients could potentially impact their perception of NOTES. Therefore, this study aimed to determine patients' acceptance of NOTES in Korea and to compare their views about laparoscopic surgery and NOTES for benign and malignant diseases.

MATERIALS AND METHODS

This study was approved by the Institutional Review Board (IRB) of Dong-A University Medical Center (No. 10-10-18). An explanation about laparoscopic surgery and NOTES for the general population was inserted into the consent form, and a clinical research nurse explained the study (Appendix 1). A questionnaire with 18 questions was distributed to the patients agreeing to participate in this study, and was returned upon self-completion (Appendix 2). The subjects were classified into 18 sub-groups based on age groups (20-39, 40-59, and 60+ years), gender (male or female), and history of prior surgery (open, laparoscopy, or none). The target number of total subjects was calculated to be 540, as determined by the minimal number for non-parametric testing (30 in each sub-group). The questionnaire survey was administered in outpatient clinics of the Surgery and Gastroenterology Departments and the Health Promotion Center at Dong-A University Medical Center for 5 months (May-September 2010), and the data were statistically analyzed with STATA/SE 11.1 (Stata Corp. LP, College Station, TX, USA).

The questionnaire elicited information about demographic

characteristics, medical check-ups, diseases, endoscopic and surgical histories, marital status and childbirth, the acceptance of NOTES, and the preferred routes for NOTES. In addition, the subjects chose laparoscopic surgery or NOTES for a hypothetical cholecystectomy and rectal cancer surgery, and responded to questions regarding the acceptable complication rate of NOTES, the appropriate cost of NOTES, and the reason(s) why they did not select NOTES.

RESULTS

Four hundred eighty-six of 540 patients (90.0%) who agreed to participate in this study completed the questionnaire. Among the subjects, 375 (77.2%) had a regular check-up, 344 (70.1%) had an associated disease, 388 (79.8%) underwent endoscopy previously, and 146 (30.0%) graduated from college or a higher academic institution. Four hundred nine patients (84.2%) said that they were willing to undergo NOTES. NOTES was preferred by the following patients: elderly; a history of treatment due to a disease; having regular check-ups; and a history of an endoscopic procedure ($p < 0.05$) (Table 1). The patients graduated from a postgraduate school or a higher academic institution tended to be cautious about NOTES. The preferred routes for NOTES were the stomach (67.1%), rectum (26.7%), and the vagina (6.2%) (Fig. 1).

The preference for NOTES was not significantly different between benign and malignant diseases (Table 2). Specifically, the acceptance rate of NOTES was 85% and 86% in benign and malignant diseases, respectively. Eighty-four percent of the patients choosing NOTES responded that the complication rate of the new surgical method should be the same or lower than laparoscopic surgery. However, if the theoretical advantage of NOTES was achieved, >70% of the pa-

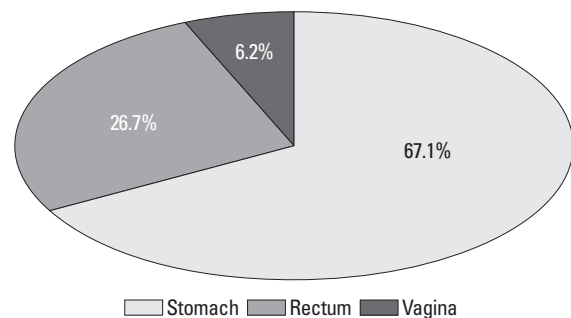


Fig. 1. Preference of route in NOTES. Among 486 patients who preferred NOTES, 326 patients (67.1%) chose transgastric approach for NOTES. NOTES, natural orifice transluminal endoscopic surgery.

tients were willing to pay >1.5 times the cost of laparoscopic surgery. Vague anxiety over a new surgical method was the most common reason why NOTES was not selected in benign and malignant diseases (64% and 73%), respectively.

DISCUSSION

NOTES is a new surgical method intended to make surgi-

Table 1. Survey of Population Demographics and Factors Associated with Preference of NOTES

	Total no. (%) (n=486)	Preferred NOTES (%) (n=409, 84.2%)	<i>p</i> value
Age distribution (yrs)			0.000
20-39	178 (36.7)	127 (71.3)	
40-59	162 (33.3)	147 (90.7)	
60-79	146 (30.0)	135 (92.5)	
Gender			0.509
Male	244 (50.2)	208 (85.2)	
Female	242 (49.8)	201 (83.0)	
Previous surgical history			0.848
Open	173 (35.5)	143 (82.7)	
Laparoscopy	164 (33.7)	129 (78.7)	
None	155 (31.8)	130 (83.9)	
Education			0.000
Up to elementary school	81 (16.7)	73 (90.1)	
Up to high school	203 (41.7)	183 (90.1)	
Up to college and beyond	202 (41.6)	153 (75.7)	
Regular medical check-up			0.002
Yes	375 (77.2)	326 (86.9)	
No	111 (22.8)	83 (74.7)	
Previous endoscopy			0.000
Yes	388 (79.8)	340 (87.6)	
No	98 (20.2)	69 (70.4)	
Co-morbidity			0.000
Yes	344 (70.8)	309 (89.8)	
No	142 (29.2)	100 (70.4)	

NOTES, natural orifice transluminal endoscopic surgery.

Table 2. Survey of Population Perception of NOTES Based on Benign and Malignant Diseases

	Benign gallbladder surgery (%)	Rectal cancer surgery (%)
Preference		
Laparoscopic surgery	73 (15)	68 (14)
NOTES	413 (85)	418 (86)
Acceptable complication rate of NOTES		
5%	347 (84)	349 (84)
10%	66 (16)	69 (16)
Appropriate cost of NOTES comparing laparoscopic surgery		
Equivalent	129 (31)	134 (32)
1.5 times	232 (56)	243 (58)
2 times	39 (9)	33 (8)
>2 times	13 (3)	8 (2)
Reason for choosing laparoscopic surgery	73	68
No advantage of NOTES over laparoscopic surgery	7 (10)	8 (12)
I do not like to remove something from my mouth or rectum	10 (13)	10 (15)
NOTES sounds more risky	9 (12)	NA
NOTES is too new	47 (64)	50 (73)

NOTES, natural orifice transluminal endoscopic surgery; NA, not available.

cal interventions less morbid. Since the use of natural orifices for access routes creates some technical challenges and raises concerns about infections and viscerotomy closure, many animal experiments on the feasibility of NOTES have been conducted during the last several years.⁸⁻¹¹ After a phase of laboratory investigation, many NOTES procedures have been safely performed in humans, including transvaginal cholecystectomy, transgastric cholecystectomy, various gynecologic procedures, sleeve gastrectomy, and liver biopsy.^{12,13} Nevertheless, there is skepticism in both the medical community and regulatory bodies about the wisdom of application of NOTES in humans.

In previous survey studies involving NOTES, patient preferences for NOTES as a method of cholecystectomy were 56-78%.²⁻⁴ A study conducted in a surgical outpatient clinic revealed that the complication rate, convalescence, and post-operative pain were more important than cost, aesthetic effect, length of hospital stay after surgery, and type of anesthesia in influencing patients' decisions. NOTES was preferred by patients graduated from college or a higher academic institution, and the preference for NOTES was low in patients >70 years of age and those who had undergone an endoscopic procedure.² Another study performed in an outpatient clinic of an Internal Medicine Department reported that the rate of preference for NOTES was very high (78%); NOTES was preferred by younger patients and patients with a history of an endoscopic procedure.³ These patients were inclined to have NOTES because it provoked less pain and left no scar.³ In addition, a survey on the perception of transvaginal NOTES cholecystectomies among female patients reported that 68% of the patients wanted NOTES because it was not associated with post-operative hernias and caused less pain. However, a subset of younger and nulliparous patients worried about their sex life and infertility after undergoing NOTES. The most common reason given for not preferring NOTES was the possibility of infection.⁴ In contrast with a positive perception of NOTES in these studies, other surveys of the general population, surgeons, and paramedical staff have reported a much lower acceptance rate.^{5,6}

Gastroscopy is a very common example of a national health screening program which is conducted in countries with high incidence rates of gastric cancer, such as Korea and Japan. In Korea, adults >40 years of age are advised to have a gastroscopy every 2 years. The routine nature of this

procedure might be the basis for the high acceptance rate of NOTES by the patients whom we surveyed and where the stomach is preferred as a route for NOTES in the current study. According to the findings of the current study, patients and surgeons thought that the complication rate of the new surgical method should be similar to existing techniques. Of note, the patient's willingness to pay an additional cost for the new method with clinical benefits has significant implications for clinicians.

A questionnaire-based survey, as in the current study, can lead to subject and investigator bias. The current study considered not only the patients with a history of surgery and existing disease in the outpatient clinics of the Surgery and Gastroenterology Departments and the Health Promotion Center, but also their guardians as individuals with no history of disease, therefore, it was a systematic study which evaluated surgical history, age, and gender together. This questionnaire survey was also conducted by just one clinical research nurse in order to obtain consistency and to minimize the bias.

Although NOTES has gained considerable attention from gastroenterologists and surgeons worldwide, there are obstacles to NOTES that should be addressed. Some of the obstacles are technical challenges that are being addressed by new instrument development. Another obstacle is providing appropriate training to practitioners who want to start performing NOTES procedures. A third and still formidable obstacle is obtaining approval of IRBs and regulatory bodies to complete clinical trials and device development, so that NOTES becomes easier to perform and the safety demonstrated in the early NOTES experience can be confirmed on a large scale. On the basis of this study, patients would appear to be interested in the potential benefits of NOTES and would embrace it if their concerns about safety are met. Given the outstanding results that have been published by groups in Germany¹¹ and elsewhere, we believe that qualified surgical endoscopists can meet these safety concerns, and that NOTES development has the potential to flourish.

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APPENDIX 1

What is laparoscopic surgery?

Laparoscopic surgery means surgery for an organ in the abdominal cavity conducted by inserting trocars into the abdominal cavity on the abdominal wall, and by putting a camera and laparoscopic tools into the trocar. It leads to less wound, less postoperative pain, shorter convalescence and few wound-related complication than open surgery.

What is natural orifice transluminal endoscopic surgery (NOTES)?

NOTES is a surgical method inserting an endoscope through the mouth, the anus or the vagina (natural orifice), incising the internal surface of the esophagus, the stomach, the rectum or the vagina (transluminal) to enter into the abdominal cavity or the thoracic cavity and conducting an endoscopic operation. Therefore, it provokes mild postoperative pain and prevents skin wound-related postoperative complication (wound infection, hemorrhage, wound hernia and intestinal adhesion) due to no wound on the abdominal skin. However, NOTES makes a wound on the internal surface of the bowel to insert an endoscope instead of skin wound and needs special equipments including an endoscope.

APPENDIX 2

Questionnaire

1. Gender; Male () Female ()
2. Day of birth; Born in 19
3. Final academic background;
Elementary school () Middle or high school () College () Postgraduate school or higher ()
4. Do you have a regular medical check-up (by 1-2 years)?
Yes () No ()
5. Have you taken medications or regular examinations after diagnosed as a specific disease by a physician?
If you have, which disease did you have?
Yes; Gastrointestinal disease () Large intestine · anus disease () Gynecologic disease () Other ()
No ()
6. Have you taken endoscopy? If you have, which type of endoscopy did you undergo?
Yes; Gastroscopy () Colonoscopy () Bronchoscopy () Other ()
No ()
7. Have you undergone surgery? If you have, which type of surgery was it?
Yes; Open surgery () Laparoscopic surgery ()
No ()
8. (Only for females) Have you been married and have you given birth?
Married; No () Yes ()
Childbirth; No () One () Two () Three or more ()

9. Do you have an intention to undergo NOTES?

Yes () No ()

10. Which route is considered to be the best among three routes of NOTES?

Stomach () Vagina () Rectum ()

11. This includes questions made on the assumption that you are expected to undergo surgery due to a following disease.

1) If outcomes of laparoscopic surgery and NOTES for cholecystectomy are as follows, please answer questions below

Laparoscopic cholecystectomy is a surgical method conducted for most gallbladder stone patients. It needs 1-2 day admission after the surgery and leaves three 0.5-1 cm wounds on the abdomen. Its postoperative complication rate is around 5% and most patients can return to their work within 2-3 weeks after surgery. It costs around 1 thousand US dollar as out-of-pocket payment.

NOTES cholecystectomy is a surgical method resecting the gallbladder by inserting an endoscope through the mouth, the anus or the vagina, incising the bowel for the endoscope to enter into the abdominal cavity. It produces no wound on the abdomen, patients can be discharged on the day of the operation or the next day and patients can return to their work in around one week after surgery.

A. Which one do you prefer, laparoscopic surgery or NOTES?

a. Laparoscopic surgery b. NOTES

B. If you choose NOTES, what is an acceptable complication rate of NOTES cholecystectomy?

(the complication rate of laparoscopic surgery is less than 5%)

a. Less than 5% b. Less than 10% c. Less than 15% d. Less than 20%

C. If you choose NOTES, what is an appropriate cost of NOTES compared to laparoscopic surgery?

a. It should be same with the cost of laparoscopic surgery
b. 1.5 times of the cost of laparoscopic surgery
c. 2 times of the cost of laparoscopic surgery
d. Over 2 times of the cost of laparoscopic surgery

D. If you choose laparoscopic surgery, why do you do?

a. NOTES does not seem to have considerable benefits in terms of recovery compared to laparoscopic surgery
b. I don't want for the resected organ taken out through my mouth, anus or vagina even though I am under anesthesia
c. I worry about bowel incision for endoscopic entrance into the abdominal cavity
d. I have a vague anxiety over a new surgical method

2) If outcomes of laparoscopic surgery and NOTES for rectal cancer are as follows, please answer following questions

Laparoscopic rectal surgery is a surgery widely conducted to treat rectal cancer. It needs 7-8 day admission after sur-

gery and leads to one 4-5 cm wound and 4-5 0.5-1 cm wounds on the abdomen. Its complication rate is around 10% and most patients return to their work in four weeks after surgery. It costs about 4 thousands US dollar as out-of-pocket payment.

NOTES rectal surgery is a surgery resecting the rectum by inserting a special endoscope through the anus. It provokes no wound on the abdomen, patients can be discharged in 4-5 days after surgery and can return to their work in two weeks after it. Recurrence rate of rectal cancer after the surgery is same with that of laparoscopic surgery.

- A. Which one do you prefer, laparoscopic surgery or NOTES?
 a. Laparoscopic surgery b. NOTES
- B. If you choose NOTES, what is an acceptable complication rate of NOTES rectal surgery?
 (the complication rate of laparoscopic surgery is around 10%)
 a. Less than 10% b. Less than 15% c. Less than 20% d. Over 20%
- C. If you choose NOTES, what is an appropriate cost if NOTES compared to laparoscopic surgery?
 a. It should be same with the cost of laparoscopic surgery
 b. 1.5 times of the cost of laparoscopic surgery
 c. 2 times of the cost of laparoscopic surgery
 d. Over 2 times of the cost of laparoscopic surgery
- D. If you choose laparoscopic surgery, why do you do?
 a. NOTES does not seem to have considerable benefits in terms of recovery compared to laparoscopic surgery
 b. I don't want for the resected organ taken out through my mouth, anus or vagina even though I am under anesthesia
 c. I have a vague anxiety over a new surgical method

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