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ORIGINAL PAPER

The learning curve for robotic-assisted pyeloplasty in urologists with no prior robotic experience using an *ex-vivo* model: A prospective, controlled study

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Summary

***Introduction:** Despite the increasing trend of utilizing robotic techniques in pyeloplasty, little is known about the learning curve for robot-assisted pyeloplasty (RAP) amongst urologists with no prior robotic experience. Therefore, the present study aimed to evaluate the learning curve of residents in the last year or recently appointed urologists performing RAP using an ex-vivo model.*

***Methods:** A prospective ex-vivo model study was conducted including participants who were either residents in the last year or recently appointed urologists. All participants had obtained the E-BLUS certification, or they were able to complete its 4 tasks successfully in a dry lab, without prior robotic experience. Each participant performed four consecutive RAPs using the avatera system on an ex-vivo porcine model. The primary endpoint of the present study was the change in the average time to complete the anastomosis from the first to the fourth attempt.*

***Results:** Nine urologists and 8 residents were enrolled in this study. Each surgeon demonstrated a reduction in the time to complete anastomosis from the 1st to 4th attempt with an average of value of 4.41 ± 1.06 minutes (p = 0.003). The decrease in time was statistically significant in both urologists and residents subgroups (4.5 ± 1.41 minutes p = 0.049 and 4.33 ± 0.71 minutes p = 0.035 respectively).*

***Conclusions:** The training on the ex-vivo model could lead, in only a few attempts, to a significant improvement in skills and in the required time of experienced-naïve surgeons to complete an RAP.*

KEY WORDS: *Learning curve; Pyeloplasty; Robotic-assisted; Robotics; Avatera system.*

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INTRODUCTION

The use of robotics in medical procedures has already been implemented in various medical specialties, including neuronavigation and stereotactic neurosurgery (1-3). In urology, applications of robotic systems have included laparoscopic camera control, percutaneous renal access, prostate biopsy, and transurethral resection of the prostate (4). Laparoscopic pyeloplasty was initially proposed for the treatment of *ureteropelvic junction* (UPJ) obstruction, with a success rate of over 90%. Besides, laparoscopic pyeloplasty is associated with reduced hospital stay and postoperative complications compared to the open approach (5).

However, intracorporeal suturing remains a technical challenge in the laparoscopic approach and may increase the operative time. The tedious learning curve of laparoscopic pyeloplasty constitutes another limitation (6).

In this regard, *robot-assisted pyeloplasty* (RAP) has emerged as a feasible alternative to overcome the technical difficulties of conventional laparoscopic pyeloplasty (7). The RAP coveys all the advantages of conventional laparoscopic pyeloplasty while also decreasing the technical difficulties with intracorporeal suturing and shortening the operative time (8). It was reported that the high incidence of UPJ obstruction, which leads to a higher volume of cases, and the previous experience with laparoscopic surgery have improved the learning curve and outcomes of RAP (6).

The present study aimed to evaluate the learning curve of novice surgeons performing Robotic-assisted pyeloplasty using a recently introduced robotic system on an ex-vivo porcine model.

PATIENTS AND METHODS

Study participants and robotic system

We conducted a prospective ex-vivo model study that enrolled residents in the last year or new urologists. All participants were required to pass the *European Training in Basic Laparoscopic Urological Skills* (E-BLUS) training program or to achieve the goals in its four tasks in a similar dry lab. We limited the participation in the present study to novice surgeons who did not have any prior experience with robotic surgery to perform four consecutive RAPs using the avatera system (*avateramedical GmbH, Germany*). The avatera system is a robotic system that is based on activated robotic force feedback. The robotic cart is a four-arm component of the system that can be controlled by the surgeon and consists of three arms for controlling the instruments (in a one-to-one master-slave fashion) and one arm to hold and control the endoscope. The second component of the system is a separate control unit for the operating surgeon. Because of this, it is easily adaptable to the majority of operating rooms. It is equipped with a camera that has a resolution of full HD, while the single-use instruments are entirely articulated and can move in a range of 7 degrees of freedom. Since the instruments are disposable, the possibility of cross-contamination is minimal, without the need for sterilization. The special shape of the eyepiece, which leaves the surgeon's ear and mouth uncovered, is an additional advantage that has been developed. This design makes it easier for the surgeon to communicate clearly with the operating team during surgical procedures (9).

Ethical standards

The study has been carried out in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. The experiments were carefully designed and preapproved by the Veterinary Administration of the Prefecture of Western Greece and conducted according to Directive 2010/63/EU (*http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri= OJ:L:2010:276:0033:0079:EN: PDF*).

Animal model and experiment

The assessment of the learning curve was based on conducting four consecutive ex-vivo anastomoses on a porcine model, with strict compliance to relevant guidelines for the use of laboratory animals. The porcine model consisted of the urinary bladder and both ureters, as described by *Sanchez Hurtado et al.* (10). It was placed upside-down, while the bladder was considered as a dilated pelvis and the ureter as the proximal part of it (Figure 1). The normal *ureterovesical junction* (UVJ) was considered as a stenotic *ureteropelvic junction* (UPJ). The supply of porcine urinary bladders was performed by a slaughterhouse.
A 4-hour theoretical educational training course was performed to all the participants by the avateramedical, presenting the use and care of the robotic system. Afterward, each participant completed a 2-hour E-BLUS task-based training to familiarize themselves with the instruments and the function of the robotic system. Three trocars were placed in an artificial insufflated abdominal model based on the set-up of the conventional robotic pyeloplasty, followed by the application of three robotic arms; one for the endoscope, one for the Metzenbaum Scissors and the Needle Holder (the two instruments were exchanged during the procedure), and one for the Atraumatic Grasper (Figure 2). The three ports were used as none of the participants have previous experience with RAP.
The ureter was resected horizontally in proximity to the renal hilum, followed by spatulation of its tip (Figure 3). The anastomosis was performed using a Vicryl 4-0 suture in a running way (Figure 4). Afterward, a 4F ureteral catheter was inserted from the distal part of the ureter, and indigo carmine (5 mL) was injected to ensure the patency and the water-tightness of the anastomosis. The time between the first incision and the completion of the indigo carmine test was recorded as the time needed to complete the UP anastomosis. The anastomosis leakage events were also recorded. After the completion of the fourth attempt, the participants filled out a Likert-scaled Questionnaire

Figure 1.
Ex- vivo pyeloplasty model set-up.

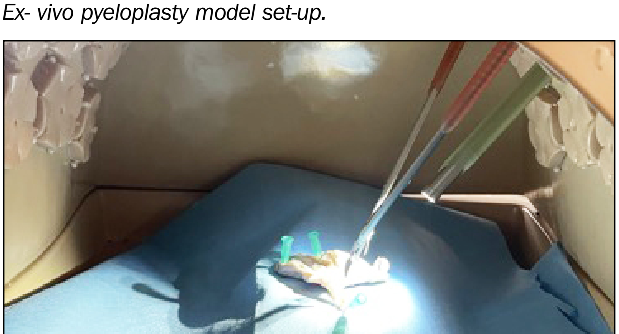


Figure 2.
Incision of the Ureteropelvic Junction.

Figure 3.
Spatulation of the ureter.

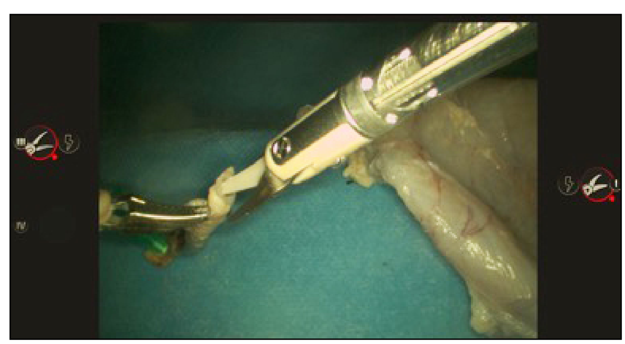


Figure 4.
Ureteropelvic anastomosis.

Table 1.
Postoperative evaluation questionnaire (1 being the lowest and 5 being the highest score).

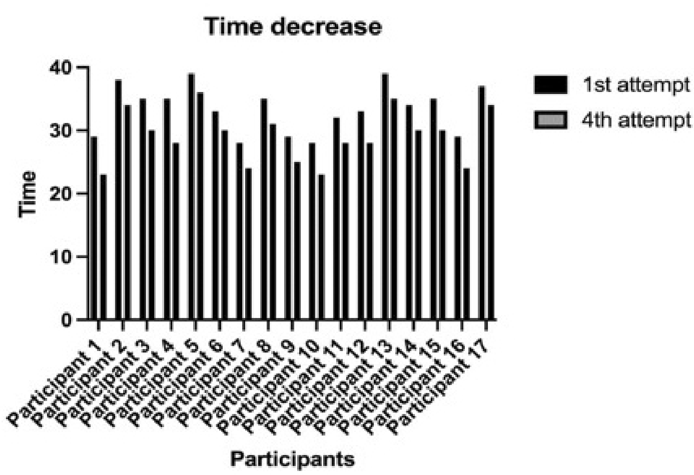
Parameter	Scores				
Vision	1	2	3	4	5
Comfort	1	2	3	4	5
Confidence	1	2	3	4	5

evaluating the Vision, Comfort and Confidence to perform RAP after the training. The overall questionnaire score ranged from 3-15 (1-5 points per question) (Table 1).

Statistical analysis

Data were analyzed using the Prism (*GraphPad, Boston, USA*) version 9. The time to complete the anastomosis and the reduction in time were described using mean, *standard deviation* (SD), median and range, while the percentage of change was calculated. The overall questionnaire rating was described using mean, SD, median and range. The trend of change in the time to complete the anastomosis was analyzed using paired t-test. A two-tailed p-value < 5% was considered statistically significant. The learning curve factor (b factor) and the learning percentage (p percentage) is calculated based on the cumulative average model (*Wright model*) (11, 12).

Figure 5.
The trend of change in time required to complete the pyeloplasty between the 1st and 4th attempts.



Results

In total 9 urologists and 8 residents on the final year of residency were included into the study. The urologists had a competency of basic laparoscopic operations (including laparoscopic varicocelectomy, laparoscopic hernia repair and laparoscopic nephrectomy), while the residents had a prior experience of participation in at least 20 laparoscopic operations (including radical nephrectomies, partial nephrectomies, radical prostatectomies and pyeloplasties).

Each participant successfully completed the four attempts of RAP. Each surgeon demonstrated a reduction in the time to complete anastomosis from the 1st to 4th attempts, as shown in Figure 5. There was a significant improvement, as demonstrated by the significant decrease in the average time to complete the anastomosis from 33.41 ± 3.8 minutes at the first attempt to 29 ± 4.2 minutes at the fourth attempt (p = 0.003). The mean reduction in the time to complete the pyeloplasty was 4.412 (4.96 to 3.87) minutes, with a percentage reduction of 13.5% (Table 2).

Among the 1st attempt of all the participants, 4 events of anastomosis leakage occurred, while 2 events of anastomosis leakage were noticed among the 2nd attempts. On the 3rd and 4th attempts, no anastomosis leakage was observed. The mean overall score in the postoperative evaluation questionnaire was 11.94 ± 1.09 (median value: 12, range 10-14). In detail, the mean vision score, the mean comfort score and the mean confidence score were 4.41 ± 0.62, 4.18 ± 0.64 and 3.35 ± 0.49 respectively. The b factor of the overall learning curve was -0.965 and the p learning percentage is 1.95.

A stratification of the participants was performed into urologists and residents groups based on prior laparoscopic experience. In both groups, the reduction in time was achieved at a statistically significant level. In urologist groups, the 1st and 4th RAP was completed in a mean value of 32.89 ± 3.79 minutes and 28.56 ± 4.19 minutes respectively (p = 0.0351). The time to accomplish the anastomosis was diminished by a mean value of 13.44%, as it needed 4.33 ± 0.71 fewer minutes (Table 3). The mean overall score of the

Table 2.
The required time to complete the pyeloplasty in the 1st and 4th attempts (Paired t-test).

Variables		1st anastomosis	4th anastomosis	P value
Time to complete the pyeloplasty (min)	Mean ± SD	33.41 ± 3.8	29 ± 4.2	< 0.003*
	Median (range)	34 (28-39)	30 (23-36)	
Time reduction (min)	Mean ± SD	4.41 ± 1.06		
	Median (range)	4 (3-7)		
	% of reduction	13.47%		

Table 3.
The required time to complete the pyeloplasty in the 1st and 4th attempts in Urologists Group (Paired t-test).

Variables		1st anastomosis	4th anastomosis	P value
Time to complete the pyeloplasty (min)	Mean ± SD	32.89 ± 3.79	28.56 ± 4.19	< 0.0351*
	Median (range)	33 (29-39)	28 (25-35)	
Time reduction (min)	Mean ± SD	4.33 ± 0.71		
	Median (range)	4 (3-5)		
	% of reduction	13.44%		

Table 4.
The required time to complete the pyeloplasty in the 1st and 4th attempts in Residents Group (Paired t-test).

Variables		1st anastomosis	4th anastomosis	P value
Time to complete the pyeloplasty (min)	Mean ± SD	34 ± 3.89	29.5 ± 4.47	< 0.0498*
	Median (range)	35 (29-39)	30 (23-36)	
Time reduction (min)	Mean ± SD	4.5 ± 1.41		
	Median (range)	4 (3-7)		
	% of reduction	13.50%		

postoperative questionnaire was 12.33 ± 1.12 (Vision 4.44 ± 0.73, Comfort 4.44 ± 0.53 and Confidence 3.44 ± 0.53). The b factor of the urologists subgroup's learning curve was -2.90. In the residents group, the time needed to perform the 1st and 4th pyeloplasty was 34 ± 3.89 minutes and 29.5 ± 4.47 minutes respectively (p = 0.0497). The mean difference in time between the two attempts was 4.5 ± 1.41 minutes leading to a mean reduction ratio of 13.50% (Table 4). The mean postoperative questionnaire score was 11.50 ± 0.93 (Vision 4.38 ± 0.52, Comfort 3.88 ± 0.64 and Confidence 3.25 ± 0.46). The b factor of the residents subgroup's learning curve was -2.89.

Discussion

The results of the current study showed that the time of anastomosis reduced by 7.7% to 20.7%, with an average reduction of 13.5%, after four pyeloplasties. A pilot study by *Sung et al.*, compared robotic-assisted and laparoscopic pyeloplasty. Based on the results, no significant difference in total surgical time (115.2 minutes for robotic and 94.5 minutes for laparoscopic, p = 0.2), anastomosis time (75.7 minutes for robotic and 64.3 minutes for laparoscopic, p = 0.3), and the number of suture bites per ureter (13.0 for robotic and 12.5 for traditional, p = 0.8) was noticed. Five out of 6 robotic and 3 out of 4 laparoscopic pyeloplasties presented with immediate watertight anastomosis (13). *Lorincz et al.* conducted a study to investigate the feasibility of robot-assisted minimally invasive pyeloplasty in piglets. All seven piglets underwent the procedure without complications, and the results showed that robotic assistance enhanced surgical dexterity and precision. The mean setup and anastomosis times were 19 minutes and 51 minutes, respectively. The results demonstrated that robot-assisted pyeloplasty is a technically feasible procedure with acceptable morbidity in an animal model (14). *Chammas Jr. and his colleagues* conducted a study to assess the learning curve for robotic pyeloplasty. The study included in total 100 procedures performed on 127 patients and divided them into three groups (open pyeloplasty, laparoscopic pyeloplasty, and RAP) to analyze the learning curve. The results showed a significant decrease in surgical time and hospital stay after 25 cases. The median anastomosis time and operative time were decreased in the RAP as the number of procedures were increased, without significant difference (p > 0.05) (15). The reduction in anastomosis time in our study was observed earlier, indicating that using the avatera system could be associated with a shorter learning curve.

The ex-vivo training model consisted of a porcine urinary bladder accompanied by both ureters. This model was evaluated in details by *Sanchez-Hurtado and his colleagues* (10). The authors conducted the evaluation of face and content validity and enrolled 127 urologists who performed various Laparoscopic Ureteric Reconstructive Techniques.

Afterward, the participants fulfilled a Likert-scaled questionnaire. The final rating range could be 1-10 points. The mean rating was 9.19 ± 0.82, while the comments performed by the expert urologists who participated were positive.

In robotic pyeloplasty, the learning curve is particularly important as the procedure is technically demanding and requires a high level of dexterity and precision (16). The results of the study indicate that residents and new urologists can achieve a reduction in the time of anastomosis after four attempts at ex vivo robotic pyeloplasty using the avatera system. The reduction in the time of anastomosis suggests that the participants were able to improve their proficiency in the performance of the procedure, resulting in a reduction in the overall time required to complete the anastomosis. This improvement may be translated into ameliorated surgical outcomes, such as reduced complication rates and improved patient outcomes. In contrast, in a retrospective study conducted by *Sorensen et al.*, 33 children, who underwent RAP between 2006 and 2009, were compared to a matched group who underwent open pyeloplasty. The results showed that the mean overall operative time was 90 minutes longer (38%) for the RAP arm. After 15 to 20 robotic cases, the overall operative time was consistently within 1 SD of the average open pyeloplasty time with no significant difference in overall operative time. The decrease in overall operative time was due to a decrease in anastomosis time rather than access time (17). The learning curve in robot-assisted laparoscopic pyeloplasty is influenced not only by individual surgical experience but also by the experience of the surgical team. *Sampinato et al.* reported that junior surgeons were associated with a more rapid learning process with an earlier inflection point and comparable levels of expertise as senior surgeons after seven procedures (18). In our study, the progress of the less experienced residents' group was greater than the urologists' group. More precisely, the mean decrease in time was 4.33 ± 0.71 minutes and 4.5 ± 1.41 minutes for the residents' and urologists' groups respectively.

It is also worth noting that all participants in the study obtained the E-BLUS certification or could complete the four tasks in the dry lab, indicating that they had a basic level of proficiency in the use of laparoscopic surgery. The certification and dry lab experience likely provided a foundation for the participants to build upon during the ex vivo pyeloplasty procedure, contributing to the observed reduction in the time of anastomosis. *Dothan et al.* reported that previous experience in open and laparoscopic pyeloplasty was associated with a shorter learning curve in the robotic approach (15).

We acknowledge the existence of some limitations in the present study. The present study was based on ex-vivo models, which are limited in replicating the complexities of human anatomy, including blood flow, tissue response, and variability among patients. As a result, the learning experience may not accurately reflect the challenges a surgeon would face during an actual procedure. Besides, ex-vivo models do not allow for the possibility of encountering intraoperative complications, such as bleeding or unexpected anatomical variations. This limits the urologist's ability to gain experience in managing these challenges in a real-life setting. Lastly, in our study, all the participants had obtained or were capable to obtain the E-BLUS certification. Thus, the results of the ex-vivo study may not be generalizable to all urologists, as individual learning curves can vary based on prior experience, skill level, and other factors.

Conclusions

In conclusion, our study demonstrates that ureteropelvic anastomosis was precisely, effectively, and comfortably performed using the robotic system. Owing to its simplicity, residents and new urologists can improve their competency in the performance of robotic-assisted pyeloplasty using a porcine ex-vivo model.

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