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Abstract
Much of the discussion pertaining to natural orifice transluminal endoscopic surgery (NOTES) focuses on technical issues, with little attention to women's perception and to their willingness to consent to this surgery, especially in the field of obesity. Aim of this study was to evaluate obese women's perception of NOTES and trans-vaginal access. Sixty two obese patients undergoing bariatric surgery were given a written description of NOTES with an anonymous questionnaire exploring their concerns and opinions regarding this technique. The risk of complications was the most important aspect with regard to surgical procedures for 87.1% of patients, while the aesthetic result counted only for 16.1%; none of the patients would accept an increased risk of surgical complications for a better aesthetic result, and 74.2% of them would prefer a standardized traditional surgical approach. Nulliparous women were more concerned about the potentially negative effects of NOTES on fertility than multiparous women and younger women were more worried about the effects on sexual function than older women. 83.9% of patients refusing NOTES stated that the main reason for their refusal was the lack of definitive data on the beneficial effects. Bariatric NOTES potentially offers obese women a scarless intervention, but only a few obese women expressed worries about the cosmetic/aesthetic effects of surgery, while most of them were worried about effects on future fertility and sexual life. Our study highlights a strong need for early reporting of outcome data to enlighten patients about this new approach to bariatric surgery.

Introduction

Recent technological advances in the field of minimally invasive surgery have led to the development of natural orifice transluminal endoscopic surgery (NOTES). This new surgical concept enables abdominal operations to be performed through natural orifices, such as the mouth, urinary bladder, vagina or rectum using instruments introduced within a flexible endoscope [*1–3*] and could minimize incision-related complications such as wound infections, incision pain, hernias and adhesions. Furthermore, the cosmetic results of abdominal procedures could be further improved, inasmuch as it is a potentially scarless surgery. Minimizing incision-related complications could be even more important in the obese patient due to the negative effects of the thick abdominal wall causing greater postoperative pain and higher incisional hernia incidence rates [*4*].
The first report of a bariatric NOTES procedure in humans was published in 2008 by Ramos et al. who presented their experience with trans-vaginal sleeve gastrectomy [*5*]. So far, much of the published data concern case reports, the technical training aspects of NOTES, new technologies and costs of the procedure [*5*, *6*], while only few data are available on the acceptance of the NOTES approach by the general public.

Trans-gastric and trans-vaginal access to the peritoneal cavity via incision of the stomach or the posterior fornix of the vagina is associated with the possibility of complications, but it is still not possible to quantify this risk. Furthermore, for different reasons, women seem to be reticent to accept surgical access to the peritoneal cavity through the genital tract [*7*].
Although the acceptance of trans-vaginal NOTES procedures has been studied in a few papers [*7–10*], to date no study exists on the perception of this approach by obese women undergoing bariatric surgery. Since bariatric surgery could be one of the applications of NOTES in the near future, it would be of critical importance to highlight the patients' position on it. This study was carried out with the aim of investigating female bariatric patients' opinion about this new access to the abdominal cavity.

Materials and Methods

Study Population

This study was a 6-month cross-sectional survey of the perception of the trans-vaginal NOTES approach by obese women. The patients were collected among women undergoing bariatric surgery at the Digestive, Colorectal and Minimal Invasive Surgery Centre of the University of Torino. Patients were eligible for the study if they met the following criteria: female gender; age 18–60 years; body mass index (BMI) of 35–40 kg/m^2 and obesity-related comorbidities or BMI > 40 kg/m^2 irrespective of the presence or absence of comorbid conditions; ability to read and complete the questionnaire.

Questionnaire

The questionnaire used in the present survey was specifically prepared for the study. The questionnaire was consigned to patients evaluated for bariatric surgery by a bariatric surgeon of our department who clearly specified to be a member of the surgical team and who clearly explained the anonymity of the paper and that their answers would not influence the surgical indication or the technique proposed.
The patients were clearly told that NOTES was currently not being practiced in the department and that they would not be offered NOTES for their bariatric procedure. The participants were allowed to complete the questionnaire on receiving it or to return it later.
The document consisted of informations regarding the anonymity of the questionnaire, the research nature of the questionnaire itself and a descriptive part of the technical procedure of NOTES, drawing attention to the potential benefits to be derived from this type of surgery and explaining that it is a relatively new and not established technique, with still limited data on the outcome and the safety profile.
The questionnaire itself consisted of two parts. The first one was designed to register demographic data. The following data were collected: weight (kg) and height (m), age (years), education status (classified as primary school, junior high school, senior high school, university), co-morbidities (cardio-vascular diseases, respiratory and metabolic disorders), previous abdominal surgical procedures, data on parity (number of pregnancies, number of term deliveries and mode of delivery). Furthermore, it was asked if patients knew the existence of the NOTES technique before participating in the survey (yes/no) and to score from 1 (no importance) to 5 (most important) the following aspects of surgical procedures: risk of complications, postoperative pain, hospital length of stay, recovery time, aesthetic result.
The second part of the questionnaire was designed to analyse the perception of patients as to NOTES and was composed of 13 questions (Appendix 1).

To compare results between sub-groups, patients were classified as of low educational status (primary school and junior high school, n=30) and high educational status (senior high school and university, n=32), as nulliparous if they had no deliveries (n=14) and multiparous when they had one or more deliveries (n=48) and as younger (18–40 years old, n=24) and older (41–60 years old, n=38).

Statistical Analysis

The data were entered into a prospective spreadsheet in Excel 2007 (Microsoft Corp., Redmond, WA, USA) and analysed using SPSS software (SPSS Inc., Chicago, IL, USA). Continuous variables were reported as mean ± standard deviation. Categorical variables were reported as frequencies and percentages and were compared by chi-square test with Yates correction. The reported p values are two-tailed. A value of $p<0.05$ was considered to be statistically significant.
The study protocol was approved by the local Ethical Committee.

Results

Between January and June 2009, 136 obese women underwent bariatric procedures in our department. The questionnaire was proposed to all of them; 95 patients (69.9%) agreed to fill in the form and 62 (45.6%) of them returned it fully completed, thus entering the study.
Mean BMI (calculated as weight in kg/height in m^2) was 45.3 kg/m² (range, 35.3–66.6). Data concerning age, educational status, co-morbidities, previous abdominal surgery and parity are shown in Table 1.
Table 1
Study population

	Number of patients (N)	**Percent (%)**
Age, years		
18–40	24	38.7
41–60	38	61.3
Educational status		
Low level	30	48.4
Primary school	6	
Junior high school	24	
High level	32	51.6
Senior high school	24	
University	8	
Comorbidities		
Cardio-vascular diseases	10	16.1
Respiratory diseases	8	12.9
Metabolic diseases	22	35.5
Previous abdominal surgery		
Yes	36	58.1
No	26	41.9

	Number of patients (N)	Percent (%)
Parity status		
Nulliparous	14	22.6
Multiparous	48	77.4

Eight patients out of 62 (12.9%) reported that they had previous information about NOTES before reading the questionnaire.

The score for the five main characteristics of surgical procedures are shown in Fig. 1. Mean values were 4.8□±□0.5 for complications risk, 3.6□±□1.0 for postoperative pain, 2.6□±□1.1 for hospital length of stay, 2.5□±□1.3 for recovery time and 2.3□±□1.4 for cosmetic/aesthetic result. Specifically, the risk of complications was classified as most important by 87.1% of patients; postoperative pain, hospital length of stay and recovery time were classified as most important by 19.4%, 4.8% and 16.1% of patients, respectively; finally, the cosmetic/aesthetic result of the surgical procedure was considered as most important by 16.1%. Comparison between younger and older patients as regards to the importance of surgical scars did not show statistically significant differences.

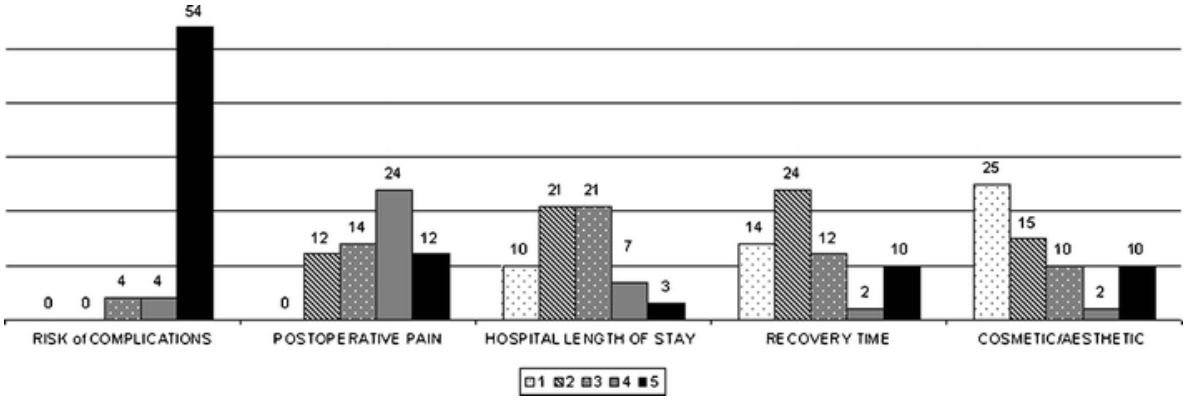

Fig. 1

Score evaluation of the main characteristics of surgical procedures. [Question: How do you rate the following characteristics of a surgical operation? (1 not important—5 most important)”]

The answers to the questions on NOTES are summarized in Table 2.

Table 2

Questionnaire results

Questions	Number of patients (N)	Percent (%)
Now that you know about the existence of NOTES, would you prefer an established current technique (laparoscopy, open surgery)?		
Yes	46	74.2
No	16	25.8
Would you agree to a higher risk of complications for a better aesthetic result?		
Yes	0	0
No	62	100
Would you agree to undergoing a trans-vaginal surgical procedure?		
Yes	14	22.6
No	48	77.4
Would you agree to undergoing a trans-gastric surgical procedure?		

Questions	Number of patients (N)	Percent (%)
Yes	34	54.8
No	28	45.2
If you answered that you would agree to undergoing a trans-vaginal or trans-gastric procedure, why would you do so?		
To improve cosmetic/aesthetic results	8	22.2
To minimize the risk of incisional hernias	32	88.9
To minimize postoperative pain	34	94.4
Would you agree to a NOTES approach for both benignant and malignant diseases or only for minor benignant diseases such as appendicitis or gall bladder stones?		
Both	30	48.4
Only minor benignant diseases	32	51.6
Are you concerned about infection issues with NOTES?		
Yes	52	83.9
No	10	16.1
Are you concerned about how the trans-vaginal NOTES approach might effect your sexual life?		
Yes	50	80.6
No	12	19.4
Are you concerned about future fertility issues of trans-vaginal NOTES approach?		
Yes	36	58.1
No	26	41.9
Would you suggest this approach to a female member of your family?		
Yes	38	61.3
No	24	38.7
If research data demonstrated that the trans-vaginal approach is equivalent with regard to risk of complications to the laparoscopic one, would you prefer the trans-vaginal method?		
Yes	32	51.6
No	30	48.4
If research data demonstrated that the trans-gastric approach is equivalent with regard to risk of complications to the laparoscopic one, would you prefer the trans-gastric method?		
Yes	40	64.5
No	22	35.5
If you refused a surgical procedure with the NOTES approach, why would you do so?		
Too high risks	6	9.7

Questions	Number of patients (N)	Percent (%)
Lack of definitive data on benefits	52	83.9
No interest	4	6.5

A total of 74.2% of patients stated that even with knowledge of NOTES they would still prefer a traditional surgical approach (open surgery or standard laparoscopy); the analysis by educational level showed that the traditional approach was indicated as the preferred method by 80% of patients with lower education level compared to 68.7% of patients with higher educational level (p = 0.4707). A personal history of previous abdominal surgery was not statistically significant with regards to the preference of traditional techniques to NOTES.

None of the patients would accept an increase in complication rates in favour of a better aesthetic outcome. A total of 22.6% of patients would accept a trans-vaginal procedure compared to 54.8% for a trans-gastric one; overall, 36 patients (58.1%) would accept a trans-vaginal and/or a trans-gastric approach. Among patients agreeing to a trans-vaginal or trans-gastric approach, 22.2% would undergo it for an aesthetic purpose, 88.9% to minimize the risk of incisional hernias and 94.4% to reduce post-operative pain (multiple answers were possible).

A total of 83.9% of patients stated that they were concerned about the post-operative infection rate related to the NOTES approach. The possible effects of a trans-vaginal NOTES procedure on sexual life were considered as worrying by 80.6% of patients. Among patients aged 18–40 years, 100% showed worries about NOTES' effects on sexual life, whereas among patients aged 41–60 years, only 68.4% did (p = 0.0062). The effects of this approach on future fertility status were considered worrying by 58.1% of patients. Classifying patients into nulliparous and multiparous, the influence of NOTES on future fertility was considered as an important worry for 85.7% of the nulliparous women compared to 50% of multiparous ones (p = 0.0380).

Overall, 61.3% of patients would suggest the NOTES approach to a female member of their family. In the event that research studies demonstrated that the trans-vaginal approach is equivalent to the laparoscopic one in terms of risks of complications, 51.6% of patients would choose the trans-vaginal method; for the trans-gastric approach, this percentage was 64.5%.

Finally, when asked about the reason why they would refuse a NOTES procedure, 9.7% indicated that it is too dangerous, 83.9% indicated the lack of defined beneficial effects and 6.5% declared that they were not interested in it.

Discussion

In the last few years, many reports have been published on NOTES procedures, with both trans-vaginal and trans-gastric approach [*11–14*]. The majority of these were performed with the so-called hybrid technique with the help of at least one laparoscopic port. Of the possible accesses, the vagina has gained most popularity since it is readily accessible, is easy to decontaminate and provides safe entry and simple closure [*15*, *16*]. In the specific field of bariatric surgery, technical reports and limited case series describing sleeve gastrectomy have been published [*5*, *17–20*] but with very few of these reporting medium-long-term results and the women's opinion about this technique [*8*, *21*].

The first cases of sleeve gastrectomy with hybrid access laparoscopic/trans-vaginal were published in 2008 by Marchesini et al. [*19*]. The authors concluded that sleeve gastrectomy should be performed in the traditional laparoscopic way, while the NOTES technique should be used to explore the abdominal cavity and the trans-vaginal access adopted as a collateral port to extract the operative specimen. Fisher et al. [*20*] reported a similar technique with the help of only one abdominal port to enable the safe trans-vaginal introduction of the instruments under vision in order to minimize the complication rate. They highlighted that the obese patient mostly benefits from this

approach, which reduces the risk of hernia and post-operative pain, resulting in a more rapid recovery and return to normal activities.

To the best of our knowledge, no study exists regarding obese women's perceptions of trans-vaginal NOTES surgery. Some papers report data on women's opinion on NOTES technique in general. Peterson et al. [*8*] reported that in 100 women asked for NOTES cholecystectomy 73% would consider a trans-vaginal procedure, and 68% indicated that if the data show equivalency between laparoscopic and trans-vaginal procedures, they would prefer the latter approach. On the other hand, in another recent paper [*22*], observational data from 300 women revealed that 75% were indifferent or sceptical towards the NOTES technique for cholecystectomy, even if the two approaches (NOTES and laparoscopy) were defined as similar in outcome. In Rao et al. [*9*], a hypothetical scenario was given in which the respondent presents as an emergency in a hospital requiring an appendectomy. Only 34.4% of participants feel comfortable with the use of newer surgical techniques without evidence of a safety profile, and the NOTES approach would be chosen by 11.8% of participants.

In our survey on obese women, the NOTES approach would be chosen by 25% of participants, while 75% would prefer more standardized surgical techniques.

One of the main results of our survey is that the aesthetic result of a surgical procedure is not seen as a critically important aspect by obese women: only 16% of patients placed this aspect as the most important. This is probably due to the fact that pathologically obese women are more interested in reducing co-morbidities and improving their quality of life than in getting better aesthetic results, inasmuch as loss of weight is a satisfying aesthetic result itself, regardless of the presence of surgical scars. Moreover, we did not find any significant age-dependent differences regarding aesthetic concerns.

On the other hand, the safety profile of surgical procedures was considered to be of vital importance; in our sample, the risk of complications was considered the most important aspect of a surgical procedure by nearly 90% of patients. This result is in line with other published surveys [*7*, *8*, *21*, *22*]. In a recent paper [*23*] on 420 subjects, the most important concern regarding surgical therapy was the fear of surgical complication, with 92% placing it first, whereas postoperative scars were the first concern for only 2% of the participants. Furthermore, analysing the relationship between surgical scars and the risk of complications, 86% of subjects would choose a larger scar but lower risk, whereas only 11% would choose a smaller scar but higher risk.

It seems evident that the current lack of strong data on the safety profile of NOTES worries potential patients: three quarters of our patients would prefer a traditional, standardized surgical approach, and when asked why they would refuse a NOTES procedure, the absence of definitive data on real benefits was indicated by 84% of patients.

A significant aspect of this scepticism comes from the analysis of the educational status of patients as patients with a lower-level education preferred the traditional approaches compared to more highly educated women as reported also by other authors [*21*]. This might mean that a higher educational status leads to a greater interest in technological innovations and confidence in medical progress. In any case, this result underlines the importance of taking into account the cultural background of patients when different surgical approaches are proposed.

With regards to the possible access of NOTES, we registered a significant difference between the patients' perception of the trans-gastric versus trans-vaginal method: while 55% of patients would accept the former, only 23% would accept the latter. This result is in line with other published data. In Rao et al. [*9*], when asked to choose a preference for what orifice to use for NOTES, the oral route was the most preferred, and in Varadarajulu et al. [*7*] the oral orifice was the preferred approach for NOTES for 85% of patients. The reason for this preference is not completely clear but may be related to concerns about the effects of vaginal scars on subsequent fertility and sexual life. In fact, when considering specifically trans-vaginal access, it is important to emphasize patients' concerns and the strong influence of their age and parity status. In our survey, there was a statistically significant difference between younger and older patients on concerns about subsequent

sexual life: whereas all patients aged less than 40 expressed concerns, this was true for only 68% of patients older than 40. Regarding the future effects on fertility, the parity status showed a similar effect: trans-vaginal NOTES effects on fertility were a concern for 85% of nulliparous patients versus 50% of multiparous ones. Our results are in line with other papers [*8*, *22*] showing similar concerns about fertility and sexual life. In a recent paper, Bucher et al. [*10*] reported that 96% of a female population analysed for perception of conventional laparoscopy, transumbilical single-access surgery and trans-vaginal NOTES for cholecystectomy were worried about trans-vaginal access. The most important concerns were dyspareunia (68%), decreased sensibility during intercourse (43%), refusal of short-term post-operative sexual abstinence (40%) and infertility (23%).

We recognize several limits in the present study. The sample size is relatively small and a larger survey may better delineate age or parity differences; moreover, our study population is predominantly comprised of older, multiparous women and this again may introduce bias into our results. Furthermore, our survey was conducted in a surgical department were NOTES procedures are not performed, with possible effects on surgeon's knowledge of the technique and patient's confidence on it. Lastly, our questionnaire was not evaluated for validity or reliability since the time required to verify a survey questionnaire form would be excessive for the purpose of this study. Despite these limits, the major strength of the study is the fact that it is the first to give findings on obese womens' perception of trans-vaginal NOTES. Since bariatric surgery could be one of the applications of NOTES in the near future, it is of critical importance to highlight the patients' position.

In conclusion, since the public perception of new technologies plays an important role in the agreement or refusal of surgical procedures, we need to offer our patients more data on the safety profile of trans-vaginal NOTES compared to more standardized approaches such as standard laparoscopy. If future research demonstrates that trans-vaginal NOTES is equivalent to standard laparoscopy, it is possible that obese women will be more open to this option: in the present survey, only 22% of women would accept trans-vaginal NOTES, but this percentage increased to 52% in the case of a demonstrated similarity between NOTES and laparoscopy. Young nulliparous women represent the patient category that most needs to overcome the scepticism due to the as-yet badly defined complication rate regarding fertility and sexual life effects of trans-vaginal access.

Conflicts of Interest

Stefano Rocchietto, Gitana Scozzari, Alberto Arezzo and Mario Morino have no conflicts of interest.

Appendix 1

Questionnaire

1. now that you know about the existence of NOTES, would you prefer an established current technique (laparoscopy, open surgery)?
   - ❑ yes
   - ❑ no
2. would you agree to a higher risk of complications for a better aesthetic result?
   - ❑ yes
   - ❑ no
3. would you agree to undergoing a trans-vaginal surgical procedure?
   - ❑ yes
   - ❑ no
4. would you agree to undergoing a trans-gastric surgical procedure?
   - ❑ yes
   - ❑ no
5. if you answered that you would agree to undergoing a trans-vaginal or trans-gastric procedure, why would you do so?
   - ❑ to improve cosmetic/aesthetic results
   - ❑ to minimize the risk of incisional hernias
   - ❑ to minimize postoperative pain
6. would you agree to a NOTES approach for both benignant and malignant diseases or only for minor benignant diseases such as appendicitis or gallbladder stones?
   - ❑ both
   - ❑ only minor benignant diseases
7. are you concerned about infection issues with NOTES?
   - ❑ yes
   - ❑ no
8. are you concerned about how the trans-vaginal NOTES approach might effect your sexual life?
   - ❑ yes
   - ❑ no
9. are you concerned about future fertility issues of transvaginal NOTES approach?
   - ❑ yes
   - ❑ no
10. would you suggest this approach to a female member of your family?
    - ❑ yes
    - ❑ no
11. if research data demonstrated that the trans-vaginal approach is equivalent with regard to risk of complications to the laparoscopic one, would you prefer the trans-vaginal method?
    - ❑ yes
    - ❑ no
12. if research data demonstrated that the trans-gastric approach is equivalent with regard to risk of complications to the laparoscopic one, would you prefer the trans-gastric method?
    - ❑ yes
    - ❑ no
13. if you refused a surgical procedure with the NOTES approach, why would you do so?
    - ❑ too high risks
    - ❑ lack of definitive data on benefits
    - ❑ no interest

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