Laparoscopic microsurgical tubal anastomosis with and without robotic assistance

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BACKGROUND: We previously reported our results with laparoscopic microsurgical tubal anastomosis with robotic assistance. The purpose of this study was to compare the duration of the procedure and hospitalization, blood loss and clinical outcomes for laparoscopic microsurgical tubal anastomosis performed with and without robotic assistance. METHODS: This was a retrospective comparative case study in an academic tertiary referral centre. Laparoscopic microsurgical tubal anastomosis was performed on 10 women with robotic assistance and the subsequent 15 patients underwent the procedure without the robot. The length of the procedure, estimated blood loss (EBL), time until hospital discharge, tubal patency and clinical pregnancy rates were compared. RESULTS: The operative times were 2 h longer with robotic assistance (P < 0.001). The increased EBL with the use of the robot (70 ± 66 ml versus 20 ± 16 ml) was statistically but not clinically significant. The robot provided no benefit in patient recovery. Tubal patency and clinical pregnancy rates were not significantly different. CONCLUSIONS: Robotic assistance increases operative times of laparoscopic tubal anastomosis without an appreciable improvement in patient recovery or clinical outcomes.

Key words: laparoscopy/robotic surgery/tubal anastomosis

Introduction

The patient benefits of reduced postoperative discomfort and morbidity, more rapid return to activity and improved cosmesis with surgery performed by laparoscopy compared with laparotomy are well established. Another advantage of laparoscopic surgery is that it follows the tenets of microsurgical technique. In addition to providing magnification, laparoscopy avoids tissue drying, foreign body contamination and tissue abrasion from packs and bleeding from an incision. It also allows for meticulous haemostasis and reduced tissue manipulation. These factors improve healing and decrease postoperative adhesion formation which could compromise the clinical outcomes.

Although microsurgical tubal anastomosis is performed through a mini laparotomy incision on an outpatient basis, patients may notice an advantage from having the procedure performed with an even less invasive laparoscopic approach. Unfortunately, laparoscopic suturing is still a very difficult and time consuming task and applying it to microsurgery further raises the degree of difficulty significantly. The use of a remotely controlled robot has the potential to facilitate laparoscopic microsuturing by allowing the surgeon to be seated comfortably, scale the surgeon’s movements by varying increments and filtering out unintentional tremors.

We performed the world’s first robotically assisted laparoscopic surgery in June of 1998 (Falcone et al. 1999). Ten women underwent laparoscopic microsurgical tubal anastomosis with robotic assistance (Falcone et al. 2000). The current study compares those results with the outcomes following the same procedure performed on the subsequent 15 patients without robotic assistance.

Materials and methods

Twenty-five patients underwent outpatient laparoscopic tubal anastomosis with the same operative technique used at laparotomy. The procedure was performed with the patient under general anaesthesia in a modified dorsal lithotomy position. A Rumi uterine manipulator (Cooper Surgical, Shelton, CT, USA) was placed to maintain the uterus in anteversion and for chromotubation. A 10 mm 0° laparoscope was inserted intra-umbilically and CO₂ pneumoperitoneum established. Ancillary 5 mm ports were placed in the right and left lower quadrants lateral to the inferior epigastric vessels.

Dilute vasopressin (0.2 IU/ml) was injected into the mesosalpinx beneath the occluded segments. The tubal segments were mobilized with a unipolar micro-needle and the occluded ends excised with scissors. Transcervical chromotubation with indigo carmine documented patency of the proximal tubal segments. The proximal end of the distal segments were cannulated and indigo carmine injected to confirm patency. The mesosalpinx was then re-approximated with an interrupted 6–0 polygalactin suture tied intracorporeally.
The anastomosis was performed by placing four interrupted 8–0 polygalactin sutures incorporating the muscularis and mucosal layers at the 3, 6, 9, and 12 o’clock positions. The 6 o’clock suture was placed first. All sutures were placed so that the knots were extraluminal. The knots were tied intracorporeally with three throws, the first being a surgeon’s knot. The serosa was also closed with interrupted 8–0 delayed absorbable sutures. No stents were used. Tubal patency was demonstrated intraoperatively with transcervical chromotubation.

The first 10 procedures were performed with robotic assistance using the Zeus system (Computer Motion, Goleta, CA, USA) for the laparoscopic suturing as previously reported (Falcone et al. 2000). The US Food and Drug Administration (FDA) approved this as a pilot study for feasibility. The Institutional Review Board of the Cleveland Clinic Foundation also approved the study and all patients provided written informed consent. The inclusion criteria included regular menstrual cycles, a normal semen analysis in the partner and a hysterosalpingogram (HSG) that demonstrated a normal uterine cavity and at least 1 cm of proximal tube bilaterally. Final tubal length had to be at least 4 cm.

The Zeus system consists of three robotic arms fixed to the sides of the surgical table. One arm is the Aesop voice-activated laparoscope holder. The other two are connected to the suturing instruments in the lower quadrant ports. An additional 5 mm port is placed suprapubically in the midline for suction/irrigation, tissue manipulation and suture insertion/removal. All microsuturing was performed with the robotic system. The surgeon was seated at a console with a video monitor and manipulated the handles which translated the movements to the instruments. An HSG was performed to assess the patency of the tubes 6 weeks postoperatively. Pregnancy was confirmed by ultrasonography after 6 weeks gestation.

The subsequent 15 cases were performed without the robot with each surgeon serving as one ‘hand’ for laparoscopic knot tying. These were our first 15 cases of conventional laparoscopic tubal anastomosis. The total operating room (OPR) and skin-to-skin (procedure) times were recorded as well as the estimated blood loss (EBL), time in the recovery room (RER) and total length of stay (LOS) as defined as the end of the procedure until hospital discharge. All times were recorded in minutes. Statistical analysis was performed with the χ² and Wilcoxon-ranked sum tests as appropriate.

Results

Patients in the nonrobotic group were older, heavier and had more prior laparotomies than the robotic group though statistical significance was only reached for age (Table I). There were four patients between 41 and 44 years of age in the nonrobotic group. One women in the robotic group was 37 and two patients in the nonrobotic group were >90 kg with a body mass index (BMI) >30 kg/m² versus none in the robotic group.

All the anastomoses were isthmic–isthmic or isthmic–ampullary except for two patients in the nonrobotic group who had bilateral ampullary–ampullary repairs and one had a bilateral ampullary–infundibular anastomosis. Follow-up HSG in the robotic group revealed patency in 17 of the 19 tubes (89.5%). One patient had only one repairable tube. Six patients in the nonrobotic group were lost to follow-up and one conceived the first cycle postoperatively so only eight had an HSG. Eleven of the 16 tubes were patent (68.8%). Three of the five occluded tubes were from the two ampullary–ampullary repairs. Excluding these two cases yielded a patency rate of 83.3%. In either case, the patency rates were not statistically different.

The study protocol for the robotic group excluded any other infertility factors. Among the nonrobotic group, there was one male factor, two anovulatory patients, one with an elevated serum FSH, one smoker, one with a prior failed tubal anastomosis and one that had two previous IVF cycles without success. There were five pregnancies in the robotic assistance group for a 50% pregnancy rate with all pregnancies delivered. There were three pregnancies in the nonrobotic group, one delivered and two spontaneous abortions. Assuming that the group for a 50% pregnancy rate with all pregnancies delivered. There were three pregnancies in the robotic group, one delivered and two spontaneous abortions. Assuming that the six patients lost to follow-up did not conceive and excluding the patients >40 years old and those with male or ovulatory factors the rate was 37.5% (P = not significant). There were no ectopic pregnancies in either group. All of the patients have been followed for over a year and all of the pregnancies occurred within the first year.

Operative times were significantly longer with robotic assistance even though several patients in the nonrobotic group were obese and had more prior laparotomies. The EBL in the robotic group was significantly greater statistically but not clinically. There were no differences in the RER times or LOS (Table II).

Discussion

The advantages of adding robotic assistance for suturing include the ability of the surgeon to be seated more comfortably, adjustable scaling of movements such that gross movements by the surgeon are translated into finer movements at the instrument tips, and reduction of unintentional tremors. In addition, the potential for remote telesurgery cannot be far behind. The Aesop robotic laparoscope holder greatly facilitates laparoscopic tubal anastomosis, with or without the use of
robotic instruments, by providing a stable hands-free image which is essential when working close-up under magnification.

The skin-to-skin procedure time was over 1.5 h longer with robotic assistance. This was predominantly the result of broken sutures due to the lack of tactile feedback during knot tying. Total time in the operating room was 2 h longer with robotic assistance as a result of the longer procedure time in addition to the time required to set up the robots. An engineer from Computer Motion, Inc. was present the entire time for all of the robotic procedures. In spite of this, malfunctions were not infrequent.

Our procedure time of 190.7 min for our first 15 cases without robotic assistance is comparable with the 230.5 min reported by Yoon et al. for their first 15 cases using an identical technique (Yoon et al., 1999). They note that the times decreased significantly after 6 months to a mean of 140.2 min with 202 patients. They did not state whether pregnancy rates also improved with the learning curve. Bissonnette et al. reported excellent results with 102 laparoscopic tubal anastomoses with a mean operating time of only 71.4 min (Bissonnette et al., 1999) using the one-stitch technique originally described by Dubuisson and Swolin (Dubuisson and Swolin, 1995).

The major difficulty with laparoscopic tubal anastomosis, with or without robotic assistance, is the limited needle angles to the tubes due to operating through fixed ports. This requires undue tissue manipulation and trauma to position the tubes at a suitable angle to place the sutures or alternatively, compromising precise suture placement. The 50% pregnancy rate in the robotic group, which excluded women >40 years of age and with other infertility factors, was less than expected compared with conventional open microsurgery (Dubuisson et al., 1995; Kim et al., 1997).

Degueldre et al. recently reported the results of a pilot study with eight patients undergoing laparoscopic tubal anastomosis with robotic assistance using the da Vinci Surgical System (Intuitive Surgical, Mountain View, CA, USA) (Degueldre et al., 2000). The intra-abdominal ends of the micro-instruments in this system have an articulating wrist action with two additional degrees of freedom, comparable with those of the human wrist. This enables more precise needle placement for tissue alignment. This system also incorporates a dual lens laparoscope for true three dimensional stereoscopic viewing. Their operating time of 181.5 min was similar to our procedure time without the robot and 1.5 h shorter than with the Zeus robotic system. It may be anticipated that clinical results could also be improved.

There is no real learning curve between the robotic and non-robotic groups because they are very different procedures. For robotic surgery, one surgeon performs the procedure while seated whereas two surgeons simultaneously perform the procedure standing at the OPR table for the non-robotic group. If anything, the learning curve would be biased in favour of the robotic group since many hours were spent in the dry laboratory practising with the robot in addition to performing the procedure on animals and human cadavers prior to the first patient. We went directly to the non-robotic group without the benefit of practising first and learning to work as a coordinated team. Also, the OPR times were biased against the non-robotic group since these patients tended to be heavier and had more prior laparotomies as well as more concurrent treatments. Even allowing for that, the times were still substantially less than the robotic group. Heterogeneity between the robotic and non-robotic groups, and the small sample sizes, preclude making any valid comparisons in tubal patency or pregnancy rates from our data.

The currently available robots carry a price tag in the range of US$600,000 to US$1,000,000 plus yearly service contracts. This expense plus the additional OPR time and disposable items for the robot greatly increases the cost of the procedure. Since patients did not benefit from the addition of robotic assistance with the Zeus system, its use cannot be justified at this time. A large prospective randomized study comparing laparoscopic tubal anastomosis with and without robotic assistance using the Zeus and DaVinci systems is needed to clarify whether there may be a role for them in this procedure.

Acknowledgement

This study was supported in part by a grant from Computer Motion, Inc., Goleta, CA, USA.

References


Submitted on May 8, 2001; resubmitted on May 22, 2002; accepted on September 18, 2002.