



Outcomes in Single-port Versus Multiport Robotic Cholecystectomy: A Systematic Review of the Literature

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Authors' contributions

This work was carried out in collaboration between all authors. Authors SS, JK and AM designed and provided the concept of the study. Authors SS, JK and MA managed the acquisition of data. Authors SS, JK, MA and AM interpreted data and completed analysis. Authors SS, JK and AM designed the final draft of the manuscript. Authors SS and AM managed the critical revision of the manuscript for important intellectual content. Authors SS and MA completed the statistical analysis. Authors SS, JK, MA and AM have maintained administrative, technical and material support. Author AM supervised the whole study. All authors read and approved the final manuscript.

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ABSTRACT

Background: Single incision laparoscopic surgery (SILS) had initially gained significant traction due to safety and feasibility that were comparable, in addition to the cosmetic advantages over traditional laparoscopy. However significant limitations of SILS including narrow working space and poor triangulation, lead to longer operating times [1]. Due to these limitations most of the surgical community have reverted back to traditional four-port laparoscopy for cholecystectomy. After the introduction of the robot, the multiport (MP) platform was the initial method used for cholecystectomy. The robotic single-site (SP) surgery platform is proposed to overcome some of the limitations of SILS while maintaining its benefits.

Objectives: We present a systematic review comparing clinical outcomes of multiport versus single-port (SP) robotic cholecystectomy for the treatment of benign gallbladder disease.

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Materials/Patients and Methods: Key words “Robotic”, “Robotic assisted”, “daVinci robot”, “daVinci robot assisted”, and MeSH terms “cholecystectomy”, “gallbladder”, “biliary”, “cholelithiasis” were searched on Medline, Embase and Cochrane databases, to acquire citations between 1980 and 2012. Two treatment arms were identified: single port (SP) and multiport (MP). Variables considered included age, gender, BMI, operating time, conversion to open, complications and mortality. Primary outcomes include; thirty day mortality, thirty day morbidity, and conversions to traditional laparoscopy or laparotomy. The secondary outcome measure was operative time. Demographics analyzed included age, sex, and body mass index (BMI).

Results: The initial search revealed two hundred and fifty five citations. Exclusion based on title criteria revealed seventy five articles. Twenty-two articles fulfilled further inclusion criteria. The SP arm included two hundred cases (six articles) and MP included three hundred and eighty three cases (sixteen articles). Pooled mean (PM) ages were 50.16 years and 47.38 years for SP and MP. BMI was 28.16 Kg/M² (SP) vs. 28.24 Kg/M² (MP). Operating times were longer in the SP group, (92.94 minutes vs. 91.13 minutes). Complication rate of 5/200 in SP group vs. 13/383 in MP group were found, and overall mortality was zero for both.

Conclusions: Single incision robotic cholecystectomy appears to be comparable to multiport robotics in terms of safety and feasibility, however larger studies, randomized, need to be conducted for more statistically significant data.

Implication for Health Policy Makers/Practice/Research/Medical Education: An understanding of the outcomes between standard multiport and single-port robotic cholecystectomy will guide further research and quality improvement with respect to cost-effectiveness of certain robotic procedures.

Keywords: Robotic surgical procedures; cholecystectomy; minimally invasive surgical procedures.

1. INTRODUCTION

Laparoscopic cholecystectomy is the most widely offered treatment for benign gallbladder disease [1]. The evolution of single incision laparoscopic surgery (SILS) and robotic surgery has introduced surgical alternatives to the traditional four-port laparoscopic approach. SILS was proposed to offer superior cosmetic appearance, and improved post-operative pain due to a decrease in the number of incisions [1]. In addition, wide acceptance of SILS has been tempered due to technical challenges such as poor anatomic visualization, narrow working space, poor triangulation, internal and external instrument clashing, longer operative times [1], and higher incidence of port-site hernia rates. These complexities have dampened enthusiasm for SILS within the minimally invasive surgical community.

Robotic Multiport cholecystectomy (MP, Robotic Multi-port Cholecystectomy) offers potential advantages over traditional four port laparoscopy such high-fidelity three-dimensional (3D) images, articulated instruments, increased degrees of wrist motion, and substantial decrease of human tremor [2,3,4,5]. The development of single port robotic cholecystectomy (SP, Robotic Single-Port Cholecystectomy) with articulated instruments and three-dimensional imaging has the potential to overcome some of the limitation of SILS

[6,7,8,9]. The SP is performed on the da Vinci Si robot with the single site, five-lumen port. It is suggested that this system allows for improved visualization of anatomy (compared to conventional laparoscopy) due to the three-dimensional camera compared with the standard two-dimensional camera. In addition decreased instrument clashing and improved triangulation of instruments with curved trocars, software reversal to align right hand manipulation with right instrument movement, and improvement of ergonomics, consequently overcoming some of the limitations of the SILS platform, but maintaining the benefits of MP [2,3,4]. There have not been any randomized control trials, systematic reviews or pooled analyses assessing the safety and efficacy of SP. Thus far there have a number of case studies and case series reporting single institution experience. We hypothesize that SP and MP robotic cholecystectomy are equivalent with respect to outcomes, mortality and overall demographics.

2. MATERIALS AND METHODS

We performed a search of the Embase, Medline and Cochrane databases with the search terms “Robotic”, “Robotic assisted”, “daVinci robot”, “daVinci robot assisted”, and MeSH terms “cholecystectomy”, “gallbladder”, “biliary”, “cholelithiasis” from 1980 to 2012. Two different authors with surgical experience analyzed

publications independently. Publications were included in the analysis if they reflected multiple robotic cholecystectomies performed using the MP and / or SP format, those performing cholecystectomy as the solitary procedure, human subjects only and written in English. The studies were grouped into two arms: SP and MP (Fig. 1). Data was then extracted from the selected studies and analyzed. The primary outcomes included thirty day mortality, thirty day morbidity, and conversions to laparoscopy or laparotomy. A secondary outcome measure was operative time. Demographics analyzed included age, sex, and body mass index (BMI).

Data from the selected studies were entered into a custom spreadsheet for analysis. Pooled means and standard deviations were generated for Patient BMI, age and operating time. In the event that the median was reported instead of the mean, the mean was calculated by: $x = \frac{a+2m+b}{4} + \frac{a-2m+b}{4n}$ where x =mean, m =median, a =lowest range value, b =highest range value, and n =sample size. Only the data range and median were given, the sample variance

was calculated as: $s^2 = \frac{1}{n-1} \left(\left(a^2 + m^2 + b^2 + \left(\frac{n-3}{2} \right) \left(\frac{(a+m)^2 + (m+b)^2}{4} \right) \right) - \left(n \left(\frac{a+2m+b}{4} + \frac{a-2m+b}{4n} \right)^2 \right) \right)$

where, s^2 =variance, m =median, a =lowest range value, b =highest range value, and n =sample size.

Standard deviation (s), as calculated by: $s = \sqrt{s^2}$. Once the mean was calculated, the pooled mean for the studies included in each group was calculated as: $x_p = \frac{x_1 n_1 + x_2 n_2 + \dots + x_i n_i}{n_1 + n_2 + \dots + n_i}$, where x_p =pooled mean, x_i =mean of each study, and n_i =sample size of each study. Similarly, the pooled standard deviation for studies included in each group was calculated as: $s_p = \frac{s_1 n_1 + s_2 n_2 + \dots + s_i n_i}{n_1 + n_2 + \dots + n_i}$ where s_p =pooled standard deviation, s_i =standard deviation of each study, and n_i =sample size of each study. Finally, a 95% confidence interval around each pooled mean is calculated as: $95\% \text{ CI} = x_p \pm 1.96 \frac{s_p}{\sqrt{n_1 + n_2 + \dots + n_i}}$, where x_p =pooled mean, s_p =pooled standard deviation, and $n_1 + n_2 + \dots + n_i$ =total sample size.

3. RESULTS

The initial search yielded two hundred and fifty five papers. Seventy-five papers were selected

for full text analysis based on their titles. Exclusion criteria included non-human subjects, non-English language, surgery on a robotic format apart from the da Vinci, or concomitant procedure with cholecystectomy, Fig. 1 illustrates study methodology.

3.1 Patient Demographics

The SP studies range from four to one hundred subjects per study. Pooled mean age of the participants for the SP studies were calculated to be 50.2 years, and for the MP studies were 47.4 years. The number of subjects per study ranged from one to fifty two in the MP studies. The pooled mean BMI was 28.16 Kg/M² for SP and 28.24Kg/M². The male to female ratios for the SP was 1:2.1 and for MP was 1:3.1, cumulatively for those studies which stated the male to female ratios. The populations of the SP and MP arms were, thus, comparable in demographics.

3.2 Single Port Operative Technique

From the available information, it appeared that the operative technique used in all of the SP studies were similar. The abdominal access is described through a two to three cm midline or transverse/crescentic periumbilical incision [6-11]. Konatantinos reports that a midline incision was used initially, however a crescent-shaped incision over the lower rim of the umbilicus is being used subsequently, to improve cosmetic result [11]. Blunt dissection, down to the fascia is described. The fascia is reported to be sharply divided and retracted. Finger sweep is then performed to check for anterior abdominal wall adhesions [9]. Kontantinos also reports the essential step of lubrication of the Gelport with water or saline, prior to insertion [11]. The Gelport is then described to be grasped using a non-crushing curved clamp and introduced through the incision [9,11]. Once the port is in situ the abdomen is insufflated to between twelve – fourteen mmHg. The curved instruments are then inserted under direct visualization. The assistant cannula is inserted last [9,11]. The use of a bariatric length grasper to increase the distance from the robotic arms has been reported [7]. The patients were then placed in reverse Trendelenburg position. Only Sugimoto reported using a needle puncture and introduction of a Mini Loop Retractor for gallbladder retraction [7]. Monopolar hook and blunt dissectors were used to dissect out the critical view. Once this had been achieved Hem-O-Lock clips were applied to the cystic artery and duct and the structures

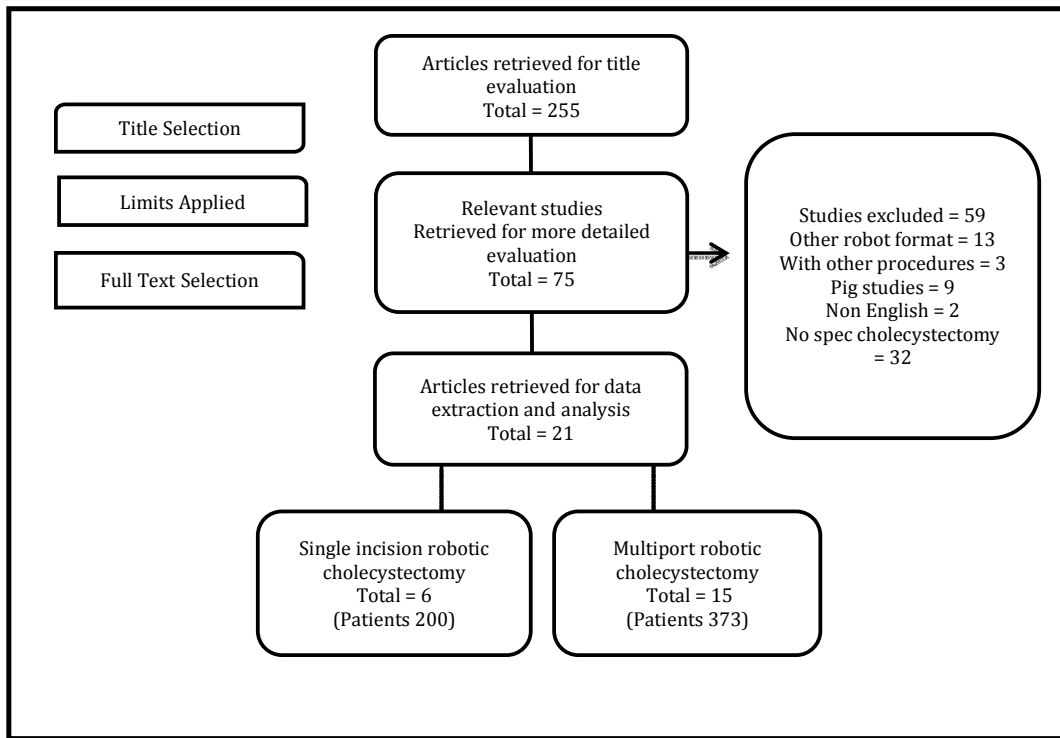


Fig. 1. Article abstraction methodology

divided with scissors or monopolar hook. The gallbladder was then dissected off the liver bed using the monopolar hook cautery. The gallbladder was then placed into an extraction bag, and removed from the abdomen along with the port. The fascia and skin were closed in layers using absorbable stitches.

Cholangiography technique was reported in two studies [8,9]. Kroh reported initially using a 4 French catheter advanced through the laparoscopic clamp at the umbilicus, however due to difficulties in angulation, a separate two millimeter stab incision was made in the right upper quadrant and a percutaneous catheter was used to perform cholangiogram [8]. Morel reported removing the laparoscopic (assistant) port and inserting a laparoscopic balloon cholangiocatheter. Once the catheter was placed into the duct the balloon was inflated. The robot was un-docked and moved back while the C-arm was brought into place.

3.3 Primary Outcomes

3.3.1 Mortality

Mortality was reported as zero for all the MP and SP studies. Complications were reported in 5/200 SP cases and 13/373 cases respectively.

3.3.2 Single port complications

Five complications were reported in the SP studies. Complications are reported as part of the Dindo – Clavian classification (DCC) of surgical complications. Of the five complications, four were grade 1 complications and one 3b complication. Wren reported two DCC grade 1 complications. Both were cases of post-operative urinary retention. One of the patients required catheterization on the first postoperative night and one patient was discharged with a catheter *in situ* [7]. This paper also reported two instances of a small piece of the access port tearing during placement of the extraction bag, which had to be retrieved [7]. Kroh reported one (DCC Grade 1 complication) case of a seroma at the trocar site, which did not need intervention after spontaneous drainage [8]. This paper did also interestingly reports two cases of partial tearing of the multiport trocar. It did make note of three episodes of loss of intraoperative loss of pneumoperitoneum, which required trocar reinsertion after undocking the robot [8]. No complications were reported in Pietrabissa series, however they did also report a tendency to tear the silicone edge during positioning in fifteen cases. Konstantinos reported a DCC Grade 3b complication, which was a case of

post-operative hemorrhage that presented with fall of hematocrit and the patient, underwent an exploratory laparoscopy within twelve hours of the operation. Hemoperitoneum with a large amount of coagulated blood, without an identifiable source of bleeding was found. The patient was reported to have had a history of long-term anticoagulation during her pregnancy [11]. In addition one case of a post-operative wound infection (DCC Grade 1) was also reported in this series, which resolved within five days [11]. Intraoperative gallbladder rupture, liver bed oozing and postoperative pain were not included as complications in our study.

3.3.3 Multi port complications

Thirteen complications were reported in the MP group. Of the thirteen complications, eight were classified as DCC grade 1, two grade 2, one grade 3a, and two grade 3b complications. Ruurda reported three instances of the replaceable hook diathermy detaching during the procedure. However the hook was retrieved two times laparoscopically. On one occasion, which was also not included in the analysis, it was via a four cm laparotomy [2]. Bodner reported one "Redo – operation" for port site bleeding (DCC Grade 3b), however no details of the procedure were included [3]. Breitenstein reported one postoperative bile leak from the cystic duct stump. This was treated with an endoscopic stent in the common bile duct (DCC Grade 3a) [12]. Vidovszky reported three complications (Two DCC Grade 1 and one Grade 2); One patient developed a port site hematoma, without change in hemoglobin. Another patient developed postoperative pulmonary edema and required medical therapy. The third patient developed deep vein thrombosis after discharge, which required readmission to the hospital and anticoagulation [13]. Heemskerk reported four DCC Grade 1 postoperative complications. Three patients had superficial wound infections and one patient developed urinary retention [14]. Jayaraman reported two complications, one patient developed an incisional hernia at the 8mm port site requiring elective repair (DCC Grade 3b), one patient had a retained stone that passed with no further treatment (DCC Grade 1) [15]. Giulianotti reported one port site infection (DCC Grade 1) [4]. Kim and Talamini did not report any complications however did make note of hook cautery falling off without causing any morbidity [5,16,17]. Cadiere reported one complication of post operative bleeding which needed a unit of blood transfusion for a hemoglobin of 8 g/dl (DCC Grade 2) [18].

3.4 Conversions

Data on conversions to either open or to conventional four port laparoscopy or the insertion of an additional port were also collected. This information was reported in all but one of the studies included. In total 7/200 (3.5%) cases were converted in the SP and 8/373 (2.1%) converted in the MP group.

3.4.1 Single port conversions

In the SP studies there were four conversions needing additional ports. Kroh reported one patient needing an additional extraumbilical port for lateral retraction in light of severe inflammatory changes secondary to acute cholecystitis [8]. Konstantinos reported that in three cases an additional assistant port was necessary for traction purposes, in two cases an additional robot arm was used for hepatic retraction and in one case an assistant was used for deeper dissection of Calot's triangle [11]. Wren reported one conversion to open. This was cited to be due to significant adhesions of the omentum to the diaphragm, in addition to severe cholecystitis with a shrunken gallbladder. This patient was excluded from the outcome analysis as it was converted to first a multiport laparoscopy and then to an open procedure [7]. Pietrabissa reported two conversions to open, one of which was initially converted to conventional four port laparoscopy. The reason cited for conversion was unexpected chronic inflammation at the hilum of the gallbladder [10].

3.4.2 Multi port conversions

In the MP treatment arm eight cases were converted to open or conventional laparoscopy. Vidovszky reported three conversions to open or standard laparoscopy secondary to severe inflammation and poor visualization [13]. However the nature of each conversion was not reported, hence these were all placed in the open conversion category in this study. Ruurda reported one conversion to open, because of the surgeons' inability to expose the gallbladder sufficiently due to severe cholecystitis [2]. This study did also report one other case, which needed a four cm mini laparotomy to be made for removal of a detached replaceable hook of the electrocautery instrument, however this was included in the complications sections of this paper. Bodner reported two conversions to conventional laparoscopy due to robotic system breakdown [3]. Giulianotti and Talamini both

reported one conversion each, however did not report reason for the conversion [4,5].

3.5 Secondary Outcomes

3.5.1 Operative times

Operative times were reported in all of the papers reviewed. In papers in which medians were reported, the mean was calculated as shown in the methods section. There was no significant difference in the operative time between the SP and MP groups. SP mean was 92.94 (CI = 90.47 – 95.40), and the MP mean was 91.13 (CI = 88.05 – 94.21).

4. DISCUSSION

This analysis comparing multiport and single port robotic cholecystectomy represents the first attempt to pool together data on this subject for analysis. Due to the small sample sizes and heterogeneity of the data statistical significance cannot be elucidated between the primary outcomes. Both techniques appear to be safe and feasible with postoperative outcomes similar to one another. However, the low overall incidence of major complications expected with a cholecystectomy, which ever way performed, would require a much larger number of patients to prove any safety advantage/ disadvantage of one technique over another [10].

The complexity of the cases included in the case series were relatively high, (extensive adhesions, post infectious tissue alterations, atypical anatomy, acute cholecystitis and higher BMI) and many were completed without conversion or complication [9]. Thus it appears that the selection bias, which existed with SILS cholecystectomy, does not exist with SP robotic cholecystectomy. However indications for SP or MP cholecystectomy should be controlled in future studies to reveal and allow for reliable comparisons of outcomes.

The pooled SP operative times recorded showed no statistical significant differences to MP. This is different from the SILS format, which had significantly longer operating times as compared to conventional four port laparoscopy. It may be that the learning curve for the SP robotic cholecystectomy is shorter than SILS cholecystectomy as most surgeons had one or two structured days of training prior to attempting the procedure. Also the robotic operating time is also markedly affected by the docking times of

the robot, which was not consistently reported. Future studies should account for this carefully, to delineate the learning curves of the operating room team and the surgeon independently. Information regarding the surgeon's previous conventional laparoscopic cholecystectomy and SILS cholecystectomy experience level will also influence the learning curve and this should also be controlled for in future studies.

The majority of the papers included in this pooled analysis failed to quantify the cost implications of the procedures being performed. Moving into an era where increased scrutiny will be placed on cost effectiveness it is important for future studies to comprehensively assess for cost implications. The cost as well as outcomes must be taken into consideration when assessing this novel technique.

This pooled analysis was limited to patient demographics and operative times due to the paucity of literature currently published on this topic. There was vast heterogeneity in the quality of the reports, with inconstant attention paid to inclusion and exclusion criteria for patients, total operative time, docking time and actual operating time, previous laparoscopic and robotic experience of the operating surgeon, operative technique, cholangiography inclusion and technique, conversion reporting (additional port vs. laparoscopic vs. open), complications reporting as well as the lack of randomization.

5. CONCLUSION

MP and SP are novel techniques to perform a very common procedure. This paper combines the early reports on these two novel formats. It highlights the need for larger, randomized studies to delineate the safety, efficacy and cost efficiency of these two techniques and also compared to conventional laparoscopy, prior to it being adopted by the wider community of general surgeons.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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