

# Have we overcome the complications of laparoscopic nephrectomy? A prospective, cohort study using the modified Clavien–Dindo scale

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## ABSTRACT

**Introduction:** Apart from the complexity of procedure and surgeon's experience, surgical complication rates depend on case definition and method of recording data. We prospectively evaluated the complications of laparoscopic nephrectomy (LN) in a current cohort of patients, graded on the modified Clavien–Dindo (CD) scale and compared them with historical cohorts.

**Methods:** In the Institutional Review Board approved protocol, all patients undergoing LN over a 30-month were enrolled in the study. Clinical parameters, operative data, in-hospital course, and 30-day follow-up were recorded prospectively in an electronic database by a resident who did not perform any of the surgeries. The complications were analyzed using the CD scale.


**Results:** A total of 103 patients (age 14–80 years) underwent LN (30 radical, 73 simple) during the study period. Forty-three of these procedures were for inflammatory conditions (stone disease or tuberculosis). Six procedures were converted to open surgery due to vascular injury (2), bowel injury (1), and adhesions (3). There were 45 (46%) complications in the 97 procedures completed laparoscopically including 34 low-grade (CD grade 1, 2) and 11 high-grade (CD grade 3, 4) complications. There was no mortality. Complications were similar in patients undergoing surgery for inflammatory or noninflammatory conditions.

**Conclusions:** LN continues to be associated with postoperative complications in 46% of cases. However, the complication rates appear to be higher than historical series, possibly due to the more rigorous case-definition and prospective recording.

## INTRODUCTION

Over the past three decades, a number of studies have evaluated the complication rates associated with laparoscopic nephrectomy (LN).<sup>[1-6]</sup> However, a wide variation in what is considered a complication and how it is reported has resulted in a lack of uniform data on outcomes.<sup>[7]</sup> Till recently, there was no standardized reporting system for post-operative complications in urology and other surgical specialties. In 1992, Clavien *et al.*<sup>[8]</sup> proposed the Clavien classification

system to grade post-operative complications. A modified version of system (Clavien–Dindo [CD]) was published in 2004 which looked the therapeutic consequences to rank complications.<sup>[9]</sup> This modified system is divided into seven grades (Grade 1–5) with two subgroups for Grade 3 and 4 with Grade 5 representing the death of a patient. This system is simple, convenient, reproducible, comprehensive, and logical and has been used in numerous surgical fields.<sup>[10-12]</sup> It has also been used for many urological procedures and has been proposed as the current standard to assess post-operative complications.<sup>[13-16]</sup>

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Most existing data reflect the experience of large volume focused centers and may not reflect the outcomes in a more realistic, varied clinical practice. We have previously reported our experience with LN and its complications in a cohort of over 500 patients.<sup>[17,18]</sup> However, those reports, like most others, were retrospective in nature and did not focus on complications alone. The availability of the CD system allows us to make a more objective assessment of our complications and we report the outcomes of this prospective evaluation of complications in the current cohort of patients.

## METHODS

This prospective, cohort study was approved by the institutional ethics committee and all included patients provided written informed consent. Patients who fulfilled the inclusion criteria were included over 30 months. All patients who underwent LN were enrolled without exception. The choice of surgical approach (transperitoneal or retroperitoneal) was on surgeon discretion. No patient declined consent for inclusion.

Patients were evaluated and treated as per the standard clinical protocols with no study-specific investigation or intervention. Patients' demographics, clinical data, and intra- and post-operative complications based on the modified CD scale<sup>[9]</sup> were recorded until the time of discharge. At discharge, all patients were provided the contact number of the study investigator to self-report any complication. In addition, all patients were contacted through telephone or letters at 1 month after surgery and requested to return for a follow-up evaluation. For those who did not return, a telephonic interview was conducted to assess complications in the preceding 1 month.

In case a patient suffered more than one complication, all were recorded and the most severe complication was graded. Events unrelated to surgery such as urinary retention requiring a bladder catheterization were also graded as grade 3A complication (intervention under local anesthesia). Similarly, patients electively monitored in the Intensive Care Unit (ICU) due to multiple comorbidities were graded as CD-4 complication. The decision on the existence of a complication or its grading was taken on the surgical rounds or in the morbidity meeting. Since ours is a teaching institution, multiple urologists were involved in the treatment and decision-making process, and there was significant oversight ensuring accurate recording of complications. The resident recording the complications was not the operating surgeon. All data were recorded prospectively in an electronic database and retrieved for this report.

## RESULTS

A total of 103 patients (60 male, 43 female) who underwent LN were included in the study. The mean age was

38.9 years (range 14–80 years). Sixty-four procedures (62%) were on the right side. Thirty of the 103 procedures (29%) were for malignancies with a mean tumor size of 63.2 mm (range 14–110 mm). Eighty procedures (77.6%) were performed transperitoneally and 23 were retroperitoneoscopic. The indications for simple nephrectomies are given in Table 1.

Six of the 103 (5.8%) procedures were converted to open surgery. All six were during nephrectomies for benign conditions. Three of these were due to intraoperative injuries including one trocar injury to the common iliac artery that required a Dacron graft, one large bowel injury and one gonadal vein avulsion with bleeding. The other three conversions were for nonprogress in dissection due to adhesions. Four of these were during retroperitoneoscopic procedures.

Excluding the six conversions, 45 out of the 97 patients (46%) who underwent a completed laparoscopic procedure suffered a postoperative complication [Table 2]. The majority of these (34/45; 75%) were low grade (CD-1, 2) primarily comprising fever and constipation. Among the 11 higher grade (CD-3, 4) complications, half related to urine retention and catheterization. Five patients required some form of intervention other than bladder catheterization. This included one re-exploration and splenectomy for a splenic laceration, one pigtail catheter drainage of a retroperitoneal hematoma, two pleural aspirations, and one wound drainage and secondary suturing. There was no mortality or overall adverse outcome [Table 2].

Forty-three of our 103 procedures were performed for inflammatory conditions (stone disease - 39, tuberculosis - 4). Among these 43 patients, 3 were converted to open surgery and 16 of the remaining 40 (40%) suffered a postoperative complication. This included 12 low-grade (CD-1, 2) and 4 high-grade (CD-3A) complications.

## DISCUSSION

We found that almost one in two of our patients undergoing LN suffered a postoperative complication. This number

**Table 1: Indications for surgery**

Indication	Number of patients (n=103)
Malignancy	30
Benign	73
Noninflammatory	30
PUJO	24
Ureteric stricture	3
Ectopic kidney	1
Hydatid cyst	1
Others	1
Inflammatory	43
Stone	39
Genitourinary tuberculosis	4

PUJO=Pelviureteric junction obstruction

is higher than the 8%–20% reported from other recent literature [Table 3]. Laparoscopy is a standard approach to nephrectomy and has been documented to be superior to open surgery in terms of lower analgesia use, shorter hospital

stay, and quicker recovery.<sup>[19-21]</sup> There has been an evolution in techniques and over the years, it would be expected that complications would have declined. Complications after surgery could depend on a number of factors and

**Table 2: Operative parameters and complications by type of surgery**

Parameter	Indication		Surgical approach	
	Malignant	Benign	TP	RP
Procedures (n)	30	73	80	23
Mean operating time (min, range)*	129.8 (60-360)	114.2 (45-350)	113.3 (45-240)	142.6 (90-350)
Blood loss (mL, range)*	165.3 (20-900)	131.7 (10-1200)	137.3 (10-1200)	161.5 (10-900)
Blood transfusion (1 unit each)*	1	2	3	0
Hospital stay in days (mean)*	3.86	3.38	3.6	3.1
Intraoperative complications (%)	1 (3.1)	3 (3.5)	2 (2.5)	2 (8.6)
Injury to the appendix	1	0	1	0
Trocar injury, right common iliac artery	0	1	1	0
Large bowel injury	0	1	0	1
Gonadal vein avulsion	0	1	0	1
Conversions (%)	0	6 (7)	2 (2.5)	4 (17.3)
Due to complications	0	3	1	2
Adhesions	0	3	1	2
Laparoscopy completed (n)*	30	67	78	19
Complications (n=45; 46%)* (%)	19 (63.4)	26 (35.6)	37 (47.4)	8 (42.1)
Complications CD ≤2	12	22	27	7
Grade 1	9	18	20	7
Fever (focus not identified)	2	8	8	2
Fever, thrombophlebitis	1	2	1	2
Loose stools	0	1	1	0
Constipation/abdominal distension relieved with purgatives/suppositories	4	5	7	2
Vomiting requiring antiemetics	2	0	2	0
Pain requiring opioids	0	1	1	0
Fever with wound infection	0	1	0	1
Grade 2	3	4	7	0
Anemia, transfusion, fever	1	1	2	0
Wound infection, antibiotic changed	2	0	2	0
Ileus, chest infection	0	1	1	0
Ileus	0	1	1	0
Fever, thrombophlebitis, chest infection	0	1	1	0
Complications CD >2	7	4	10	1
Grade 3	5	4	9	0
Urine retention, catheterized, α blockers	3	1	4	0
Retroperitoneal collection, USG-guided pigtail inserted	0	1	1	0
Pleural effusion requiring aspiration, urine retention, catheterized, α blockers	1	0	1	0
Pleural effusion requiring physiotherapy, urine retention, catheterized, α blockers	0	1	1	0
Pneumothorax requiring aspiration	0	1	1	0
Wound infection; drainage and secondary closure	1	0	1	0
Grade 4	2	0	1	1
Readmission for splenic laceration, laparotomy, ICU stay	1	0	1	0
Postoperative ICU stay for 20 h	1	0	0	1
Complications CD 5 (mortality)	0	0	0	0

\* Excludes patients converted to open surgery. TP=Transperitoneal, RP=Retroperitoneal, ICU=Intensive Care Unit, USG=Ultrasound sonography, CD=Modified Clavien-Dindo scale

**Table 3: Literature on complications of laparoscopic nephrectomy**

Series	Design	Year	n	Surgery	Complications (%)	Major	Minor	CD
Garg <i>et al.</i> <sup>[1]</sup>	Prospective	2014	62	Simple	11 (17.7)	0	11	Yes
Xu <i>et al.</i> <sup>[2]</sup>	Retrospective	2014	88	Radical	17 (19.3)	1	16	Yes
Khan <i>et al.</i> <sup>[3]</sup>	Retrospective	2013	29	All	16 (55.1)	5	11	Yes
Deger <i>et al.</i> <sup>[4]</sup>	Prospective	2007	163	Radical	7 (4.2)	2	5	No
Chan <i>et al.</i> <sup>[5]</sup>	Retrospective	2001	67	Radical	10 (15)	Not specified 8% transfusions		No
Gill <i>et al.</i> <sup>[6]</sup>	Prospective	2001	100	Radical	14 (14)	3	11	No
Present study	Prospective	2016	103	All	45 (43.6)	11	34	Yes

CD=Modified Clavien-Dindo scale

apart from factors such as complexity of the procedure and experience of the surgeon, definition of a complication, and the method of its recording may have a significant impact on the reported rate.

In terms of complexity of the procedure, 42% of procedures in our series were performed for stone disease or tuberculosis. For LN, both these pathologies can make a surgery more difficult, and thus prone to more complications since both are associated with inflammation and adhesions.<sup>[17]</sup> While these are usually intraoperative complications, they may have an influence on the postoperative course, particularly those arising from infections, bowel handling, and blood loss. However, our data suggest that both intraoperative conversions and postoperative complication rates were similar in patients with or without these conditions (3/43 vs. 3/60 conversions; 16/40 vs. 29/57 complications, respectively).

In terms of surgical experience, while we have previously reported over 500 nephrectomies performed laparoscopically,<sup>[17]</sup> we are a teaching institution with surgeons of varying experience and skill and at different stages of their learning curve. This particular report includes all cases operated over the study period without exclusion and would thus include all levels of experience. However, the major impact of experience is likely to be on intraoperative complications and conversions rather than that postoperative complications of the type recorded on the CD scale.

Considering the limited impact of these two factors, we believe that using a strict, standardized definition of complications in a prospective manner may have been significantly responsible for our reporting a higher rate. The use of the CD scale for reporting complications after urological surgery has shown an increasing trend.<sup>[22]</sup> Ours is one of a few reports using the modified CD scale for LN and possibly, the sole prospective study focused only on complications. It is thus likely that this strict definition with prospective recording of data resulted in a more accurate and higher reporting of complications.

Garg *et al.*<sup>[1]</sup> recently reported a prospective, randomized trial comparing transperitoneal with retroperitoneoscopic nephrectomies. Of their 62 cases, three were lost to follow-up and five were converted to open surgery. They reported a total of 11 postoperative complications on the CD scale, giving an incidence of 17.7%. However, unlike our series, they report no patient requiring intervention for urinary retention or constipation (not ileus or obstruction), two conditions which were responsible for 13/45 (29%) of our reported complications. Similarly, fever of short duration with no specific cause was reported as a complication in 10/45 (22%) of our patients but was not seen in that series. It is possible that our study, focusing only on complications, resulted in a lower threshold for reporting.

Xu *et al.*<sup>[2]</sup> reported a retrospective review of complications in LN. Among the 88 patients, they reported a 19% incidence of complications. They provide a long list of complications that were recorded including constipation. However, this study retrieved data from 2006 to 2012. The long period and retrospective nature of records could be a reason for the lower recording of complications.

Khan *et al.*<sup>[3]</sup> reported a 55% complication rate in 29 elderly patients above 75 years of age, undergoing LN or nephroureterectomy. This included 11 low-grade and 5 high-grade complications. This incidence is higher than our own but again comes from a retrospective report. Further, the elderly population here could be a cause for the higher incidence of complications;<sup>[23]</sup> the mean age of the patients was 80 years compared with 39 years in our study.

Earlier studies used the terms “minor” or “major” to report complications. The lack of a standard definition caused variability in such reports. Chan *et al.*<sup>[5]</sup> described a retrospective study of 67 patients with 15% complication rate (excluding 8% requiring blood transfusion) while Gill *et al.*,<sup>[6]</sup> in a study of 100 procedures, described a 14% complication rate; 3% major and 11% minor. In both of these studies, complications were poorly defined and intraoperative complications were also included in the reports. In one of the larger reports on 163 procedures, Deger *et al.*<sup>[4]</sup> compared outcomes of laparoscopic radical nephrectomy at two institutions in Europe. They report only a 4.2% incidence of complications but do not define whether this included postoperative complications or not. Compared with our own previous reports,<sup>[17,18]</sup> our current series has a significantly higher postoperative complication rate. We believe this again stems from the prospective and deliberate nature of our current study compared with the previous retrospective reports.

This study is limited by the relatively small number of patients. However, since this reflects the practice pattern in most institutions where surgeons of varying experience operate, increasing numbers may not decrease surgeon influenced complications but would help prevent outliers affecting the results. Lack of true blinding in recording the complications is also a potential limitation. This could lead to fewer complications being recorded as surgeons may ignore minor complications. Since our data are recorded by a resident who did not actually perform these cases and all cases are reviewed by multiple urologists who have not performed the surgery, it is expected that the influence of this lack of blinding would have been minimal.

While our report highlights the importance of prospective recording of data in studies evaluating complications, the high rates must be viewed in the context of the method used for data gathering. The objective of this report is not to create alarm about LN, which we believe is a standard of care for eligible patients, but to highlight the potential

impact of definitions and methodology on outcomes. A 45% complication rate would appear worrisome but does not necessarily suggest adverse outcomes. This lack of impact is confirmed by the low hospital stay and blood transfusion rate in our cohort. Some of our “complications” arose due to elective, intensive monitoring of patients while others (constipation, vomiting, change of antibiotics, bladder catheterization, and transient fever) may have been missed altogether in retrospective data collection if not actively sought. While evaluating complications after robotic radical prostatectomy, Schroeck *et al.*<sup>[24]</sup> suggested that a difference in expectations between the patient and surgeon is an important reason for patient dissatisfaction even after a successful procedure. The primary message would thus be that comparing surgeons, institutions, or reports based on their stated complications rates should not be done at face value since these would depend significantly on how such complications are recorded.

## CONCLUSIONS

Using a strict definition and prospective data recording, we found that 46% of patients undergoing LNs suffered a complication. Using the CD score prospectively resulted in a greater number of events being recorded as a complication as compared with previous literature. However, major complications, conversion to open surgery, and overall recovery and operative parameters are similar to studies not using the scoring system.

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