New Hybrid Mini-laparoendoscopic Single-site Partial Nephrectomy With Early Unclamped Technique for Renal Tumors With Intermediate PADUA Score (IDEAL Phase 2a)

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OBJECTIVE To evaluate a new hybrid technique, which we defined as mini-laparoendoscopic single-site partial nephrectomy (MILESS-PN), for renal masses presenting an intermediate PADUA score.

MATERIALS AND METHODS Forty consecutive cases of MILESS-PN performed between April 2013 and November 2015 were included in this study. Mini-laparoendoscopic single-site surgery consisted of the simultaneous use of two 3-mm pararectal trocars and an umbilical SILS trocar; the sequence of steps of MILESS-PN was comparable with standard laparoscopic partial nephrectomy. Demographic data and the main perioperative and oncological outcome parameters were gathered and analyzed.

RESULTS The median operative time was 134.6 (interquartile range [IQR] 110-180) minutes with a median warm ischemia time of 12.1 (IQR 9.5-15.5) minutes. Postoperatively, 4 early complications were recorded and the median hospital stay was 4.2 (IQR 3.5-6.0) days. The median renal tumor size was 3.6 (IQR 2.4-5.3) cm with a median PADUA score of 8.3 (IQR 8-9). The definitive pathologic results revealed a renal cell carcinoma in 32 cases (80%), an angiomyolipoma in 3 cases (7.5%), and an oncocytoma in 5 cases (12.5%). All tumors were removed with negative surgical margins, and at the median follow-up of 34.5 (IQR 24-48) months, all patients were alive without evidence of tumor recurrence or port-site metastasis. A statistically significant decrease in the estimated glomerular filtration rate (eGFR) was observed postoperatively (postoperative vs preoperative median eGFR: 87.6 [IQR 70.4-101.8] and 104.7 [IQR 82.7-123.3], $P < .0001$) and at 6 months (6 months vs preoperative eGFR 93.6 [IQR 79.1-110.2] and 104.7 [IQR 82.7-123.3], $P < .0001$).

CONCLUSION MILESS-PN for renal tumors with an intermediate PADUA score in well-selected patients is not associated with increased risks for the patients, presenting excellent oncological and functional results at the midterm follow-up. Mini-laparoendoscopic single-site surgery could represent a valid alternative to laparoendoscopic single-site surgery or minilaparoscopy because of its higher surgical reproducibility. UROLOGY 111: 104–109, 2018. © 2017 Elsevier Inc.

Currently available evidence suggests that localized kidney cancer is best managed by nephron-sparing surgery (NSS) whenever technically feasible. Open partial nephrectomy still represents the gold standard NSS procedure. Laparoscopic partial nephrectomy (LPN) has also gained popularity but is currently performed in a few high-volume reference centers, and its diffusion has been limited by the steep learning curve.[1] Conversely, robotic-assisted LPN is gaining momentum as a promising procedure, which is able to bridge the technical difficulties of LPN in favor of a broader diffusion of minimally invasive NSS.[2]

The evolution of minimally invasive techniques has spurred an impetus in the surgical community to reduce the invasiveness of laparoscopic surgery. Laparoendoscopic single-site surgery (LESS) has been developed in an attempt to further reduce the morbidity and scarring associated with surgical intervention. The first 2 large series of urologic LESS were published in 2009.[3,4] Since then, other early single-center experiences have been reported, as have early comparative studies, albeit limited by small numbers, a

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nonrandomized design, and a lack of standardization in the assessment of postoperative outcomes. All the spectra of extirpative and reconstructive urological procedures have been described with LESS to date.[5]

Laparoendoscopic single-site surgery-partial nephrectomy (LESS-PN) was first reported in 2009, with the description of both laparoscopic and robotic approaches.[6,7] LESS-PN intuitively represents a very challenging procedure, because of the potential need for hilar clamping and extensive suturing, and for the increased risk of perioperative complications.[6-9]

A multi-institutional study we coauthored[9] demonstrated that anatomic tumor characteristics as determined by the PADUA score are independent predictors of a favorable surgical outcome and that patients presenting with low–PADUA score tumors represent the best candidates for LESS-PN. In the past few years, based on a number of LESS publications and statements from the LESS-NOTES working group, there has been a decreasing interest on LESS because its peculiar features represent significant challenges for the surgeon compared with standard laparoscopy.

Recently, minilaparoscopy (ML) has been rediscovered in an attempt to reduce the trauma on the abdominal wall derived from standard laparoscopic access, improving cosmetic outcome, and recovery.[10] This rediscovery has been fueled by the availability of a more reliable instrumentation and by the fact that ML allows a minimal abdominal scar, meanwhile preserving the key principle of triangulation. Nevertheless, the main limitations of ML are represented by the difficulty to use instruments with larger dimensions, such as a vascular stapler, and to apply this technique in patients with obesity or prior abdominal surgery.[10]

To overcome the technical limitations of conventional LESS and ML and equally combining the advantages of both these surgical procedures, we ideated a hybrid technique, which we defined as mini-laparoendoscopic single-site (MILESS) surgery,[11] consisting of the simultaneous use of two 3-mm pararectal trocars and an umbilical SILS trocar. In the current report, we present our technique and our preliminary experience with the mini-laparoendoscopic single-site partial nephrectomy (MILESS-PN) for renal tumors with an intermediate PADUA score (8-9), providing a step-by-step description of the operative technique (phase 2a according to the IDEAL methodology[12]).

MATERIALS AND METHODS

Study Design

Our cohort consisted of 40 consecutive patients treated with MILESS-PN based on a clinical diagnosis of enhancing renal mass with an intermediate PADUA score between April 2013 and November 2015. Raw data were collected and gathered into a standardized datasheet, which was specifically built for the study purpose. All patients gave a written informed consent after being informed about the surgical procedure and being counseled that additional incisions could have been necessary.

Outcome

The following information were collected: age, gender, body mass index, pre- and postoperative renal functions, prior abdominal surgery, specific comorbidities, as well as American Society of Anesthesiologists (ASA) score and the Charlson comorbidity index score, tumor stage and grade, surgical margin status, operative time, warm ischemia time (WIT), and estimated blood loss.

Additional collected data included the surgical approach, the access site, the use of additional ports, preoperative and postoperative serum hemoglobin levels, transfusion data, the conversion to open surgery or to standard laparoscopy, the length of stay, postoperative pain evaluated based on a visual analog scale score at discharge, and the incision length.

Both medical and surgical complications occurring at any time after surgery were captured, including the inpatient stay as well as in the outpatient setting. The complications were classified as early (onset: < 30 days), intermediate (onset: 31–90 days), or late (onset: > 90 days) complications, depending on the date of onset. All complications were recorded with a grade assigned according to the modified Dindo-Clavien classification.[13] The PADUA score was used to assess the characteristics of the tumors.[14]

The function of the kidney was evaluated by measuring the serum creatinine and the estimated glomerular filtration rate (eGFR), calculated using the modification of diet renal disease equation, preoperatively and postoperatively and at the 6-month follow-up. Moreover, chronic kidney disease (CKD) of each patient was defined in stages according to the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative.

Cosmesis was evaluated using a body image questionnaire, an 8-item questionnaire incorporating body image and cosmetic subscales, each with a high internal consistency (Cronbach a of 0.80 and 0.83, respectively)[15,16] (Supplementary Fig. S1). The body image scale measures patients' perception and satisfaction with their bodies after surgery, and is calculated by reverse scoring and summing the responses to questions 1-5; the body image scale ranges from 5 to 20 with a higher number representing greater body image perception. The cosmetic scale assesses satisfaction with surgical scars and is calculated by simply summing responses to questions 6-8, for a score range of 3-24, with a higher score indicating greater cosmetic satisfaction.[15,16]

All operations were performed for localized incidentally discovered renal masses of <7 cm; all indications were elective.

One laparoscopic surgeon (F.G.), with an experience of >200 laparoscopic and >30 LESS partial nephrectomies, performed all procedures.

The length of follow-up was calculated from the date of surgery to the date of the most recent documented examination. In all patients, a physical examination and ultrasonography were performed every 3 months, and a computed tomography or magnetic resonance imaging was performed every 6 months in the first year after surgery.

Surgical Technique

The surgeon has been trained on dry and wet laboratories before starting the first case on humans. The sequence of steps of MILESS-PN is comparable to standard LPN.[17]

Instruments. The SILS trocar (Covidien, formerly Tyco Healthcare GmbH, Neustadt, Donau, Germany) is a specialized multilumen with two 5-mm working channels and one 12-mm channel. A 30° lens high-definition laparoscopic camera (Karl Storz, Tuttlingen, Germany) with a 5-mm diameter and a 50-cm length is inserted through one of the 5-mm channels of the

Table 1. Preoperative data

	MILESS-PN
N	40
Median age (y)	54 IQR 46-62
Gender (female-to-male ratio)	0.7
Median BMI (kg/m^2)	26.2 IQR 24.5-28.5
Left and right kidney	33, 7
Median ASA score	2 IQR 1-2
Median Charlson comorbidity score	2 IQR 1-2
Median preoperative hemoglobin (g/dL)	16.1 IQR 13.6-19.0

ASA, American Society of Anesthesiologists; BMI, body mass index; IQR, interquartile range; MILESS-PN, mini-laparoendoscopic single-site partial nephrectomy.

Table 2. Intraoperative and postoperative data

	MILESS-PN
N	40
Median operating time (min)	134.6 IQR 110-180
Median blood loss (mL)	115.8 IQR 50-300
Median WIT (min)	12.1 IQR 9.5-15.5
Transfusion rate (%)	0
Median hemoglobin at discharge (g/dL)	14.4 IQR 11.5-17.0
Postoperative day of oral intake	1.0
Median VAS (1-10) at discharge	1 IQR 0-2
Median analgesic requirement (metamizol, mg)	10.3 IQR 5-19
Median length of stay (d)	4.2 IQR 3.5-6.0
Median time for tumor excision (min)	2.8 IQR 1.5-4.5
Median time for suturing (min)	3.9 IQR 3.5-6.0
Median skin incision (cm)	3.9 IQR 3-5
Conversion rate to conventional laparoscopy (%)	0
Conversion rate to open surgery (%)	0

VAS, visual analog scale; WIT, warm ischemia time.

SILS trocar and frees the other 5- and the 12-mm channels for the simultaneous insertion of instruments with a diameter of ≥5 mm (ie, suction and irrigation cannula, spoon forceps, bulldog clamps, 5-mm grasping forceps for retraction). Two 3.5-mm trocars were used to introduce the dissector, scissors, and the needle holders.

Placement of the SILS Port and of the 3-mm Trocars. With the patient in a 60° position, a mini laparotomy (5 cm) was performed for the insertion of the SILS trocar. The endoscopic camera was introduced and two 3.5-mm trocars were inserted in the ipsilateral midclavicular line (Supplementary Fig. S2).

MILESS Partial Nephrectomy. After the identification of the renal vessels (Supplementary Fig. S3), the kidney was mobilized within the Gerota fascia and defatted, and the tumor was localized.

The renal artery was then clamped with 1 laparoscopic bulldog clamp and introduced through the 12-mm channel, and the tumor was excised with cold curved shears in a near-bloodless field (Supplementary Fig. S4A and B). After having performed hemostasis of the renal parenchyma with running sutures, the bulldog clamp was removed (*early unclamped technique*). Afterward, renal parenchyma repair was completed with running sutures (Supplementary Fig. S5). A PDS clip was secured on the suture to prevent it from pulling through. Another PDS clip was applied to the suture flush with the opposite renal surface, compressing the kidney. Fibrin glue was applied to the cut renal parenchyma surface. The en bloc specimen was extracted in a 10-mm Endocatch II bag (Covidien formerly Tyco Healthcare Gmbh, Neustadt/Donau, Germany). The SILS trocar was then removed, the fascia was then closed with an interrupted 2-0 Vycril suture, and the skin was approximated with an intracutaneous suture.

RESULTS

Study Population

Table 1 summarizes the clinical and pathologic characteristics of the patients evaluated in the present study. The patient population was generally young (median age of 54, interquartile range [IQR] 46-62), nonobese (median body mass index of 26.2 kg/m^2, IQR 24.5-28.5), and healthy (median preoperative ASA score of 2, IQR 1-2; Charlson comorbidity index score of 2, IQR 0-2). Two patients (5%) had a prior abdominal surgery.

Surgical Outcomes

The median operative time was 134.6 (IQR 110-180) minutes with a median estimated blood loss of 115.8 (IQR 50-300) mL and a median WIT of 12.1 (IQR 9.5-15.5) minutes (Table 2). A conversion to conventional laparoscopy or open surgery did not occur in any cases. No case was converted to a radical nephrectomy. Postoperatively, 4 early complications (10%) were recorded: 2 patients developed a flank hematoma and 1 patient developed fever; in all cases, conservative therapy was proposed (Clavien grade 1). In 1 case, the patient required an endoscopic intervention (Clavien grade 3), placing a mono-J stent that was removed after 1 week after performing retrograde pyelography. The median times for tumor excision and suturing were 2.8 (IQR 1.5-4.5) and 3.9 (IQR 3.5-6.0) minutes, respectively. The median hospital stay was 4.2 (IQR 3.5-6.0) days and the median visual analog scale score at discharge was 1.2 (1-2).

Oncological Outcomes

Most renal masses were malignant (80%). The median renal tumor size was 3.6 (IQR 2.4-5.3) cm with a median PADUA score of 8.3 (IQR 8-9) (Table 3). The definitive pathologic results revealed a pT1a renal cell carcinoma (RCC) in 14 (35%) patients, a pT1b RCC in 18 (45%) cases, an angiomyolipoma in 3 cases (7.5%), and an oncocytoma in

Table 3. Oncological outcomes

	MILESS-PN
N	40
Median tumor size (cm)	3.6 IQR 2.4-5.3
Median PADUA score	8.3 IQR 8-9
Renal cell carcinoma (%)	80
Angiomyolipoma (%)	7.5
Oncocytoma (%)	12.5
Tumor stage, patients (%)	
pT1a	14 (35)
pT1b	18 (45)
Tumor grade (Fuhrman classification), patients (%)	
Grade 1	0
Grade 2	8 (20)
Grade 3	24 (60)
Positive surgical margins (%)	0
Tumor recurrence and port-site metastases at the follow-up (patients)	0

5 cases (12.5%). All tumors were removed with negative surgical margins, and at the median follow-up of 34.5 (IQR 24-48) months, all patients were alive without evidence of tumor recurrence or the port-site metastasis.

Renal Functional Outcomes

A statistically significant decrease of eGFR was observed postoperatively (postoperative vs preoperative median eGFR: 87.6 [IQR 70.4-101.8] and 104.7 [IQR 82.7-123.3], $P<.0001$) and at 6 months (6 months vs preoperative eGFR 93.6 [IQR 79.1-110.2] and 104.7 [IQR 82.7-123.3], $P<.0001$) (Table 4, Supplementary Fig. S6). Nevertheless, no patient was upstaged to CKD stages 3-5, and no kidney was postoperatively lost because of warm ischemic injury.

Cosmesis

The median periumbilical skin incision was 3.9 cm (IQR 3-5) (Supplementary Fig. S7). All patients were enthusiastic with the appearance of the scars; the median body image score and the median cosmesis score were 19.5 (range 18-20) and 23.5 (range 22-24), respectively.

DISCUSSION

NSS was initially reserved for patients at high risk of developing renal failure after kidney surgery to treat renal cancer.

Van Poppel et al,[18] in a randomized, prospective phase 3 trial, reported an equivalent oncological outcome after NSS and radical nephrectomy and suggested that NSS may be considered as an acceptable approach for small asymptomatic RCC. Furthermore, Scosyrev et al[19] could demonstrate that NSS substantially reduced the incidence of at least a moderate renal dysfunction (eGFR <60) when compared with radical nephrectomy. The main challenge presented for NSS is also the preservation of renal function, which is directly influenced by the length of the WIT.[1,17-21] Early unclamping of renal vessels during NSS is one of the best ways to reduce the WIT.[19-21]

The evolution of minimally invasive techniques has furthered an impetus in the surgical community to reduce the invasiveness of laparoscopic surgery.

Over the last 10 years, LESS techniques in urology have been popularized worldwide.[22]

Although almost every laparoscopic procedure in urology has been duplicated by using a LESS approach, only a few studies have been reported so far on problems and challenges encountered during LESS-PN.[5-9] Only patients with solitary, exophytic, peripheral, enhancing, small (PADUA score of ≤7) renal masses and normal contralateral kidney are considered the best candidates for LESS-PN.[5-9] Furthermore, additional trocars are required in 61.6% of all cases during LESS-PN.[9]

In parallel with the recent development of potentially “scarless”' surgical techniques, such as NOTES and LESS, there has been a renewed interest of the surgical community toward a rediscovery of ML. This interest has been driven by 2 main reasons: the boosting of manufacturers that leads to the availability of a new generation of purpose-built instrumentation[23] and the fact that ML seems to be ready for immediate implementation as it is based on the same established principles of standard laparoscopy.[10] In urology, however, only small case series and case-control studies on ML have been reported so far.[10,24-26] A large spectrum of the common urologic procedures for both upper and lower urinary tract diseases has been performed and has been shown to be feasible, duplicating the principles of standard laparoscopy. Not surprisingly, only reconstructive procedures, which do not require an additional incision to extract a surgical specimen, thus maximizing the benefits of the minilaparoscopic approach, were the most common.

Nevertheless, the main technical problems of ML are still represented by the difficulty to use instruments with larger dimensions (≥10 mm) and by the impossibility to apply this technique in patients with obesity or prior abdominal surgery.[10]

Considering the necessity of one 3-mm additional trocar in LESS[9] and the technical limitations of the ML,[10] a question could be raised whether or not the simultaneous use of two 3-mm trocars during LESS could equally combine the advantages of LESS and ML, by reproducing the triangulation of the instruments, without compromising the cosmetic results. This technique represents the principle on which we ideated the MILESS.[11,27] In the literature, we find some study describing a hybrid LESS by using 3-, 5-, or 12-mm additional trocars.[28,29] Recently, Kallidonis et al described a similar hybrid technique combined with ML instruments as the standard LESS equipment.[28] The authors described 30 reconstructive and oncological cases, concluding that the combination of LESS and mini-laparoscopic instrumentation as routine equipment of reconstructive LESS improved the intraoperative ergonomics of procedures requiring complex suturing and reconstructive tasks.

Table 4. Renal function

	Median	Lower Quartile	Upper Quartile	Mean	SD	*P* Value
Preoperative eGFR	104.7	100	117.6	105.69	12.24	
Postoperative eGFR	87.6	74.8	97.6	85.98	11	
eGFR at 6 mo	93.6	89.7	107.8	96.58	11	
Difference (postoperative-preoperative)	−20	−25.5	−12.6	−19.71	7.67	<.001
Difference (6 mo-preoperative)	−8.7	−12.8	−6.6	−9.11	4.08	<.001

eGFR, estimated glomerular filtration rate.

Nevertheless, the limitations of the present study included the inability to standardize the technique according to the IDEAL model, which is required to describe and assess the development of each surgical innovation.[12]

In our series, all MILESS-PNs were performed for renal tumors with a median renal tumor size of 3.6 cm and a median PADUA score of 8.3. Interestingly, all tumors could be removed with negative surgical margins, and at the median follow-up of 34.5 months, all patients were alive without evidence of tumor recurrence or port-site metastasis. Furthermore, when compared with LESS-PN, MILESS-PN presented better perioperative and oncological outcomes at the follow-up. In 2013, we reported a multicentric study evaluating 190 consecutive patients treated with LESS-PN in tertiary referral centers.[9] When comparing LESS-PN to MILESS-PN, the latter technique presented better perioperative outcomes and especially a reduced WIT (MILESS 12.1 minutes vs LESS 16.5 minutes). Furthermore, the overall postoperative complication rates were inferior after MILESS-PN (10% after MILESS-PN and 14.7% after LESS-PN), whereas LESS-PN presented a higher rate for positive surgical margins (0% vs 4.25%) and tumor recurrences at follow-up (0% vs 1%).

A technically modifiable risk factor during NSS impacting the remnant renal function is the duration of renal ischemia. The best cutoff to consider for a safe NSS procedure has been debated over the past few years, and has been recently suggested to be 20 minutes.[19] In general, the concept that every minute of ischemia may count is recognized.[20] Furthermore the concept of renal mass preservation during partial nephrectomy has been recently introduced when evaluating postoperative renal function.[30] In our study, an early unclamping technique was used in all patients, thus allowing a median WIT of <20 minutes. However, no assessment of residual renal parenchyma was performed.

When specifically assessing renal functional outcomes, a decline in eGFR and a higher rate of patient with CKD stage 2 were noted. However, a recovery of the renal function was observed at the last available assessment at 6 months (CKD stage 1). Overall, the observed figures of decrease in eGFR are similar to those reported for other partial nephrectomy techniques.[30]

Although 2 patients had undergone prior abdominal surgeries, the patient population was generally young, nonobese, and healthy. Moreover, according to a stage 2a study, to better codify the technique, we prefer to exclude the difficult cases. Using the Dunker methodology,[15] we queried body image and cosmesis among patients who underwent MILESS-PN. All patients were enthusiastic with the appearance of scars, and both the median body image score and the median cosmesis score were 19.5 (range 18-20) and 23.5 (range 22-24), respectively.

The limitations of the present study mainly are the limited series and short follow-up, although the preliminary results appear promising. In addition, these data reflect results from 1 surgeon sharing a significant experience with laparoscopy and LESS.

Finally, one might argue that any new surgical technique should be compared with the original one before one can draw any conclusions concerning its benefits. The present study represents a work in progress as the IDEAL model for surgical innovation[12] recommends that the next step should be the evaluation of the learning curve and the prospective comparison with LESS, ML, and conventional LPN.

CONCLUSION

MILESS-PN for renal tumors with an intermediate PADUA score in well-selected patients is not associated with increased risks for the patients, presenting excellent oncological and functional results at the midterm follow-up. MILESS could represent a valid alternative to LESS or ML because of its more feasible surgical reproducibility.

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APPENDIX

SUPPLEMENTARY DATA

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.urology.2017.09.017.