

Transvaginal natural orifice transluminal endoscopic surgery (NOTES): a survey of women's views on a new technique

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Abstract

Background Laparoscopic and minimally invasive surgery has changed the surgical landscape irrevocably. Natural orifice transluminal endoscopic surgery (NOTES) offers the possibility of surgery without visible scars. Transvaginal entry offers potential benefits because it gains access to the peritoneal cavity without the need to open an abdominal viscus. Much of the discussion pertaining to NOTES focuses on technical and training issues, with little attention to date paid to the opinions of women. The perceptions of female health care workers and patients were sought in relation to their views on transvaginal NOTES. **Methods** This study surveyed 300 women using a 12-point questionnaire devised by a multidisciplinary group of surgeons interested in minimally invasive surgery. The questionnaire was designed to establish the opinions of women with respect to NOTES surgery versus standard laparoscopic procedures. Responses were de-identified. **Results** Three-fourths of the women surveyed were neutral or unhappy about the prospect of a NOTES procedure, and this remained constant even when it was stipulated that laparoscopic cholecystectomy and NOTES had equivalent safety and efficacy. Younger nulliparous women were most concerned about the potential negative effect of NOTES on sexual function. A minority were concerned about the cosmetic effect of surgery, although surgical scars were perceived as more important to younger respondents.

Conclusions Potentially, NOTES surgery offers women a scarless operation with the possibility of less pain than experienced in standard laparoscopic surgery. Few women, however, were troubled about the cosmetic effect of surgery. The effect of NOTES on sexual function was expressed as a particular concern by younger women. In all groups and across all ages, peritoneal access using the transvaginal route was met by significant scepticism. In Australia, women remain to be convinced about the potential advantages of the emerging NOTES technology.

Keywords NOTES · Patient perceptions · Questionnaire · Transvaginal cholecystectomy

Over the past 20 years, laparoscopic surgery has become the accepted gold standard for many operations previously performed via laparotomy. The commonly noted advantages of a rapid recovery time, a shorter hospital stay, reduced pain, and improved cosmesis after such interventions are widely reported [1–4]. Laparoscopic cholecystectomy (LC) particularly has been embraced worldwide. Many hundreds of thousands of patients undergo LC annually, with acceptably low rates of morbidity and mortality [5].

Recent technological advances in the field of minimally invasive surgery have culminated in the development of natural orifice transluminal endoscopic surgery (NOTES) [6]. This technique allows excision of organs such as the gallbladder, the ovary, and the appendix using instruments introduced into the peritoneal cavity within a flexible endoscope [7–9]. The flexible scope may be introduced into the peritoneal cavity via the vagina, the stomach, or the rectum.

The transvaginal approach to the abdomen has been championed because it would avoid a breach of the

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gastrointestinal tract, thereby preventing possible contamination of the peritoneal cavity [10]. In addition, use of the female genital tract to gain access to the peritoneal cavity without transgression of the abdominal wall may further improve recovery times, avoid abdominal scars, and cause less pain than standard laparoscopic operations [11].

The issues surrounding NOTES parallel the debates that took place at the introduction of laparoscopic surgery. Much of this discussion centers around the technical, training, and financial considerations of the procedure [12, 13]. Little significance has been given to acceptance of the practice by the general public.

Transvaginal access to the peritoneal cavity via an incision at the posterior fornix of the vagina clearly is associated with the possibility of complications, but quantification of this risk currently is not possible. In addition, for a variety of different reasons, some women may be reticent to accept surgical exploration of the peritoneal cavity using this route of entry.

Public interest in minimally invasive surgery is high, and the importance of a generally positive perception of this technique is likely to be extremely important to the success or failure of such an intervention. To date, we are unaware of any transvaginal NOTES cholecystectomy procedures undertaken in Australia, and no data exist as to the attitudes of female Australians toward such a concept.

This study first aimed to investigate the opinions of female patients and health care workers at a teaching hospital with respect to their acceptance or rejection of NOTES compared with standard laparoscopic surgery. Second, the study investigated the surveyed population with respect to the effects of age and parity on the opinions expressed.

Materials and methods

The attitudes of females toward the possibility of undergoing a NOTES procedure via the transvaginal route of the peritoneal cavity entry was assessed using an anonymous questionnaire. Three groups were selected in an attempt to investigate whether the setting in which the questionnaire was delivered influenced the results. Group 1 consisted of female health care professionals. Group 2 was composed of patients who were to undergo or had undergone a LC. Group 3 comprised patients attending a gynecologic clinic. Three similar questionnaires (varying only due to the setting of the patient) were constructed. Approval for use by the local ethics committee at the investigating hospital was obtained.

Appendices 1, 2, and 3 show these questionnaires in full. The de-identified questionnaires were collated by a single independent researcher and analyzed using SPSS statistical software, version 17.0 (SPSS Inc., Chicago, IL) to compare responses between groups, ages, and parity.

Results

For this study, 300 individuals were surveyed including 195 health professionals (HP), 37 patients who were undergoing or recently had undergone LC, and 68 gynecologic clinic (GC) patients. The demographics of the three groups did not vary significantly except that the LC group was found to be significantly older (see Table 1 for raw data). The vast majority of the individuals surveyed were Australian or European born. Except for scars after surgery, very similar responses (no statistical differences) were obtained from the three groups.

When asked whether they disliked scars after a surgical procedure 66% replied “no.” This response was similar between the HP (64%) and GC (67%) patients, but more frequent among the LC patients (86%). When the patients were divided according to age, cosmesis appeared to become more of an issue, with 37% of 20- to 39-year-olds disliking scars compared with 29% of 40- to 55-year-olds and 11% of patients older than 55 years ($p = 0.012$, chi-square). The response to the issue of cosmesis was not statistically different between the parous and nulliparous women.

The subsequent question asked whether it would be preferable to undergo an alternative operative method that avoided abdominal scars. To this question, 58% responded “yes,” although this was less likely with increasing age ($p = 0.01$, chi-square). The respondents then were requested to rank how they felt about having an abdominal operation through the vagina. They responded by circling one of five responses: very happy, happy, unsure, unhappy, or very unhappy. Whereas 32% said they would be unhappy or very unhappy to undergo a transvaginal procedure, 18% stated that they would be happy or very happy. The remainder (50%) felt neutral.

These findings were similar among the three different age groups. However, the parous patients were more likely to be happy or very happy with a transvaginal procedure than the nulliparous women ($p = 0.03$, chi-square).

The questionnaire then asked whether the patients would be concerned that a NOTES procedure might have a negative effect on their sexual function. Overall, 42% of the women were concerned with this possibility, although this appeared to be markedly influenced by age ($p = 0.003$, chi-square). Younger respondents were more concerned with this possibility: 50% of the 20- to 39-year-olds, 32% of the 40- to 55-year-olds, and 34% of the patients older than 55 years.

When the patients were asked whether they would prefer NOTES or LC, the majority ($n = 194$, 65%) said they would prefer LC. These results were maintained for the three individual groups and for the patients of different ages and parities. However, the patients who stated that

Table 1 Summary of questionnaire results^a

	Group			
	All	HP	GC	LC
No. of subjects	300	195	68	37
Mean age (years)	39.9	38.8	38.4	48.9
Dislike scars (%)				
Yes	32	36	33	14
No	68	64	67	86
Would prefer alternative method (%)				
Yes	60	70	46	31
No	40	30	54	69
Happy with vaginal operation (%)				
Very happy	5.4	3.6	9	8.3
Happy	12.5	13.9	9	11.1
Neutral	49.8	44.8	62.7	52.8
Unhappy	17.8	19.1	13.4	19.4
Very unhappy	14.5	18.6	6	8.3
Concerns about sexual function (%)				
Yes	42.4	47.7	35.8	25.7
No	31.5	28.5	32.8	45.7
Unsure	26.1	23.8	31.3	28.6
Would prefer NOTES to LC (%)				
Yes	27.1	16.5	43.9	52.9
No	68.1	78.2	53	41.2
Unsure	4.9	5.3	3	5.9
Would you be happy to consider NOTES for gynecologic surgery (%)				
Very happy	10.1	8.8	14.9	8.3
Happy	34.5	34.2	31.3	41.7
Neutral	37.8	35.8	43.3	38.9
Unhappy	10.5	11.9	7.5	8.3
Very unhappy	7.1	9.3	3.0	2.8
Would surgeon gender influence your decision (%)				
Yes	17.9	18.2	22.4	8.3
No	70	68.4	70.1	77.8
Unsure	12.1	13.4	7.5	13.9

All values are percentages (%) unless stated otherwise

HP health professionals, GC gynecology clinic, LC laparoscopic cholecystectomy, NOTES natural orifice transluminal endoscopic surgery

they minded scars were more likely to want a NOTES procedure ($p = 0.03$, chi-square). The patients were no more likely to prefer NOTES for a gynecologic procedure. Again, no difference was observed among the three different groups (HP, LC, and GC), age groups, or parities. Finally, only 17% of the patients stated that surgeon gender would influence their decision to undergo a NOTES procedure. This decision was not influenced by patient age or parity.

Discussion

Transvaginal NOTES appears to be technically possible. However, the globalization of such a technique may well

depend on the degree of acceptance from the general public. Although safety and efficacy are of primary importance, issues of the patients' perception of abdominal scars and the influence of such surgery on sexual function may well have an impact on the widespread acceptability of such a procedure. This study represents the largest survey of women's attitudes about transvaginal NOTES published to date.

The questionnaires were given to three different groups in an attempt to investigate whether the setting of the survey influenced responses. It was postulated that patients attending a gynecologic clinic would be more open to the possibility of undergoing a NOTES type procedure. Similarly, it was suggested that after an LC, patients would

react more favorably to an option that might cause less pain and leave no visible scars.

The settings, however, did not affect the answers obtained from the groups except for cosmesis. This may well be an effect of the higher mean age of the respondents in the LC group compared with the remaining two sets of responders. The fact that the LC group was not more in favor of the NOTES procedure suggests that postoperative pain relief in this group was adequate. Similarly, the administration of a NOTES questionnaire in a gynecology outpatient setting did not make women more accepting of a transvaginal operation.

The results from this survey suggest that one major incentive for the NOTES procedure, the absence of abdominal scars, might not be such an important factor for many patients. The majority of women (66%) are not concerned about the scars produced by surgery. However, as might perhaps be expected, younger respondents were more concerned with cosmetic issues, although this still remained a minority response. When given the option of an operation that did not produce scars, scarcely more than half of the individuals surveyed responded positively, although this response decreased significantly with increasing age.

These results suggest that cosmesis is very much the province of the younger group, although not exclusively. In this survey, only 1 in 10 respondents older than 55 years were concerned by scars after surgery. It appears that even in the youngest group, only one-third of the patients indicated that they disliked scars produced by routine laparoscopic surgery.

The results of this study appear to be in contrast to those obtained from previously conducted investigations, all conducted in the United States. In the Peterson et al. [14] survey of 100 women, 68% showed a preference toward a NOTES procedure due to the lower risk of abdominal hernia and a possible reduction in postoperative pain. Concern with respect to cosmesis, however, was remarkably similar to the results presented in this article (34%), with only 39% of the patients highlighting this as an important feature of the NOTES surgery. Perhaps as expected, nulliparous and younger women (<40 years) were more concerned with the possible impact of NOTES surgery on their sexual function and fertility.

A second study conducted by Swanstrom et al. [15], demonstrated that 56% of the 192 patients surveyed would choose a NOTES procedure over an LC. Again, cosmesis was not nearly as important as procedure-related risks, pain, and recovery time. Finally, Varadarajulu et al. [16] in a survey of 100 patients comprising men and women found that 78% preferred that their cholecystectomy be performed with a NOTES procedure. In general, older female

patients and those with prior endoscopic experience were more likely to opt for the NOTES option.

Australian women appear to be less convinced about the potential benefits of NOTES procedures than their American counterparts. This may be due to cultural differences, but a more likely explanation is public awareness and perception of the technique. Because much of the NOTES technology has been developed in the United States, it likely has a much higher profile in both the mass media and the medical literature. Public interest in minimally invasive procedures is high, and new procedures may thus be championed with little convincing evidence. A number of procedures have now been performed with NOTES technology, although no evidence of potential advantages over standard laparoscopic surgery currently exists.

The results of this study and work conducted previously suggests that younger nulliparous women are most concerned with cosmesis, although this group expresses the greatest concern over any change in sexual function. Such a dichotomy is difficult to resolve because NOTES is ideally suited to this group. However, with a paucity of evidence concerning the results of such procedures, little reassurance with respect to preservation of sexual function can be given.

A prospective study investigating a variety of hysterectomy techniques, including vaginal hysterectomy, concluded that sexual function was not negatively affected by any of the surgical methods investigated [17]. Similarly, it may be more difficult to gain access to the peritoneal cavity in nulliparous women than in parous women because their pelvic floor structures have not undergone the changes associated with vaginal fetal delivery.

Surveyed women appear to be concerned about the possibility of a hernia after laparoscopic surgery, although little emphasis has been placed on the possibility of a vaginal herniation after NOTES surgery. Studies of prolapse after vaginal hysterectomy indicate a low rate for this complication, which occurs when pelvic floor tissues are weak preoperatively [18]. After transvaginal NOTES, because the colpotomy is performed in the posterior fornix, the uterine suspensory ligaments (apical support) remain unaffected by the procedure, so the incidence of prolapse (hernia) likely is low. However, detachment of the posterior vaginal wall fascia from the pericervical ring theoretically may increase the risk of posterior vaginal wall prolapse (enterocoele).

Public perception of new procedures such as NOTES is likely to play a large part in the acceptance or rejection of these techniques. Currently, many questions about NOTES remain, although it is hoped that they will be answered by well-conducted, future trials. It seems that such trials in conjunction with a positive mass media portrayal may be required to change current perceptions of this technique among Australian women.

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Appendix 1: Healthcare Professionals Questionnaire

Questionnaire

Background:

Key hole (laparoscopic) surgery using small incisions, is a well established technique. However, there is now a new concept in surgery known as 'N.O.T.E.S.' (Natural Orifice Transluminal Endoscopic Surgery). This utilises a natural orifice (e.g. the vagina) to allow entry into the abdominal cavity so that operations such as a cholecystectomy (removal of the gallbladder) can be performed with the use of specialised equipment. In the case of cholecystectomy, the gallbladder would be removed from the body via the vagina, leaving no visible scars. It may also be potentially less painful. In a few specialist centres, this procedure is now being performed although there are no clinical trials to support its use. As a woman, we would be interested to hear your views regarding the utilisation of the vagina as a way of performing this type of surgery.

Your age: _____ years

Have you had children? **Y/N**

Are you known to have gall stones? **Y/N**

Have you had a cholecystectomy (removal of gall bladder)? **Y/N**

Have you had an abdominal operation before? **Y/N**

Would you mind abdominal scars as part of an abdominal operation? **Y/N**

Would you find it preferable if you could have the operation (laparoscopic cholecystectomy), using an alternative method resulting in no scars? **Y/N**

If yes, is this because of: **a) Cosmetic reasons**
 b) Potential for less pain
 c) Both
 d) Other (please state).....

How do you feel about using the vagina as an entry site for an operation? (Please circle)

a) Very happy b) Happy c) Not sure d) Unhappy e) Very unhappy

Would you be concerned that surgery through the vagina (NOTES) may have a negative impact on your sexual function? **a) Yes b) No c) Not sure**

Would you prefer to have a laparoscopic (key hole) cholecystectomy or a NOTES cholecystectomy?

a) Laparoscopic cholecystectomy b) NOTES cholecystectomy

If NOTES cholecystectomy was shown to be as effective and as safe as laparoscopic cholecystectomy which would you prefer? **a) Laparoscopic cholecystectomy b) NOTES cholecystectomy**

If you required a gynaecological procedure such as a sterilisation, how would you feel about this being performed vaginally (NOTES sterilisation), rather than with standard key hole surgery? (Please circle)

a) Very happy b) Happy c) Not sure d) Unhappy e) Very unhappy

Finally, would the sex of the surgeon influence your decision as to whether to undergo a NOTES procedure?
Yes/No/Unsure

Thank you

Appendix 2: Gynecology Outpatient Group

Questionnaire

Background:

Key hole (laparoscopic) surgery using small incisions, is a well established technique. However, there is now a new concept in surgery known as ‘N.O.T.E.S.’ (Natural Orifice Transluminal Endoscopic Surgery). This utilises a natural orifice (e.g. the vagina) to allow entry into the abdominal cavity so that operations such as a cholecystectomy (removal of the gallbladder) can be performed with the use of specialised equipment. In the case of cholecystectomy, the gallbladder would be removed from the body via the vagina, leaving no visible scars. It may also be potentially less painful. In a few specialist centres, this procedure is now being performed although there are no clinical trials to support its use. As a woman, we would be interested to hear your views regarding the utilisation of the vagina as a way of performing this type of surgery.

Your age: _____ years

Have you had children? **Y/N**

Are you known to have gall stones? **Y/N**

Have you had a cholecystectomy (removal of gall bladder)? **Y/N**

Have you had an abdominal operation before? **Y/N**

Would you mind abdominal scars as part of an abdominal operation? **Y/N**

Would you find it preferable if you could have the operation (laparoscopic cholecystectomy), using an alternative method resulting in no scars? **Y/N**

If yes, is this because of: **a) Cosmetic reasons**
 b) Potential for less pain
 c) Both
 d) Other (please state).....

How do you feel about using the vagina as an entry site for an operation? (Please circle)
a) Very happy, b) Happy, c) Not sure, d) Unhappy, e) Very unhappy

Would you be concerned that surgery through the vagina (NOTES) may have a negative impact on your sexual function? **a) Yes b) No c) Not sure**

Would you prefer to have a laparoscopic (key hole) cholecystectomy or a NOTES cholecystectomy?
a) Laparoscopic cholecystectomy b) NOTES cholecystectomy

If NOTES cholecystectomy was shown to be as effective and as safe as laparoscopic cholecystectomy which would you prefer? **a) Laparoscopic cholecystectomy b) NOTES cholecystectomy**

If you required a gynaecological procedure such as a sterilisation, how would you feel about this being performed vaginally (NOTES sterilisation), rather than with standard key hole surgery? (Please circle)
a) Very happy b) Happy c) Not sure d) Unhappy e) Very unhappy

Finally, would the sex of the surgeon influence your decision as to whether to undergo a NOTES procedure?
Yes/No/Unsure

Thank you

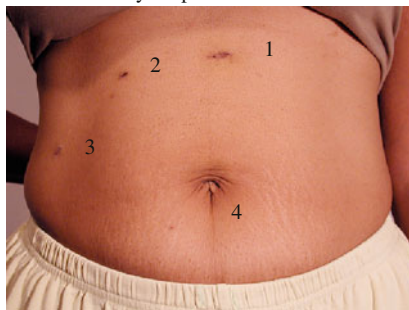
Appendix 3: Laparoscopic Cholecystectomy Group

Questionnaire (Cholecystectomy group)

Background:

You will be having keyhole surgery (laparoscopic cholecystectomy) to remove your gallbladder. This means that you will have 4 small scars as shown in the picture below. New technology has been invented which means that gallbladder operations could now be done via the vagina. This means that you could have the operation with no scars and maybe less pain. This is called *N.O.T.E.S.* surgery.

We would be interested to hear your personal views about having an operation done through your vagina.



Your age: _____ years Your country of birth _____

Have you had children? (Please circle one)
Yes/No

Have you had an operation on your belly before? (Please circle one)
Yes/No

Would you mind having scars on your belly as part of an abdominal operation? (Please circle one)
Yes/No

Would you prefer it if you could have an operation, using an alternative method resulting in no scars? (Please circle one)
Yes/No/Not bothered

If yes, is this mainly because: **a) My belly would look better**
 b) It may be less painful
 c) Other (please state).....

How would you feel about having a belly operation through your vagina? (Please circle one)
a) Very happy, b) Happy, c) Not sure, d) Unhappy, e) Very unhappy

Would you be concerned that surgery through the vagina may have a negative impact on your sexual function? (Please circle one)
Yes/No/Not sure

If a scarless vaginal operation was shown to be as good and as safe as a keyhole operation on the belly, which would you prefer? **a) Keyhole operation b) Scarless vaginal operation**

If you required a gynaecological procedure such as a sterilisation, how would you feel about this being performed through your vagina, rather than with standard keyhole surgery? (Please circle one)
a) Very happy, b) Happy, c) Not sure, d) Unhappy, e) Very unhappy

Finally, would the gender of the surgeon influence your decision whether to undergo an operation through your vagina? (Please circle one)
Yes/No/Not sure

Thank you for your time

This questionnaire was prepared by the University of Adelaide, Masters of Minimally Invasive Surgery Group, and has received ethical approval for its conduct. All information is regarded as strictly confidential.

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