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A Comparison of NOTES Transvaginal and Laparoscopic Cholecystectomy Procedures Based upon Task Analysis

Arun Nemani, M.S.^a, Ganesh Sankaranarayanan, Ph.D.^a, Jaisha S. Olasky, M.D.^b, Souheil Adra, M.D.^b, Kurt E. Roberts, M.D.^c, Lucian Panait, M.D.^d, Steven D. Schwartzberg, M.D.^e, Daniel B. Jones, M.D.^b, and Suvranu De, Sc. D.^a

^aCenter for Modeling, Simulation and Imaging in Medicine (CeMSIM), Rensselaer Polytechnic Institute

^bBeth Israel Deaconess Medical Center, Harvard Medical School

^cYale School of Medicine

^dDrexel University College of Medicine

^eCambridge Health Alliance

Abstract

Background—A virtual reality-based simulator for Natural Orifice Translumenal Endoscopic Surgery (NOTES) procedures may be used for training and discovery of new tools and procedures. Our previous study [19] shows that developing such a simulator for the transvaginal cholecystectomy procedure using a rigid endoscope will have the most impact on the field. However, prior to developing such a simulator, a thorough task analysis is necessary to determine the most important phases, tasks, and subtasks of this procedure.

Methods—19 rigid-endoscope transvaginal hybrid NOTES cholecystectomy procedures and 11 traditional laparoscopic procedures have been recorded and de-identified prior to analysis. Hierarchical task analysis (HTA) was conducted for the rigid-endoscope transvaginal NOTES cholecystectomy. A time series analysis was conducted to evaluate the performance of the transvaginal NOTES and laparoscopic cholecystectomy procedures. Finally, a comparison of electrosurgery based errors was performed by two independent qualified personnel.

Results—The most time consuming tasks for both laparoscopic and NOTES cholecystectomy are removing areolar and connective tissue surrounding the gallbladder, exposing Calot's triangle, and dissecting the gallbladder off the liver bed with electrosurgery. There is a positive correlation of performance time between the removal of areolar and connective tissue and electrosurgery dissection tasks in NOTES ($r = 0.415$) and laparoscopic cholecystectomy ($r = 0.684$) with $p <$

Corresponding Author: Suvranu De, Rensselaer Polytechnic Institute, 110, 8th Street, Troy, NY 12180, Phone: (518) 276-6096, Fax: (518) 276-6025.

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Arun Nemani has no conflicts of interest or financial ties to disclose.

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0.10. During the electrosurgery task, the NOTES procedures had fewer errors related to lack of progress in gallbladder removal. Contrarily, laparoscopic procedures had fewer errors due to the instrument being out of the camera view.

Conclusion—A thorough task analysis and video-based quantification of NOTES cholecystectomy has identified the most time consuming tasks. A comparison of the surgical errors during electrosurgery gallbladder dissection establishes that the NOTES procedure, while still new is not inferior to the established laparoscopic procedure.

Keywords

NOTES; Laparoscopic cholecystectomy; task analysis; surgical skill metrics; surgical simulator

Introduction

This paper presents a structured task analysis of a hybrid transvaginal cholecystectomy procedure along with a comparison of performance time and electrosurgery-based operative errors with traditional laparoscopic cholecystectomy procedures. Natural orifice transluminal endoscopic surgery (NOTES) is an emerging approach to different procedures that utilizes the patient's natural orifices including the mouth, anus, and vagina to gain access to the peritoneal cavity. Since laparoscopic procedures have already been shown to reduce invasiveness and complications when compared to open surgery, NOTES must be comparable to laparoscopic surgery regarding invasiveness and reduced complications in order to be viable [1, 2].

Albeit growing concerns of the futility of NOTES, an initial white paper indicated promising interest in the surgical endoscopy community for NOTES based procedures due to its novel access approaches [3–5]. This interest is supported by reports showing benefits for NOTES based procedures such as reduced surgical site infections, post-operative pain, recovery time, adhesions, and hernia formations [6–8]. Furthermore, there are cases showing decreased post-operative complications for cholecystectomy via NOTES [9, 10]. There are also several complications for NOTES that include poor optimal access routes, operative field visibility, scope and tool maneuverability, increased grasping distances, and the lack of specific suturing and anastomotic devices that are designed for NOTES [7, 11]. Clearly NOTES specific training is needed to overcome these issues. Since the skill set required to perform NOTES has been identified, training programs are needed in order for physicians to gain proficiency in NOTES and overcome the technical challenges that ensue [11].

One method for delivering training is to use simulators that teach and evaluate surgical procedures. Virtual reality (VR) simulators have advantages since they are immersed in fully controllable environments where the user can repeatedly practice standardized tasks while the simulator records objective measurements of surgical skill [12]. Numerous studies show the benefits of VR simulators. In these cases users that received laparoscopic surgical training via VR simulators had faster learning curves, reduced operative errors and faster performance times when compared to users that had no VR simulator based training [12–16].

Only physical simulators have been developed for NOTES as no VR simulator currently exists. Physical simulators such as the endoscopic-laparoscopic interdisciplinary training entity (ELITE) and natural orifice simulated surgical environment (NOSsE™) show faster learning curves and increased performance times for NOTES procedures when compared to control groups that did not receive physical simulator training [17, 18]. These physical simulators, however, use porcine or latex based organ models that may not be anatomically accurate for human models. Furthermore, physical simulators require a large amount of resources and may not provide quantitative real-time performance feedback to trainees as VR simulators.

With the outlined benefits of a VR simulator, it is important to select a specific procedure that will have the most impact to the surgical community. A questionnaire-based needs analysis was conducted at the annual National Orifice Surgery Consortium for Assessment and Research (NOSCAR) meeting in Chicago in 2011 that showed experts preferred cholecystectomy as the first choice of simulation for the development of a NOTES simulator [19]. The same study indicated that a hybrid technique using rigid instruments was the preferred NOTES approach for cholecystectomy. For an immediate impact to the surgical community and to establish the potential of a VR NOTES simulator, transvaginal cholecystectomy using rigid tools was chosen for this study as per the NOSCAR questionnaire results.

The first step in developing the VR NOTES cholecystectomy simulator is to perform a thorough task analysis of the entire NOTES cholecystectomy procedure. The purpose of task analysis is to systematically delineate a complex procedure into different steps to identify the important ones along with process flow [20]. Hierarchical task analysis (HTA) has been used for laparoscopic procedures where it is broken down into phases, tasks, and subtasks and effectively identified key tasks and subtasks [21–23]. Each task and subtask can then be individually evaluated for surgical skill. Furthermore, HTA has been conducted specifically on laparoscopic cholecystectomy indicating 17 tasks that comprise the entire procedure [24]. However, there are no published works regarding HTA for NOTES cholecystectomy.

This work, for the first time, performs HTA for rigid endoscope NOTES cholecystectomy identifying key phases, tasks, and subtasks for the entire procedure. Furthermore, we compare performance time metrics for select tasks and subtasks between NOTES and laparoscopic cholecystectomy procedures. Operative error analysis comparisons during one specific task, electrosurgery, is also conducted.

Methods

Nineteen rigid endoscope transvaginal NOTES cholecystectomy procedures were observed and videotaped at the Yale University School of Medicine Hospital, New Haven, CT. Eleven laparoscopic cholecystectomy procedural videos were also collected from surgeries performed at Washington School of Medicine, St. Louis, MO, Cambridge Health Alliance, Cambridge, MA, and Yale University School of Medicine Hospital, New Haven, CT. All these videos were de-identified to remove any patient data prior to analysis. For completeness, both these procedures are discussed briefly below.

For the transvaginal NOTES procedure, prior to transvaginal access, pneumoperitoneum must be established within the patient. Ideal pressure settings are generally 12–15 mmHg of pressure with a flow rate of 10L / min of CO₂ [25]. Once pneumoperitoneum is established, access to the peritoneal cavity is gained with a 5 mm umbilical trocar. Inspection of the peritoneal cavity is performed to rule out severe gallbladder inflammation or pelvic adhesions, which will preclude performance of the transvaginal cholecystectomy. Subsequently, the vaginal walls are retracted using speculums to clearly visualize the cervix and to expose the posterior fornix. Access into the cul de sac can be achieved by blunt insertion or a small incision under endoscopic visualization within the “Triangle of Safety” [25–29]. Once transvaginal access is established, a rigid endoscope can be guided through the single vaginal port until transillumination of the abdomen is achieved [29]. Figure 1 shows an external view of the rigid endoscope transvaginal NOTES cholecystectomy procedure.

With the exception of transvaginal access, closure, and the viewing angle, the major cholecystectomy objectives for rigid endoscope transvaginal NOTES cholecystectomy are similar to laparoscopic cholecystectomy. The objective of the cholecystectomy procedure is the careful isolation and removal of the gallbladder [30, 31]. There are several components that detail a cholecystectomy procedure that include: gall bladder retraction, establishing critical view, clip and cut cystic duct (CD) and cystic artery (CA), remove gallbladder, and final inspection [15, 30, 31]. The last task for laparoscopic cholecystectomy is closing the fascia at the umbilical trocar site. However, the last remaining task for the entire rigid endoscope transvaginal NOTES cholecystectomy is vaginal closure. This step is performed once the gallbladder has been completely extracted from the abdomen and the vaginal incision is closed with a 2-0 suture [32, 33].

Each video was analyzed frame by frame using Windows Media player and iMovie. Each of the critical subtasks were timed using specific guidelines for start and end times, which are defined in the next section. Inter-rater reliability test was conducted for the task event definition by using a different rater unfamiliar with this work. Cohen’s kappa value was used to evaluate inter-rater reliability [34]. Generally a coefficient of agreement ranging from $0.41 < k < 0.60$ indicates moderate agreement. A range from $0.60 < k < 0.8$ indicates a substantial agreement and $k > 0.8$ is deemed as perfect agreement [20, 35].

Operative errors were counted for the electrosurgery task for each procedure. These errors have already been validated as the most significant ones that occur during the electrosurgery task by a previous study [16]. These errors were then normalized per sample size as the number of procedures differs for the NOTES and laparoscopic data sets. These are summarized in Table 1 below.

IBM SPSS (IBM, corp.) software was used for all statistical analysis including non-parametric data set differentiation and correlation tests. Two-tailed Mann-Whitney tests were conducted to statistically different non-parametric sample sets. Pearson’s correlation tests were conducted to correlate the various subtasks in the NOTES and laparoscopic procedures. Inter-rater reliability tests were conducted by evaluating the Cohen’s kappa coefficient for error analysis results.

Results

Figure 2 shows the HTA trees for rigid endoscope transvaginal NOTES cholecystectomy. We have identified a total of nine phases that each has several tasks and sub-tasks. Forward arrows indicate a linear progression to the next step and double headed arrows indicate either step can be performed first. Dotted line boxes indicate an option where only one task or subtask needs to be selected for the procedure. Tasks and subtasks with bold text are used for video analysis. Furthermore, these task trees have been face validated by expert laparoscopic surgeons. Task trees were taken to a group of expert laparoscopic and NOTES surgeons for numerous iterations until all experts face validated the task trees.

Table 2 lists the descriptions of start and end times based upon the task trees above.

Figure 3 shows the time series data for major cholecystectomy subtasks for laparoscopic surgery. Figure 4 shows the time series data for rigid endoscope NOTES transvaginal cholecystectomy. Two-tailed Mann-Whitney tests indicate that the *remove areolar and connective tissue* task for the laparoscopic procedure in Figure 3 is statistically different from the *areolar and connective tissue* task for the NOTES procedure in Figure 4 ($p=0.0005$). The same case applies for the *expose Calot's triangle* tasks ($p=0.0001$) and *electrosurgery* tasks ($p=0.0412$) in laparoscopic and NOTES procedures. Inter-rater reliability showed $k = 0.68$ ($p < 0.05$) indicating there is substantial agreement between the two raters.

Correlation studies between the three most time consuming tasks (remove areolar and connective tissue, expose Calot's triangle, and electrosurgery) indicate that there is a positive correlation between electrosurgery and remove areolar and connective tissue subtasks in the laparoscopic ($p = 0.029$, $r = 0.615$) and NOTES ($p = 0.077$, $r = 0.280$) data sets with a confidence level of $p = 0.90$. No other correlations within these three tasks were found.

Figure 5 shows the frequency of an error during the electrosurgery task for all of the NOTES and lap cholecystectomy trials according to published error definitions [16]. Two independent raters were asked to count the number of errors for all of the NOTES and laparoscopic trials and showed high inter-rater reliability ($r > 0.80$, $p < 0.05$). Error counts were normalized to the number of procedures within the NOTES and laparoscopic data sets. Results indicate that there are significantly less *lack of progress* (LOP) type errors for the rigid endoscope NOTES approach. *Instrument out of view* (IOV) error is higher for the rigid endoscope NOTES approach. There are, however, no significant differences between NOTES and laparoscopic approach regarding the remaining error types. Error measures were normalized to the number of errors per procedure type (NOTES/lap).

Figure 6 details the total time for each of the procedures of rigid endoscope NOTES and laparoscopic cholecystectomy. The total time for this study is the sum total of each task and subtask for each trial used for video analysis as highlighted in Figure 2. Two-tailed Mann-Whitney tests indicate that the NOTES data set is significantly different than the laparoscopic data set ($p = 0.0001$). Thus average total time for a rigid endoscope transvaginal procedure is significantly faster than the sample set for traditional laparoscopic

procedures. Figure 7 shows the total procedure time starting with gallbladder retraction and ending when the specimen is retrieved via the endobag. Two-tailed Mann-Whitney tests indicate that the NOTES data set is significantly different than the laparoscopic data set ($p = 0.0015$).

Discussion

The task analysis trees delineate the entire rigid endoscope NOTES cholecystectomy procedure into nine different phases, each of which has several tasks and subtasks. This is important because it allows for the rigid endoscope transvaginal cholecystectomy procedure to be compartmentalized into distinct phases, which can be used for quantitative assessment of surgical skill. Furthermore, since each phase, task, and subtask, can be individually evaluated for surgical performance, they can be used for monitoring surgical skill training. Since rigid endoscope transvaginal cholecystectomy is a relatively new access approach, all comparisons for surgical skill evaluation are being made with the traditional laparoscopic cholecystectomy. Tasks and subtasks for video analysis were specifically chosen to encompass as many phases of the NOTES cholecystectomy procedure that can be clearly differentiated in the endoscope video and also have common tasks with laparoscopic cholecystectomy. This is to ensure we can directly compare tasks in NOTES and laparoscopic cholecystectomy via video analysis. Any tasks or subtasks that cannot be video recorded, such as colpotomy during transvaginal procedures, are not included in the quantitative comparison. Results indicate that the three tasks: exposure of the Calot's triangle, removal of areolar and connective tissue, and electrosurgery are less time consuming for the rigid endoscope NOTES cholecystectomy compared to the laparoscopic approach.

Both laparoscopic and NOTES procedures varied in difficulty. Surgical skill, however, was not equally varied for the laparoscopic and NOTES procedures. For example, expert surgeons performed all of the NOTES procedures, whereas a mixture of experts and novice residents performed the laparoscopic procedures. Furthermore, it is possible that the degree of complications were different for the laparoscopic and NOTES procedures. Although, limited conclusions can be made on the total performance time results between NOTES and laparoscopic procedures due to the variance in case difficulty and physician experience, we are still able to identify the three main tasks that require the most amount of time for both approaches in cholecystectomy. It is important to differentiate tasks that are deemed essential and tasks that are critical. Essential tasks describe tasks that are absolutely required to successfully complete the phase level or the procedure itself. Critical tasks indicate which tasks are the most demanding when evaluating for surgical skill. As previously mentioned, task analysis allows us to determine the critical tasks of a procedure that will require the most attention for training resources. Ultimately, the tasks remove areolar and connective tissue, expose Calot's triangle, and electrosurgery will require the most attention during surgical skills training.

There is a strong correlation between the electrosurgery task and the task to expose Calot's triangle for laparoscopic and rigid endoscope transvaginal cholecystectomy. This can be due to the difficulty of tissue detachment from the gallbladder if the tissue is fibrotic in nature or

if there is an excess in fibrofatty tissue surrounding the gallbladder bed. In these cases, the surgeon would not only take extra time to dissect the areolar and connective tissue from the gall bladder, but also to perform electrosurgery on the thickened tissue. Furthermore, the increased time can serve as a predictive metric in our simulator where increases in time performance for the areolar and connective tissue removal task can be attributed to an increased time in the electrosurgery task in the simulator.

Error analysis during the electrosurgery task indicates there is no significant difference between the NOTES and laparoscopic sample sets, with the exception of *instrument out of view* (IOV) and *lack of progress* (LOP) error types. The commonality of errors is an interesting observation given that the viewing angle is different for the transvaginal and the laparoscopic approaches. The insignificance of error data between the two sample sets may also indicate that there may be other error definitions specific to rigid endoscope NOTES cholecystectomy, which requires further study. Although qualified physicians performed the error analysis in this study, it cannot be directly used to evaluate performance between the rigid endoscope transvaginal and laparoscopic approaches. The variability in case complications and surgeon experience between the NOTES and laparoscopic data sets further indicate that the error results cannot be used directly. Rather, the error analysis is used as a guide for the frequency of errors expected during a given cholecystectomy procedure that can be incorporated into a training simulator for transvaginal cholecystectomy. Since errors can be computed in real time within a virtual training simulator, each error type within the electrosurgery task can provide immediate feedback to the trainee. Ultimately, electrosurgery errors can be clearly defined for virtual surgical simulators according to guidelines set as shown in Table 2 and can be used to measure surgical proficiency.

The results for total procedure time shown in Figures 6 and 7 indicate that the total average time for transvaginal procedures are substantially lower than the laparoscopic procedures. Furthermore, total task time for transvaginal procedures are also lower than the reported average operative time for laparoscopic cholecystectomy procedures [36].

One of the most obvious limitations in this study is data variability. Being a relatively new and experimental procedure, a limited number of surgeons are engaged in performing a transvaginal cholecystectomy procedure. Hence, our study presents data from two surgeons that perform all of the rigid endoscope transvaginal procedures. However, as NOTES techniques gain more traction within the surgical community, more surgeons will be proficient to perform NOTES cholecystectomy that will increase data variability. Another limitation is that time is the only metric used to measure the tasks within the cholecystectomy procedure that are critical for surgical skill evaluation. The difficulty and complexity of the case with respect to the gallbladder can also be incorporated as procedure performances will vary with increasing case difficulty. Other metrics of motor performance such as velocity and jerk analysis can be used to measure proficiency and help identify the most critical tasks for training [37].

Conclusion

In this manuscript, we have presented the first hierarchical task analysis for rigid endoscope transvaginal cholecystectomy. Video analysis indicates that the most time consuming tasks are removing areolar and connective tissue surrounding the gallbladder, exposing Calot's triangle, and dissecting the gallbladder off the liver bed with electrosurgery. A comparison of the surgical errors during electrosurgery gallbladder dissection establishes that the NOTES procedure, while still new is not inferior to the established laparoscopic procedure. Moreover, the methodology in this work can be applied to other NOTES procedures as well including procedures using flexible endoscopes. A flexible scope approach presents new challenges such as endoscope maneuverability and limited tool movement, which present their own new tasks and subtasks. Furthermore, a comparison of task analysis results for flexible and rigid endoscope transvaginal cholecystectomy may provide insight on the different skill requirements for the two transvaginal approaches.

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Figure 1.
External view of the rigid endoscope transvaginal NOTES cholecystectomy procedure.

Figure 2.

(a) Hierarchical decomposition tree for the *transvaginal entry*, *stabilize GB*, and *vaginal closure* phases. (b) Hierarchical decomposition tree continued for the remaining phases.

Figure 3.
Time series results for major tasks in a laparoscopic cholecystectomy (n = 11).

Figure 4. Time series results for major tasks in rigid endoscope transvaginal cholecystectomy (n = 19).

Figure 5.

Normalized total number of errors for each type. LOP, lack of progress; GBI, gallbladder injury; LI, liver injury; IP, incorrect plane of dissection; BNT, burn nontarget tissue; TT, tearing tissue; IOV, instrument out of view.

Figure 6.
Total time for tasks used in video analysis for laparoscopic and NOTES cholecystectomy procedures.

Figure 7.
Total task time for laparoscopic and NOTES cholecystectomy procedures.

Table 1

Operative error definitions for the electrosurgery task of the laparoscopic cholecystectomy procedure [16].

Operative error definitions during electrosurgery for gall bladder removal	
1.	Lack of Progress (LOP): No progress made in excising the gallbladder for an entire minute of the dissection. Dealing with the consequences of a predefined error represents lack of progress if no progress is made in excising the gallbladder during the period.
2.	Gallbladder Injury (GI): There is gallbladder wall perforation with or without leakage of bile. Injury may be incurred with either hand.
3.	Liver Injury (LI): There is liver capsule and parenchyma penetration, or capsule stripping with or without associated bleeding.
4.	Incorrect plane of dissection (IP): The dissection is conducted outside the recognized plane between the gallbladder and the liver (i.e., in the submucosal plane on the gallbladder, or subcapsular plane on the liver).
5.	Burn nontarget tissue (BIS): Any application of electrosurgery to nontarget tissue, with the exception of the final part of the fundic dissection, where some current transmission may occur.
6.	Tearing tissue (TI): Uncontrolled tearing of tissue with the dissecting or retracting instrument.
7.	Instrument out of view (IOV): The dissecting instrument is placed outside the field of view of the telescope such that its tip is unviewable and can potentially be in contact with tissue. No error will be attributed to an incident of a dissecting instrument out of view as the result of a sudden telescope movement.

Table 2

Subtask event descriptions for timeline analysis.

Task	Start Time Event	End Time Event
Remove Areolar and connective tissue	First visual instance of grasper moving towards fibrofatty tissue surrounding gallbladder	Last motion action where grasper shear fibrofatty tissue
Expose Calot's Triangle	First visual instance of grasper insertion into Calot's triangle zone	Retraction of grasper from navel port
Clip CD	First visual instance of clipper moving towards cystic duct	Retraction of clipper from cystic duct
Clip CA	First visual instance of clipper moving towards cystic artery	Retraction of clipper from cystic artery
Cut CD	First visual instance of cutter moving towards cystic duct	Retraction of cutter from cystic duct
Cut CA	First visual instance of cutter moving towards cystic artery	Retraction of cutter from cystic artery
Electrosurgery	First instance of electrosurgery tool making contact with gall bladder tissue	Complete separation of gall bladder from liver
Capture GB	First visual instance of endobag opening wide	First visual instance of endobag closing shut with specimen intact
Retrieve GB	First visual instance of endobag retracting from operating area	Last visible instance of endobag inside peritoneal cavity