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A prospective, Randomized Comparative Study Between Mini and Conventional Laparoscopic Nephrectomy

Maher MA Mohamed; Ahmed GE Abd El Raouf; Nasr E; Ahmed Y Abo Alsaad

New Damietta University Hospital, Urology Department, Faculty of Medicine, Al-Azhar University, Egypt
Corresponding author: Maher MA Mohamed, **Tel:** 010681686

ABSTRACT

Background: Renal cancer is the commonest renal tumor and is usually treated by radical nephrectomy. Development of laparoscopic surgery was associated with reduction of post-surgical complications and the invent of mini-laparoscopic devices proposed to be associated with marked reduction of postoperative complications. **Objective:** to compare between mini and conventional laparoscopic nephrectomy as regards perioperative complications. **Patient and Methods:** Eligible patients underwent transperitoneal conventional or minilaparoscopy (ML) or conventional laparoscopy depending on surgeon preference. Preoperatively, patients were evaluated by history and clinical examination, with routine Lab and radiological investigations. Both operative and postoperative data were collected and documented. **Results:** both groups were comparable as patient demographics, associated medical diseases, preoperative data or the type of nephrectomy. However, operative time was significantly shorter, while blood loss was significantly larger in conventional group. In addition, postoperative pain was significantly higher and duration of hospital stay was significantly longer in conventional group. Finally, total cosmoses score was statistically decreased in conventional group. **Conclusion:** Compared with mini-laparoscopy, conventional laparoscopy showed better intraoperative parameters as shorter operative time, blood loss and less need for conversion to open surgery. However, the overall complications were comparable for both groups.

Keywords: Radical nephrectomy; end stage renal disease; laparoscopic nephrectomy; conventional; mini-laparoscopy.

INTRODUCTION

Renal cell carcinoma represents the commonest malignant disease of the kidney and accounts for 3% of malignancies of adult patients and the surgical removal is still the most important procedure in the eradication of renal cell carcinoma [(1)]. Simple nephrectomy is used in the treatment of most benign renal tumors associated with long-lasting loss of renal function. Indications include chronic pyelonephritis, obstructive or reflux nephropathy, renal tuberculosis, multicystic dysplastic kidney, endovascular hypertension, attained renal cystic disorders among patients on dialysis, nephrosclerosis, autosomal dominant polycystic kidney and hypertension developed after kidney transplantation [(2)].

Clayman *et al*. [(3)] carried out the first laparoscopic nephrectomy to treat a 3 cm renal mass in old patient. This achievement is one of the milestones in minimally invasive surgery as it delivered the solution for laparoscopic removal of a large solid organ.

Conventional laparoscopic surgery involves the use of several (three to six), large (5 mm, 10/12 mm) ports inserted through commensurately sized skin incisions for retraction of tissues, and the essential triangulation of the surgeon's right- and left hand instruments for the surgical dissection. Efforts are ongoing to further reduction of morbidity and advance the cosmetic consequences of laparoscopic surgery. These comprise use of mini-laparoscopic, 2 mm 'needle-ports' usage of normal orifices, and use of purpose-intended single port appliances [(4)]. Mini-Laparoscopic Surgery," which uses 2-3 mm diameter devices, was announced and shaped in 1990s, but did not catch on due to early limitations of such devices, high costs and associated injuries. But once new devices have found, the use of mini laparoscopic maneuvers were settled [(5)].

The aim of our study is to compare between mini and conventional laparoscopic nephrectomy as regards operative as well as postoperative incidents and complications.

PATIENTS AND METHODS

A prospective randomized study protocol was approved by the local research and ethical committee of Faculty of Medicine, Al-Azhar University. Between July 2017 and July 2018, all patients who were admitted to Urology Department (Al-Azhar University Hospital, New Damietta) for nephrectomy were tested for eligibility for the study. Patients who fulfilled the following criteria were eligible for ***inclusion*** in the study: 1) age older than 18 years, 2) patients' physical states ASA I and II, 3) those who prepared for nephrectomy (simple or radical). On the other

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hand, patients who have one or more of the following were excluded from the study: 1) patients who have a contraindication to laparoscopic surgeries (e.g., coagulopathy, ASA > grade II, patients under therapy for psychiatric problems and pregnancy), 2) patients with previous transperitoneal upper abdominal surgery. Eligible patients were asked to participate in the study and an informed consent was signed. They underwent transperitoneal conventional (22 patients) or minilaparoscopy (ML) (22 patients) depending on surgeon preference. Some operations were performed by experienced laparoscopic surgeons, while the others were performed by beginners as this study represents the initial experience in our department.

Preoperatively, history and physical examination were carried out as the initial steps in patients' evaluation. Then routine laboratory investigations were carried out and included complete blood count, liver function tests, serum creatinine, coagulation profile, and urine analysis. In addition, before simple nephrectomy abdominal and pelvic ultrasonography, KUB, non-contrast computerized tomography (NCCT), and radioisotope renography were done. For cases of renal tumors multi-detector contrast-enhanced CT was done. Surgical intervention was done under general anesthesia and were done as described by Simforoosh *et al*. [6], and Novitsky *et al*. [7]. The following operative date was recorded: 1) operative time in minutes, 2) estimated blood loss (EBL) in ml, 3) intraoperative complications, 4) extra-ports placement, and 5) conversion to conventional laparoscopy or open surgery in operations of ML. The postoperative evaluation included: 1) Analgesic requirement during early postoperative period (48 hours), regarding type, frequency, and dose using the visual analogue scale (VAS); 2) preoperative hemoglobin level 3) need of blood transfusion, 4) postoperative complications measured by to modified Clavien-Dindo classification [8], 5) duration of hospital stay, 6) time to return to normal activities, and 7) cosmetic outcome. The cosmos was evaluated using patient scar assessment questionnaire (PSAQ) [9].

Statistical analysis: All data were computed using a commercial program "SPSS" (version 20). Categorical variables presented as frequency and percent distribution and were compared using Chi-Square test or Fisher exact test. Continuous variables were presented as mean ± standard deviation (SD) and were compared using t-test for parametric data and Mann-Whitney-u test for non-parametric data. P value ≤ 0.05 was the cut off for significance of the differences between the two groups.

RESULTS

In the present study, patient age ranged from 19 to 77 years, and there was no significant difference between conventional and Mini-Lab groups (51.55±11.12 vs 46.36±16.34 years respectively). In addition, there was no significant difference groups as regard to sex distribution (males represented 50.0% and 45.5% of between conventional and Mini-lab groups respectively). Finally, BMI ranged from 18 to 22.60 and there was no significant difference between both groups. ASA class was I in 90.7% of all studied populations and 9.3% of them were ASA class II, and there was no significant difference of conventional and Mini-Lab groups. The medical comorbidity was in the form of diabetes, ischemic heart disease (IHD), hypertension (HTN) and liver disease was reported in one patient; three comorbidities were in conventional and one in Mini-Lab groups, with no significant difference between groups (Table 1).

As regard to preoperative data, hemoglobin concentration, there was no significant difference between conventional and Mini-Lab groups (11.65±0.58 vs 11.79±0.40 g/dl respectively). The patient's main clinical presentation was pain among the vast majority of patients as it was reported in 75% of all studied patients, and ESRD in 25% and there was no significant difference between conventional and Mini-Lab groups. Preoperative computed tomography showed hydronephrosis in 47.7%, while pyelonephritic changes were detected in 52.3% of all studied populations and there was no significant difference between conventional and Mini-Lab groups (Table 2).

The type of nephrectomy was radical in 15.9% and simple in 84.1% of all studied patients, and there was no significant difference between conventional and Mini-laboratory groups. The operative time ranged from 53 to 160 minutes, and there was statistically significant decrease of operative time in conventional when compared to mini-laboratory group (78.86±12.39 vs 114.36±27.62 minutes respectively). The blood loss (ml), ranged from 110 to 430 ml, and there was statistically significant increase of blood loss

in conventional when compared to Mini-laparotomy group (267.95±73.67 vs 159.77±31.21 ml, respectively). Conversion to open surgery was reported in two patients representing 4.5% of all studied patients. Both patients were in mini-lab group representing 9.1% of such group. However, the difference between both groups was statistically non-significant. Results about recent complications revealed that, there was no complications in 93.2% of studied patients, bleeding was reported in 2 patients (4.5%) and duodenal injury was reported in one patient (2.3%). All were in Mini-Lab group, with no significant difference between both groups. The postoperative pain was mild in 36.4% of all studied patients, moderate in 56.8% and severe in 6.8% and there was statistically significant increase of moderate and severe pain in conventional when compared to Mini-Lab groups (81.8%, 13.6% vs 31.8% and 0.0% respectively). The duration of hospital stay ranged from 2 to 8 days, and there was statistically significant increase in conventional when compared to mini-laparotomy group (3.73±1.52 vs 2.68±0.48 respectively). The total cosmoses score, ranged from 40 to 49 and there was statistically significant decrease in conventional when compared to Mini-laparotomy groups (43.95±1.13 vs 46.36±1.53 respectively) (Table 3).

Table (1): Patient characteristics and medical comorbidity among studied populations.

Variable		Conventional	Mini-Lab.	P
Age (year)		51.55±11.12	46.36±16.34	0.22 (ns)
Sex	Male	11(50.0%)	10(45.5%)	0.76 (ns)
	Female	11(50.0%)	12(54.5%)	
BMI		19.81±1.00	20.05±1.23	0.48 (ns)
ASA Class	I	19(86.4%)	20(95.2%)	0.32 (ns)
	II	3(13.6%)	1(4.8%)	
Medical Comorbidity	None	19(86.4%)	21(95.5%)	0.39 (ns)
	DM	1(4.5%)	0(0.0%)	
	IHD	0(0.0%)	1(4.5%)	
	HTN	1(4.5%)	0(0.0%)	
	Liver disease	1(4.5%)	0(0.0%)	

Table (2): Preoperative data among studied populations.

Variable		Conventional	Mini-Lab.	P
Preoperative hemoglobin		11.65±0.58	11.79±0.40	0.35 (ns)
Main clinical Presentation	Pain	16(72.7%)	17(77.3%)	0.72 (ns)
	ESRD	6(27.3%)	5(22.7%)	
Preoperative CT	Hydroneph.	12(54.5%)	9(40.9%)	0.36 (ns)
	Pyeloneph.	10(45.5%)	13(59.1%)	

Table (3): type of nephrectomy and outcome among studied populations.

Variable		Conventional	Mini-Lab.	P value
Type of Nephrectomy	Radical	5(22.7%)	2(9.1%)	0.21 (ns)
	Simple	17(77.3%)	20(90.9%)	
Operative time (minutes)		78.86±12.39	114.36±27.62	<0.001*
Blood loss (ml)		267.95±73.67	159.77±31.21	<0.001*
Conversion to open surgery		0(0.0%)	2(9.1%)	0.24(ns)
Recent Complications	None	22(100.0%)	19(86.4%)	0.09 (ns)
	Bleeding	0(0.0%)	2(9.1%)	
	Duodenal injury	0(0.0%)	1(4.5%)	
Postoperative Pain	Mild	1(4.5%)	15(68.2%)	<0.001*
	Moderate	18(81.8%)	7(31.8%)	
	Severe	3(13.6%)	0(0.0%)	
Duration of hospital stay		3.73±1.52	2.68±0.48	0.004*
Total cosmoses score		43.95±1.13	46.36±1.53	<0.001*

DISCUSSION

Laparoscopy has emerged as a powerful minimally invasive surgical tool to treat renal lesions. In a wide variety of applications, patients benefit from decreased morbidity without sacrificing therapeutic outcomes. In mid-1990s, there has been development in surgical intervention from open techniques toward minimally invasive approaches, as technological improvements and techniques refinement have allowed urologists to do a wide range of complex processes with laparoscopy, ranging from treatment of malignancy to reconstructive surgery[10]. Laparoscopic surgery classically uses three to six ports for a certain procedure. With each port, there is increasing possible complications from bleeding, hernia, damage of internal organ, and reducing the cosmetic disability. As a result of the risks associated with number and size of ports, a surge of interest has arisen in less invasive alternatives as LESS and different forms of reduced port laparoscopic surgery as ML, micro-laparoscopy, and needloscopy [11]. The first significant advantage of ML was noticed in less blood loss (P<0.001). that can be attributed to the fact that ML still carry the advantages of conventional laparoscopy such as triangulation, good traction and absence of instrument crowding in addition to the small sizes and diameters of instruments and ports. Unfortunately, the median EBL in our cases of conventional laparoscope (190 to 430 ml) wasn't comparable to the average estimated blood loss (100–300 ml) that was reported in study of Eskicorapci *et al.* [12]. In ML, the published data by Soble and Gill [13] showed that the mean EBL was 30 ml in their large series of ML nephrectomy that was not comparable to our study (mean EBL 159.77) as it represents our initial experience. One of the main advantages of laparoscopic surgery over open approaches is decreasing postoperative pain, but the

impact of further reduction in port size is still not yet well established in urologic procedures. Among our patients, the postoperative pain was statistically significantly increased in conventional when compared to Mini-Lab groups. Non-urologic prospective randomized studies have revealed that the use small incision markedly decrease postoperative pain and analgesic needs by comparing traditional and ML surgical procedures that showed revealed pain scores in ML group (3.9 versus 4.9, P=0.04) [(7)]. The possible explanations of conflicting results include a multifactorial cause of post-surgical pain, different analgesic regimens that may overcome the effect attributable to the smaller accesses.

Shorter hospital stay and recovery period are also another advantage of ML, it ranged from 2 to 8 days, and there was statistically significant increase in conventional when compared to mini-laparotomy group (3.73±1.52 vs 2.68±0.48 respectively). This difference is achieved after exclusion of the 2 cases of complications that had more time of hospitalization. In conventional laparoscope there was a significant advantage of less hospital stay in comparison to other study by Gill *et al.* [(14)] (1.4 to. 5.8 days), that generally shows significant advantage of laparoscopy. The mean operating time of conventional laparoscope is comparable to initially reported studies in the range of 240 minutes that decreased in subsequent publications to 150 minute [(14)]. Mean operation time of 135 minutes in the present series confirmed the decreasing operation times with increasing experience. Dunn *et al.* [(15)] reported a reduction of the operative time by about half comparing the first 10 and the last 10 patients who exposed to a laparoscopic radical nephrectomy in the same institution. The results of ML comparable to the study of a prospective non randomized trial of Pini *et al.* [(16)] where the mean operative time in ML group was 100 minutes and 109 minutes in standard laparoscopy group (P=0.8). The incidence of conversion to open surgery were 0–8% due to vascular injury or injury to the viscera as in the study of Janetschek *et al.* [(17)] and Barrett *et al.* [(18)] respectively. The rate of complication was reported to be 5–34% as in Rassweiler *et al.* [(19)] and Dunn *et al.* [(15)] respectively with differences because of some authors including minor complications and others including major ones.

In our series we used the patient scar assessment questionnaire (PASQ) for evaluation of postoperative scar. This questionnaire was originally described by plastic surgeons to be applied for cosmetic assessment of linear scar. The advantage of PSAQ is that the subjective nature of the questionnaire which depends on patient opinion and satisfaction about his scar which, can be measured in an objective manner. This questionnaire was applied for cosmetic evaluation of different scars, as thyroidectomy [(20)] and laparoscopic surgery scars [(21)]. The most important finding in our series was that scars resulting from both techniques (conventional and ML) were similarly perceived by the patients. Only there was a trend for better appearance of the scar by patients in ML group, it ranged from 40 to 49 and there was statistically significant decrease in conventional when compared to Mini-laparotomy groups. Our results were comparable to the published data of PSAQ in several trials especially that comparing standard and ML in urologic procedures [(22)] as they concluded that ML has better cosmetic outcomes in comparison to standard laparoscopy. In our series, the 2 patients who were converted to open surgery, were dissatisfied with scar symptoms and appearance, both of them were started as ML, so their cosmetic outcome was estimated with ML group. There are some points of strength and limitations of this study. It represents the initial experience by our department. Limitations include non-randomized design, and heterogeneity of indications. Therefore, randomized controlled trials with larger number of patients are required to avoid selection bias and statistical errors.

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