

Perception of preference and risk-taking in laparoscopy, transgastric, and rigid-hybrid transvaginal NOTES for cholecystectomy

Michael C. Sulz^a, Andreas Zerz^{b,c}, Markus Sagmeister^a, Thomas Roll^d, Christa Meyenberger^a

^a Department of Medicine, Division of Gastroenterology and Hepatology, Kantonsspital St. Gallen, Switzerland

^b Department of Surgery, Division of Laparoscopic Surgery, Kantonsspital St. Gallen, Switzerland

^c Department of Surgery, Kantonsspital Bruderholz, University Hospital Basel, Bruderholz, Switzerland

^d Department of Internal Medicine, Kantonsspital St. Gallen, Switzerland

Summary

QUESTIONS UNDER STUDY: Few data are available regarding patients' perceptions of new cholecystectomy (CC) techniques, in the context of the patients' risk behaviours. We investigated patients' preferences for transgastric pure natural orifice transluminal endoscopic surgery (NOTES; transgastric NCC) and rigid-hybrid transvaginal NOTES CC (tvNCC) compared with the standard laparoscopic CC (SL-CC), and patients' risk behaviours.

METHODS: A total of 140 inpatients scheduled for elective laparoscopic CC were enrolled in this prospective single-centre study, from January 2009 to January 2010. Patients judged the potential advantages and disadvantages of transgastric NCC and tvNCC compared with SL-CC. The individual's risk behaviour was analysed by means of the validated 40-item Domain-Specific Risk Attitude Scale (DOSPERT).

RESULTS: Of the 140 recruited patients, 57 (65% females; mean age 51.5 years) were analysed. Twenty-five percent of males opted for transgastric NCC and 75% opted for SL-CC. Among females, 10.8%, 37.8% and 51.4% opted for transgastric NCC, tvNCC and SL-CC, respectively. Faster convalescence was graded as the primary potential advantage of transgastric NCC, whereas the potential risk of long-term stomach injuries was considered a primary disadvantage. Females graded the reduction of hospital-acquired morbidity as the primary advantage of tvNCC. The risk assessment showed significantly more risk-taking behaviour in the recreational domain of life among patients who opted for innovative surgical techniques than among those opting for conventional surgery.

CONCLUSIONS: Transgastric NCC is rarely accepted by females but accepted by a quarter of males. Females consider rigid-hybrid tvNCC and SL-CC similarly attractive. Despite promising new techniques, three-quarters of male and one half of female patients still prefer the standard laparoscopic CC.

Key words: *cholecystectomy; NOTES; perception; risk-taking; survey; transgastric; transvaginal surgery*

Introduction

Laparoscopic cholecystectomy (CC) was introduced into clinical practice in the mid-1980s [1] and is currently accepted as the standard of care. Recent advances in the field of interventional endoscopy and in laparoscopic surgery promise various benefits in terms of fewer wound complications, less pain, quicker convalescence and better cosmetic outcomes. One new area is natural orifice transluminal endoscopic surgery (NOTES). Pure NOTES implies entering the abdominal cavity via natural orifices with an endoscope avoiding any parietal incision [2, 3]. Various transgastric procedures (e.g., tubal ligation, cholecystectomy, gastrojejunostomy, splenectomy and oophorectomy) have been performed in animal models [4–8]. In humans, CC via pure NOTES has been performed through the vagina [9, 10]. To date, pure transgastric NOTES CC (transgastric NCC) has not been attempted in humans. Whether transgastric NCC achieves significant improvements in the clinical setting compared with standard laparoscopic cholecystectomy (SL-CC) is not yet clear. Hybrid NOTES is a combination of endoluminal access and transparietal assistance. Since 2007, rigid-hybrid transvaginal NOTES CC (tvNCC) has been evaluated worldwide [11–15].

Given the current stage of fast emerging innovative techniques, whether patients are willing to undergo pure NOTES procedures is of interest. Few data are available in the literature, with varying conclusions [16–20]. The aim of this prospective study was to analyse whether patients favour pure transgastric NCC and rigid-hybrid tvNCC over SL-CC. We also assessed an individual's general risk-taking and perception of risk in order to characterise the type of patient who accepts or declines an innovative surgical procedure. We hypothesised that patients who choose innovative CC techniques are willing to accept greater risk,

especially in the domain of health and safety, than patients who choose conventional CC.

Material and methods

The prospective interview-based single-centre survey was designed to assess patients' opinions about two innovative surgical procedures for CC, pure transgastric NCC and rigid-hybrid tvNCC. Patients were admitted for elective SL-CC. The study was performed in a tertiary surgical centre in the eastern part of Switzerland with a service population of approximately 500,000 people. The study was approved by the local ethics committee.

Recruitment of patients

From January 2009 to January 2010, all inpatients admitted for elective SL-CC were recruited as possible candidates prior to surgery. Inclusion criteria involved all female and male adult patients aged 18–85 years with symptomatic cholelithiasis being admitted for elective laparoscopic CC. Exclusion criteria were the following: acute cholecystitis, previous cholecystitis, known malignancy, hepatobiliary diseases other than biliary stones (e.g., benign stenosis of the biliary duct or liver cirrhosis), former open or laparoscopic abdominal surgery other than vaginal hysterectomy, oophorectomy, inguinal or femoral hernia repair, high perioperative risk (ASA III/IV), abnormal clotting time (international normalised ratio [INR] >1.4), low platelet count (<100,000/ml), pregnancy and missing informed consent. The entire assessment was performed by a single independent interviewer who was a fully trained physician not performing or involved in any surgical or endoscopic procedures. All baseline parameters were recorded in a prospective database.

Patient opinion of surgical techniques

All surgical techniques (i.e., SL-CC, transgastric NCC, and rigid-hybrid tvNCC [for females only]) were explained and illustrated by the interviewer with a standardised protocol using written and graphic material (Appendix 1). The potential advantages and disadvantages of each technique were discussed in a standardised manner as shown in Appendix 1. Regarding pure transgastric NCC, participants were informed that this type of surgery had not yet been undertaken in humans and that, therefore, potential advantages and disadvantages were theoretical. Furthermore, we stated that at the time of recruitment no studies of NOTES in humans were available to determine complication rates. Regarding rigid-hybrid tvNCC, female participants were informed that our hospital has been offering this surgery for CC since 2008 (worldwide evaluated since 2007). We explicitly stated that the presented collection of potential advantages and disadvantages covers the majority of information. The interviewer had a neutral view towards all procedures and recommended none of them. The complete survey was pilot-tested by the first author with a group of 15 healthy Swiss soldiers aged 19–28 years on the basis of perception and feasibility.

The patients' opinion of the techniques and their potential advantages and disadvantages was assessed per a standardised questionnaire based on a rating scale of 1 (not relev-

ant) to 4 (relevant) (Appendix 2). The participant was then asked to decide which technique he/she would opt to undergo (males: SL-CC or transgastric NCC; females: SL-CC, transgastric NCC or rigid-hybrid tvNCC).

Risk-taking and perception

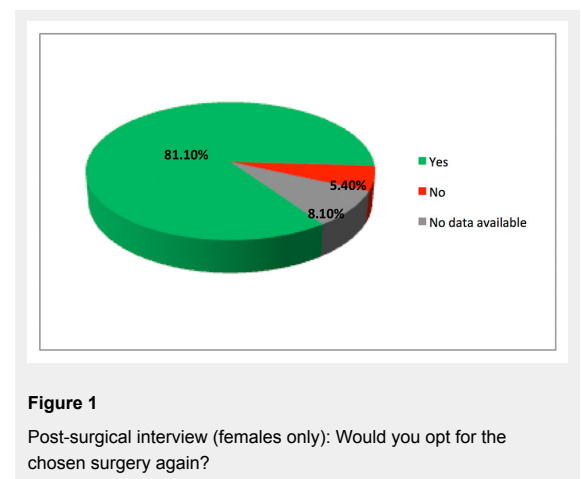
For a standardised assessment of a patient's risk-taking and perception of risk, we used the validated 40-item Domain-Specific Risk Attitude Scale (DOSPERT) in German [21, 22] (Appendix 3) after the patient completed their assessment of the surgical techniques. The DOSPERT risk-taking subscale evaluates behavioural intentions, where the likelihood of respondents engaging in risky behaviours originating from five domains of life (ethical, financial, health/safety, social and recreational) is determined using a 5-point rating scale ranging from 1 (extremely unlikely) to 5 (extremely likely). Item ratings are added across all items of a given subscale to obtain subscale scores. Higher scores indicate greater risk-taking in the domain of the subscale. The risk-perception subscale evaluates the respondent's gut-level assessment of how risky each behaviour is on a 5-point rating scale ranging from 1 (not at all) to 5 (extremely risky).

Statistical analysis

For categorical variables, data were described with absolute and relative frequencies. For continuous and ordinal variables, arithmetic means together with standard deviations and medians were given. Based on arithmetic means, rankings of ratings regarding advantages and disadvantages of surgical techniques were done in a descriptive way. Two-sided statistical significance testing was applied to compare measurements between males and females as well as between patients who would opt for innovative versus conventional techniques. Ratings regarding advantages and disadvantages as well as DOSPERT scales were compared between these patient groups using the Mann-Whitney U test. A p-value ≤ 0.05 was considered to indicate statistical significance.

Results

From January 2009 to January 2010, 140 patients (54.3% females) were recruited, of whom 49 (35%) denied to participate in the study interview and 29 (20.7%) were excluded



due to predefined exclusion criteria. A total of 60 patients (42.9%) concluded the first assessment, and three did not want to perform the risk behaviour assessment. Thus, a total of 57 patients (65% female, age 18–83 years, mean age 51.5 years) completed the study. Table 1 shows the baseline characteristics regarding the group of patients favouring SL-CC and the group of patients favouring innovative techniques (i.e., transgastric NCC and tvNCC).

Patient perception

The number of males and females opting for each procedure is given in table 2. The ranking of each potential advantage of transgastric NCC and tvNCC is given in table 3. The most important potential advantage of transgastric NCC was “quicker convalescence”, and the least important potential advantage of transgastric NCC was “natural medicine”. “Scarless surgery” was ranked with a mean value of 2.56 (females: 2.68; males: 2.35) (table 3). The potential advantages “less pain”, “quicker convalescence”, “scarless surgery”, “no risk of abdominal hernia”, and “natural medicine” were rated significantly higher by patients with preference for innovative techniques compared than those patients with preference for SL-CC (table 3). The primary advantage of tvNCC was the reduction in hospital-acquired morbidity. “Quicker mobility”, “quicker convalescence”, “shorter hospital stay”, “fewer infections of the abdominal wall”, “no risk of abdominal hernia”, and “scarless surgery” were advantages which were graded significantly higher by females who opted for tvNCC than those who opted for SL-CC (table 3).

The ranking of potential disadvantages regarding transgastric NCC and tvNCC is shown in table 4. The potential risk of long-term injuries of the stomach was the most important disadvantage of transgastric NCC, followed by “lack of expertise”. The least important potential disadvantage of transgastric NCC was “intentional damage of a previously intact organ”. The primary disadvantage of tvNCC was the risk of vaginal/pelvic infection.

The phone interview with females after surgery (n = 19 SL-CC; n = 14 rigid-hybrid tvNCC; n = 1 open CC; two females did not answer; one female did not undergo any surgery) revealed that the majority (81.1%) would choose the same technique again (fig. 1), and 93.8% of females would recommend the selected surgical procedure to their relat-

ives and friends (fig. 2). The initial decision for the surgical technique of CC was changed by 15.6% of females during or after the preoperative interview with the operating surgeon (fig. 3).

Risk-taking and perception

Only risk-taking in the domain of recreation was significantly higher in the group of patients who opted for innovative techniques as compared with those who would opt for conventional CC (table 5). Risk-taking and perception of risk did not significantly differ in any of the other domains of life, or in the domain of health and safety (table 5).

Discussion

Few data are currently available regarding patients' perceptions of innovative NOTES surgery [16–20]. The study designs (e.g., composition of study participants, concept of questionnaires and selection of compared surgical techniques) were often different, making it difficult to compare studies. The strength of our study was its ability to recreate real-life situations for patients as best as possible. We selected CC as surgical intervention as one of the most frequent interventions in abdominal surgery. Patients admitted exclusively for elective SL-CC were recruited intentionally. In this setting, patients were considered more likely to be interested in understanding their surgery and also the variety of technical alternatives. We excluded patients with acute cholecystitis, because emergency situations are often associated with uncertainty and anxiety, thus limiting the value of a questionnaire and a complex risk behaviour assessment.

Our study revealed that half of female patients still preferred the standard laparoscopic CC, whereas 38% of females opted for rigid-hybrid NCC. Transgastric NCC was rarely accepted by females. However, 25% of men stated that they would accept transgastric NCC as an unproven surgical procedure. Rao et al. [23] reported similar results regarding patients' preferences towards appendectomy via NOTES compared to single port, laparoscopic, and open surgery, based on a hypothetical scenario of acute appendicitis. This study showed that NOTES was the least preferred and single port surgery the most popular method, followed by conventional laparoscopy. Although NOTES

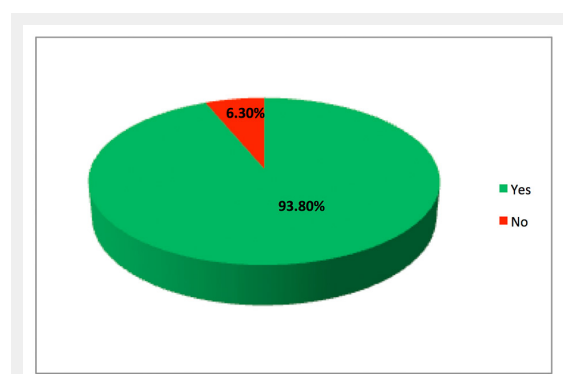


Figure 2

Post-surgical interview (females only): Would you recommend the chosen surgical procedure to your relatives and friends?

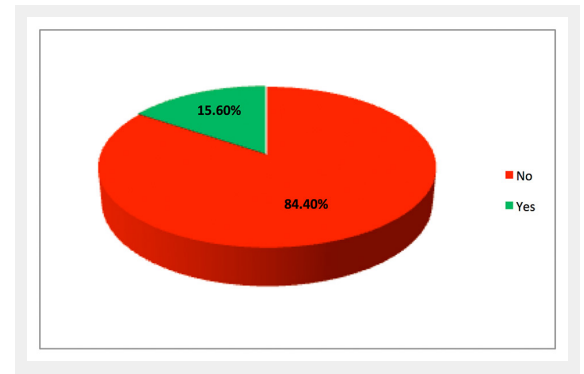


Figure 3

Post-surgical interview (females only): Was the initial decision changed after the pre-operative interview with the operating surgeon?

Table 1: Baseline characteristics regarding patient groups opting for standard SL-CC versus innovative techniques of CC.				
Patient characteristics	Participants opting for:			
	Standard SL-CC		Innovative techniques (tvNCC or transgastric NCC)	
	n	%	n	%
Sex				
Female	19	55.88%	18	78.26%
Male	15	44.12%	5	21.74%
Age (graded)				
≤ 60 years	21	61.76%	16	69.57%
> 61 years	13	38.24%	7	30.43%
BMI (graded)				
≤ 25	12	35.29%	8	36.36%
> 25.1	22	64.71%	14	63.64%
Marital status				
Unmarried	7	20.59%	8	34.78%
Married	24	70.59%	12	52.17%
Divorced	2	5.88%	3	13.04%
Widowed	1	2.94%		
Children				
Without children	8	23.53%	9	39.13%
With children	26	76.47%	14	60.87%
Education				
Junior high school / failed graduation	7	21.88%	2	8.70%
Secondary school	4	12.50%	8	34.78%
High school / grammar school	21	65.63%	13	56.52%
Sportiness				
Not or slightly sporty	29	85.29%	19	82.61%
Sporty/very sporty	5	14.71%	4	17.39%
Occupational training				
Trainee	4	11.76%	1	4.35%
Completed training	28	82.35%	21	91.30%
University graduate	2	5.88%	1	4.35%
Ethnic background				
Northern Europe	25	73.53%	20	86.96%
Asia	2	5.88%		
Southern Europe	7	20.59%	3	13.04%
Afro-American				
Working capacity				
Working	27	79.41%	20	86.96%
Lost working capacity				
Unemployed	1	2.94%		
Retired	6	17.65%	3	13.04%
Denomination				
Catholic	14	41.18%	11	47.83%
Evangelic	10	29.41%	3	13.04%
Other	5	14.71%	5	21.74%
Atheist	5	14.71%	4	17.39%
Smoking status				
Nonsmoker	27	79.41%	15	68.18%
Former smoker	3	8.82%	3	13.64%
Smoker	4	11.76%	4	18.18%

Transgastric NCC = pure transgastric NOTES cholecystectomy; NOTES = natural orifice transluminal endoscopic surgery; SL-CC = standard laparoscopic cholecystectomy; tvNCC: rigid-hybrid transvaginal NOTES cholecystectomy

Table 2: Patients' choice of the technique of CC.				
Decision for:	Males		Females	
	N	%	N	%
Transgastric NCC	5	25%	4	10.8%
TvNCC	na	na	14	37.8%
SL-CC	15	75%	19	51.4%

NOTES = natural orifice transluminal endoscopic surgery; transgastric NCC = pure transgastric NOTES cholecystectomy; tvNCC = rigid-hybrid transvaginal NOTES cholecystectomy; SL-CC = standard laparoscopic cholecystectomy

appendectomy was not preferred, considering the overall preference for the route of NOTES in the whole study population, the oral route was the most popular (37.1%; vaginal route only 3.8%) [23]. However, in our study 37.8% of females opted for rigid-hybrid transvaginal NCC. Notably, the safety and feasibility study of rigid-hybrid tvNCC by our surgical colleagues revealed an acceptance rate of 85% [13]. This significant difference could be explained by possible interview bias (i.e., surgeon's emphasis regarding the choice of an operative technique). It may be argued that 84.4% of females in our study stated that their initial decision remained unchanged *after* the preoperative interview with the operating surgeon.

Other investigators have shown a preference towards NOTES (68% of women and 78% of men and women) [16, 17]. Our study compared patients' perceptions of transgastric NCC and rigid-hybrid tvNCC; whereas pure transgastric NOTES is not yet established in the clinical setting, rigid-hybrid tvNCC has been evaluated clinically and is currently offered to women worldwide. Our hospital has been offering the option of tvNCC since 2008, reporting a large case volume in this field [13]. A possible reason for the different observations here is that women in our study could choose from these innovative surgical options and fa-

voured the technique, which has already being evaluated for potential advantages over pure transgastric NCC. Women in other studies [16, 17] might have opted for the hybrid procedure (tvNCC) if it was an available technical alternative to pure NOTES procedures.

Our ranking analysis of the potential advantages of tvNCC and transgastric NCC revealed that scarless surgery was not particularly important for patient perception, a finding which is consistent with several other NOTES studies [17, 19, 20]. From the patient's perspective, the most relevant potential advantages of transgastric NCC are quicker convalescence, and fewer hospitalisation-induced complications and quicker convalescence for tvNCC. Similar results were obtained by the surveys mentioned above [17, 19, 20]. Similar to the present study, Peterson et al. [17] found that women were mainly concerned with infection issues (83%) and the impact of transvaginal NOTES surgery on a healthy sex life (81%). Bucher et al. [24] showed that 96% of females had worries regarding transvaginal access, including dyspareunia (68%) or decreased sensitivity during intercourse (43%). These aspects seem to hinder women from opting for minimally invasive surgery through the vaginal route. However, Linke et al. [13, 25] showed that dyspareunia is even less frequent after tvNCC than before sur-

Table 3: Ranking of potential advantages of transgastric NCC and tvNCC.

Potential advantage of transgastric NCC	All (n = 57)	Females (n = 37)	Males (n = 20)	Group opting for SL-CC (n = 34)	Group opting for innovative techniques (n = 23)	p-value
	Mean			Mean		
Less pain	2.67	2.81	2.40	2.44	3.00	0.021
Quicker mobility	3.14	3.14	3.15	2.94	3.43	0.077
Quicker convalescence	3.39	3.38	3.40	3.15	3.74	0.032
Shorter hospital stay	3.07	2.97	3.25	2.94	3.26	0.326
Fewer hospitalisation induced complications (e.g., infections, deep vein thrombosis)	3.23	3.19	3.30	3.06	3.48	0.067
Fewer infections of abdominal wall	3.26	3.35	3.10	3.09	3.52	0.092
No risk of abdominal hernia	2.81	2.92	2.60	2.50	3.26	0.007
Fewer adhesions within abdominal cavity	3.21	3.32	3.00	3.06	3.43	0.190
Scarless surgery	2.56	2.68	2.35	2.00	3.39	0.001
Quicker resumption of work	3.11	3.11	3.10	2.91	3.39	0.059
"Natural medicine" (access by natural orifices)	2.02	2.14	1.80	1.76	2.39	0.044
Potential advantage of rigid-hybrid tvNCC	All females (n = 37)	Females opting for SL-CC (n = 19)	Females opting for tvNCC (n = 14)			p-value
	Mean	Mean				
Less pain	3.08	2.79	3.57			0.019
Quicker mobility	3.16	2.74	3.79			0.005
Quicker convalescence	3.30	3.00	3.79			0.042
Shorter hospital stay	3.16	2.84	3.71			0.011
Fewer hospitalisation induced complications (e.g., infections, deep vein thrombosis)	3.41	3.26	3.71			0.152
Fewer infections of abdominal wall	3.24	2.95	3.79			0.016
No risk of abdominal hernia	2.97	2.42	3.71			0.003
Fewer adhesions within abdominal cavity	3.27	3.11	3.64			0.174
Scarless surgery	2.68	1.95	3.57			0.001
Quicker resumption of work	3.16	2.95	3.57			0.065
"Natural medicine" (access by natural orifices)	2.08	1.89	2.29			0.553

NOTES = natural orifice transluminal endoscopic surgery; transgastric NCC = pure transgastric NOTES cholecystectomy; tvNCC = rigid-hybrid transvaginal NOTES cholecystectomy; SL-CC = standard laparoscopic cholecystectomy
 Rating scale: 1 = No advantage at all; 2 = Small advantage, but not relevant for me to favour this surgical technique; 3 = Important advantage; 4 = Very important, clearly relevant for me to favour this surgical technique.

gery, and vaginal infections were not significantly more frequent.

Our findings point out that, in regard to transgastric NCC, patients are mainly concerned about delayed healing of the stomach wall and long-term stomach problems. Although pure transgastric NCC is not yet performed in humans, a few publications from North America have looked at staging, access, and insufflation in transgastric NOTES pro-

ocols [26–29]. Recently, Nau et al. [30] concluded from a retrospective review that transgastric pure NOTES is a safe alternative for accessing the peritoneal cavity in humans, and the risk of bacterial contamination secondary to peroral and transgastric access is clinically insignificant. Knowing the fears of patients regarding transgastric NCC and the recently published data about safety and feasibility of transgastric access should improve the quality of pre-surgic-

Table 4: Ranking of potential disadvantages of transgastric NCC, and rigid-hybrid tvNCC (females only), ranking between the group opting for standard technique and the group opting for each innovative technique (right).

Potential disadvantage of transgastric NCC	All (n = 57)	Females (n = 37)	Males (n = 20)		Group opting for SL-CC (n = 34)	Group opting for transgastric NCC (n = 9)	
	Mean			p-value	Mean		p-value
Longer operation time	2.49	2.43	2.60	0.544	2.82	1.67	0.005
Risk of peritonitis due to damage of the stomach wall	3.18	3.32	2.90	0.066	3.38	2.44	0.007
Difficult healing of damaged stomach wall	3.47	3.54	3.35	0.411	3.68	2.89	0.051
Potential long-term damage of the stomach	3.61	3.73	3.40	0.054	3.76	3.11	0.097
Potential injury of vessels	2.89	3.11	2.50	0.008	3.03	2.11	0.007
Potential damage of the gut	2.96	3.24	2.45	0.002	3.15	2.11	0.005
Lack of expertise	3.18	3.35	2.85	0.067	3.44	1.89	0.001
Intentional damage of a previously intact organ	1.63	1.59	1.70	0.532	1.82	1.11	0.067

Potential disadvantage of rigid-hybrid tvNCC	Females only (n = 37)	Group opting for SL-CC (n = 19)	Group opting for tvNCC (n = 14)	
	Mean	Mean		p-value
Longer operation time	2.16	2.53	1.86	0.065
Risk of vaginal infection by intentional injury of the posterior vaginal wall	3.14	3.63	2.43	0.001
Difficult healing of vagina	3.05	3.47	2.43	0.006
Possible damage to sexual function	2.97	3.32	2.43	0.035
Lack of expertise with associated technical failure and complications	2.76	3.37	2.07	<0.001
Intentional damage of a previously intact organ	1.46	1.74	1.14	0.142

NOTES = natural orifice transluminal endoscopic surgery; transgastric NCC = pure transgastric NOTES cholecystectomy; tvNCC = rigid-hybrid transvaginal NOTES cholecystectomy; SL-CC = standard laparoscopic cholecystectomy
 Rating scale: 1 = No disadvantage at all; 2 = Small disadvantage, but not relevant for me to favour this surgical technique; 3 = Important disadvantage; 4 = Very important, clearly relevant for me to decline this surgical technique.

Table 5: Risk behaviour analysis according to the DOSPERT score (risk perception and risk taking), shown for patients opting for standard SL-CC (left) and for patients opting for innovative techniques of CC (right).

Risk perception subscales	Patients opting for SL-CC (n = 34)			Patients opting for innovative techniques (n = 23)			p-value
	Mean	Median	SD	Mean	Median	SD	
Social	19.35	19.50	5.31	19.74	20.00	3.89	0.85
Recreational	34.38	35.50	5.25	33.30	35.00	5.78	0.45
Gambling	16.03	16.00	3.25	15.70	16.00	3.50	0.81
Health and Safety	33.50	34.00	4.36	33.74	35.00	5.25	0.70
Ethical	32.94	33.00	5.48	33.26	36.00	6.28	0.72
Investment	15.12	16.00	3.52	14.22	15.00	3.38	0.32
Financial (investment and gambling)	31.15	32.00	5.91	29.91	32.00	6.47	0.63

Risk taking subscales	Mean	Median	SD	Mean	Median	SD	p-value
	Social	25.21	24.50	4.49	27.00	26.00	4.46
Recreational	12.59	11.50	4.55	14.70	13.00	4.74	0.05
Gambling	6.00	4.50	3.22	5.39	5.00	1.44	0.75
Health and safety	13.38	12.00	5.34	14.00	14.00	4.58	0.47
Ethical	11.38	10.00	4.21	11.83	10.00	4.03	0.61
Investment	6.97	5.50	3.72	7.00	7.00	2.52	0.53
Financial (investment and gambling)	12.97	10.50	5.92	12.39	12.00	3.30	0.70

CC = cholecystectomy; SD = standard deviation; SL-CC = standard laparoscopic cholecystectomy

al interviews. However long-term results are not available which makes it difficult to address patients' fear without improved evidence.

To the best of our knowledge, this is the first study assessing patients' perceptions of innovative minimally invasive surgery and general risk-taking behaviours in combination. The strength of the validated and widely used DOSPERT scale is that it involves different domains of life for risk assessment – an important issue because individuals have not shown themselves to consistently seek risk across different domains and situations [21, 22, 31, 32]. In our study, only the risk-taking subscale of recreation showed a significant difference between participants who opted for innovative/experimental surgical techniques and those who opted for standard surgery. Thus, the group of patients who opted for one of the innovative techniques in our survey exhibited greater risk-taking in the recreational domain of life than those who opted for the standard technique. This finding is not unexpected. However, clinicians who feel responsible for their patients need to be aware of the different temperaments of patients to protect them from taking unnecessary risks regarding medical decisions. No significant difference was found regarding risk-taking in the domain of health and safety.

The main limitation of this study is the relatively small sample size compared to other survey studies [16, 17, 19, 20]. The reason for the small sample size may have been the fairly long interview time in addition to the pre-surgical examination and interview by the anaesthetist and surgeon. In addition, the exclusion rate was high (20.7%), mainly because we aimed to imitate the potential clinical settings for pure NOTES procedures as much as possible. Moreover, our surgical colleagues performed a feasibility and safety study of rigid-hybrid tvNCC (9/2008-9/2009). This situation reduced the number of female elective CC patients being recruited into our survey study. We did not recruit females who already underwent a pre-surgical interview prior to our study inclusion, which significantly delayed the inclusion of female patients.

In conclusion, the results of this study indicate that transgastric NCC is rarely accepted by females but accepted by 25% of males. Females consider the minimally invasive nature of rigid-hybrid tvNCC and the standard laparoscopic SL-CC to be attractive. Regarding rigid-hybrid tvNCC, females were mainly concerned about infection and the impact of the procedure on a healthy sex life. These aspects seem to hinder women from opting for minimally invasive surgery through the vaginal route. Thus, explaining recent safety data on tvNCC could reduce a woman's fear and improve further their perception. Regarding transgastric NCC, patients were concerned mainly about delayed healing of the stomach wall and long-term stomach problems. This issue should be taken seriously but is so far not answered sufficiently by controlled studies.

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Correspondence: Michael Christian Sulz, MD; Department of Medicine, Division of Gastroenterology and Hepatology, Kantonsspital St. Gallen, Rorschacherstrasse 95, CH-9007 St. Gallen, Switzerland, [michael.sulz\[at\]kssg.ch](mailto:michael.sulz[at]kssg.ch)

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Appendices

Appendix 1: Graphic material to explain the standard laparoscopic cholecystectomy procedure to patients



Appendix 2: Questionnaires

Questionnaire regarding advantages of transgastric NCC (males and females)

The patient is asked to assess each of the following 11 potential *advantages* of transgastric NCC on a rating scale of 1–4:

1 = “no advantage at all”; 2 = “small advantage, but not relevant for me to favour this surgical procedure”; 3 = “important advantage”; 4 = “very important, clearly relevant for me to favour this surgical procedure”.

- Less pain
- Quicker mobility
- Quicker return to my pre-existing state of health
- Shorter hospitalisation
- Fewer hospital-acquired complications (e.g., infections, deep vein thrombosis, and/or pulmonary embolism due to little mobility)
- Fewer postoperative wound infections (especially within the abdominal wall)
- No risk for scar hernia formation within the abdominal wall
- Fewer intra-abdominal adhesions
- Surgery without visible scars ("scarless surgery")
- Quicker resumption of work
- Evolution to “natural medicine” by using natural orifices

Questionnaire regarding disadvantages of transgastric NCC (males and females)

The patient is asked to assess each of the following 8 potential *disadvantages* on a rating scale of 1–4:

1 = “no disadvantage at all”; 2 = “small disadvantage, but not relevant for me to decline this surgical procedure for cholecystectomy”; 3 = “important disadvantage”; 4 = “very important disadvantage, clearly relevant for me to decline this surgical procedure”.

- Longer operation time
- Risk of infection or peritonitis induced by intentional injury of the stomach wall
- Difficulty healing for the stomach wall/stomach perforation
- Potential long-term damage of the stomach (stenosis)
- Injury of vessels
- Injury of intestine
- Lack of expertise with associated technical failure and complications (I feel like a “test animal”)
- “In my point of view the technique of NOTES is a non-ethical surgical procedure due to the fact that the stomach is an intact organ that is intentionally injured”

Questionnaire regarding advantages of tvNCC (females only)

The female patient is asked to assess each of the following 11 potential *advantages* of tvNCC on a rating scale of 1–4:

1 = “no advantage at all”; 2 = “small advantage, but not relevant for me to favour this surgical procedure”; 3 = “important advantage”; 4 = “very important, clearly relevant for me to favour this surgical procedure”.

- Less pain
- Quicker mobility
- Quicker return to my pre-existing state of health
- Shorter hospitalisation
- Fewer hospital-acquired complications (e.g., infections, deep vein thrombosis, and/or pulmonary embolism due to little mobility)
- Fewer postoperative wound infections (especially within the abdominal wall)
- No risk for scar hernia formation within the abdominal wall
- Fewer intra-abdominal adhesions
- Surgery without visible scars ("scarless surgery")
- Quicker resumption of work
- Evolution to “natural medicine” by using natural orifices

Questionnaire regarding disadvantages of tvNCC (females only)

The female patient is asked to assess each of the following 6 potential *disadvantages* of tvNCC on a rating scale of 1–4:

1 = “no disadvantage at all”; 2 = “small disadvantage, but not relevant for me to decline this surgical procedure for cholecystectomy”; 3 = “important disadvantage”; 4 = “very important disadvantage, clearly relevant for me to decline this surgical procedure”.

- Longer operation time
- Risk of vaginal infection by intentional injury of the posterior vaginal wall
- Difficult healing of the vagina
- Possible damage to sexual function
- Lack of expertise with associated technical failure and complications (I feel like a “test animal”)
- “In my point of view the technique of transvag. CC is a non-ethical surgical procedure due to the fact that the vagina is an intact organ that is intentionally injured”

Open question

For males: What is the main reason for you to undergo transgastric NCC?

For females: What is the main reason for you to undergo transgastric NCC, tvNCC, or SL-CC?

Choice of surgery*For males*

Assuming that transgastric NOTES would be a cholecystectomy technique within a controlled trial as an alternative to the standard cholecystectomy, which method would you prefer?

- Standard laparoscopic cholecystectomy
- Transgastric NCC

For females

The rigid-hybrid NCC is currently offered in our hospital. Transgastric NOTES cholecystectomy has been performed in animal trials only. Assuming that transgastric NOTES would be a cholecystectomy technique within a controlled trial as an alternative to the standard cholecystectomy, which method would you prefer?

- Standard laparoscopic cholecystectomy
- Transgastric NOTES cholecystectomy
- Rigid-hybrid transvaginal NOTES cholecystectomy

Appendix 3: DOSPERT- risk-taking and risk-perception subscales

Risk-taking subscale

For each of the following statements, please indicate the likelihood that you would engage in the described activity or behaviour if you were to find yourself in that situation. Provide a rating from *Extremely Unlikely* to *Extremely Likely* using the following scale:

1	2	3	4	5	6	7
Extremely Unlikely	Moderately Unlikely	Somewhat Unlikely	Not Sure	Somewhat Likely	Moderately Likely	Extremely Likely

Risk-perception subscale

People often see some risk in situations that contain uncertainty about what the outcome or consequences will be and for which there is the possibility of negative consequences. However, riskiness is a very personal and intuitive notion, and we are interested in your gut level assessment of how risky each situation or behaviour is.

For each of the following statements, please indicate how risky you perceive each situation. Provide a rating from *Not at All Risky* to *Extremely Risky*, using the following scale:

1	2	3	4	5	6	7
Not at All Risky	Slightly Risky	Somewhat Risky	Moderately Risky	Risky	Very Risky	Extremely Risky

The 40 items are as follows:

- Admitting that your tastes are different from those of your friends. (S)
- Going camping in the wilderness beyond the civilization of a campground. (R)
- Betting a day's income at the horse races. (G)
- Buying an illegal drug for your own use. (H)
- Cheating on an exam. (E)
- Chasing a tornado or hurricane by car to take dramatic photos. (R)
- Investing 10% of your annual income in a moderate growth mutual fund. (I)
- Consuming five or more servings of alcohol in a single evening. (H)
- Cheating by a significant amount on your income tax return. (E)
- Disagreeing with your father on a major issue. (S)
- Betting a day's income at a high stake poker game. (G)
- Having an affair with a married man or woman. (E)
- Forging somebody's signature. (E)
- Passing off somebody else's work as your own. (E)
- Going on a vacation in a third-world country without prearranged travel and hotel accommodations. (R)
- Arguing with a friend about an issue on which he or she has a very different opinion. (S)
- Going down a ski run that is beyond your ability or closed. (R)
- Investing 5% of your annual income in a very speculative stock. (I)
- Approaching your boss to ask for a raise. (S)
- Illegally copying a piece of software. (E)
- Going whitewater rafting during rapid water flows in the spring. (R)
- Betting a day's income on the outcome of a sporting event (e.g., baseball, soccer, or football). (G)
- Telling a friend if his or her significant other has made a pass at you. (S)
- Investing 5% of your annual income in a conservative stock. (I)
- Shoplifting a small item (e.g., lipstick or a pen). (E)
- Wearing provocative or unconventional clothes on occasion. (S)
- Engaging in unprotected sex. (H)
- Stealing an additional TV cable connection off the one you pay for. (E)
- Not wearing a seatbelt as a passenger in the front seat. (H)
- Investing 10% of your annual income in government bonds (treasury bills). (I)
- Periodically engaging in a dangerous sport (e.g., mountain climbing or sky diving). (R)
- Not wearing a helmet when riding a motorcycle. (H)
- Gambling a week's income at a casino. (G)
- Taking a job that you enjoy over one that is prestigious but less enjoyable. (S)
- Defending an unpopular issue that you believe in at a social occasion. (S)
- Exposing yourself to the sun without using sunscreen. (H)
- Trying out bungee jumping at least once. (R)

38. Piloting your own small plane, if you could. (R)
39. Walking home alone at night in a somewhat unsafe area of town. (H)
40. Regularly eating high cholesterol foods. (H)

Note: E = ethical, I = investment, G = gambling, H = health/safety, R = recreational, and S = social.

Figures (large format)

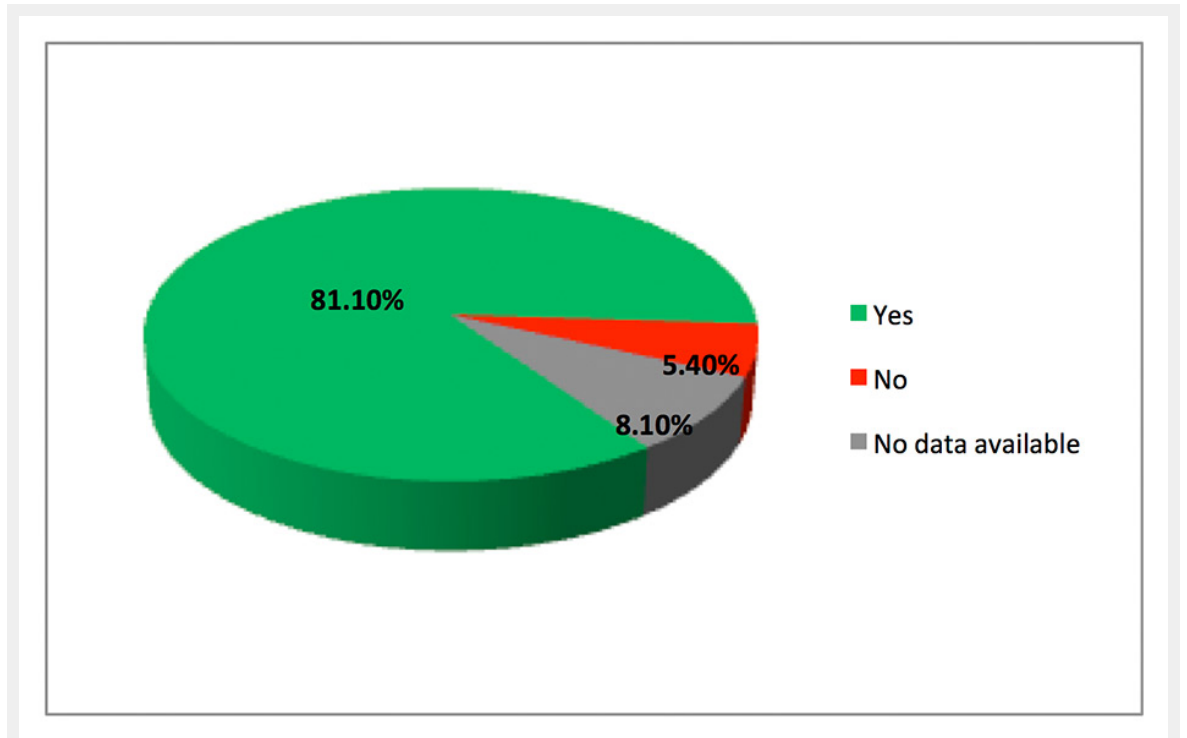


Figure 1
Post-surgical interview (females only): Would you opt for the chosen surgery again?

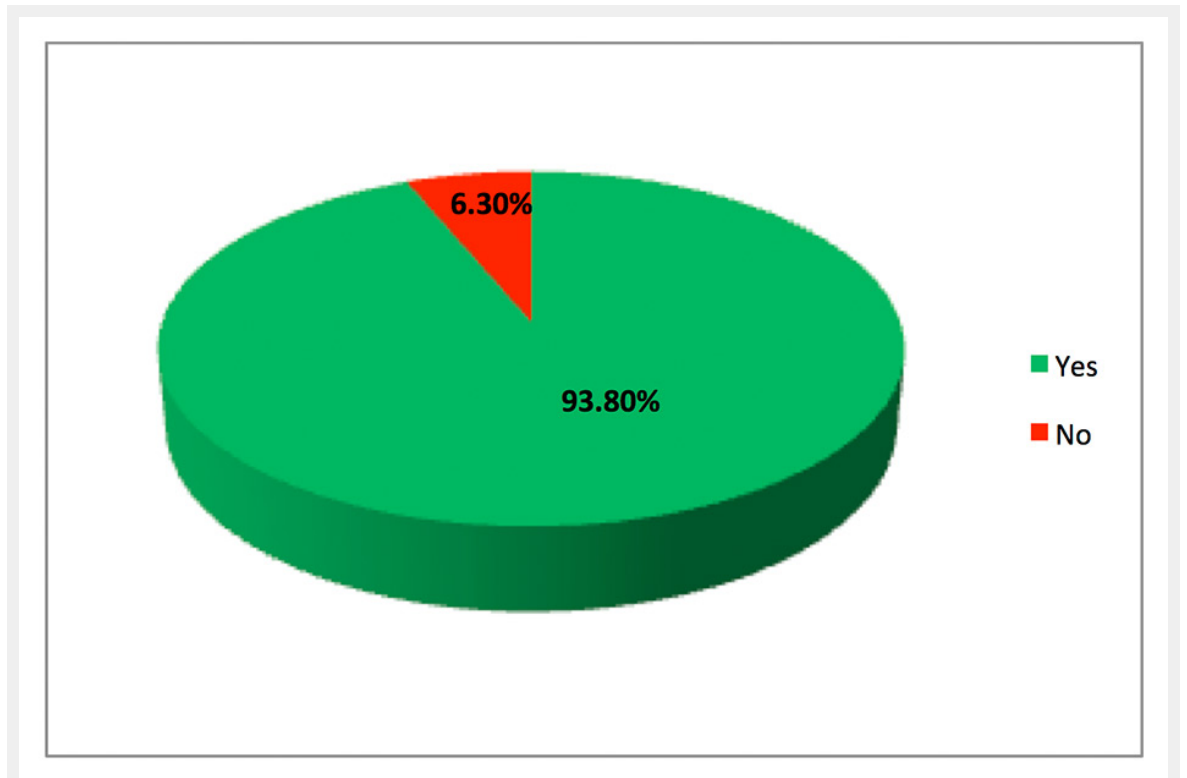


Figure 2
Post-surgical interview (females only): Would you recommend the chosen surgical procedure to your relatives and friends?

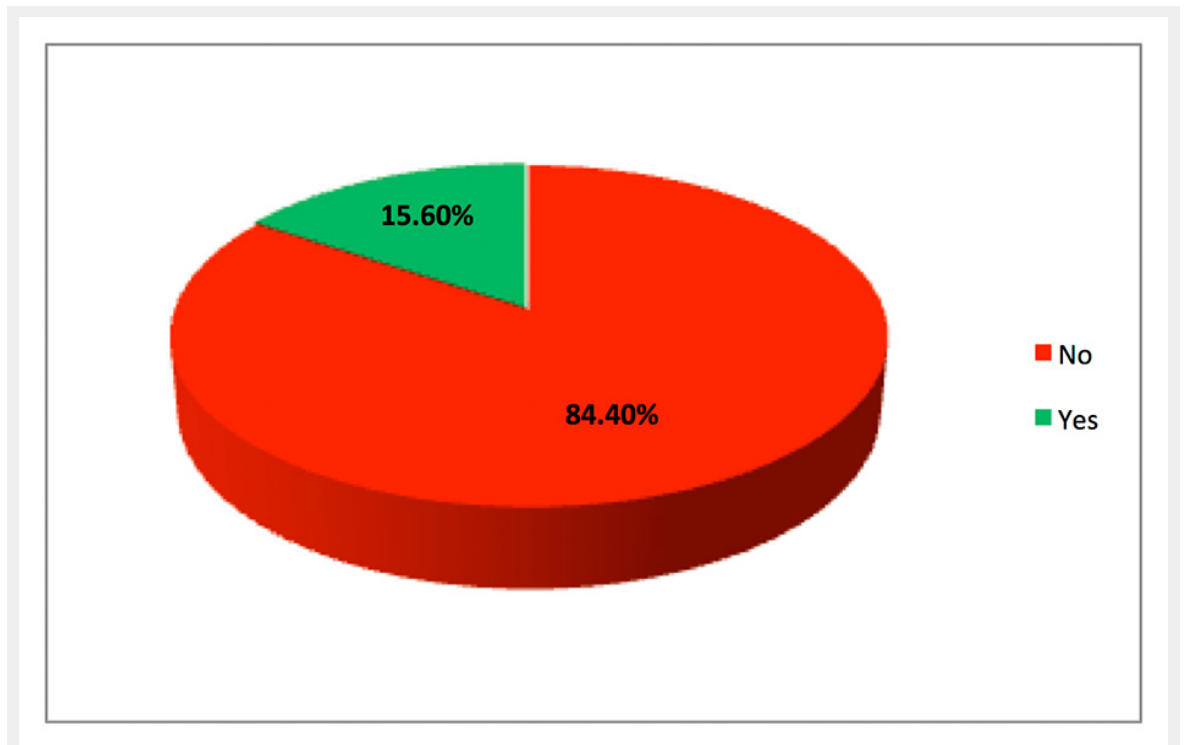


Figure 3

Post-surgical interview (females only): Was the initial decision changed after the pre-operative interview with the operating surgeon?