

NOTES. Study on patients' perspective

Jarek Kobiela, Tomasz Stefaniak, Dariusz Laski, Malgorzata Mackowiak, Alicja Czurylo, Stanislaw Hac, Andrzej J. Lachinski, Zbigniew Sledzinski

Department of General, Endocrine and Transplant Surgery, Medical University of Gdansk, Poland

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Abstract

Introduction: Rapid development of minimally invasive surgery has led to escalation of the demands placed on health care professionals. Nowadays the patient is the one to choose where and how she/he wants to be operated on. Peri-operative and postoperative quality of life is the most common item impacting the patients' choice. Laparoscopic surgery is undoubtedly advantageous in several applications; however a further improvement of medical services has been introduced: the NOTES technique. This novel surgical approach definitively eliminates the problem of having scars. Though NOTES is still in the clinical trial stage, it might become an alternative for selected procedures soon. At this point it is necessary to define the patients' expectations and preferences.

Aim: To evaluate patients' opinions on the four surgical approaches: open, laparoscopic, transvaginal and transgastric.

Material and methods: For this purpose a special questionnaire was designed and one hundred randomly selected women were asked to complete it.

Results: The laparoscopic access was preferable in most aspects, closely followed by the transvaginal access. Open and transgastric approaches were considered as dangerous and disadvantageous.

Conclusions: Currently NOTES is a possible reality of tomorrow for some procedures. The transvaginal access was scored as "attractive", "cosmetically attractive" and "technologically advanced", as opposed to the transgastric access. The fact of manipulation in the intimate region requires thorough attention in future NOTES studies. Though the patients currently prefer the laparoscopic approach, this study proves that further development of transvaginal NOTES technology is acceptable and to some extent desired by the patients.

Key words: NOTES, minimally invasive surgery, transvaginal cholecystectomy.

Introduction

It took modern surgery several decades to provide satisfactory mortality and morbidity rates. However, since the 90s it has been increasingly emphasized to provide patients not only with a curative operation but also to ensure good quality of life. This was achieved by the rapid development of laparoscopic surgery. Since then laparoscopic surgery has been intensively investigated to provide scientific proof of its superiority. Nowadays medical centers put much

effort into recruiting patients for their everyday practice as well as for medical trials or introduction of innovative procedures. Therefore the patient can choose between different medical centers offering the same procedures with different standards or extras. Among those the most convincing argument is the postoperative quality of life. This all gives an impression that surgical procedures or surgical care in general is a product and healthcare providers are increasingly interested in winning the cut-throat

Address for correspondence:

Jarek Kobiela MD, PhD, Department of General, Endocrine and Transplant Surgery, Medical University of Gdansk, 7 Debinki St, 80-211 Gdansk, Poland, phone: +48 503 114 069, fax: +48 58 349 24 10, e-mail: kobiela@gumed.edu.pl

competition. This is why millions of dollars are spent annually on improving quality of care. One of those improvements was natural orifice transluminal endoscopic surgery (NOTES) – a new surgical approach offering patients surgery with no scar. It was accepted by the industry and an enormous effort was made to provide health care professionals with an adequate armamentarium [1]. Several animal studies have proved the feasibility and safety of NOTES procedures. Transgastric or transvaginal cholecystectomy and nephrectomy, transgastric fallopian tube ligation, splenectomy, peritoneoscopy and even transvesical and transdiaphragmatic thoracoscopy were reported [2-8]. From 1997 the first human studies were attempted aiming to introduce NOTES procedures into everyday practice. Human studies involved limited numbers of cases of transgastric appendectomy, fallopian tube ligation, peritoneoscopy and a pioneer transvaginal cholecystectomy performed in 2007 [9-11]. At this moment human NOTES procedures are a clinical experiment. However, before long they will be offered to patients as an exclusive product. This may change in the future and NOTES might become a simple alternative for all in selected procedures [12].

The paradigm shift initiated by NOTES was such an overwhelming phenomenon for both healthcare providers and the industry that not much effort has been put into evaluating actual patients' expectations and desires. Accessing the peritoneal cavity through the stomach, vagina or the rectum was an obvious and viable approach for the surgeons and medical technology engineers. For the patients, however, rupturing healthy organs such as the stomach or the vagina to access the peritoneal cavity might not be an acceptable and justified approach to avoid small scars left after the laparoscopic approach.

Aim

The aim of this study was to evaluate patients' opinions and preferences on the currently available accesses for cholecystectomy including two NOTES accesses – transgastric and transvaginal.

Material and methods

A two-part questionnaire was designed for the purpose of this study. The first part was a detailed description of four accesses in surgery including

open, laparoscopic, transgastric and transvaginal approaches. The descriptions were designed to be informative but not judgmental. Major features, known advantages and disadvantages as well as potential complications and side effects were listed for all procedures. Patients were informed that they would be under general anesthesia during all proposed procedures. As the questionnaire was addressed to non-medical subjects, specialist medical vocabulary was avoided and descriptions were kept clear and simple, involving basic and obvious information. The second part involved several items divided into the following sections: demographic data, previous medical experience, evaluation of the studied accesses. The study group comprised one hundred randomly selected women who offered to voluntarily complete the above-mentioned questionnaire. All questionnaires were taken by a general surgery senior resident who was available to give answers to all additional questions.

Statistical analysis

Statistical analysis was performed with Statistica PL software licensed for the Medical University of Gdansk. For questions 1 and 2 a value scale was used with the range 1-4. In these cases modal values were presented. In questions 1 and 2 the result was bimodal and for the groups with the highest scores frequencies were compared with *t*-tests. For questions 3-6 (a number of answers, more than one could be chosen) Kruskal-Wallis H tests were used for global comparisons and Fisher's exact tests were used for comparisons between individual groups.

Results

Demographic data

The studied women were aged between 23 and 60 years (average 53 – perimenopausal age), sexually active, 92% were at least once pregnant and 85% had at least one labor. Sixty-two percent of recruited women had body mass index (BMI) > 25 kg/m² and 34% had BMI > 30 kg/m². The examined group represents a typical 5 F (fair skin, female, forty, fat, fertile) cholecystectomy patient. Seventy-three percent of the patients reported secondary education. Sixty-four percent of the studied women were inhabitants of a city with a population of over 200,000 and 36% were recruited from smaller cities. Average reported

income was slightly over the average salary for the country.

Previous medical experience

Eighteen percent of the surveyed women had US-confirmed cholelithiasis and 6% suffered from symptomatic cholelithiasis. Forty-three percent of the study group have had cholecystecomized relatives. Eleven percent of the women had undergone minor surgery in the past and 3% had undergone major surgery in the past. Gastrosocopy was previously performed in 7% of the patients. Gynecological examination was previously performed in all patients.

Evaluation of the access

The attitude towards individual surgical accesses was based on the following items: attractiveness of the access (question 1), fear of complications related to the access (question 2), the potential cosmetic effect of different surgical accesses (question 3), the anticipated reduction of the intensity of postoperative pain (question 4), technological advancement of the procedure as perceived by the participants (question 5), perception of benefits against risks of the procedure (question 6). In the final item overall preference of the access indicated for a potential future cholecystectomy was questioned (question 7).

Both laparoscopic and transvaginal approaches were considered most attractive, with the highest level of attractiveness chosen by respectively 71% and 85% (Figure 1). Open and transgastric approach-

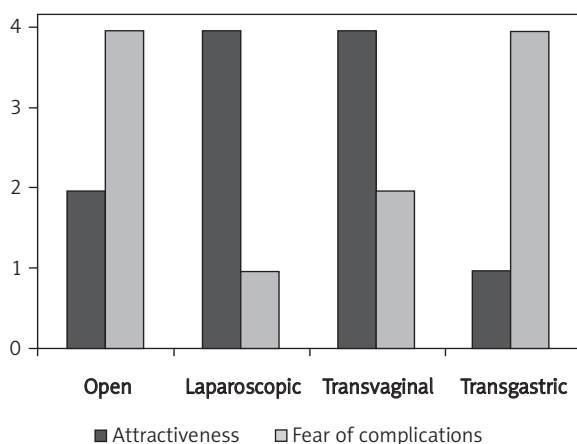


Figure 1. Attractiveness and fear of complications related to the access (most often chosen answer given on 1 to 4 scale)

es were considered less attractive, with modal values of respectively 2 (range: 1-4) (61% of participants) and 1 (range: 1-4) (83% of participants).

The participants expressed the highest concerns about the risks associated with the procedures of open and transgastric surgery (respectively, 88% and 87% reported with the highest modal value) (Figure 1). Laparoscopic and transvaginal approaches were far less fearsome for the participants (respectively, 77% chose the lowest score, 1, and 61% chose the intermediate level, 2)

Studied accesses differed significantly in terms of the perceived cosmetic effect (Figure 2). The participants perceived the transvaginal access as offering the best cosmetic result ($p < 0.05$). It was followed by laparoscopic and transgastric access (laparoscopic vs. transgastric approach – no statistical significance). The worst cosmetic effect was attributed to the open approach ($p < 0.05$).

The participants anticipated that the laparoscopic access would offer the most significant reduction of postoperative pain ($p < 0.05$), followed by transvaginal access (Figure 2). Both open and transgastric

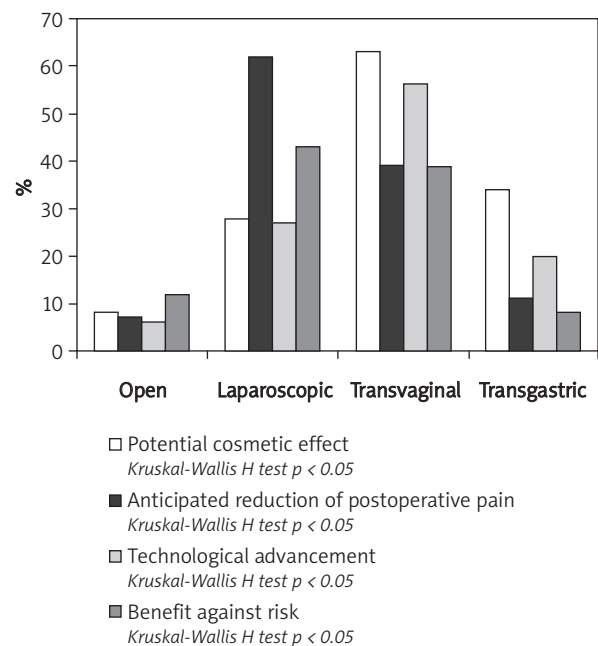


Figure 2. The potential cosmetic effect, anticipated reduction of the intensity of postoperative pain, technological advancement of the procedure, and perception of benefits against risks of different surgical accesses presented as the number of answers (more than one could be chosen)

approaches were seen as offering significantly lower and comparable pain reduction (open vs. transgastric access – no statistical significance).

The participants perceived the transvaginal approach as the most technologically advanced ($p < 0.05$) (Figure 2). It was followed by both transgastric and laparoscopic approaches. The open approach was perceived as the least advanced technologically ($p < 0.05$).

The participants perceived both laparoscopic and transvaginal approaches as offering the highest prevalence of benefits over risks, while open and transgastric approaches were considered as less beneficial ($p < 0.05$) (Figure 2).

The overall preference of the participants pointed to the laparoscopic approach ($p < 0.05$), followed by the transvaginal approach (Figure 3). The open and transgastric approaches were considered significantly less attractive by the participants.

Discussion

NOTES technology probably has the best public relations among recently introduced surgical innovations. With all the breaking news on NOTES published by the media, one might get an impression that NOTES is a valid option for patients today. Despite rapid progress in peritoneal cavity access, navigation skills, access side closure techniques and others, NOTES might only be a reality of tomorrow [13-15], and then only for selected procedures. But even for those the implementation of NOTES will be to a large extent a patient-driven process.

Comparison of open and laparoscopic procedures is no longer an open debate. Scientific proof for superiority of the laparoscopic approach was in most cases obtained after the procedures were introduced to everyday practice. The explosion of laparoscopic surgery in the 90s required only limited scientific data and was largely based on the cosmetic benefit. All the unknown was justified by avoiding the laparotomy scar. Nowadays with all the EBM data the advantages of laparoscopy are obvious not only for health care professionals but also for potential patients. The laparoscopic approach is commonly known for better cosmesis, reduced postoperative pain, shorter hospital stay and smaller infection risk. This belief was illustrated in our study as laparoscopic access was the most preferable and well perceived. It was indicated to be the most attractive. Transvaginal NOTES cholecystectomy in general was a runner-up. In a study performed by Swanstrom *et al.* NOTES chole-

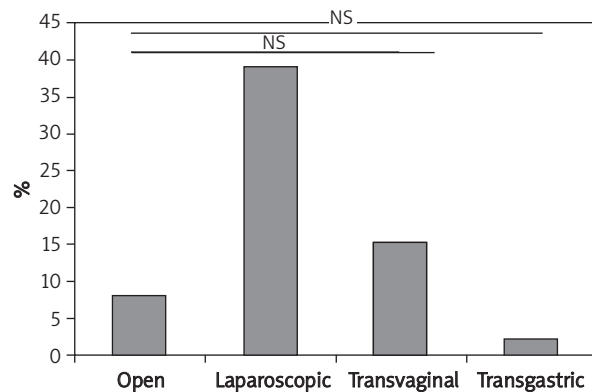


Figure 3. Overall preference of the access presented as number of answers (“I do not know” bar not shown)

cystectomy was preferred (56% of the respondents) over laparoscopic cholecystectomy (44%) [16]. In Peterson’s study the surveyed Californian population showed even more enthusiasm towards transvaginal NOTES (68% would want a transvaginal procedure) [17]. For the studied subjects fear of complications and anticipated pain were more important factors than cosmetic benefit and all together their perception of benefits against risks was more favorable for transvaginal NOTES cholecystectomy. In our study this advantage was not observed ($p = 0.667$).

Origin of transvaginal access acceptance

It is obvious that there is a group of patients with special attention for the body image and for those the benefits offered by NOTES are undeniable [18]. In those patients, however, the genitals play an important role in creation of the body image and self perception [19]. This is related not only to the sexual area but somehow represents the perception of general well-being of the patient.

In contrast, there is a group of patients for whom the genitals are perceived mainly for their excretory function and therefore the potential instrumentation or intervention in this intimate field does not imply emotional involvement. Instrumentation during routine gynecological examinations or even the fact that the vagina is a natural way of delivery may explain why such a significant percentage of the study group would accept transvaginal access and consider it as an interesting option for removal of even such a distant and unrelated organ as the gall bladder. Potential concerns might involve the impact on sex life, relation with the partner and fertility issues. These

concerns were illustrated in Peterson's study, especially in young, nulliparous women [16]. In our previous study the general attitude of male sexual partners of potential NOTES transvaginal cholecystectomy patients was negative. This was especially observed in young, sexually active males with high appreciation of sexual life [20]. Potential problems would probably exceed the physical aspect of sexual satisfaction and could impair the emotional areas [18]. These potential problems were raised in a study on gynecologists' perception of transvaginal access [19]. Their main concerns involved postoperative infections, visceral lesions, infertility and adhesions. With scarce evidence in NOTES patients, transvaginal hysterectomy studies could be used for references.

Origin of transgastric access rejection

Although gastroscopy was performed only in 3% of the patients, it is commonly perceived as a painful examination causing large physical as well as psychological discomfort [21]. This common knowledge on gastroscopy might be projected to NOTES technology as a similar endoscope (or even thicker) is introduced through the mouth in the transgastric technique. And this may be an important issue despite the fact that NOTES would be performed under general anesthesia with absence of the feared discomfort. For all the patients who had undergone gastroscopy the transgastric approach was scored worse in all studied aspects. Similar observations were made by other authors [22].

Pain factor

The significantly reduced level of pain in laparoscopic compared to open surgery is obvious not only for doctors but also for society. However, it does not seem so obvious for non-medical subjects that no skin cut at all means even further decrease in postoperative pain. It was described that the visceral wall has much fewer nervous terminal endings responsible for feeling pain than skin and the incision causes incomparably lower pain [8]. However, for the women the expected pain originating from the genital region, although perceived as less severe than that related to the transgastric approach, was scored higher than after a laparoscopic procedure. In other studies the expected pain after NOTES cholecystectomy was lower than after either the open or laparoscopic approach [16, 22]. In a recent study by Hucl *et al.* the preference

of NOTES for appendectomy was greater in patients than physicians and was related to reduced pain and absence of hernia rather than lack of scarring [23].

Technology factor

NOTES technology (especially transvaginal) as a novelty might be additionally appealing to a group of patients who are generally enthusiastic for innovations of any kind. Undergoing revolutionary, technologically advanced surgery might fit their preferences. This determinant however would be expected to be observed more commonly in male patients.

Summary

To summarize, the laparoscopic access was preferable in several aspects, and was followed by the transvaginal access. Open and transgastric approaches were considered as dangerous and disadvantageous. The transvaginal access was scored as "attractive", "cosmetically attractive" and "technologically advanced", as opposed to the transgastric access. The fact of manipulation in the intimate region requires thorough attention in future NOTES studies. The results will allow one to better choose and discuss the NOTES accesses and address the patient concerns.

Conclusions

This study contributes to further development of NOTES technology as a treatment option accepted by patients with special attention to transvaginal access. The perception of NOTES seems to be population specific, as other studies have shown different levels of enthusiasm towards it. Ultimately the evolution of surgical approaches might in selected settings lead to the point where the NOTES technique will be perceived as natural and obvious as laparoscopic surgery is now.

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