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ORIGINAL PAPER

Feasibility study of a novel robotic system for transperitoneal partial nephrectomy: An in vivo experimental animal study

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Summary

Purpose: To evaluate the safety and feasibility of partial nephrectomy with the use of the novel robotic system in an in vivo animal model.
Methods: Right partial nephrectomy was performed in female pigs by a surgical team consisting of one surgeon and one bedside assistant. Both were experienced in laparoscopic surgery and trained in the use of the novel robotic system. The partial nephrectomies were performed using four trocars (three trocars for the robotic arms and one as an assistant trocar).
The completion of the operations, set-up time, operation time, warm ischemia time (WIT) and complication events were recorded. The decrease in all variables between the first and last operation was calculated.
Results: In total, eight partial nephrectomies were performed in eight female pigs. All operations were successfully completed. The median set-up time was 19.5 (range, 15-30) minutes, while the estimated median operative time was 80.5 minutes (range, 59-114). The median WIT was 23.5 minutes (range, 17-32) and intra- or postoperative complications were not observed. All variables decreased in consecutive operations. More precisely, the decrease in the set-up time was calculated to 15 minutes between the first and third attempts. The operative time was reduced by 55 minutes between the first and last operation, while the WIT was decreased by 15 minutes during the consecutive attempts. No complications were noticed in any operation.
Conclusions: Using the newly introduced robotic system, all the advantages of robotic surgery are optimized and incorporated, and partial nephrectomies can be performed in a safe and effective manner.

KEY WORDS: *Robot-assisted surgery; Avatera system; Partial nephrectomy; Kidney cancer; Animal model.*

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INTRODUCTION

Renal cell carcinoma is the 13th most common malignancy worldwide and the 10th most identified cancer in Europe (1). The gold-standard treatment for small renal masses (< 4 cm) is currently the nephron-sparing surgery (2). By preserving the affected kidney, this established surgical treatment aims at optimal oncological outcomes while maintaining normal renal function and avoiding chronic kidney disease (3, 4).
In recent years, minimally invasive techniques have dominated the surgical field, especially in urology.
Consequently, laparoscopic surgery has been widely utilized. However, the steep learning curve and the advanced technical skills, which are associated with laparoscopic surgery, contribute to the underperformance of demanding laparoscopic procedures such as *partial nephrectomy* (PN) (5). In particular, the restricted motion of laparoscopic instruments can compromise the surgeon's effort to accomplish tumor resection and hemostatic renorrhaphy in limited *warm ischemic time* (WIT) (6). Robotic assistance is an established trend in surgery providing high-definition, three-dimensional imaging, along with better articulation of the wristed instruments, there wise, making demanding surgeries like partial nephrectomy more easily feasible (7).
The use of robotic surgery in urology is growing exponentially, thus many novel robotic systems have been introduced in the last decade (8). A novel robotic system is a new suggestion and it consists of two main components; the surgical robot with four robotic arms in which the endoscope and the instruments are mounted, and a separate console unit for the surgeon with multiple adjustments for the eyepiece, the seat, and the handling mechanism. As the eyepiece offers a high-resolution image and does not cover the surgeon's ears and mouth, the cooperation over team members is optimized (9). Four instruments are provided: *Bipolar Metzenbaum Scissors* for cutting and coagulation, *Atraumatic Grasper* for holding and grasping tissue, *bipolar Maryland Dissector* for dissecting and coagulating tissue and *Needle Holder* for suturing. All instruments are compatible with 5 mm trocars (9). Unlike other robotic systems, the single-use instruments minimize the sterilization costs and eliminate any risk of cross-contamination (9).
The aim of the present study is to highlight the feasibility

of partial nephrectomy with this novel robotic system in an *in vivo* animal model.

Materials and methods

Compliance with ethical standards

Ethics approval was obtained from the corresponding state services and eight female pigs, approximately 30 kg each, were used.
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*).

Preparation of the pigs

The pigs were kept unfed 12 hours prior to the procedure. *Ketamine, Atropine Sulfate* and *Xylazine* were used for initiating the anesthesia. Following intubation, the pigs were connected to the ventilator and anesthesia was maintained using *Propofol* 5%.

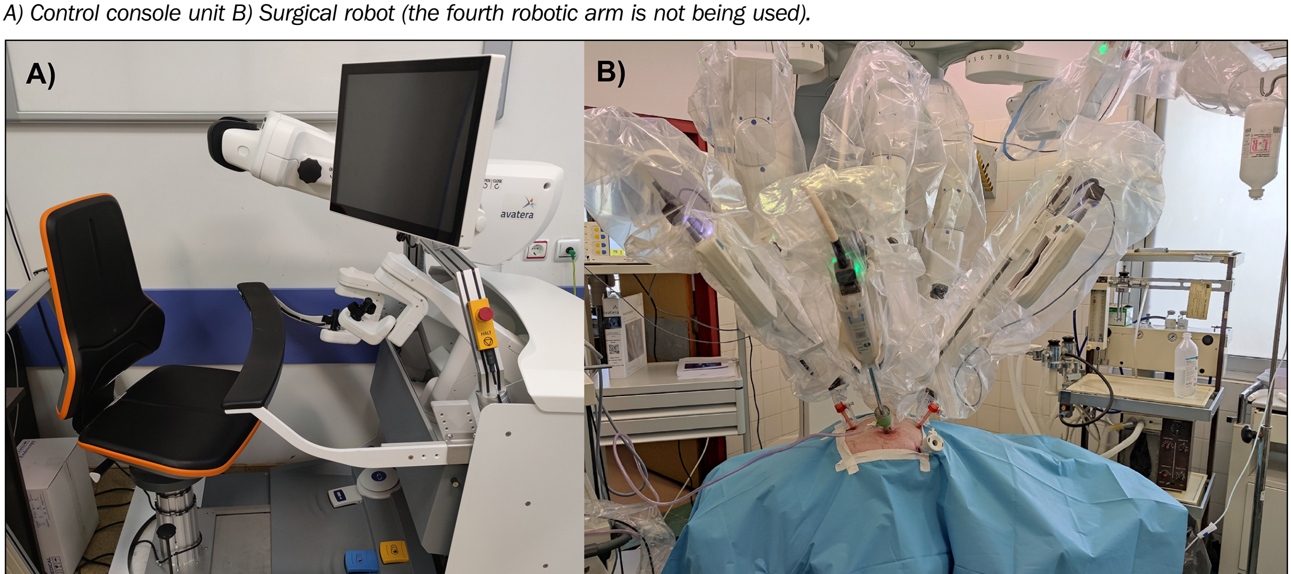
Surgical team

Each operation was performed by two surgeons: the primary surgeon (with experience of more than 100 laparoscopic and robotic surgeries) and the bedside assistant surgeon (with experience of more than 100 laparoscopic and robotic surgeries as assistant). The primary surgeon performed the operation via the control console, and the bedside assistant surgeon was standing next to the patient and the robot. The assistant surgeon, familiar with all surgical steps of partial nephrectomy, assisted with dissection and operated the suction, changed the surgical instruments, passed and retrieved sutures and was competent in laparoscopy or capable of converting to open surgery, if necessary. Prior to the study, both surgeons participated in a training program on the use of this novel robotic system.

Surgical technique

After anesthesia was initiated, the pig was placed in a lateral position. All partial nephrectomies were performed at the right kidney. Three of the four robotic arms were used, and the procedure was performed through four ports. A 10 mm port for the camera was placed in the midclavicular line at the same level as the umbilicus. Two 5 mm ports were placed at approximately 4 mm laterally from the camera trocar, one above and one below the level of the umbilicus. A 12 mm assistant port was placed at the midline, between the umbilicus and the xiphoid, for the assistant's instruments and the suction. All the currently provided surgical instruments were utilized: the *bipolar Metzenbaum Scissors*, the *Atraumatic Grasper*, the *bipolar Maryland Dissector*, and the *Needle Holder*. The primary surgeon seated in the console unit and was not scrubbed in, while the assistant surgeon was set at the operating table (Figure 1).
After the placement of the trocars and the achievement of pneumoperitoneum, the procedure was initiated. The peritoneum surrounding the right kidney was incised and pulled medially with the use of grasper, exposing the kidney. Holding the grasper on the left arm and the bipolar dissector on the right arm, further mobilization of the kidney was performed, and the renal hilum was identified. A bulldog clamp was placed at the renal artery and the period of warm ischemia was initiated (Figure 2). Afterwards, the excision of a small part of the lower or upper pole of the kidney (the supposed tumor) was performed with the use of bipolar scissors. The specimen was put in a laparoscopic bag and removed from the assistant's 12 mm port. Renorraphy followed using a running suture and placement of Hem-o-Lok clips to keep tension (Figure 3). When renorraphy was completed, the bulldog clamp was removed from the renal artery and the blood flow to

Figure 1.
A) Control console unit B) Surgical robot (the fourth robotic arm is not being used).



the kidney was restored. A thorough inspection for bleeding took place. Upon completion of the partial nephrectomy, all the ports were removed, and the abdomen was deflated. Lastly, the fascia and the skin were sutured. Immediately after finalizing the procedure, sedation was discontinued, and all pigs were extubated and monitored postoperatively.

Table 1.
The outcomes of the investigated variables in the first and the eighth operation.

	Set-up time	Operative time	Warm ischemia time	Complications
Median (range) (minutes)	19.5 (15-30)	80.5 (59-114)	23.5 (17-32)	No
1st Operation	30 min	114 min	32 min	No
8th Operation	15 min	59 min	17 min	No
Decrease (1st to 8th operation)	15 min	55 min	15 min	
Min: minutes.				

Figure 2.
A) Identification of renal artery and veins (left instrument → bipolar Maryland dissector, right instrument → bipolar Metzenbaum scissors).
B) Bulldog clamp on renal artery and initiation of warm ischemia time.

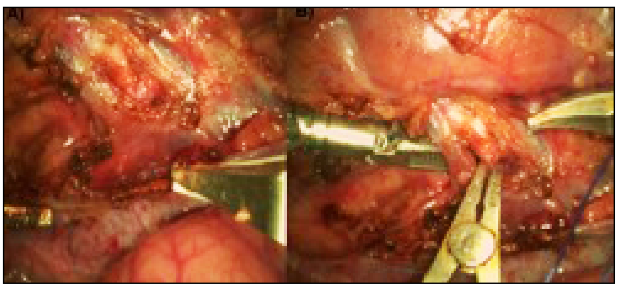
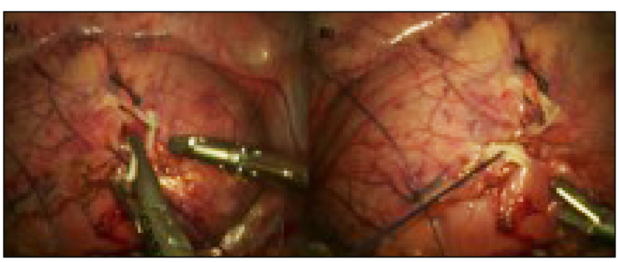


Figure 3.
A) Suturing and clip placement of renal parenchyma.
B) Final look of the kidney with clips after partial nephrectomy.



Data collection
The collected intra and postoperative data included the set-up time, the operative time, the WIT, and the presence of complications. The set-up time was defined as the time between the incision for the first trocar and the application of the last robotic arm. The time between the first robotic maneuver and the suture of the trocar incisions was considered as the operative time. WIT was defined as the time between the placement and removal of the bulldog clamp. The recorded complications were stratified into system-related or not. The decrease in every variable between the first and last operation was also evaluated.

Results
In total, eight partial nephrectomies were performed in eight female pigs. All operations were successfully completed. The estimated median set-up time was 19.5 minutes (range, 15-30), while the median operative time was calculated to 80.5 minutes (range, 59-114). The median needed WIT was 23.5 minutes (range, 17-32). Regarding the complications, major or system-related ones were not recorded.
The improvement during the consecutive attempts was also evaluated. More precisely, during the first attempt, the set-up, operation and warm ischemia times were 30, 114 and 32 minutes, respectively. On the eighth operation, the set-up and the operation were completed in 15 and 59 minutes, respectively, while the estimated needed WIT was 17 minutes. The decrease in the set-up time was calculated to 15 minutes between the first and third attempt. The operative time was reduced by 55 minutes between the first and last operation, while the WIT was decreased by 15 minutes during consecutive attempts. All the results are summarized in Table 1.

Discussion
Nowadays, minimally invasive techniques are well-established in urology. Robotic assistance is increasingly adopted in the urological field and adjusted in a variety of surgical procedures (10). The idea of robotic surgery is to perform minimally invasive procedures without the technical difficulties of laparoscopy (11). Major benefits of the robotic approach are the high-resolution stereoscopic image and the fully articulating instruments, which allow precise control (6). In the case of partial nephrectomy, precise control helps surgeons to carry out more difficult cases and approach hilar or large endophytic tumors (12-15).
Compared to *Laparoscopic PN* (LPN), the *Robotic PN* (RPN) offers better outcomes. In particular, recent data suggest that RPN is associated with reduced WIT, fewer complications, lower conversion rates to open surgery, better post-surgery renal function, and reduced hospitalization time (16, 17). Furthermore, a remarkable benefit of robotic surgery is the minimization of the learning curve. It has been shown that RPN's learning curve is steeper than the learning curve of LPN, having an immediate impact on the operative times, WITs and blood loss (18, 19).
In the present study, the feasibility and safety of RPN with the use of a novel robotic system were investigated on a porcine *in vivo* model. The transperitoneal access was used although the retroperitoneal access has been also utilized in the literature (20). The duration of the surgery was significantly reduced within only eight operations, an indicator of a steep learning curve in the use of this novel robotic system. The set-up time was considerably different between the first and the last surgeries, as it was the first setting and docking of the novel robotic system in our department after initial basic training, and all the new elements had to be assimilated. This important step was easily improved, as mentioned in the Results section. Especially, the simplified controlling mechanisms of the novel robotic system can

make any surgeon proficient in setting up the robot easily and in a short time. WIT is of utmost importance in partial nephrectomy and this step was significantly improved during consecutive operations.

Prolonged WIT is associated with acute or chronic renal dysfunction, thus it has to be maintained to a minimum (21). The precise time limit is still controversial. More dated studies showed that renal damage may be reversible when WIT is less than 30 minutes (22). Contemporary studies set a goal of 20 minutes (21, 23). In our study, this goal was achieved, as the median WIT was 23.5 minutes. In comparison with laparoscopy, robotic assistance has decreased the technical complexity of tumor excision and intracorporeal suturing by providing articulated instruments and consequently more angles for the surgeon. Therefore, as mentioned above, robotic surgery has better outcomes concerning WIT than laparoscopy (17). This is supported by large comparison studies. Particularly, *Wang et al.* compared 199 RPN with 176 LPN noticing a significant difference in mean ischemia time between RPN (19.7 min) and LPN (35.2 min) (24). In the study of *Benway et al.*, WIT favored robotic surgery. 129 RPN and 188 LPN were compared and the difference was almost 9 minutes (19.7 min of WIT for robotic and 28.4 min for laparoscopic approach) (25). Besides the superiority of RPN compared to LPN, *open PN* (OPN) is associated with significantly lower WIT (8.7 *vs* 15.4 minutes, p = 0.001), as presented by *Kowalewski et al.* (26).

The feasibility of RPN has been evaluated using various novel robotic platforms. *Fan et al.* investigated the successful completion of RPN using the novel *KangDuo Surgical Robot-01* (KD-SR-01) system (*SuZhou Kang Duo Robot Co., Ltd., Suzhou, China*). One RPN was performed on a 60 kg female porcine. The estimated operative time was 94 minutes, while the set-up time was 4.5 minutes. No complications were reported (27). In our study, the median operative and set-up times were 80.5 and 19.5 minutes, respectively. The feasibility and safety of RPN with KD-SR-01 were also investigated in a clinical study conducted by *Xu et al.* In total, 17 RPN were performed with a mean operative time of 110.5 ± 37.6 minutes. The median set-up time was calculated to 3.3 minutes (range, 2.2-6.3), while the mean ischemia time was 16.9 ± 9.0 minutes (28). The performance of RPN using the *Versius* (*CMR, Cambridge, UK*) robot was investigated in a study conducted by *Hussein et al.* Six RPN were performed with a median operative time of 170 minutes and without reported malfunctions of the robotic system (29). *Hugo RAS system* (*Medtronic, Minneapolis USA*) was also evaluated on both cadaveric and live cases. Three RPN (one on the right and two on the left side) were performed in cadavers. The recorded mean operative and docking times were 98 minutes and 7 minutes, respectively, while no major complications or clashing of the arms occurred (30). Additionally, *Gallioli et al.* presented their initial experience in 10 cases of RPN using the Hugo RAS system. The median docking time was 9.5 minutes (range, 9-14) and the median console time was 138 minutes (range, 124-162). The estimated, median WIT was 13 minutes (range, 10-14), whereas one case was completed clampless. One postoperative pseudoaneurysm bleeding was treated by selective embolization (31).

In the present study, this novel robotic system, which gathers all the advantages of a robotic system trying to maximize them and simplify its use, was utilized. High-definition 3-D vision and wristed instrumentation are the main elements. Easy handling of the robot and console helps to minimize the set-up time and learning curve. Many safety mechanisms ensure that the operation will be carried out without any risks for the patients. Moreover, all instruments are for single use which neutralizes the possibility of contamination and infections.

Unfortunately, this new system has some disadvantages that can be improved. At the time of the study, the single-use instruments have a life span of one hour of continuous usage which means that during surgery they must be exchanged, most probably more than once. Another disadvantage is the lack of haptic feeling, which, nevertheless, characterizes all robotic systems (9).

Despite the encouraging results of the present study, there are some limitations and weaknesses that should be addressed in future studies. Firstly, this is an *in vivo* experiment, but still, surgical times and difficulties will be different in human operations. Most notably, the intraperitoneal space differs, and the softer tissue of a pig's renal parenchyma makes it harder to suture. However, the instruments used and the procedure followed were almost identical to clinical practice. Secondly, a small number of partial nephrectomies were performed and strong conclusions with regard to the learning curve cannot be driven. Nevertheless, our institution's recent experience with this novel robotic system let us anticipate a steep learning curve with this robot as we have already performed several urological procedures. To the best of our knowledge, this is the first time that this novel robotic system has been tested in a complex surgical procedure like partial nephrectomy and we tried to evaluate all its elements.

Conclusions

Minimally invasive approaches have emerged and been adopted in urology. Robotic assistance has helped surgeons to overcome the technical challenges and disadvantages of laparoscopic surgery and make demanding procedures such as RPN even more feasible. Using this novel robotic system, all the advantages of robotic surgery are optimized and incorporated, and partial nephrectomies can be performed in a safe and effective manner.

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Conflict of interest: *Jens-Uwe Stolzenburg* is co-founder, shareholder and medical advisor of avateramedical GmbH. *Evangelos Liatsikos* is medical advisor of avateramedical GmbH. The rest of the authors have no relevant financial or non-financial interests to disclose.