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Feasibility of Microwave Scissors-based Off-clamp Laparoscopic Partial Nephrectomy in a Porcine Model

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Abstract

Objectives: To assess the feasibility of off-clamp laparoscopic partial nephrectomy using microwave scissors.

Methods: We performed transperitoneal laparoscopic partial nephrectomy, without hilar clamping or renorrhaphy, using only microwave scissors for renal resection in a porcine model. For each kidney, two types of procedures were performed: a middle pole resection excising an area of 2-cm diameter and approximately 1-cm depth and a lower pole resection at the level of the lower polar line. The renal calyces exposed during renal resection were sealed and transected using microwave scissors. After three days of follow-up, the pigs were reoperated to inspect for postoperative complications. Euthanasia was performed to collect the remaining kidneys for histopathological examination.

Results: Ten procedures were successfully performed, without hilar clamping or suturing of the renal calyces and parenchyma, in five kidneys from three pigs. The median resecting time, blood loss, and lateral thermal injury were 23.2 min, 47.1 ml, and 6.8 mm in the middle pole resection, and were 15.1 min, 26.5 ml, and 6.9 mm in the lower pole resection, respectively. No complications were noted during reoperation, such as postoperative hemorrhage and major urine leakage. Extravasation occurred in two middle pole resections and three lower pole resections during retrograde pyelogram. Hematoxylin and eosin staining revealed thermal injury characterized by tissue microwave fixation in the near zone and acute coagulative necrosis in the intermediate zone.

Conclusions: Microwave scissors-based off-clamp laparoscopic partial nephrectomy is feasible in pigs and can be used for clinical applications.

Keywords: Laparoscopic partial nephrectomy • Off-clamp • Microwave • Renal function • Renal ischemia

Introduction

Partial nephrectomy (PN), with similar oncologic outcomes and preservation of superior renal function (RF) to those of radical nephrectomy,[1] has been widely accepted as the standard treatment for organ-confined renal tumors. Although PN is traditionally performed via an open approach with adequate oncologic control, the associated perioperative morbidity remains a major concern among the urologist community.[2] Minimally invasive PN techniques, including laparoscopic (LPN), and robot-assisted laparoscopic partial nephrectomy (RALPN), have been gaining acceptance among urologists as viable alternatives to open surgery for localized renal tumor management over the past two decades. Minimally invasive PN usually involves hilar clamping to reduce blood loss, maintain a clear surgical view, and improve the tumor margin exposure,[3] which help in accurate tumor removal and renal reconstruction. However, renal ischemia induced by hilar clamping, and the subsequent reperfusion injury potentially impair the postoperative RF.[4]

In addition, tumor resection and renal reconstruction need to be performed quickly to prevent ischemia in LPN. However, it is technically challenging[5] to do so because of the limited workspace resulting from trocar installation and the insufficient dexterity of laparoscopic instruments. Consequently, LPN has several limitations such as prolonged ischemia time, greater blood loss, a higher postoperative complication rate, a higher positive surgical margin rate, and a steeper learning curve than those observed with open surgery.[5] Although these limitations have been diminished in RALPN using a dexterous robotic endo-wrist, the cost-effectiveness remains controversial.[6] As a potential solution to these limitations and clamping issues, "zero-ischemia"[3] LPN/RALPN has been proposed and performed by using several energy devices, including j-hook electrocautery,[7] radiofrequency vessel-sealing devices,[8] lasers,[9] ultrasonic devices,[10] and soft coagulation.[11] However, these techniques can only target small and superficial tumors. In addition, they require hemostatic agents. There were no accepted devices whose hemostatic performance is sufficient to perform off-clamp PN for patients with large and highly complex renal tumors.

We investigate the usefulness and safety of a novel technique that enables the surgeon to perform off-clamp minimally invasive PN without limiting the target tumor or requiring hemostatic agents, with less procedural burden and maximal RF preservation. We propose off-clamp LPN by using microwave scissors (MWS)[12–14] to achieve this. While the MWS allows a promptly seamless sealing based on interblade microwave irradiation and an arbitrary timing for mechanical transection,[12–14] the MWS-based LPN has the potential to be a practical option to execute renal resection adaptively and safely without hilar clamping. This study aims to assess the feasibility of the MWS-based off-clamp LPN using a porcine model.

Materials and methods

Microwave scissors

The MWS (Acrosurg Revo S, Nikkiso Co., Ltd., Tokyo, Japan), as shown in Figure 1A, are mechanical laparoscopic scissors that cut manually but can irradiate microwaves between the two scissor blades because each blade is connected to a transmit antenna and a ground antenna of a coaxial cable for microwave transmission.[12] The microwaves impose an electrical field with an alternating direction at a frequency of 2.45 GHz on the tissue placed between the scissor blades. This electrical field intrinsically generates dielectric heat by oscillating the water molecules, causing direct tissue coagulation without thermal heat sink effects.[15] The timing of microwave irradiation and cutting can be arbitrarily adjusted,[12] allowing MWS to be used flexibly and adaptively as cold scissors, scissors for cutting with seamless sealing like bipolar radiofrequency and ultrasonic sealers,[14,16] or a simple coagulator without involving cutting. Therefore, we can use the MWS to perform dissection, transection, vessel sealing,[14,17,18] and tissue coagulation[13,16] based on the tissue properties and bleeding conditions. The generator's power output was set as 60 W for renal resection.

Figure 1B shows its manipulation as a sealer. We first bit the vessel or tissue gently with the scissor blades, irradiated microwaves, and then mechanically cut them according to the operator-dependent timing while visually confirming the tissue condition. Figure 1C shows the manipulation of MWS as a coagulator. We closed or partially opened the scissor blades and placed the blade side to the bleeding area while irradiating microwaves. The interblade microwave irradiation induced a dielectric heating volume around the scissors that can coagulate the tissue and stop bleeding without transection.

The MWS is currently approved and commercially available only in Japan.

Animal experiment and surgical techniques

This animal study strictly complied with the Science Council of Japan's Guidelines for Proper Conduct of Animal Experiments (2006) and the relevant laws on the protection of animals. The research protocol was approved by an ethical review board of the research and training facility of Nikkiso Co., Ltd. (M.ReT Miyazaki, Miyazaki, Japan) where this study was conducted, approval No. 20210901.

Three pigs weighing approximately 30 kg each and raised in a pathogen-free environment were used for this experiment. The pigs were inducted by combining an intramuscular injection of 30 μg/kg medetomidine hydrochloride (Domitor 10 mg/10 ml, Orion Pharma, Espoo, Finland), 0.1 mg/kg butorphanol tartrate (Betorfar 5 mg/10 ml, Meiji Seika Pharma, Tokyo, Japan), and 0.2 mg/kg midazolam (Midazolam 10 mg/2 ml, Sandoz Pharma K.K., Tokyo Japan) before transportation to the operating theatre. Induction was secured by an intravenous injection of 10 mg/kg thiopental sodium (Ravonal 0.5 g/20 ml, Nipro ES Pharma, Osaka, Japan) before endotracheal intubation. General anesthesia was maintained by 1–3% sevoflurane inhalation. Central venous catheterization was carried out for fluid administration and monitoring of the central venous pressure if necessary. An ear venous line was established for blood sampling. Prior to skin incision, intravenous infusion of 2 mg/kg marbofloxacin (Marbocyl 2%, Meiji Seika Pharma, Tokyo, Japan) and an intramuscular injection of 0.02 mg/kg buprenorphine hydrochloride (Buprenorphine 0.2 mg/1 ml, Nissin Pharma, Yamagata, Japan) were used for antibiotic prophylaxis and analgesia.

We performed two types of transperitoneal LPN for each kidney without hilar clamping or renorrhaphy: a middle pole resection, in which the resection volume was determined by a 2-cm-diameter circle and approximately 1-cm depth (LPN-A), and a lower pole resection at the level of the lower polar line (LPN-B). For the first pig, we only operated on the left kidney to avoid a prolonged operating time and anesthetic burden. After improving the surgeon's experience in the first pig, both kidneys of the remaining two pigs were used for the experiment.

LPNs for the left kidney were first performed in the right lateral position. Laparoscopy began with four trocars, as shown in Figure 2. The camera port was placed lateral to the left rectus muscle, 3 cm under the umbilicus level. On the left midclavicular line, working ports 1 and 2 were placed below the costal margin and at the lower abdominal quadrant, respectively. The assistant port was placed lateral to the rectus muscle, halfway from the umbilicus to the pubic bone. Pneumoperitoneum was produced by carbon dioxide insufflation. The intra-abdominal pressure was maintained by 10–12 mm Hg.

The posterior peritoneum and Gerota's fascia were detached to expose the left kidney. The renal artery and vein were dissected and controlled using vessel loupes. Although hilar clamping was not carried out, laparoscopic bulldog forceps were available for use in the case of an unstoppable bleed occurring. The anterior surface of the kidney's middle pole was marked around a 2-cm-diameter circular marker to determine the resection range of the LPN-A (Figure 3A). The kidney's lower polar line was marked to determine the excision level of the LPN-B (Figure 3E).

At the beginning of the LPN procedure, we coagulated the renal parenchyma along the marked excision line using the MWS before resection. We used the MWS to bite and seal the renal parenchyma and then cut them mechanically while slightly lifting the resected tissue up using a blunt-tip suction tube held by the other hand (Figure 3B,3F) to confirm the resection surface. The renal calyces exposed during renal resection were sealed and transected (Figure 3F) using MWS. After removing the resected specimen freely, the surgical margin of the remaining kidney, if oozing, was recoagulated using the MWS to consolidate the hemostasis. We then repositioned the animal in the left lateral position and performed the operation in a similar manner on the right kidney. Blood was sampled before and after every LPN procedure to measure hemoglobin (HGB) and the serum creatinine (SrCre) concentration.

Three days after surgery, the pigs were reoperated to inspect postoperative complications and intra-abdominal conditions. Finally, euthanasia was performed to collect the remaining kidneys. Retrograde pyelogram of the remaining kidney was performed ex vivo to identify the extravasation of the collecting system.

Outcome measurements

We recorded the kidney size, kidney volume resected, resecting time (RT), blood loss (BL), pre- and post-procedural HGB and SrCre concentrations, and short-term postoperative complications including bleeding and urine leakage, and extravasation of the collecting system of the remaining kidney during the retrograde pyelogram. The BL was determined by the amount of blood suctioned plus the subtracted weight of the dry gauzes before the procedure from the blood-absorbed gauzes. Changes in HGB and SrCre were determined by subtracting preprocedural concentrations from the corresponding postprocedural concentrations. The intra-abdominal condition, including the remnant kidney status, ascites, hematoma, and internal bleeding from the resecting sites, if any, were recorded at the reoperation stage before euthanasia.

Histopathological evaluation

The renal remnants were sectioned perpendicularly to the base of the surgical margin to macroscopically assess the characteristics of the thermal injury zone induced by the MWS. We performed hematoxylin and eosin staining for histopathological evaluation. The lateral thermal injury (LTI) was defined as the largest depth of the thermal injury zone that was limited between the cutting edge to the border between the heat-affected zone and the intact zone. The microscopic features of the thermal injury zone were assessed, and the LTI was measured using a microscope (IX83 Inverted Microscope, Olympus Corporation, Tokyo, Japan) integrated with image processing software (Olympus Cellsens Dimension 1.18, Olympus Corporation, Tokyo, Japan).

Results

Perioperative results

The perioperative outcomes are presented in Table 1. Five LPN-As and five LPN-Bs were successfully performed with a complete hemostatic resecting area (Figure 3C,3G). The median RT and BL were 23.2 min and 47.1 ml in the LPN-A and were 15.1 min and 26.5 ml in the LPN-B, respectively. Except for the first LPN-A that had an outlier BL (135 ml), all other procedures had BL of <60 ml. No bleeding cases were difficult to control using the MWS. Hemostatic agents were not required. No postoperative complications, such as intra-abdominal bleeding or major urine leakage (recognized by ascites appearance), were noted during the reoperation.

We noted calyceal entry in one LPN-A because of the urine accumulated in the resected bed. However, we only coagulated the resected bed using MWS without suturing. The retrograde pyelogram showed extravasation in two LPN-As, including the case noted during operation. On the other hand, we exposed the lower renal calyx in four LPN-Bs. We seamlessly sealed and transected those renal calyces (Figure 3F) using MWS. One calyx was completely sealed without leakage, while the others were indicated that extravasation occurred by the pyelogram.

Thermal injury zone

The median LTI induced by the MWS on the remaining kidney was 6.85 mm (range 5.9–10.0 mm). The thermal injury zone (Figure 3D,3H) included two zones: (1) the near zone, which had closer contact with the scissor blades, was characterized by tissue microwave fixation in which the morphology of renal glomeruli and renal tubules was well maintained, and (2) the intermediate zone, that separates the near zone from the intact zone, exhibited the acute stage of coagulative necrosis characterized by edema of the interstitial space and infiltration of macrophages and neutrophils.

Discussion

We successfully performed off-clamp LPN without renorrhaphy or hemostatic agents in a porcine model using only MWS for renal resection. We performed two types of LPN: a middle pole resection and a lower pole resection at the level of the lower polar line, mimicking clinical scenarios of various renal tumor locations. We showed that MWS was able to securely control bleeding of the renal tissue. Hence, we consider that MWS-based coagulation is adequate to prevent perioperative bleeding in LPN.

Off-clamp versus on-clamp PN

Theoretically, off-clamp PN associated with no renal ischemia and reperfusion injury potentially reduces the risk of postoperative acute kidney injury and progressed chronic kidney disease (CKD).[3,4,19] A previous study compared no ischemia to warm-ischemia PN on patients with solitary kidney[20] and showed that the warm-ischemia group was significantly more likely to develop acute kidney injury and new-onset stage IV CKD regardless of the preoperative RF, tumor size, and PN technique. The authors, therefore, recommend no-ischemia PN when technically feasible in patients with solitary kidney.

In two-kidney patients, the benefits of off-clamp PN in preserving postoperative RF vary among studies. Several studies have shown that off-clamp PN had no advantage in postoperative RF preservation[21,22] compared with on-clamp PN. Those results proved that on-clamp PN is acceptable in appropriately selected patients with two kidneys. In contrast, a propensity score-matched study[23] indicated that on-clamp PN was significantly associated with a higher risk of developing stage ≥3b CKD when compared with off-clamp PN. There were no differences in postoperative complications between the two groups.

In summary, PN without hilar clamping is beneficial in terms of postoperative RF preservation, especially for patients with solitary kidneys or low baseline RF. However, the off-clamp procedure requires quick tumor resection and reconstruction to reduce BL and is technically challenging. Consequently, urologists tend to make an acceptable compromise with on-clamp PN. Therefore, the off-clamp LPN technique in the present study using MWS for the control of bleeding, without the requirement for renorrhaphy, is advantageous as a practical option because the renal ischemia and reperfusion injury can be completely avoided with less BL.

Benefits and risks of sutureless PN

In addition to minimizing renal ischemia and reperfusion injury, healthy renal remnant preservation was considered a target to optimize postoperative RF as it can be modified.[19] To achieve this objective, minimal PNs such as enucleation and enucleoresection techniques were suggested instead of wedge resection,[19,24] whereas sutureless PN was considered as a solution to avoid renorrhaphy-related devascularization.[25,26] The resected bed must be carefully ablated using energy devices to prevent hemorrhage. However, it results in normal nephron loss induced by thermal injury in the renal remnant. Therefore, the benefit of sutureless PN in RF preservation is uncertain.

In principle, PN conventionally involves hilar dissection for clamping and tumor resection followed by renorrhaphy. Renorrhaphy usually includes suturing of the opening calyx to prevent urine leakage and parenchymal approximation to stop bleeding. However, these steps are technically challenging, especially in minimally invasive PNs. In addition, suturing procedures may be hastily terminated to reduce renal ischemia, resulting in renovascular complications.[27] Sutureless PN is a potential solution to avoid these limitations. Bleeding of the resected bed is controlled by using surgical energy devices with a sufficient coagulative effect for the renal tissue.[28] However, a deep thermal injury in the resected bed may cause urinary complications such as urine leakage and pelvic stenosis, requiring sufficient coagulative energy devices that can induce a shallow LTI in the renal tissue.

Advantages, limitations, and perspectives of MWS-based off-clamp minimally invasive PN

Microwaves afford more direct heating than other energy forms because of intrinsically dielectric oscillation without vascular heat sink effect when ablating organs with high blood perfusion[15] and were understood to have excellent energy for coagulation. Several studies[29,30] used microwave coagulators to coagulate the renal parenchymal incision before tumor resection and successfully performed PN without hilar clamping. Major postoperative complications, including arteriovenous fistula, pelvic stenosis, and renal infarction induced by renal artery thrombosis and spasm, limit the indications for such techniques to small exophytic tumors with underlying renal parenchyma.[29] However, it is easy to imagine that the suboptimal probe thickness, puncture direction, and tunnel left after probe removal must have impacted these complications.

The MWS has the potential to avoid the limitations of the microwave coagulator because the scissor blades can be precisely controlled under operator's vision, while the renal tissue is coagulated by microwaves radiated between the scissor blades with an arbitrary transition timing based on the bleeding condition. Our off-clamp LPN technique using MWS recorded lower BL compared with off-clamp open PN using ultrasonic[31] or radiofrequency ablation devices[31] in similar porcine renal resections reported previously. Moreover, even though the proposed technique requires no clamping, its RT and BL were lower than those in on-clamp LPNs[32,33] in which renal bleeding was controlled with renorrhaphy,[32,33] renorrhaphy with hemostatic agents,[33] or electrocautery with hemostatic agents,[32] respectively. The MWS was able to stop bleeding from both cortical and medullary vessels. This suggests off-clamp LPN technique using MWS can completely avoid renal ischemia and reperfusion injury and reduce the risk of renovascular complications involving hilar dissection.

Although no major urine leakage was observed during the reoperation, the extravasation that occurred in half of the trials in the retrograde pyelogram remains a concern in terms of the calyceal sealing effect of MWS. The sealing and cutting timing of the MWS are adjustable,[12] allowing operators to coagulate and seal tissue flexibly[18] and control renal bleeding adaptively based on the tissue conditions. However, proper calyceal sealing requires sufficient sealing time, but it entirely depends on the operators. If the renal calyces are cut after premature coagulation, this might result in improper sealing and urine leakage. Therefore, we suggest that the closing suture applied to the opening of the calyx should be considered as a countermeasure to prevent urine leakage. In addition, the approximately 7-mm median LTI caused by MWS in the renal remnant is responsible for the normal nephron loss observed with the present technique. However, the similar on-clamp PN followed by renorrhaphy may induce the equivalent normal nephron loss due to devascularization. Fujisaki et al[34] reported that soft coagulation by a radiofrequency device, which has been applied to perform off-clamp sutureless open[35] and minimally invasive PN[11] for small renal tumors in humans, induced an approximately 5-mm-deep LTI in porcine open PN model. However, the investigator did not assess the control of bleeding from large vessels in the renal medulla, which may result in a shallower LTI.

Although the number of LPN has dramatically decreased in the era of robotic surgery, the cost-effectiveness of RALPN is still controversial.[6] MWS-based off-clamp LPN can improve patient outcomes and has the potential to be a viable and affordable option for those who cannot adopt robots. In contrast, if the MWS was installed into surgical robots and realized as "MWS-based off-clamp RALPN", it could provide an accurate manipulation of MWS based on the dexterous and precise control,[7] and a mist-less unique robotic-surgery environment even with energy devices.

This study has several limitations—the small sample size, short follow-up period, and no comparison with the conventional PN. In addition, porcine kidneys are not as well vascularized as human kidneys. Additional studies with long-term follow-ups, therefore, are warranted.

Conclusion

We propose a novel minimally invasive PN technique—MWS-based off-clamp LPN. In this initial assessment, the present technique is feasible in pigs with short RT and less BL. MWS-based coagulation can adequately control renal bleeding without the need for hilar clamping or renorrhaphy. These findings suggest that using MWS can open up a new surgical treatment modality for localized renal tumors.

Author contributions

Study concept and design: Nguyen H.N., Tani T.

Acquisition of data: Nguyen H.N., Naka S., Tani T.

Analysis and interpretation: Nguyen H.N., Yamada A., Tani T., Mukaisho K.

Study supervision: Tani T.

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Declaration of conflicting interests

Nguyen H.N., Yamada A., and Tani T. belong to the endowed department funded by Nikkiso Co., Ltd., and Micron Shiga Inc. in the university. Tani T. declares that he is the representative of Micron Shiga Inc. and the inventor of microwave scissors (MWS). Micron Shiga Inc. receives royalties provided by intellectual property of MWS from Nikkiso Co., Ltd. The other authors declare no conflict of interest.

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Table 1 Perioperative outcomes of microwave scissors-based off-clamp laparoscopic partial nephrectomy.

Parameter	**Middle pole resection (*n* = 5)**	**Lower pole resection (*n* = 5)**
KVR (g), median (range)	2.4 (2.2–3.1)	12.7 (6.7–15.5)
%KVR (%), median (range)	3.6 (2.16–4.62)	18.8 (9.98–21.94)
RT (min), median (range)	23.2 (14.7–30.2)	15.1 (13.2–17.5)
BL (ml), median (range)	47.1 (15.4–135.0)	26.5 (7.1–58.6)
HGB change[§] (g/dl), median (range)	0.0 (-0.6–1.0)	-0.3 (-0.7–0.4)
SrCre change[§] (mg/dl), median (range)	0.0 (0.0–0.3)	0.0 (-0.3–0.2)
LTI (mm), median (range)	6.8 (5.9–7.2)	6.9 (5.9–10.0)
Bleeding, *n*	0	0
Urine leakage, *n*	0	0
Calyceal entry/transection and sealing, *n*	1	4
Extravasation during pyelogram, *n*	2	3

KVR = kidney volume resected, %KVR = percentage of kidney volume resected, RT = resecting time, BL = blood loss, HGB = hemoglobin, SrCre = serum creatinine, LTI = lateral thermal injury

[§] HGB change, SrCre change were obtained by subtracting the preprocedural concentration from the corresponding postprocedural concentration.

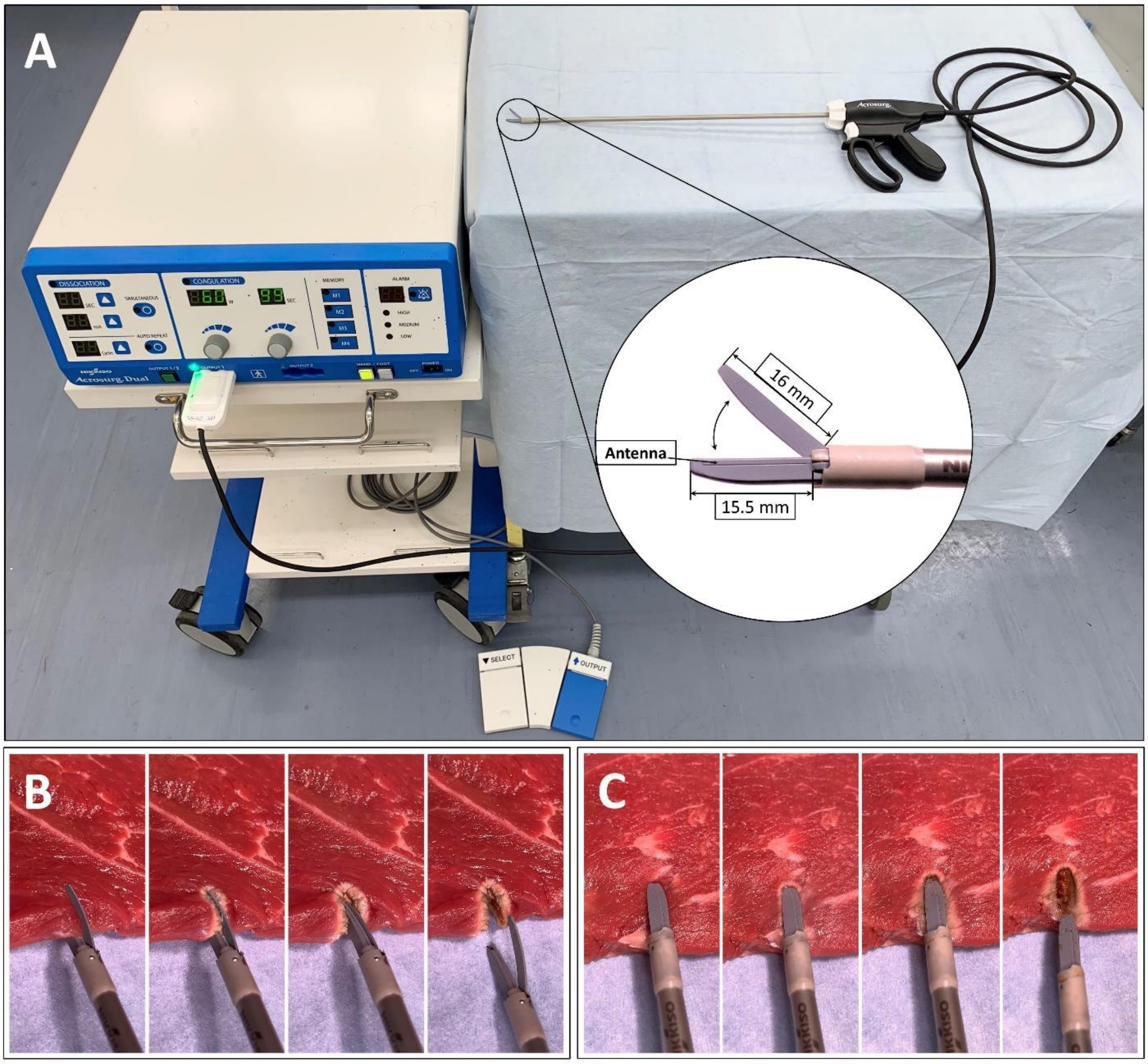

Figure 1 Microwave scissors (Acrosurg Revo S 350 mm) and the generator (A). Microwave scissors can be manipulated to seal and then transect tissue mechanically (B) or coagulate tissue without transection (C).

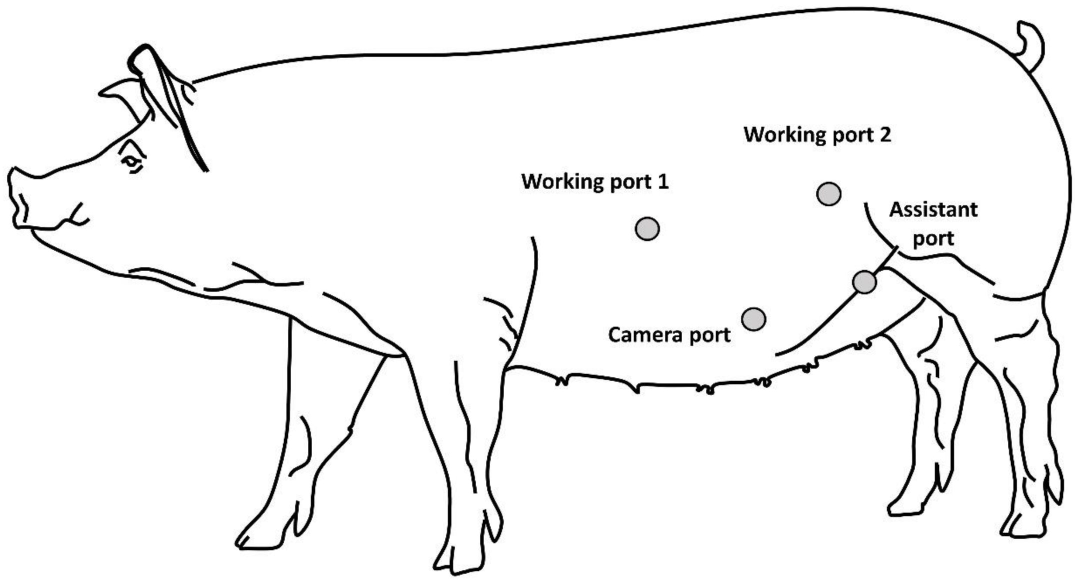

Figure 2 Trocar placement.

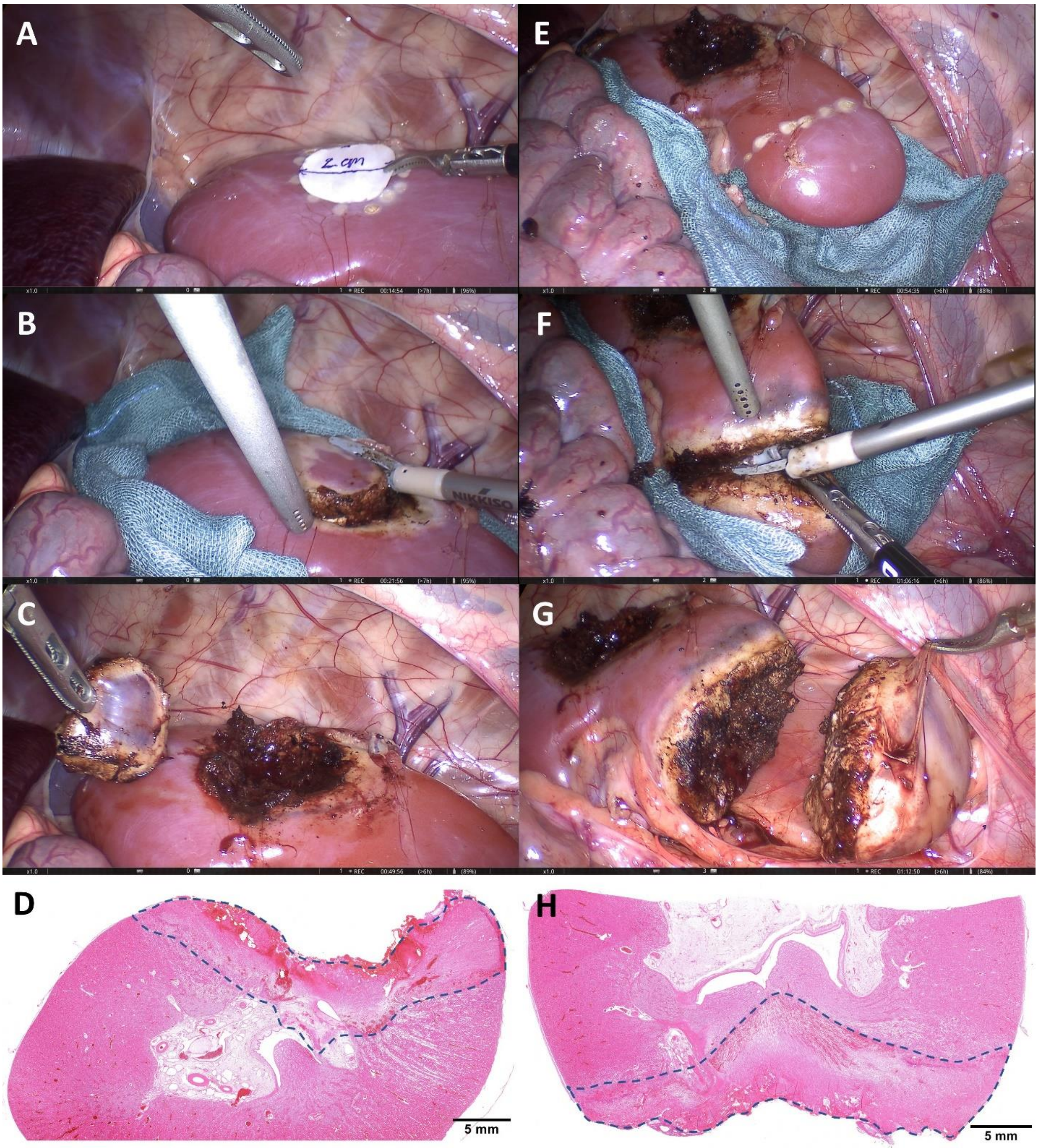

Figure 3 A–C. Middle pole resection. A. Excision line was marked around a 2-cm-diameter circle marker. B. Renal resection using microwave scissors. C. Resected area and specimen excised after resection. E–G. Lower pole resection. E. Excision line was marked at the level of the lower polar line. F. Lower pole resection and calyceal sealing using microwave scissors. G. Kidney's lower pole excised and resected area that was completely coagulated. D, H. Hematoxylin and eosin staining of the renal remnant perpendicular to the resected bed of the

middle (D) and lower pole resection (H). The area limited by the dashed line indicates the thermal injury induced by the microwave scissors on the remaining kidney.