

PD11-06

**EVALUATION OF LAPAROENDOSCOPIC
SINGLE SITE SURGERY
VERSUS MINILAPAROSCOPY IN
RADICAL NEPHRECTOMY:
PROSPECTIVE RANDOMIZED
COMPARATIVE STUDY**

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INTRODUCTION

LAPAROENDOSCOPIC SINGLE SITE SURGERY (LESS)

- LESS represents an improvement to mimic the standard laparoscopic surgery, wherein the entire technique is done through a solitary skin incision⁽¹⁾
- It offers cosmesis and therapeutic outcomes equally, if not superior, to standard laparoscopy⁽¹⁾
- The feasibility and safety of LESS has been showed in various urological procedures⁽²⁾
- Regarding LESS complications, the literatures concluded that urologic LESS has low complication rates, resembling those observed in laparoscopic series.⁽²⁾

1. Mishra S, Desai M. Standard Laparoendoscopic Single-Site Surgery minimally invasive urology 2015; 131-143
2. Raman JD, Cadeddu JA, Rao P et al. Single-incision laparoscopic surgery: initial urological experience and comparison with natural-orifice transluminal endoscopic surgery. BJU Int 2008; 101:1493–6

MINI LAPARROSCOPY (ML)

■ In 1998, Minilaparoscopy or needlescopic surgery was first described and defined by “Gagner and Garcia Ruiz” as minimally invasive surgery with instruments that are 3mm or less.⁽³⁾

■ By definition, needlescopic surgery includes instruments 3 mm in diameter or less. The number of ports or instruments is not a part of the current definition which is an unsettled issue at this time, because the majority of needlescopic cases use one or more 5- to 10-mm ports.⁽⁴⁾

3. Gagner M, Garcia-Ruiz A. Technical aspects of minimally invasive abdominal surgery performed with needlescopic instruments. Surg Laparosc Endosc 1998; 8(3):171–9.

4. David M, Todd A. Needlescopic surgery: what’s in the toolbox? Surg Endosc 2013; 27:1040–1044.

■ ML allows the performance of surgical procedures as in standard multi-port laparoscopy with no loss of triangulation, the site of instrument insertion is maintained, and the learning curve is not modified.⁽⁵⁾

■ The deformity caused by the percutaneous surgical set (PSS 3mm trocar) is five times less than the deformity from a 5mm trocar.⁽⁶⁾

5. Kwasnicki RM, Aggarwal R, Lewis TM, et al. A comparison of skill acquisition and transfer in single incision and multi-port laparoscopic surgery. J Surg Educ 2013;70(2):172–9

6. Pini G, Porpiglia F, Rassweiler J, et al. Minilaparoscopy, needlescopy and microlaparoscopy: decreasing invasiveness, maintaining the standard laparoscopic approach. Arch Esp Urol 2012; 65: 366e83.

AIM OF THE WORK

The aim of the study is prospective randomized comparison of the results of LESS RN versus ML RN in terms of technical feasibility, limitations, complications and outcomes.

PATIENTS & METHODS

■ This study was conducted on thirty adult patients presenting to the Genitourinary Surgery Department at Alexandria Main University Hospital (between January 2016 and January 2018) diagnosed as having renal parenchymal tumors indicated for radical nephrectomy.

■ Patients were randomized into two equal groups, each one containing 15 patients (n=15).

■ **Group I** : Mini laparoscopy

■ **Group II** : LESS

■ In this study, we used “The CLOSED ENVELOPE” blind randomization technique.

■ Inclusion Criteria:

All patients with renal parenchymal tumors who were not amenable to nephron-sparing renal surgery and indicated for radical nephrectomy.

■ Exclusion criteria:

- Those with absolute contraindications of laparoscopy
- Patients less than 18 years.

In the current study, all cases were done by the same surgical team.



LESS technique:

Covidien (SILS) access port was inserted through 2.5 cm midline umbilical incision, where An EndoEye 5-mm camera (Olympus) and both articulating and straight instruments were used in all cases.



- Radical nephrectomy was done by the standard technique.
- The specimen was entrapped in custom-made bag and removed through port insertion site, where the umbilical incision was widened according to the specimen size

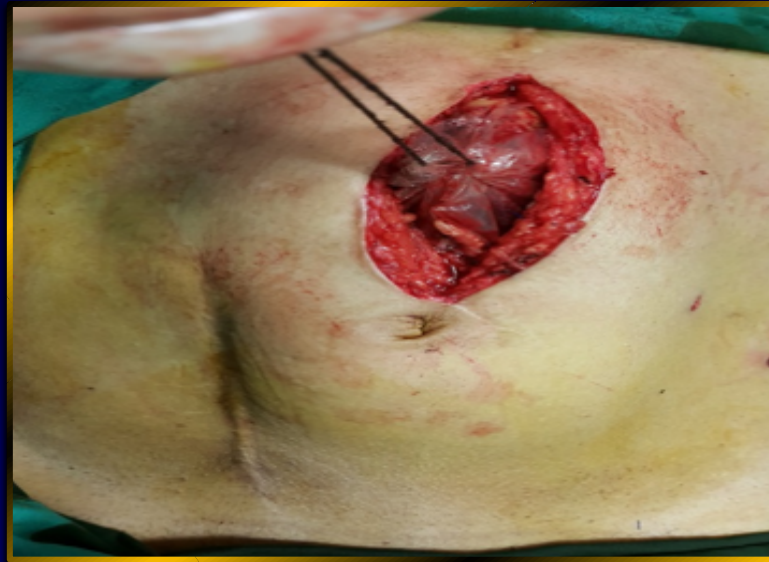


- ML technique:

We have used 3-mm instruments including 3-mm laparoscope (Karl Storz) and one 10-mm port was used in order to introduce the 10-mm Hem-O-Clip to control the renal pedicle.



- Radical nephrectomy was done by standard technique.
- The specimen was entrapped in custom-made bag and removed through port insertion site, where the site of insertion of the 10-mm port was extended to enable specimen extraction.



All patients included in this study were subjected to:

- 1. Full history taking.**
- 2. Clinical examination.**
- 3. Radiologic evaluation as indicated (Ultrasound and triphasic C.T. abdomen & pelvis)**
- 4. (R.E.N.A.L.) Nephrometry score for the evaluation of the characteristics of the renal tumors.**
- 5. Renal function measurement via estimated glomerular filtration rate (eGFR).**
- 6. Intra-operative assessment including operative time, blood loss, technical difficulties, conversion rate, numbers of ports used and any encountered complications.**

7. Post-operative assessment of:

- **Pain using visual analogue pain scale (VAS).**
- **Hospitalization time including the day of admission, day of surgery, and postoperative hospitalization stay.**
- **Complications according to the Clavien–Dindo classification system.**
- **Cosmetic outcome using the Patient and Observer Scar Assessment Scale (POSAS) 6 months following the surgery.**
- **Specimen pathological report regarding type of renal tumor, size and status of surgical margin.**

RESULTS

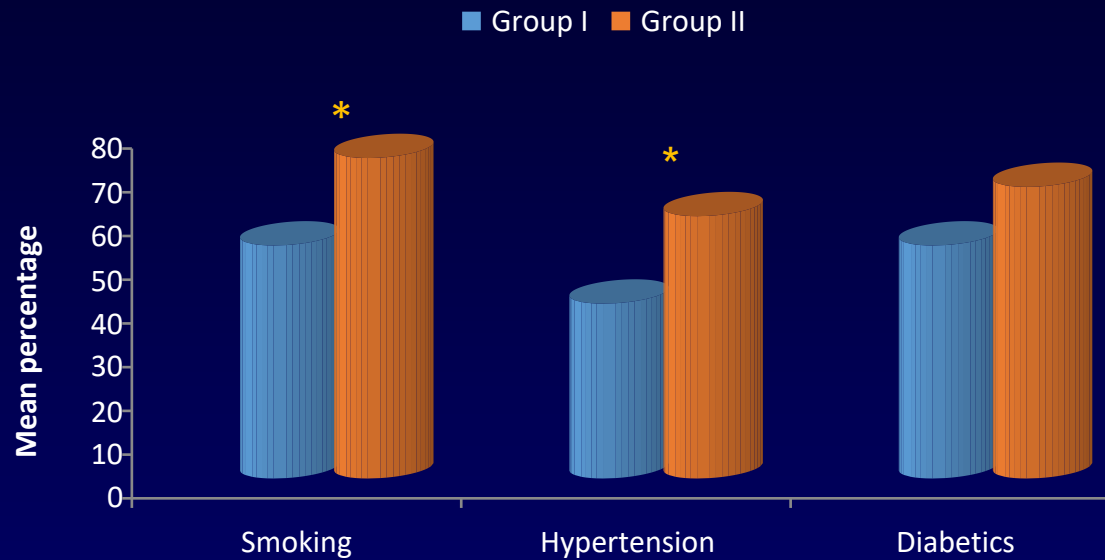
DEMOGRAPHIC DATA

	Group I		Group II		P
Age					
Range	47-72		45-73		0.426
Mean	60		59.4		
S.D.	8.38		9.01		
Sex	No	%	No	%	0.236
Male	7	46.7	8	53.3	
Female	8	53.3	7	46.7	
BMI category					0.185
25-30	2	13.3	5	33.3	
30-35	6	40.0	7	46.7	
35-40	5	33.3	2	13.3	
40+	2	13.3	1	6.7	
BMI					0.101
Range	28-43		27-46		
Mean	35.07		32.93		
S.D.	4.27		4.68		

There was no statistical significance between the two studied groups as regards demographic data. ($P > 0.05$)

CLINICAL DATA

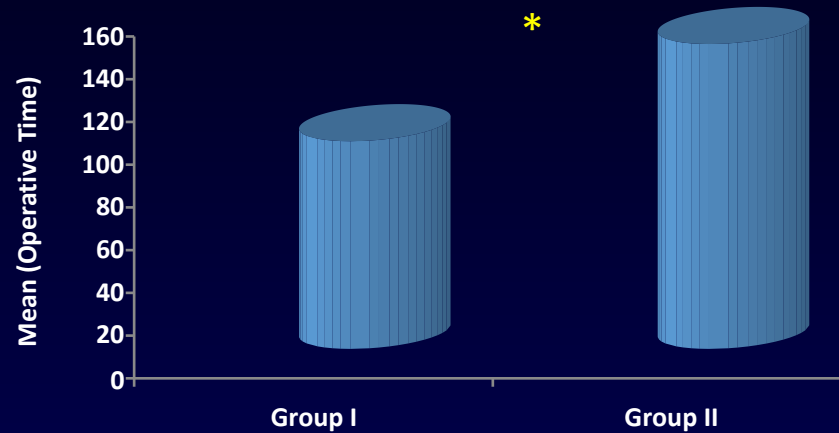
	Group I		Group II		P
	No.	%	No.	%	
ASA score					
I	3	20.0	7	46.7	0.221
II	10	66.7	5	33.3	
III	2	13.3	3	20.0	
Smoking	8	53.3	11	73.3	0.036*
Hypertension	6	40.0	9	60.0	0.041*
Diabetics	8	53.3	10	66.7	0.21



- In group II LESS, there were 3 patients who suffered from chronic renal disease (CKD).
- There was no statistical significance between two studied groups regarding neither eGFR level pre and post-operative nor hemoglobin level pre and post operative.
- There was no statistical significant relation between the two studied groups regarding neither the side and tumor size nor the R.E.N.A.L. score..

OPERATIVE TIME

There was a statistical significance between two studied groups regarding operative time ($P < 0.05$).



	Group I	Group II	P
Operative Time			
Range	54.0-136	115-180.0	
Mean	97.60	142.7	0.021*
S.D.	25.6	16.3	

- There was no statistical significance between the two groups regarding blood loss.
- In both groups, none required blood transfusion , no conversion to CL or to open and no additional ports were used in cases of LESS group
- There was no statistical significance between the two studied groups regarding the post-operative data (hospital stay, convalescence and complications)
- However, VAS was lower in LESS group than in ML group. yet, it was not statistically significant ($P=0.07$)

COSMETIC OUTCOME

comparison between the two groups regarding the Patient and Observer Scar Assessment Scale (PSAS) and (OSAS) 6 months post-operatively, showed statistical significance between the two groups in favor of LESS group II.

	Group I	Group II	P
PSAS			
Range	6-13	6-8	0.018*
Mean	9.8	6.53	
S.D.	2	0.64	
OSAS			
Range	6-13	6-9	0.0021*
Mean	9.73	7.00	
S.D.	1.67	0.93	

A)



Group I (ML)



Group II (LESS)

B)



Group I (ML)



Group II (LESS)

PATHOLOGICAL DATA and FOLLOW UP:

- T1b was the most common pathology in both groups 7 patients (46.7%) in ML group and 10 patients (66.7%) in LESS group.

	ML		LESS	
	No	%	No	%
RCC T1b	7	46.7	10	66.7
RCC T2a	0	0.0	2	13.3
RCC T2b	2	13.3	0	0.0
RCC T3a	2	13.3	2	13.3
RCC T3b	2	13.3	0	0.0
Adult cystic nephroma	0	0.0	1	6.7
Carcinoma of collecting duct of Bellini	1	6.7	0	0.0
Oncocytoma	1	6.7	0	0.0

- All patients of both groups were followed-up at 1 week, 1 month and 6 months postoperatively. CT chest, abdomen and pelvis were done for all of them. All patients had no recurrence at operative beds and with no distant metastasis.

SUMMARY & CONCLUSION

■ This is the first randomized comparative study between LESS and ML in radical nephrectomy for treatment of renal parenchymal masses

■ Both LESS RN and ML RN are valid options for treatment of renal neoplasms

■ LESS RN is an evolving technique in which the whole procedure is performed via a single skin incision, that could be the site for specimen retrieval giving better cosmetic outcomes

- ML RN allows performing the surgical procedures with a technique similar to Conventional Laparoscopy.
- In ML, the surgical trauma is reduced due to the limited diameter of the instruments
- In ML, there is a separate wound for specimen extraction that affects the cosmetic outcomes.
- Although ML RN presents a better ergonomics in view of triangulation, there is a need for better instrumentations.

■ Each procedure has its own technical difficulties and limitations.

- In LESS:
 - the loss of ergonomics that were presented by the parallel inclusion of instruments via the multi-port, crossing of the instruments
 - lack of triangulation.
 - steep learning curve
 - LESS seems to be more expensive due to the disposable ports and instruments.

- In ML,
 - the instruments themselves represent the main limitation because they are weak and tend to bend specially when exerting counter traction during dissecting large masses.
 - the 3-mm laparoscope has a significantly limited and poor-quality field of vision. Moreover, in case of bleeding, the illumination-induced light absorption causes a substantial decrease in image quality.
 - It was necessary to add a 10-mm port in all cases to have access to control the renal pedicle using the hem- O-lock.
 - during suction or de-smoking, as the flow becomes weak because the 3-mm trocar just admits the 3-mm instrument, and the caliber of this 3-mm suction tube is relatively small with weak flow.

