Overcoming the Challenges of Single-Incision Cholecystectomy With Robotic Single-Site Technology

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Objective: To analyze the preliminary experience with the new da Vinci single-site technology for cholecystectomy.

Hypothesis: Single-incision laparoscopic cholecystectomy is technically challenging and a related learning curve clearly exists. A novel approved robotic single-port platform has recently been introduced. This technology may help overcome some of the limitations of manual single-incision surgery relating to triangulation of instruments, ergonomics, and surgical exposure.

Design: A prospective longitudinal observational study was conducted on 100 consecutive da Vinci single-site cholecystectomies.

Setting: Five Italian centers of robotic general surgery.

Main Outcome Measures: Primary end points were feasibility without conversion and the absence of major complications. Operative times were analyzed to define the learning curve using a mixed regression model. A questionnaire collected the opinions of the surgeons involved in using the new technique.

Results: Two patients underwent conversion. No major intraoperative complications occurred, but there were 12 minor incidents (7 ruptures of the gallbladder and 5 cases of minor bleeding from the gallbladder bed). Mean (SD) total operative time was 71 (19) minutes, with a mean (SD) console time of 32 (13) minutes. No significant reduction in the operative times was observed with the increasing of each surgeon’s experience. The technique was judged more complex than standard 4-port laparoscopy but easier than single-incision laparoscopy.

Conclusions: Da Vinci single-site cholecystectomy is an easy and safe procedure for expert robotic surgeons. It allows the quick overcoming of the learning curve typical of single-incision laparoscopic surgery and may potentially increase the safety of this approach.

overcome many limitations of classic SILS in regard to triangulation, ergonomics, quality of vision, and range of motion of instruments. It was cleared for sale in Europe in spring 2011. Our report describes a prospective longitudinal observational study conducted on the first 100 da Vinci single-site cholecystectomies performed at 5 Italian centers of robotic general surgery to address the feasibility, efficacy, and safety of this procedure.

### METHODS

#### DA VINCI SINGLE-SITE TECHNOLOGY

Single-site instruments and accessories are designed for the Si version of the da Vinci Surgical System (Figure 1) and have been described in previous studies.\(^1\)\(^2\)\(^3\) The docking clamps of the robot automatically recognize the shape of the single-site curved cannulas and reassign each master control to the slave instrument on the opposite side, compensating for the crossing of the curved cannulas. The system includes a range of 5-mm nonwristed, semirigid instruments including a monopolar hook, different types of graspers, curved scissors, a medium-large Hem-o-lok clip applier (Teleflex Medical), needle drivers, and a suction irrigator. The single-site port is disposable; all instruments are reposable with a limited number of uses and the metallic cannulas are reusable with disposable caps.

### PROCEDURE DETAILS

A vertical skin incision of approximately 2 cm is made through the umbilicus, the fascia, and the peritoneum to accommodate the single-site port. After establishment of the pneumoperitoneum and docking of the camera and 2 curved single-site canulas, the operating surgeon starts the dissection phase at the conole: the cystic duct and artery are dissected with the monopolar hook, and the gallbladder is detached from the liver bed and inserted into a 10-mm disposable specimen bag. The single-site port is finally removed through the abdominal incision with the specimen bag attached. The fascia defect is closed with interrupted reabsorbable suture and the skin reaproximated with subcuticular continual suture.

### STUDY DESIGN

A multi-institutional robotic surgical consortium, comprising 5 teams of general surgeons from 5 different Italian centers with proven skill and experience with da Vinci surgery (>100 cases each) and access to the Si System, was created to validate the robotic single-site technology for cholecystectomy. Each team of surgeons was required to undergo a stepwise 1-day training program in an animal laboratory under direct supervision of the robot manufacturing company before enrolling patients in the study. The tutorial covered port and cannula placement, docking of the patient cart, and tissue dissection.

Between March 1, 2011, and August 31, 2011, a total of 100 patients within the consortium were enrolled for a robotic single-site cholecystectomy. The study incorporated the learning curve of each surgical team with the new system. Patients were selected based on the following criteria: symptoms and imaging consistent with cholelithiasis; being aged 18 to 80 years; good satisfactory physical status as reflected by an American Society of Anesthesiologists class 1 or 2 only; nonobese with a body mass index (BMI, calculated as weight in kilograms divided by height in meters squared) of less than 30; and no previous right-upper or periumbilical abdominal surgery. Each participating institution received appropriate institutional review board approval. The procedure was explained in full to patients, who were also informed of its innovative nature and the expected outcomes and foreseeable potential risks. They were also informed of the available alternatives before written consent was given.\(^4\)

For each operation of the study, surgeons had to follow a specifically designed step-by-step procedure guide. Perioperative information of each procedure was collected by qualified designated personnel using standardized case report forms and entered into a multi-institutional database. Information included patients’ demographics and BMI; operating times (including access preparation, console, defect closure, and total times); problems encountered with single-site technology (ie, gas loss or instrument collision) or with the patients’ anatomy (ie, adhesions or exposure); and occurrence of intraoperative complications, such as bleeding or gallbladder perforation, or conversions (to 4-port laparoscopy or to open surgery) and the reasons for this. The primary goal of the study from an efficacy standpoint was completion of the procedure without conversion. The primary goal in terms of safety was freedom from major adverse events such as serious intraoperative injury or death. Other goals and focal points included measuring the times required to complete the procedure and analyzing the effect of the learning curve on the different recorded times. The issue of cost was not addressed by our study. In addition to collecting data about the procedure, at the completion of the study, an 11-item questionnaire was administered to each of the 5 operating surgeons to gather their technical and clinical opinions about robotic single-site technology.

### STATISTICAL ANALYSIS

Continuous data are reported in terms of mean and standard deviation, median, and range; categorical data are reported in terms of count and percentage. A mixed regression model, with a random effect to account for surgeon variation differences, was fitted to evaluate the association of surgical times, corresponding to the main steps of the procedure with patient number (as a proxy for experience). The slopes of the curves measuring the effect of progressive learning and their 95% confidence intervals are shown. To graphically represent the learning curves, each surgeon’s individual operative time data was plotted against his level of experience (ie, case number) together with the best linear fit. Stata version 12 (Stata Corp) was used for computation. All tests were 2-sided.

### RESULTS

The study group included 71 women and 29 men, with a mean (SD) age of 53.4 (12.9) years (range, 19-78 years)
and a mean (SD) BMI of 24.4 (3.7) (range, 16.5-29.7). Of the first 100 patients who underwent single-site robotic cholecystectomy, 2 (2%) were converted to open surgery owing to unexpected chronic inflammation at the hilum of the gallbladder. One of these patients was first converted to 4-port classic laparoscopy then to open surgery. There were no deaths from any cause during the study period and no major intraoperative injury was reported. Minor intraoperative complications occurred in 12 patients (12%), including 7 ruptures of the gallbladder and 5 cases of minor bleeding from the gallbladder bed. The single-site port was sometimes difficult to put into position (mean difficulty score, 3.2, with a range between 1 [easy] and 5 [very difficult]), and a tendency to tear the internal silicone edge during this phase was reported in 15 cases (15%) by 4 of the 5 evaluating surgeons. A minor gas leak between the cannulas and the silicone port that did not require any specific action was also noted during 7 operations (7%) by 3 surgeons. Total (SD) operative time was 71 (19) minutes (median, 70 minutes; range, 39-140 minutes). Subcomponents of this operative time included insertion of the robotic SILS device (mean [SD], 13 [6] minutes; median, 15 minutes; range, 5-35 minutes), console cholecystectomy time (mean [SD], 32 [13] minutes; median, 31 minutes; range, 12-80 minutes), and closure of the parietal incision (mean [SD], 17 [8] minutes; median, 16 minutes; range, 5-47 minutes). Regarding the learning curve analysis, 5 different surgeons (1 for each center) were involved in the study. Each operated on 12 to 42 patients (median, 18 patients). To increase the homogeneity of the data, the analysis of the learning curves was limited to the first 20 patients operated on by each surgeon. The results from the mixed linear models are summarized in Table 2. Graphs plotting time as a function of experience (number of patients) are presented in Figure 2. As shown, none of the considered times (total time and each of its main components) appeared to significantly decrease with the number of patients operated on, although some shortening of the total operating time could be observed. More specifically, cumulative analysis of the console time, which represents the most important operative step, was graphically represented by an almost flat line, showing no significant reduction in the time required for the robotic dissection of the gallbladder with the increasing of each surgeon's experience. The quality of vision with the 8.5-mm 3-dimensional optics was rated slightly inferior to that provided by standard 12-mm da Vinci optics by 2 of the 5 surgeons. The ergonomy of the single-site setup in comparison with standard multiport robotic surgery was judged worse by 2 surgeons and equal by the other 3. In rating the degree of difficulty encountered during the console dissection with the da Vinci single-site cholecystectomy, in comparison with other techniques, all surgeons agreed in stating that it was more complex than standard 4-port laparoscopy but easier than single-incision laparoscopy (3 of 3 with experience with SILS). All 5 surgeons believed that single-site cholecystectomy may offer a cosmetic benefit to the patient, whereas only 2 thought the procedure is likely to lessen postoperative pain.

Table 1. Answers of the 5 Surgeons to the 11-Item Questionnaire on Technical and Clinical Opinion on Robotic Single-Site Technology

<table>
<thead>
<tr>
<th>Questions</th>
<th>Surgeon 1</th>
<th>Surgeon 2</th>
<th>Surgeon 3</th>
<th>Surgeon 4</th>
<th>Surgeon 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Robotic single-site port insertion difficulty score, 1 = easy to 5 = difficult</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Major gas leak during surgery</td>
<td>Never</td>
<td>Sometimes</td>
<td>Never</td>
<td>Sometimes</td>
<td>Sometimes</td>
</tr>
<tr>
<td>Quality of 3-dimensional vision: 8.5-mm camera vs 12-mm camera</td>
<td>Worse</td>
<td>Same</td>
<td>Never</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Ergonomics of robotic single-site vs robotic 4-port cholecystectomy</td>
<td>Worse</td>
<td>Worse</td>
<td>Same</td>
<td>Same</td>
<td>Same</td>
</tr>
<tr>
<td>Robotic single-site vs laparoscopic 4-port cholecystectomy</td>
<td>More difficult</td>
<td>More difficult</td>
<td>More difficult</td>
<td>More difficult</td>
<td>More difficult</td>
</tr>
<tr>
<td>Robotic single-site vs SILS cholecystectomy</td>
<td>No SILS experience</td>
<td>No SILS experience</td>
<td>Easier</td>
<td>Easier</td>
<td>Easier</td>
</tr>
<tr>
<td>Robotic single-site has cosmetic advantage</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Robotic single-site leads to less postoperative pain</td>
<td>No</td>
<td>Do not know</td>
<td>Do not know</td>
<td>Do not know</td>
<td>Yes</td>
</tr>
<tr>
<td>Robotic single-site is a safe operation for the patient</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Safety of robotic single-site is equal to 4-port</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Are you considering other applications of robotic single-site surgery?</td>
<td>Do not know</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Abbreviation: SILS, single-incision laparoscopic surgery.

Table 2. Mixed Linear Model to Assess the Association of Operating Time and Surgeon’s Experience (Using Number of Patients Operated on as a Proxy)

<table>
<thead>
<tr>
<th>Operative Step</th>
<th>Random Effect for Surgeon, Slope (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access preparation time</td>
<td>-0.18 (-0.40 to 0.05)</td>
<td>.12</td>
</tr>
<tr>
<td>Console time</td>
<td>0.32 (-0.23 to 0.87)</td>
<td>.26</td>
</tr>
<tr>
<td>Defect closure time</td>
<td>0.01 (-0.32 to 0.34)</td>
<td>.95</td>
</tr>
<tr>
<td>Total operating time</td>
<td>-0.11 (-0.88 to 0.66)</td>
<td>.78</td>
</tr>
</tbody>
</table>
The da Vinci single-site cholecystectomy was regarded as a safe procedure by all surgeons involved in our study and as safe as the standard 4-port laparoscopic operation. Four out of 5 surgeons participating in this trial claimed to be considering extending the application of the da Vinci single-site technology to the treatment of other conditions.

**COMMENT**

Laparoscopic cholecystectomy has now been performed for more than 20 years and represents the gold standard treatment for symptomatic cholelithiasis. This procedure has been reported to be relatively easy to master with robotic assistance, with functional results similar to those of conventional laparoscopy. Despite the greater stability and higher precision of the da Vinci robotic system combined with its 3-dimensional vision, no clear evidence has demonstrated any advantage of this technology over simple 4-port laparoscopic cholecystectomy, with the drawback of a prolonged operative time and a higher cost. During recent years, the laparoscopic technology has made an important developmental step forward from multiple-site to single-site incision interventions. Since its introduction, single-incision laparoscopic cholecystectomy has not gained widespread use, mostly because of the physical limitations of this technology that compromise optimal triangulation, the ergonomy of the procedure, and the quality of vision, leading to problems of tissue exposure. Traditional instruments and platforms have significant limitations when used for SILS. Thus, the current solution to reduce the difficulty of SILS is the adoption of articulating instruments and of 5-mm extra-long scopes with a deflectable tip. Still, these issues are largely governed by the skill and efficiency of the operator and cameraman using inline instruments that are limited in their maneuverability. Additional transabdominal suspending sutures to retract the gallbladder are often required to expose the hilum of the gallbladder and safely complete the cholecystectomy owing to the limited number of instruments that can be introduced simultaneously through most available single-access devices. Use of this method violates the principle of true single-site surgery and might reduce part of its claimed benefit. The introduction of robot-assisted remote single-site cholecystectomy with the da Vinci Si System creates a totally new benchmark for SILS. This technology was designed to overcome the constraints of SILS and minimize some of its related difficulties by reducing the manual skill required and potentially shortening the surgeon’s learning curve. The use of robotics alleviates external instrument conflicts and provides some
aid with triangulation, both of which are capable of reducing the trauma to the liver and surrounding structures induced by the intermittent retraction of the fundus of the gallbladder and the blind insertion of instruments that can occur during standard SILS. It is also conceivable that the robotic solution might reduce the intraoperative bleeding from the liver bed and the spillage of bile from the gallbladder often encountered during SILS procedures, which could play a role in the occurrence and degree of postoperative pain and complications. In a systematic review by Antoniou et al²¹ of 29 studies of SILS cholecystectomies including 1166 patients, the practice to suspend the gallbladder with the use of sutures was correlated with a significant increase of the complication rate from 3.3% to 13.3%. The primary purpose of this multicenter longitudinal observational study was to show the feasibility and safety of single-site da Vinci cholecystectomy in a large series. The observed 2% conversion rate with a 12% incidence of minor intraoperative complication (7% incidence of bile spillage from the gallbladder and 5% of minor bleeding from the liver bed) and the absence of major complications are comparable with the results of most published series of SILS cholecystectomies.¹⁸,²⁰,²¹

In surgery, one important factor in deciding whether to embrace a new technology for an old problem is the degree of difficulty in mastering the new skill set. The time to complete the task is the parameter most commonly used to objectively evaluate a learning curve. Four comparative studies on conventional 4-port laparoscopic vs multiport robotic cholecystectomy have described reaching equivalent operative times using the robot after a learning curve of 20 to 50 procedures.¹⁰,²²-²⁴ A learning curve for the robotic set-up time was observed in all reported studies as an important component of the total operative time. However, greater advantages are expected when the robotic system is used in a more complicated operative setup such as with the SILS cholecystectomy. Although experienced laparoscopic surgeons can safely perform an SILS cholecystectomy in about the same time they do using the 4-port technique,²⁵ the steep learning curve and potential complications of this technology²⁶,²⁷ might have prevented its implementation on a larger scale. Solomon and colleagues²⁸ reported a learning curve of approximately 10 cases to master the SILS cholecystectomy, dropping the average operative time from 110 minutes to a plateau of 75 minutes. Kambaty et al²⁹ also noted that the operative time tended to stabilize after the first 10 cases, following a decrease from an initial time of 105.3 minutes to the 74.4 minutes of the 10th case. In a series of 80 patients, Qiu³⁰ observed the effect of the learning curve on operative time extending during the first 20 cases of SILS cholecystectomy, with a significant progressive shortening of the duration of surgery during this training period, before reaching the typical plateau of proficiency. Our hypothesis was that with the features of the new single-site robotic platform, surgical skills would be more easily mastered and the learning curve would be shortened. Indeed, we observed that the learning curve of the 5 surgeons into console dissection had largely taken place prior to this study, as demonstrated by the flat timeline with increasing experience, which supports the hypothesis that the ergonomic aid provided by the robot in the single-site setting obviates the need for specific extra training for surgeons already familiar with laparoscopic cholecystectomy and multiport robotic surgery. In this preliminary study, we did not address the issue of costs, having decided to focus only on the potential value of the new technology. Clearly, one could easily argue that the use of the robot for a cholecystectomy is unnecessary and too expensive. However, when looked at in the light of the evolution of surgical technique, we believe that single-site robotic technology is taking SILS beyond its current limits and it would be easy to anticipate its adoption in the performance of more complex intra-abdominal procedures, currently feasible only with a multiport approach, as well as for natural orifice surgery.

In conclusion, this study demonstrated that robotic single-site cholecystectomy can be performed with high standards of safety and efficacy by general surgeons experienced with robotic surgery after 1 day of structured training with the new technology. The robotic technology is a compensatory technique that can overcome the constraints and the ergonomic limitations of SILS and is potentially capable to realize the full potential of the single-access approach.³¹ We showed that it allows the quick overcoming of the learning curve that is typical of most new procedures, particularly of the laparoscopic single-incision approach. This is likely to increase the safety of SILS and, in turn, expand its adoption to a wider number of general surgeons and surgical procedures. The relatively short time needed to complete the single-site robotic cholecystectomy and the low morbidity encountered in our study support the opinion shared by the surgeons involved in the study that this technique may turn out to be safer than classic single-incision laparoscopic cholecystectomy. Nevertheless, the low overall incidence of major complications expected with a cholecystectomy, however performed, would require a much greater number of patients to prove any safety advantage of one technique over another.

Future randomized prospective trials are also needed to establish the possible advantage offered by this technology in terms of postoperative pain and cosmetic results as well as the long-term sequelae related to the umbilical wound.


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