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Female population perception of conventional laparoscopy, transumbilical LESS, and transvaginal NOTES for cholecystectomy

Pascal Bucher · Sandrine Ostermann · François Pugin · Philippe Morel

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Abstract
Background Recent population survey has shown a preference for transumbilical laparoendoscopic single-site surgery (U-LESS) compared with natural orifice transluminal endoscopic surgery (NOTES) for cholecystectomy, assuming similar surgical risk. This study was designed to evaluate the perception and preference of women regarding conventional laparoscopy, U-LESS, and transvaginal NOTES (TV-NOTES) with particular interest to access perception.
Methods An anonymous questionnaire on laparoscopic, U-LESS, and TV-NOTES cholecystectomy, without regards to risks or advantages, was given to female medical/paramedical staff ($n = 100$), patients ($n = 100$), and the general population ($n = 100$). Women participants (median age, 35 (range, 16–79) years) were queried about preference, perception of the different accesses, and personal informations. Of the respondents, 54% had children, 79% had stable relationships, and 96% were sexually active (vaginal intercourse).
Results With similar operative risk, 87% preferred U-LESS, 4% TV-NOTES and 8% laparoscopy. LESS/NOTES choice was influenced by a desire of improved cosmetics (82%) and lower pain (44%). 96% had worries regarding transvaginal access, among them: dyspareunia (68%), decreased sensibility during intercourse (43%), refuse of short-term sexual abstinence (40%), and infertility (23%). Transumbilical access evocated worries in 35%: umbilical pain (19%), postoperative umbilical sensibility (15%), and incisional hernia (11%). Postoperative intercourse abstinence after TV-NOTES evocated worries in 76% (defined as 3 weeks in survey): feel less attractive (40%), less feminine (32%), tension with their intimate (35%), lover non-acceptation (20%), possible abortion of new relationship (26%), and feel less comfortable socially (16%).
Conclusions The high acceptation rate for U-LESS approach compared with TV-NOTES may be related to fears regarding postoperative sexuality and fertility. The importance of temporary postoperative sexual abstinence (vaginal intercourse) is high and may be difficult to influence. Future research on TV-NOTES should focus on the access risk to be able to scientifically reassure our patients. For now, U-LESS seems to be favor compared with TV-NOTES for cholecystectomy in female patients.

Keywords Laparoendoscopic single-site surgery (LESS) · Single port access (SPA) · Single incision laparoscopic surgery (SILS) · Laparoscopy · Natural orifice transluminal endoscopic surgery (NOTES) · Cholecystectomy · Survey · Trans-vaginal · Sexual intercourse · Abstinence

As laparoendoscopic single-site surgery (LESS) continues its diffusion worldwide as a possible future evolution of standard laparoscopy, natural orifice transluminal endoscopic surgery (NOTES) still struggles with limitations related to its accesses [1–4]. However, transvaginal NOTES (TV-NOTES) is sometimes viewed as a particular natural orifice access, mainly because, as transparietal surgery, it is a transepithelial access and allows use of conventional laparoscopic instruments [5]. Thus,

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P. Bucher (✉) · S. Ostermann · F. Pugin · P. Morel
Department of Surgery, University Hospital Geneva, 24 rue Micheli-du-Crest, 1211 Geneva, Switzerland
e-mail: pascal.bucher@hcuge.ch

TV-NOTES has recently been shown to be applicable clinically, at least technically [6]. But many ethical issues remain to be solved regarding this access and scientific knowledge about the real and potential risks of this approach needs evaluation [6–8]. In contrast, few ethical issue have to be overcome in transumbilical LESS (U-LESS), and the potential or real risks of this approach are known, thus allowing clinical research to focus on potential advantages and risk quantification [3, 9, 10].

However, if scientific knowledge regarding safety, curability, and enhanced recovery has ethically to be our main concern regarding development of surgical techniques, we should remember how laparoscopy was pushed forward by patients demand and surgeons' acceptance without any scientific demonstration of superiority [11–13]. Evaluation of patients' perception and interest for minimally invasive surgery at this time would have allowed the surgical community to control its development and diffusion allowing safer evolution from open surgery to minimally invasive surgery respecting the principle of "primum non nocere" [14].

Having learned from the laparoscopic revolution that patients' demand may be one major trigger for surgical evolution, our goal in this work was to investigate women's perception and preference for cholecystectomy between conventional laparoscopy, U-LESS, and TV-NOTES. This question is critical because it may help us to better project surgical research, technical development, and investment regarding the emerging approaches [12].

Methods

Survey development and structure

The investigators (PB, SO) developed the survey (Addendum 1). Elements of the questionnaire included age, educational status, profession, experience of prior surgery, children, marital status, and sexuality. Eight questions regarding perception of different approach for cholecystectomy (laparoscopy, transumbilical LESS or transvaginal NOTES) were submitted. Surveyed woman who preferred transumbilical LESS or transvaginal NOTES were questioned for reasons of their preference and eventual concern on accesses.

Survey population

This study was a cross-sectional survey of preferences for the technique of cholecystectomy, during a 12-week period, of women. Female investigators directly contacted a sample of medical staff and paramedical staff, patients, and general population women. Medical staff responders were university surgeons, internists, and anesthesiologists. Paramedical staff responders consisted of nurses, scrub nurses, and paramedics from university hospital. Patients were collected in the visceral surgery unit, whereas the general population persons surveyed were approach through street interviews. Medical/paramedical staffs and patients were collected in a public hospital. Possible participants from the patient and general population group, which had a medical-related profession, were not included in the survey. The study excluded patients who required emergency surgery, women younger than aged 16 years, and those unable to read and complete the questionnaire.

Survey information

No information on the concept of laparoscopy, transumbilical LESS, and transvaginal NOTES were provided to women surveyed except a description of access together with a drawing illustration possible scars. Operative risk was stated to be similar among surgical approaches. No information about risks, advantages, or scientific knowledge of these techniques was exposed. The possible access referred to LESS was the umbilicus. The orifice referred to NOTES was the vagina. For the last three questions, it was stated that transvaginal NOTES cholecystectomy would imply a vaginal intercourse abstinence of 3 to 6 weeks. These questions investigated the importance of vaginal intercourse abstinence and which technique they would choose knowing that transvaginal may imply this abstinence.

Survey conduction

Participation in the study was voluntary and there was no reward for participation. Surveyed woman were then offered the female investigator (SO) to complete the anonymous eight-question survey in French. Surveyed women were allowed to complete the questionnaire at the time of distribution or to return it later. For some questions, multiple responses were allowed, (i.e., reason for scarless choice, worries regarding accesses, worries regarding vaginal intercourse abstinence), allowing a total of >100%.

Survey sample size

Based on recent population surveys, we assumed that more than 75% would choose the scarless approach [10, 13]. To know whether this proportion was significantly different from the 50% distribution required a sample size of 65 per groups (medical/paramedical staff, patient, and population samples), with an alpha of 0.05 (2 tailed) and a power of 80%.

Addendum 1 Female perception of laparoscopic, U-LESS, and TV-NOTES cholecystectomy survey

Etude abord cholécystectomie

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Participante répondant au questionnaire:

Age: ..... Avez-vous des enfants : ☐ Oui ☐ Non

Formation : ☐ Ecole obligatoire ☐ Collège ☐ Université

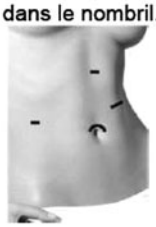
Profession : ☐ Médicale ou paramédicale ☐ Autre

Déjà été opérée du ventre : ☐ oui ☐ non

QUESTIONNAIRE :

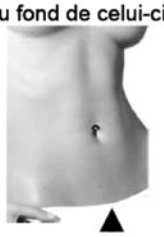
1. **Quelle approche chirurgicale choisiriez-vous pour une opération de la vésicule biliaire si celle-ci ont toutes les même risques :**

Laparoscopie ☐
Quatre petites cicatrices sur le ventre, dont une dans le nombril.



Single Port Access ☐
Une seule cicatrice dans le nombril.

Trans-vaginal NOTES ☐
Un accès au travers du vagin, avec une cicatrice Au fond de celui-ci.



2. **Si vous avez choisit le NOTES trans-vaginal ou le Single Port Access, pourquoi ?**
   - ☐ Absence de cicatrice visible
   - ☐ Moins de douleur éventuelle
   - ☐ Techniques nouvelles
   - ☐ Autre :.....

3. **Quel abord préféreriez-vous pour une opération de la vésicule biliaire sans cicatrice visible (Single port access ou NOTES trans-vaginal):**

   ☐ Nombril ☐ Vagin

4. **Avez-vous des craintes concernant un abord trans-vaginal:** ☐ Oui ☐ Non

   Si vous avez des craintes concernant un abord trans-vaginal, quelles sont-elles :
   - ☐ Partie intime, vous ne voulez pas qu'elle serve d'abord pour une chirurgie du ventre
   - ☐ Douleur lors des rapports sexuels
   - ☐ Perte de sensibilité lors des rapports sexuels
   - ☐ Difficulté pour avoir des enfants
   - ☐ Stérilité
   - ☐ Ne veux pas devoir observer une période d'abstinence liée à la cicatrisation du vagin après l'opération.
   - ☐ Autre: .....

Survey statistics

Categorical variables were reported as frequencies and percentages and were compared by the Chi-squared or ANOVA test. $P < 0.05$ was considered clinically significant. Analysis was conducted by using GraphPad InStat, version 3.1a for Macintosh (GraphPad InStat, San Diego, CA).

Results

Survey respondents

Surveys from 300 women participants were collected, including medical/paramedical staffs ($n = 100$), patients ($n = 100$), and general population sample ($n = 100$). No

Addendum 1 continued

Etude abord cholécystectomie

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5. **Sachant qu'un abord trans-vaginal NOTES, avec cicatrice au fond du vagin, implique une abstinence sexuelle (relation vaginale) allant de 3 à 6 semaines, en l'absence de complication, quel abord préféreriez-vous :**

   ☐ Nombril ☐ Vagin

6. **L'abstinence sexuelle que nécessite l'abord trans-vaginal a-t-elle une importance pour vous:** ☐ Oui ☐ Non

7. **Qu'elle conséquence l'abstinence sexuelle que nécessite l'abord trans-vaginal peut-elle avoir pour vous :**
   - ☐ Vous sentir moins féminine durant cette période d'abstinence.
   - ☐ Vous sentir moins attirante durant cette période d'abstinence
   - ☐ Gêne dans vos relations sociales
   - ☐ Peur que votre conjoint ne puisse l'accepter
   - ☐ Si vous êtes en couple, peur que votre couple en souffre
   - ☐ Autre: .....

8. **Quelle approche chirurgicale choisiriez-vous pour une opération de la vésicule biliaire en sachant que l'abord trans-vaginal NOTES nécessite une abstinence sexuelle (relation vaginale) allant de 3 à 6 semaines en l'absence de complication sur la cicatrice vaginale.**

Laparoscopie ☐	**Single Port Access** ☐	**Hybride** **Trans-vaginal NOTES** ☐
Quatre petites cicatrices sur le ventre, dont une dans le nombril.	Une seule cicatrice dans le nombril.	Un accès au travers du vagin, avec une cicatrice Au fond de celui-ci. +/- une petite cicatrice dans Le nombril

Questions Facultatives:

a) Avez-vous actuellement un conjoint: ☐ Oui ☐ Non

b) Etes-vous actuellement sexuellement active (relation vaginale): ☐ Oui ☐ Non

Merci pour votre participation,

Questionnaire à retourner:
Dr P Bucher, Chirurgie Viscérale, HUG.
Ou
Drsse Sandrine Ostermann, Département de Chirurgie, Chirurgie Viscérale, HUG

significant demographic differences were observed between the three different groups except for education level (e.g., university studies were more frequent in medical/paramedical staffs) and medical professions were only represented in the medical/paramedical staff group. Median age of women participants was 35 (range, 16–79) years and 54% had children. Among survey responders, 79% had a stable relationship and 96 were sexually active (i.e., vaginal intercourse).

Surgical approach preference

When responding to the question of a hypothetical cholecystectomy with the same risk among different techniques,

87% of the women would opt for U-LESS approach, whereas 4% would prefer TV-NOTES, and 8% laparoscopy. These rate where not influence by having children with a 6% preference rate for TV-NOTES compared with 3% for nulliparous women ($P = 0.415$).

If the necessity of postoperative vaginal intercourse abstinence was taken into account as well as a hybrid approach for TV-NOTES, women preferences were: 89% for U-LESS, 9% for laparoscopy, and only 2% for hybrid TV-NOTES. If they had to choose only between hybrid TV-NOTES with sexual abstinence and U-LESS, 99% would choose the second. Age, education, profession, marital status, children, and sexuality did not influence these results.

Reasons for scarless surgery (i.e., U-LESS and TV-NOTES) preferences were: reduce scarring (82%); potentially reduce pain (34%); innovative techniques (5%); and various others (2%).

Transvaginal access

The possibility of transvaginal access evocated worries in 96% of the women participants. The most frequent was fear of pain during vaginal intercourse after TV-NOTES cholecystectomy for 68%, whereas for 43% decrease vaginal sensibility postoperatively was feared. Twenty-three percent had worries about eventual infertility and 6% about eventual sterility. Fourteen percent had various other worries, such as non-healing, infection, prolonged vaginal discharges, and abscesses. Of importance, 62% of the women surveyed thought that it is a too intimate access for cholecystectomy. These results were not influenced by education, profession, or marital status. However, having children and age older than 45 years was associated with a decrease in fears of infertility or sterility ($p < 0.05$ and $p < 0.001$, respectively).

Transumbilical access

A transumbilical access interestingly evocated worries in 35% of women responders. Nine percent thought it was a too intimate access. The most common worry was postoperative pain (19%), followed by possible decreased sensibility (15%) and risk of incisional hernia (11%). Two percent pointed out various others concerns, including umbilical deformation. Age, education, profession, marital status, children, and sexuality did not influence these results.

TV NOTES and postoperative intercourse abstinence

TV-NOTES cholecystectomy and its related temporary postoperative sexual abstinence (vaginal intercourse) were associated with worries in 76% of women surveyed. Age, profession, education, marital status, and sexuality did not influence this rate. The different worries are summarized in Table 1. Although these worries illustrate the potential impact of transvaginal access and vaginal intercourse abstinence on the psychological health of women, these rates are not influenced by age, education, profession, marital status, and children, except for fear regarding abortion of a potential new relationship, which was significantly higher in women who did not have children ($p < 0.01$) or were not involved in a stable relationship ($p < 0.001$). On multivariate analysis, this rate was only influenced by the absence of a stable relationship.

Table 1 Women participant worries regarding post-operative vaginal intercourse abstinence after TV-NOTES

Worries	% of participants
Feeling less female	32
Feeling less attractive	41
Feeling less confident in social life	16
Fear that their lover wouldn't understand	20
Fear of disturbance in their couple	35
Feat of abortion of a potential new relationship	26
Various others	14

Discussion

The present survey evaluated women's preference between conventional laparoscopic, U-LESS, and TV-NOTES cholecystectomy provided similar risks are achieved. The majority of participating women would favor transumbilical LESS (U-LESS) for cholecystectomy. The large adoption of this form of scarless surgery may result from the place of cosmesis in our society, the importance of body image, and women concern regarding integrity of a sexually and reproductive major organ, such as the vagina [15, 16].

The medical community often does not consider the impact and importance of public opinion on their practice [12, 17]. Changes in clinical practice are conceived on the basis of scientific or technologic advance. Despite this, outside forces including economics, interspecialty politics, expert (or specialist) opinion, industry marketing, and public demand can have a tremendous impact on the adoption of new procedures [11, 17]. Development of laparoscopic cholecystectomy was introduced by a small number of pioneers, soon followed by the surgical committee in answer to public demand and industry marketing, whereas no scientific evidence could at this time support this change [11, 18]. Having learned from the laparoscopic revolution that patients' demand may be one major trigger for surgical evolution, we have to foresee the impact of

surgical innovation in the community to prepare the future of minimally invasive surgery not just following patients demand and its related industrial and medical marketing [19].

As innovations progress in minimally invasive surgery, the concept of reducing parietal trauma has gained importance and different approaches of reduced port surgery have developed. LESS has rapidly reemerged clinically and has a reduced port laparoscopy from the darkness of so-called "single wound laparoscopy" of the 1990s [20, 21]. In parallel, NOTES, emerging since 2004, has struggled with technical limitations, except for the transvaginal access, which is emerging clinically because it can be performed using conventional or slightly adapted instrumentation. Whereas U-LESS aimed at reducing parietal trauma, besides arguing that a slightly larger umbilical incision may be more deleterious compared with numerous, TV-NOTES reduces parietal trauma at the cost of a healthy organ trauma—the vagina. We will not discuss the risk of vaginal culdotomy in this article; however, we should remember that this approach is not without risk—risk of abscess, fistula, transvaginal evisceration, dyspareunia, pelvic adhesion, etc.—which all have to be quantified for working culdotomy, implicating vaginal wall forces during cholecystectomy with multiple transvaginal ports. Because we are only starting to evaluate the potential risks and advantages of these innovative approaches, it seems wise to investigate the perception of U-LESS and TV-NOTES in the female population.

Numerous reports, mainly from the United States have shown conflicting results regarding the preference of TV-NOTES over laparoscopic cholecystectomy [22–25]. These discrepancies in TV-NOTES preference may, at least in part, be explained by methodological bias in the survey used, which could have influenced women's responses [24]. A recent Australian survey has shown low acceptance rate of TV-NOTES—25%—compared with laparoscopic cholecystectomy [26]. However, in none of these surveys the possibility of U-LESS cholecystectomy was evocated to participants. Interestingly in a Central European Survey, when U-LESS approach was offered to male and female participant besides laparoscopy and NOTES, the rate of preference for NOTES was only 15%—75% for LESS and 9% for laparoscopy [13, 16]. The preferred access for NOTES in this survey was the transgastric approach, confirming previous data from U.S. surveys [10, 13, 15, 22, 27]. The present survey, evaluating women preference between conventional laparoscopic, U-LESS, and TV-NOTES cholecystectomy, shows a strong favor to the U-LESS approach, with 87%. The good perception of these new approaches is related to an interest in scarless surgery among the participants. The main reason of U-LESS and TV-NOTES choice is decreased scarring for 82% followed by potentially better pain profile only reaching 34%; these results confirm previous reports [13].

However, the choice between U-LESS and TV-NOTES seems to be influenced by women concerns regarding accesses and their related perceived risk. Worries concerning transvaginal access are by far more frequent than those related to transumbilical access (76% vs. 35%; $p < 0.001$). Moreover, worries of transvaginal access may be psychologically more important regarding patients quality of life (i.e., dyspareunia, decrease vaginal sensibility, infertility, etc.). These results confirm previous Australian reports [26]. Fear regarding potential infertility and sterility were statistically more important in nulliparous women. If these worries are confirmed by scientific data remain to be evaluated in the purpose of transvaginal nongynecologic surgeries. In this regards, the recurrent "scientific" argument showing the absence of transvaginal access consequences (i.e., dyspareunia, fertility problems, etc.) based on gynecologic condition surgeries (hysterectomy, oocytes procurement, etc.) [24] may not be adequate [8, 13, 28, 29]. Although these worries may be disregarded in accordance with reassuring scientific data, one concern may be difficult to overcome: the need for vaginal intercourse abstinence after culdotomy and its psychosocial consequences. Vaginal intercourse abstinence is mandatory, according to the experience of gynecologic surgeons, after culdotomy [29]. This abstinence varies in duration from 3 to 6 weeks, in case of normal healing after culdotomy for gynecologic pathology as reported for TV-NOTES cholecystectomy [15, 30–32]. In this regard, the present survey clearly illustrates that this requested abstinence is considered as important for more than three quarter of the women. Moreover, this abstinence is related to important psychosocial worries, which might influence postoperative quality-of-life after TV-NOTES cholecystectomy. Interestingly, some of these concerns are related to difficulties in established relationships or eventual new relationships due to fear of partner incomprehension. This requested abstinence, due to its potential psychosocial and quality-of-life influence, may be in conflict with one of the fundamental goals of minimally invasive surgery: the enhanced recovery. Thus, avoiding scars and decreasing parietal trauma may, due to "injury" of a sexually and reproductive important healthy organ—the vagina—overcome the potential benefit of TV-NOTES through increased access risk and quality-of-life impact [8, 15]. All of these issues will have to be evaluated in future research on TV-NOTES because our patients already have concerns about these issues [8]. Women clearly showed in this survey that when taking into account the fact that TV-NOTES is mainly hybrid NOTES and implies postoperative vaginal intercourse abstinence, 99% would choose the U-LESS approach as a scarless approach.

The authors recognize several limitations of this study. The sample size is limited and the survey was not evaluated for validity or reliability. This is a very rapidly progressing field and the time required to validate a questionnaire could be excessive for the purpose of this study [2, 13]. It should be noted that the results of this survey only provide a rough overview for a distinct geographic area and have several limitations with regard to the extent of explanation for participants, participant understanding of the procedures, and the meaning of risk. However, one of the major strengths of this study is its heterogeneous population. Importantly, this study is the first to investigate women population feelings on U-LESS and TV-NOTES cholecystectomy—two possible evolutions of laparoscopic cholecystectomy in the near future.

Finally, we stress that we do not regard cosmesis or psychological factors as more important than safety in surgery. However, despite the limitations of these data, we believe that, even in the absence of other advantages of U-LESS, population interest for this developing approach is an important rationale for further research and investment in this field. This implies for surgeons and surgical societies to improved feasibility, safety, and training and mentoring of U-LESS cholecystectomy.

Conclusions

The high acceptance rate for the U-LESS approach compared with TV-NOTES may be related to fears regarding postoperative sexuality, sociability, and fertility. The importance of temporary postoperative sexual abstinence (vaginal intercourse) is high and may be difficult to influence. However, this issue may be related to cultural factors and may explain the difference in acceptance rates of TV-NOTES among different regions. Future research on TV-NOTES should focus on the risk of postoperative access morbidity and consequences in the setting of nongynecologic surgeries to eventually be able to reassure our patients. For now, U-LESS should be favored compared with TV-NOTES for cholecystectomy in female patients. This should influence us to improve the feasibility and safety of LESS. This will allow us to respond to the potentially large demand without disregarding the principle of "primum non nocere."

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