Chapter 7

Robot-assisted laparoscopic choledochojunostomy: comparison to the open approach in an experimental study
Abstract

Introduction: Endoscopic stenting is currently the treatment of choice for palliative relief of biliary obstruction by a periampullary tumour. If treated surgically, a choledochojejunostomy and Roux-en-Y diversion is still performed by laparotomy in a large number of cases due to technical challenges of the biliodigestive anastomosis in the laparoscopic approach. Robotic systems may enhance dexterity and vision and might therefore support surgeons in delicate laparoscopic interventions.

The purpose of this study is to assess the efficacy and safety of performing a laparoscopic choledochojejunostomy and Roux-en-Y reconstruction with the aid of a robotic system.

Methods: Ten laparoscopic procedures were performed in pigs with the da Vinci robotic system and compared to ten procedures performed by laparotomy (controls). OR-time, anastomoses-time, blood-loss and complications were recorded. Effectiveness of the anastomoses was evaluated by postoperative observation for 14 days and by measuring passage, circumference and number of stitches.

Results: OR-time was significantly longer in the robot-assisted group than in the controls (140 vs. 82 min, p<0.05). The anastomoses times were longer in the robot-assisted cases, although not statistically significant (biliodigestive anastomosis 29 vs. 20 min, intestinal anastomosis 30 vs. 15 min, NS). Blood-loss was less than 10 cc in all robot-assisted cases and 30 cc (10-50) in the controls. In both groups, there were no intraoperative complications. In the control group, one pig died of gastroparesis on postoperative day 6. In the robot-assisted group, one pig died on postoperative day 7, caused by a volvulus of the jejunum. At autopsy, a bilioma was found in one pig in the robot-assisted group. In all pigs, the biliodigestive and intestinal anastomoses were macroscopically patent with an adequate passage. Circumference and number of stitches were similar.

Conclusion: The safety and efficacy of robot-assisted laparoscopic choledochojejunostomy was proven in this study. The procedure can be performed within an acceptable time frame.

Introduction

Endoscopic stenting is currently the treatment of choice for palliative relief of biliary obstruction by a periampullary tumour \(^1\,^2\). However, a surgical approach is recommended in case of accompanying gastric outlet obstruction, in case of failure of endoscopic treatment and in patients with relatively good projected survival \(^3\,^6\). The surgical procedure, a biliary bypass combined with gastric bypass, is usually performed through a median laparotomy.

During the last years, laparoscopic choledochojejunostomy and Roux-en-Y jejuno-jejunostomy has been reported as an alternative to the open approach \(^7\,^9\,^10\). A laparoscopic biliodigestive anastomosis appears to be feasible, but technically challenging \(^11\,^14\). For this reason the open approach is still regarded as standard procedure.

The advantages of robotic surgery systems might offer an answer to the technical obstacles in the laparoscopic approach and thereby enable surgeons to perform this delicate procedure without extensive time loss and learning curves \(^15\,^16\).

The purpose of this study is to assess the feasibility of performing a safe and effective laparoscopic choledochojejunostomy and jejunum Roux-en-Y reconstruction with the aid of a robotic surgery system and compare this procedure to today’s standard approach.
Methods

Twenty female pigs (weight 48-70 kg, median XX) were randomly divided in two groups. Ten pigs (robot-assisted group) underwent a laparoscopic jejunum Roux-en-Y reconstruction and choledochojejunostomy with use of the da Vinci robotic system (Intuitive Surgical, Sunnyvale, California) \(^{16}\). The remaining 10 pigs were operated through a median laparotomy (control group). A single surgeon (IB) with extensive experience with the robotic system but no experience in laparoscopic biliodigestive procedures operated on all pigs. The pigs were observed for 14 days postoperatively.

In the robot-assisted group, the animals were operated in supine Trendelenburg position. A 14 mmHg pneumoperitoneum was established using a Veress-needle. A 12 mm camera port was introduced at the umbilicus and two 8 mm robotic arm trocars were placed in the left subcostal space and in the right middle quadrant. Two assisting trocars (5 and 12 mm) were introduced in between the camera port and the right or left robotic port respectively (Figure 1). The robot was positioned over the pig’s right shoulder (Figure 2) and the three robotic arms were connected to camera and 8 mm trocars.

The proximal jejunum was identified and, after dissection of the mesojejunum, divided using an Endostapler (Ethicon Endosurgery, Amersfoort, the Netherlands). The proximal jejunum was reconnected approximately 20 centimetres distal to the stapling line (Roux-en-Y reconstruction). A Monocryl 4.0 suture (Ethicon, Amersfoort, the Netherlands) was used for the jejuno-jejunostomy. The anastomoses were performed in a running fashion, with separate 16 cm wires for the anterior and the posterior parts.

The common bile duct was identified, dissected and ligated with a Vicryl 3.0 suture (Ethicon, Amersfoort, the Netherlands). The Roux-en-Y loop was approximated to the proximal duodenum and the antrum of the stomach with two Vicryl 3.0 sutures to avoid tension on the biliodigestive anastomosis. An enterotomy was made in the afferent Roux-en-Y loop and the common bile duct was divided slightly proximal to the ligature. An end-to-side biliodigestive anastomosis (choledochojejunostomy) was performed with two 8-cm running sutures, starting at the posterior site using Monocryl 6.0.

In the control group, an identical procedure was performed with the use of the same stapling device and suturing materials, but access was through a 20-cm median laparotomy.

System draping time was recorded in all robot-assisted cases. Total surgery time (first incision tot closure) was recorded and divided in a start-up phase (from incision until the start of the dissection), dissection phase (time needed for preparation and dissection of the Roux-en-Y loop and ligation of the biliary duct), time required for both the biliodigestive and intestinal anastomoses and wound closure time. Intraoperative blood-loss and complications were scored during the surgical procedure. The number of stitches of both biliodigestive and intestinal anastomoses was documented. Also, the times the stitch was broken during suturing was registered.
The postoperative course was evaluated, focussing on meals, stools and complications. At autopsy the biliodigestive and intestinal anastomoses and peritoneal cavity were explored with special interest for signs of anastomosis leakage.

In both groups, the diameter of the biliodigestive anastomosis was measured by introducing dilators with increasing diameters. The circumference of the biliodigestive anastomosis was measured using a digital image of the cross-section and dedicated measuring software (UTHSCSA Image Tool). In the same manner, the circumference of the common bile duct, one centimetre proximal to the biliodigestive anastomosis, and the intestinal anastomosis were measured. The mean distance between stitches was calculated (circumference/number of stitches).

All data were entered in SPSS for windows and are expressed as median and range. Data were compared using the Mann-Whitney U-test, with significance at P values <0.05.

Figure 1

Figure 2
Positioning of the robot in relation to the pig. The pig is in supine anti-Trendelenburg position, with the robot approaching over the pig’s right shoulder.
Results

The median time for robotic system preparation with sterile drapes was 6 minutes (4-9). Total operating time was 140 min in the robot-assisted group compared to 81.5 min in the control group (p<0.001; Table 1). Except wound closure, all separately scored phases of the procedure were longer in the robot-assisted cases, with statistical significance in the dissection phase (Table 1).

Table 1  Time in minutes needed for separate phases of the procedure.

<table>
<thead>
<tr>
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<th>Robot-assisted group</th>
<th>Controls</th>
<th>P</th>
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<tbody>
<tr>
<td>Total Operating Time</td>
<td>140 (120-175)</td>
<td>81.5 (60-115)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Start-up phase</td>
<td>15 (8-19)</td>
<td>10 (5-15)</td>
<td>NS</td>
</tr>
<tr>
<td>Dissection</td>
<td>55 (44-62)</td>
<td>25 (13-40)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Intestinal anastomosis</td>
<td>30 (19-45)</td>
<td>15 (14-20)</td>
<td>NS</td>
</tr>
<tr>
<td>Biliodigestive anastomosis</td>
<td>29 (25-60)</td>
<td>20 (9-30)</td>
<td>NS</td>
</tr>
<tr>
<td>Wound closure</td>
<td>12 (10-15)</td>
<td>15 (9-25)</td>
<td>NS</td>
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</table>

We could not demonstrate a learning curve in the robot-assisted group for any of the separate time phases (Figure 3).

Figure 3
Times for separate phases of the operative procedure: No learning curve could be detected.

Blood-loss was less than 10 cc in all robot-assisted cases and mediated 30 cc (10-50) in the control group. In both groups, there were no intraoperative complications and all robot-assisted procedures were completed laparoscopically. In three robot-assisted cases, the 6.0 Monocryl stitch was torn during suturing of the biliodigestive anastomosis, necessitating a restart of the anastomosis.

Postoperatively, all pigs had their first stool on the first postoperative day and accepted their first meal on day two after surgery. In the control group, one pig died.
of gastroparesis on postoperative day 6. In the robot-assisted group, one pig died on postoperative day 7, caused by a volvolus of the jejunum.

At autopsy, signs of leakage of the biliodigestive anastomosis were found in one pig in the robot-assisted group. In this pig, a bilioma of approximately 10x10x10 cm was found. In retrospect, this pig had a diminished appetite on postoperative days two to five, but recovered afterwards.

In all twenty pigs, the biliodigestive and intestinal anastomoses were macroscopically patent with an adequate passage. The circumference of the anastomoses and common bile duct, the number of stitches and the distance between stitches were comparable in both groups (Tables 2 and 3).

Macroscopic distension of the biliary tract occurred in one pig in each group. These findings were supported by measurement of the duct and anastomosis circumference (24 vs 18 mm in the robot-assisted group, 18 vs 13 mm in the controls) The postoperative course was uneventful without signs of biliary congestion.

Table 2 Measurements for biliodigestive anastomosis and common bile duct (CBD).

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<th>Robot-assisted group</th>
<th>Controls</th>
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<tr>
<td>Diameter (mm)</td>
<td>9 (7-10)</td>
<td>8 (7-9)</td>
<td>NS</td>
</tr>
<tr>
<td>Circumference (mm)</td>
<td>1.7 (1.2-2.7)</td>
<td>1.4 (1.1-1.7)</td>
<td>NS</td>
</tr>
<tr>
<td>Number of stitches</td>
<td>10 (8-11)</td>
<td>9 (8-10)</td>
<td>NS</td>
</tr>
<tr>
<td>Distance between stitches (mm)</td>
<td>2 (1-3)</td>
<td>2 (1-2)</td>
<td>NS</td>
</tr>
<tr>
<td>CBD circumference (mm)</td>
<td>1.9 (1.3-2.7)</td>
<td>1.6 (1.3-1.8)</td>
<td>NS</td>
</tr>
</tbody>
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Table 3 Measurements for intestinal anastomosis.

<table>
<thead>
<tr>
<th></th>
<th>Robot-assisted group</th>
<th>Controls</th>
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<tr>
<td>Circumference (mm)</td>
<td>38 (29-45)</td>
<td>43 (33-55)</td>
<td>NS</td>
</tr>
<tr>
<td>Number of stitches</td>
<td>16 (15-18)</td>
<td>18 (14-20)</td>
<td>NS</td>
</tr>
<tr>
<td>Distance between stitches (mm)</td>
<td>2.3 (1.8-2.8)</td>
<td>2.5 (2.1-2.9)</td>
<td>NS</td>
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Discussion

In this study, two surgical approaches for the treatment of permanent biliary obstruction are evaluated. Currently biliary stenting through endoscopic retrograde cholangiopancreatography (ERCP) is regarded as the treatment of choice in patients suffering from biliary congestion. Randomised clinical trials have established the effectiveness of endoscopic biliary stenting and demonstrated no significant differences in survival compared to a surgical approach 6,17. Moreover, the minimal invasive endoscopic approach results in a lower 30 days mortality and morbidity and a shorter hospital stay 17,18. Also, endoscopic stent-placement has been proven to be cost-effective 1,19,20. For these reasons, surgery as the initial treatment for biliary congestion is largely replaced by the endoscopic approach.

Long-term patency of endoscopically placed biliary stents, however, appears to be inferior to surgical biliary drainage. Recurrent obstructive jaundice, caused by clogging of the stent due to duodenobiliary reflux or tumour ingrowth occurs in 20% to 50% of the patients treated with endoprostheses 19,21-23.

After a surgical biliary bypass, 0% to 16% of patients show recurrent obstructive jaundice 24-26. In patients with a relatively high life-expectancy (over 6 months), a surgical approach is therefore recommended 2,26,27. Not only does the surgical approach offer a good long-term patency of biliodigestive drainage with low readmission rates; it also offers opportunities for additional gastric by-pass, in order to avoid gastric outlet obstruction, which develops in 10% to 20% of patients with unresectable pancreatic cancer. Altogether, surgical biliary drainage is indicated in patients with a relatively high life-expectance (over 6 months) and in patients requiring a simultaneous gastric outlet by-pass 2.

The surgical treatment of choice consists of a choledochojejunostomy with or without a simultaneous gastrojejunostomy 3,28. A controlled randomised trial by Smith 6 showed a procedure-related mortality of 14 %, a major complication rate of 29 % and a total hospital stay of 26 days. Other studies show lower mortality rates, but similar results concerning morbidity and hospitalisation 17,26,27. Most authors emphasise that surgical palliation goes mainly accompanied with early (<30 days) complications, resulting in a longer initial hospital stay. This reflects the time spent recuperating from the operative trauma 26.

The surgical trauma can be minimised using a laparoscopic approach. For procedures routinely performed through laparoscopy, such as laparoscopic cholecystectomy and Nissen fundoplication, the benefits for the patient, compared with open surgery are clear and well described. Decreased hospitalisation, diminished postoperative pain, cosmetic advantages, lower complication rates and economic considerations are examples of these benefits 29-33.

Theoretically, laparoscopic choledochojejunostomy could offer identical advantages compared to the open surgical treatment. Thereby, it combines a minimal invasive approach with long-term patency and the option for an additional gastric bypass. A number of authors have described the feasibility of the laparoscopic approach 8-12,14,34,35. A case control study comparing 14 laparoscopic cases to open
palliative procedures demonstrated a significant reduction of postoperative hospitalisation (21 vs. 9 days, \( p<0.06 \)), morbidity (43 vs. 7%, \( p<0.05 \)) and mortality (29 vs. 0%, \( p<0.05 \)) \(^9\). However, to date no large series have been published and the approach is not widely accepted yet as a competing alternative. An explanation for this might be the technical complexity of this approach.

Most authors emphasise that a laparoscopic choledochojejunostomy procedure is technically challenging. During laparoscopic surgery, working through fixed abdominal entrypoints significantly diminishes manoeuvrability. Surgeons are also handicapped by the loss of visual perception of depth, intrinsic to working with a two-dimensional visualisation system \(^36\). A major obstacle during the laparoscopic approach, due to these limitations, appears to be suturing an anastomosis the size of the common bile duct \(^12-14\). Handling the delicate tissue of the thin and fragile bile duct wall and visualising the collapsing bile duct opening, with bile running through it, is technically demanding, even if proper exposition is acquired in the first place \(^12-14\). Although feasible for trained surgeons, the procedure remains time-consuming, with operating times of over 3 hours \(^11\).

Being so complex, surgeons developed alternative techniques replacing the sutured biliodigestive anastomosis, such as anastomotic devices, stapled cholecystojejunostomies and a combined laparoscopic and endoscopic biliary stenting approach \(^14,28,35,37-39\). Despite these efforts, the laparoscopic approach remained technically challenging and has not developed towards a suitable alternative for the open approach for a surgeon without extensive experience in this field of surgery.

Robotic surgical systems may prove to be of support in dealing with delicate laparoscopic procedures, such as the biliodigestive anastomosis. The system used in this experiment, the da Vinci system, enhances visualisation by a true three-dimensional view based on a double optical system. In addition, the natural working axis is restored and the surgeons viewing axis is always in line with the image acquisition axis. The surgeon can optimise the field of view due to personal control of the optical system. Additional degrees of freedom of motion, filtering of tremor and friction and the ability to downscale the movements of the robotic instruments can contribute further to the feasibility of advanced laparoscopic suturing \(^15,40,41\). The aim of this study was to compare this new laparoscopic robot-assisted approach to the current standard, and evaluate whether it could be a competing alternative for the open surgical approach. The open approach was the procedure of choice in human surgery for the surgical team involved because their yearly caseload was regarded insufficient to gain enough experience in the standard laparoscopic approach and as such to deliver an optimal level of care.

In our experiments, robot-assisted laparoscopic choledochojejunostomy and Roux-en-Y reconstruction was repeatedly proven safe and effective. The safety of the procedure was reflected by the comparable dimensions of the anastomotic parameters in the open and robot-assisted groups. The postoperative deaths could not be attributed to failure of anastomoses or to other technical inaccuracy caused by the robotic system.
Apart from safety and efficacy, the additional value of robot-assisted surgery was expressed in the relatively short operating times in this study. The operating times were significantly longer compared to the control group, but remained within reasonable limits for surgical practice by the opinion of the authors. When evaluating procedure times of standard laparoscopic biliodigestive procedures published so far, averaging over 3 hours in experienced hands, the median operating time of 140 minutes in the robot-assisted cases appears to be relatively short.\textsuperscript{8,12,14} Robotic system set-up time was not included in the operating time but is limited to 15 minutes or less in experienced hands.\textsuperscript{15,16,40} Time-loss was shown in our previous studies to occur mainly during set-up of the equipment. In the experimental laboratory, a dedicated operating theatre with a permanent system set-up eradicated this time-loss. Still, sterile draping of the robotic system consumed 6 minutes.

One would expect to attribute the time-loss during surgery merely to the actual suturing of the biliodigestive anastomoses, as most challenges are faced during this part of the procedure in standard laparoscopic surgery.\textsuperscript{11-14} However, in this experimental study the choledochojejunostomy was proven to be feasible within a reasonable time frame. Also the time needed for the jejuno-jejunostomy remained limited. However, the dissection was accountable for most of the time-loss compared to the control group. It was experienced as complex, with difficulties in identification of the jejunum in order to create the Roux-en-Y loop in the pig model, as was also emphasised previously by others.\textsuperscript{13} Defining the afferent and efferent small bowel loops requires handling and retracting a large segment of intestine. The large excursions of the robotic instruments and camera required tend to cause collisions between the three robotic arms. Obviously the robotic system is designed for delicate motions, but it does not seem to offer advantages in large-scale movements which require a large field of view. The difficulty in identifying the jejunum could therefore partly be explained by the pig's anatomy, but also by the limited mobility of the camera and robotic arms.

The short and reproducible anastomosis times from the start of the experiment on, without a significant learning curve, reflected the additional value of robot-assistance, as did the safe and bloodless dissection of the meso-jejunum and common bile duct. The robotic system seems to offer an adequate answer to the technical challenges of the procedure. The 3D-visualisation and restoration of eye-hand-target axis were regarded most helpful by the operating surgeon when suturing the four to five mm wide common bile duct to the jejunum. The additional degrees of freedom of motion, tremor and friction eradication and the ability to downscale the movements of the robotic instruments were experienced as beneficial while suturing the delicate tissue.

The main problem encountered while suturing the anastomoses was suture disruption. This occurred in three out of ten cases and resulted in a longer anastomosis time. We attribute the rupture of sutures to the lack of force feedback in the robotic instruments. While putting force on the suture in order to accomplish a patent anas-
tomosis or a secure knot, the 6-0 sutures are easily broken. This could only partly be compensated for by visual control, as was also emphasised by others. Obviously the problem of tearing thin wires may decrease when experience of the surgeons increases. Nevertheless, future generations of the robotic system should offer information on pulling and pushing forces applied, similar to standard videoscopic surgery, in order to avoid tissue crush and tears and damage to wires and needles.

In our experience and supported by the results presented, the use of a robotic system offers the opportunity to alleviate the surgical challenge of laparoscopic biliodigestive anastomosis. Hereby, the laparoscopic approach towards palliative treatment of bile duct and gastric outlet congestion might come within hands for more surgeons and therefore make the minimal invasive approach more widely accepted.

In conclusion robot-assisted laparoscopic choledochojejunostomy has been proven effective and safe in an experimental model. The procedure can be performed with acceptable time-loss. Therefore the robot assisted laparoscopic technique may prove to be reproducible in clinical practice and thereby support the minimally invasive approach as the treatment of choice for palliative surgical relief of biliary congestion. We will start with robot-assisted laparoscopic biliodigestive anastomosis supported by the results of this experimental study. The true additive value of the robotic system for this procedure can be proven only by a randomised study, but such a study should be conducted by one of those few centres that perform a large number of these interventions yearly.
References


