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ORIGINAL ARTICLE

Robotic Single-Port Cholecystectomy Using a New Platform: Initial Clinical Experience

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Abstract
Background The technique of single-port laparoscopy was developed over the past years in an attempt to reduce the invasiveness of surgery. A reduction of incisions and their overall size might result in enhanced postoperative cosmesis and potentially reduce pain when compared to conventional techniques. While manual single-port laparoscopy is technically challenging, a newly approved robotic platform used with the da Vinci Si System (Intuitive Surgical, Sunnyvale, CA, USA) might overcome some of the difficulties of this technique.
Methods Patients with cholelithiasis were scheduled for robotic single-port cholecystectomy in an initial clinical trial. Demographic data, intra- and short-term postoperative results were assessed prospectively.
Results Twenty-eight patients (22 females/6 males; median age, 48 years) underwent robotic single-port cholecystectomy in our first week of clinical cases. Median OR time was 80 min with a median docking time of 8 min and median robotic console time of 53 min. Two patients underwent intraoperative cholangiography. Eight cases presented with adhesions, tissue alterations, or anatomical abnormalities. No conversions, intra- or postoperative complications occurred.
Conclusion Robotic single-port cholecystectomy appears feasible and safe in our early experience. The robotic approach to single-port surgery seems to overcome some of the technical difficulties of manual single-port surgery. This robotic platform may facilitate completion of more complex cases.

Keywords Robotic surgery · Single incision · Laparoendoscopic single site · SILS · Laparoscopy

Introduction

Recently, minimally invasive cholecystectomy underwent a strong development towards less invasive methods such as natural orifice transluminal endoscopic surgery, reduced port, and single-incision surgery.[1–7] Reports of these new methods indicate theoretic improvements in some clinical parameters such as pain, wound-related complications, and cosmetic outcomes.[8–10] Additionally, such less invasive methods seem to find great patient acceptance.[11–13] Among the above-mentioned methods, single-port cholecystectomy appears to be gaining clinical significance with numerous reports in the recent literature.[14–18]

Besides this enthusiasm, single-port cholecystectomy is associated with technical limitations due to the enhanced complexity of the approach and limited number of specialized instruments or platforms.[19] Using conventional laparoscopic instruments for a single-port or single-incision approach leads to collisions and reduction of triangulation. Specific curved or articulated instruments on the other hand add complexity in handling especially when used crossing at the abdominal wall (right hand controls left instrument and vice versa). While instrumentation for manual single-incision surgery continuously improves and standard cases of cholecystectomy seem to be successfully performed, more complex cases, for example high body mass index (BMI) or male patients, are more likely to result in conversions to standard laparoscopy.[20]

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In an attempt to overcome the above-mentioned limitations, a few experimental reports about robotic single-incision laparoscopy can be found in the literature.[21,22] In a couple of studies, authors have used robotic instruments crossing at the level of the abdominal wall and switching robotic arm control to regain dexterity[23,24]. While these reports on the experimental setup were very promising, clinical adoption has been limited.

In the meantime, specific robotic instruments using the same principle have been developed and recently received approval in the European market. These new *da Vinci Single-Site*™ Instruments and Accessories are designed to be used with the da Vinci Si Surgical System (Intuitive Surgical International, Sunnyvale, CA, USA) to perform single-incision laparoscopic surgery. This setup re-creates intuitive control at the surgical console and should therefore facilitate single-incision surgery. We present our early clinical experience that was gathered during a limited product launch after the device received CE mark approval.

Methods

After approval of the new robotic instruments for the European market, initial patients with confirmed cholelithiasis were consented and scheduled for robotic single-incision cholecystectomy under an IRB-approved protocol. The inclusion criteria were patients between 18 and 80 years old with symptomatic cholelithiasis. The exclusion criteria included acute cholecystitis, suspicion of common bile duct stones, pregnant patients, severe lack of cooperation due to psychological or severe systemic illness, or the presence of medical conditions contraindicating general anesthesia or standard surgical approaches. All patients underwent surgery by two different surgeons already experienced in standard single-site surgery (>50 cases) and robotic surgery (>100 cases).

Demographic, intra- and postoperative data were prospectively collected. Case difficulty based solely on underlying disease and anatomy was estimated by the operating surgeon upon completion of cases based on a scale of 1 (very easy) to 10 (most difficult). All the patients were followed up at postoperative day 14 for a clinical visit and at postoperative week 6 with a phone call.

To enable single-incision surgery, curved cannulae (Fig. 1) are placed through a special silicone port, with the curves of the cannulae crossing over each other at the level of the abdominal wall. This allows alignment of the remote center and effectively re-creates triangulation of the instruments. The da Vinci Surgical System automatically switches arm control for ease of instrument control. Available instruments include non-articulating needle driver, atraumatic grasper, right-angle dissector, curved scissors, hook, clip applier, and a suction/irrigator device. The single-site instruments are flexible but not endowristed, and this is their main difference with the standard robotic instruments.

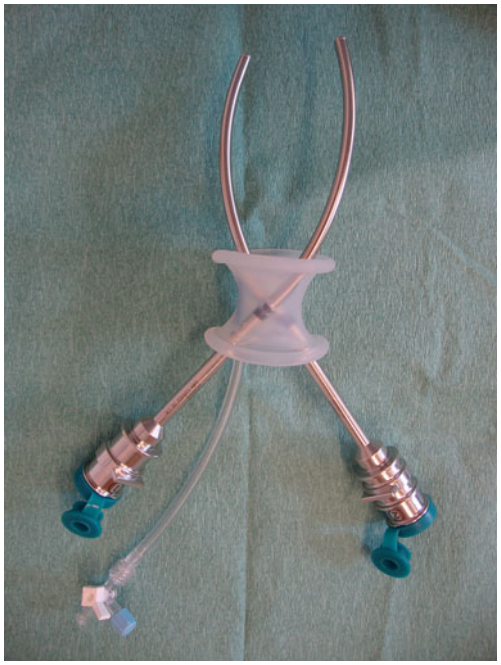

Fig. 1 Curved cannulae

Surgical Procedure

The patients were placed in supine position with the legs apart. A periumbilical skin incision of 2.0–3.5 cm was formed followed by blunt dissection to the abdominal fascia. The abdomen was entered under direct vision and a finger sweep performed to check for adhesions. Using an atraumatic clamp, a specific silicon port was grasped (Fig. 2) and inserted through the previously formed incision (Fig. 3). Insufflation to about 12 mm Hg was installed through the port using a

Fig. 2 Intuitive single-incision port before insertion

Fig. 3 Intuitive single-incision port placed in a periumbilical incision

conventional laparoscopic insufflator. A straight 8.5-mm trocar for the camera and a 5-mm laparoscopic port were introduced to confirm the operability. The 5-mm port was then removed. The patients were then placed in an 8 to 10° reversed Trendelenburg position with a slight roll to the left. The camera arm was docked to the corresponding trocar and the robotic camera was inserted. Next, curved robotic cannulae were inserted under direct vision. Two arms of the da Vinci surgical system were docked to the cannulae, and flexible robotic instruments were mounted (Fig. 4). The 5-mm assistant's trocar was reinserted. A laparoscopic grasper was used to retract the gallbladder at its fundus in a cephalad direction (Fig. 5). The triangle of Calot was exposed by lateral retraction from the robotic surgeon's left hand. The anatomy was dissected using a robotic cautery hook, and if needed, a robotic Maryland forceps. After clear identification of cystic duct and artery, both structures were clipped with robotic Hem-o-lock clips (Teleflex Medical, Ireland) and transected using robotic scissors. The gallbladder was then

Fig. 4 Insertion of second robotic cannulae

Fig. 5 The da Vinci SP Surgical System during surgery

dissected off the liver bed using the robotic cautery hook and retraction from the robotic as well as the laparoscopic grasper. After completing the dissection, the liver bed was controlled for hemostasis and the surgical field flushed using robotic suction and irrigation. The laparoscopic grasper was removed together with its trocar, and a MemoBag (Teleflex Medical, Ireland) was placed intra-abdominally through the port. The gallbladder was placed inside the bag using the robotic instruments and laparoscopic assistance. The bag was held using a laparoscopic grasper. The robotic instruments and camera were removed and the robot undocked. The robotic trocars were removed, and the port was exteriorized. Lastly, the gallbladder was removed, and the incision was closed in layers.

In the case where cholangiography was needed, this step was performed before complete dissection of the cystic duct. After proximal clipping of the cystic duct, the laparoscopic grasper was removed, and a laparoscopic balloon cholangiocatheter was inserted intra-abdominally. The catheter was placed into the cystic duct, and the balloon was insufflated to secure the correct location. The robotic instruments and camera were removed and the robot re-docked. The robotic arms were moved out of the surgical field. The C-arm was brought to the patient's left side, and cholangiography was performed in the usual fashion. After completion, the C-arm was removed. The balloon of the cholangiocatheter was desufflated to remove the catheter. The da Vinci Surgical System was re-docked and the procedure completed in its standard fashion.

Results

Twenty-eight patients underwent robotic single-incision cholecystectomy as part of this initial case series. Twenty-two patients were female and six were male. The median age was 48 years (range, 28–77). The median body mass

index was 26 kg/m² (range, 18–36). The median ASA score was 2 (range, 1–3).

The median OR time was 80 min (range, 45–195), with a median port placement time of 3 min (range, 1–8), a median docking time of 8 min (range, 1–18), and a median console time of 53 min (range, 23–134). The median estimated blood loss was 5 ml (range, 0–50). The median length of skin incision was 3 cm (range, 2–3.5). The estimated case difficulty was five cases (range, two to eight): eight cases were rated with a difficulty of five or above.

The learning curve of the procedure, with respect to operative time, is summarized in Figs. 6 and 7. Of note, the operative time decreased during the study period as the robot docking time.

Two patients underwent intraoperative cholangiography. No complications associated with this additional step were observed. The cholangiography added an additional 19 min to the operating time including additional robotic docking time. The robotic setup did not interfere with the technique of intraoperative cholangiography.

Concerning the outcomes, no intraoperative complications occurred, and no conversions or additional ports were required. Moreover, no postoperative complications, readmissions, or reoperations were reported.

Discussion

Single-incision and single-port surgery underwent a massive movement over the past years with growing numbers of procedures performed and scientific articles published. It appears that this surgical approach might become a valid method for certain procedures such as cholecystectomy under specific circumstances. While many specific instruments became available on the market to support this new surgical access with camera and multiple instruments through one incision, a recent review of single-incision laparoscopic

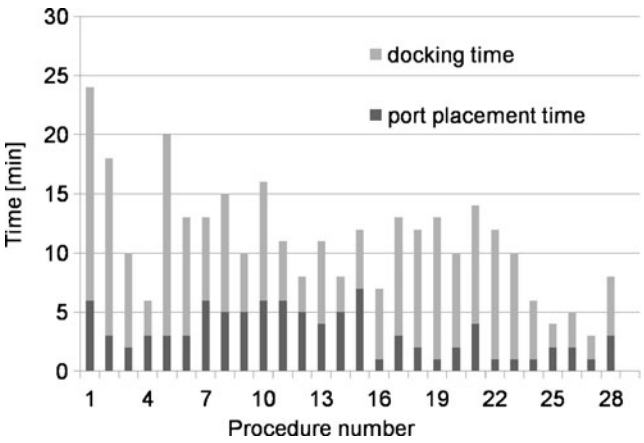

Fig. 6 Learning curve for port placement and robot docking time

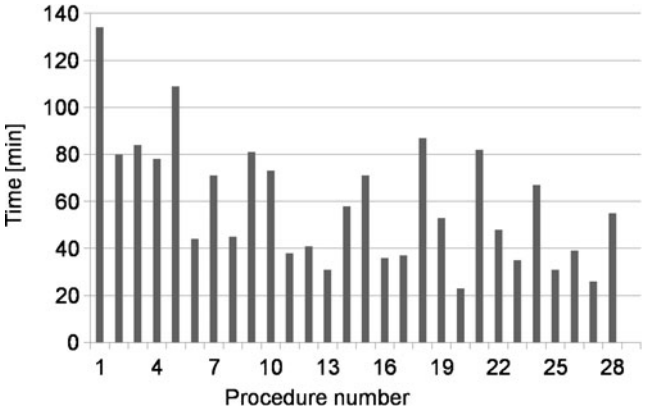

Fig. 7 Learning curve for da Vinci console time

cholecystectomy concluded that instruments still need further improvement.[20] A potential solution to such an improvement might be the robotic technology. The above described new single-site instruments by Intuitive Surgical (Sunnyvale, CA, USA) were only recently approved for the European market. The main difference between the standard robotic approach and the new single-site platform remains the semiflexible instruments with however the loss of endowristed technology. These instruments can be inserted in curved cannulae, allowing for improved triangulation that was not possible to achieve with the rigid straight cannulae.

We present a first series of clinical cases. Our very early experience suggests that robotic single-incision cholecystectomy is feasible and safe using this new platform. Previous literature suggests that conventional single-incision cholecystectomy can lead to a higher conversion rate and longer operative times.[20] Our overall operating times fall well within the available data,[20] but are longer than previously published case series of single-incision cholecystectomy from our institution.[25] We noted that a significant number of relatively difficult cases were encountered in this series (extensive adhesions, post-infectious tissue alterations, atypical anatomy, acute cholecystitis, and higher BMI) and were completed without conversions or complications. We believe that the relative complexity of cases and a certain learning curve regarding system installation and handling are responsible for the longer operative times. Docking times of the system were overall within reason, but still contribute to the length of the cases. Since the docking time already significantly decreased during these initial 28 cases, we are confident that the system can be installed in acceptable times after a few initial cases. In that sense, the last five docking took a median of 4 min. Our console times showed that these complex cases were completed successfully with reasonable surgical times comparable to the literature. Work at the console was very comfortable for the surgeon and surgical dexterity felt restored, especially when compared to manual single-port surgery. We suspect that a number of these complex cases would have been

extremely difficult to be performed with manual single-port laparoscopy, and we would have expected a higher conversion rate. Therefore, we assume after this initial clinical assessment of the da Vinci Single-Site Instruments that it might be an excellent option for complicated cases such as those with acute or chronic cholecystitis, higher BMI, or more advanced single-port procedures. Further clinical trials will have to confirm these potential advantages over manual single-port cholecystectomy, as well as the suitability of the system for other indications and cost-related issues.

Disclosure Dr. Monika Hagen has a financial relationship with Intuitive Surgical. All other authors have nothing to disclose.

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