Original Article

Assessment of Clavien-Dindo classification in patients >75 years undergoing nephrectomy/nephroureterectomy

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Abstract

Introduction: There is a paucity of a standardized post-operative complications grading system in urology especially in the elderly population. Studies show satisfactory survival and oncological outcomes albeit with a slight increase in post-operative morbidity compared to younger patients. The Clavien-Dindo classification for post-operative complications is established as a valid system worldwide and applicable in many fields of surgery.

Purpose: Retrospective assessment of post-operative complications in patients >75 years who underwent open/laparoscopic nephrectomy/nephroureterectomy for renal diseases and grading the post-operative complications according to the Clavien-Dindo classification.

Materials and Methods: Retrospective review of case notes was performed in patients >75 years who underwent a laparoscopic/open nephrectomy/nephroureterectomy between 2000 and 2008. Post-operative complications were graded according to the Clavien-Dindo classification.

Results: A total of 54 patients >75 years underwent nephrectomy/nephroureterectomy. 29 patients had laparoscopy and 25 had open surgery. Fifty one patients had a malignancy and 3 had benign diseases. Grade I, II, IIIa, IIIb and IVa were 25.6%, 41.1%, 7.7%, 7.7% and 17.9% respectively. No significant difference was noted in the 2 groups

Conclusions: We believe that in elderly patients, laparoscopic surgery can be offered safely without significantly increasing the surgical risks. The Clavien-Dindo classification is easy to use and effectively applied to categorize post-operative complications associated with nephrectomy/nephroureterectomy in elderly population. However, this system needs slight modification to incorporate intra-operative complications and large studies are needed to validate and standardize this classification for all urological procedures.

Key Words: Clavien-dindo, elderly, nephrectomy

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INTRODUCTION

Improving the quality of healthcare delivery system has been a subject of importance worldwide. A huge emphasis has been placed on reducing post-operative complications and thus reducing costs and improving the delivery of care. The lack of a standardized reporting system for postoperative complications in the field of urology and many other surgical

specialties makes interpreting literature and measuring surgical outcomes very difficult.

In 1992, Clavien *et al.* proposed the Clavien classification system to grade post-operative complications.[1] A modified version of the system (Clavien-Dindo) was published in 2004 which looked at the therapeutic consequences to rank complications. The modified system is divided in to 7 grades (Grade I-V) with 2 subgroups for grade III and IV with grade V representing the death of a patient.[1,2]

The system has been increasingly used in many fields of surgery and has been accepted as a valid and reproducible grading system. It is a simple, convenient, reproducible, comprehensive and logical system, which has been used in many parts of the world and by all grades of surgeons.[3,4] Its use in urology is gaining impetus slowly and a number of centers and surgeons are resorting to its use to measure surgical outcomes.[5-9] Over the years an increase in life expectancy has led to a tremendous increase in kidney surgery in the >75 age group. These patients pose both intra-operative and post-operative challenges to the operating surgeons.[10-15]

We carried out a retrospective analysis of patients undergoing open and laparoscopic nephrectomy and nephroureterectomy in >75 years. The purpose of our study was to assess post-operative complications based on the Clavien-Dindo classification in this subgroup of nephrectomy/nephroureterectomy patients.

MATERIALS AND METHODS

A retrospective review of case notes was performed in patients aged 75 years and above who underwent a nephrectomy (laparoscopic or open) and nephroureterectomy (laparoscopic or open) between the years 2000 and 2008. The patients were identified using a comprehensive list of nephrectomy and nephroureterectomy during the 8-year period in the two hospitals. A total of 54 patient's case notes were available for analysis.

The patients' age, gender, past medical history, American Society of Anesthesiology Grade (ASA), follow-up duration, body mass index (BMI), preoperative symptoms, and pathologic factors (tumor size, location, histologic type and Fuhrman's nuclear grade) were investigated. 5-year overall survival (OS) and 5-year cancer-specific survival (CSS) were also recorded.

Pre-operative and post-operative bloods including hemoglobin, serum creatinine and calcium were recorded. Radiological scans available for each patient were noted. Operative details were recorded from operation notes including any intraoperative complications that might have occurred. Post-operative complications were recorded and graded as per Clavien-Dindo classification which includes a period of 6 weeks postoperatively. All post-operative analgesia requirements, initiation of fluid intake and days to mobilization of all patients were also recorded.

Data was recorded in an Excel spreadsheet and statistical analysis was completed using GraphPad Prism 5 statistical software. Complications were compared using the χ^2 and fisher exact tests. All P values were 2-tailed and $P < 0.05$ was considered significant.

RESULTS

Out of the 54 patients, 29 (53.7%) patients had undergone a laparoscopic (transperitoneal) procedure while 25 patients (46.3%) had an open operation. A total of 51 had malignancy while 3 patients required surgery for benign disease. The mean age was 80.4 years in the laparoscopic group and 81.3 years in the open group. In our series 55% of the procedure was done for a malignancy in the laparoscopic group compared to 45% in the open group 9 [Table 1].

The post-operative complications were stratified according to the Clavien-Dindo Classification system [Table 2]. A total of 39 complications were noted ranging from atrial fibrillation,

Table 1: Data of patients undergoing laparoscopic and open nephrectomy/nephroureterectomy

Type of surgery	Laparoscopic (%)	Open (%)	*P* value	95% confidence
Number of patients	29 (53.7)	25 (46.3)		
Age	80.4	81.3		
Male	19 (35.2)	13 (24.1)		
Female	10 (18.5)	12 (22.2)		
Malignancy	28 (55)	23 (45)		
RCC (pTa)	0	0		
RCC (pT1)	7	5		
RCC (pT2)	0	4		
RCC (pT3)	11	5		
RCC (pT4)	0	1		
TCC (pTa)	3	4		
TCC (pT1)	3	1		
TCC (pT2)	2	0		
TCC (pT3)	1	2		
TCC (pT4)	1	1		
Benign disease	1	2		
5-year cancer specific survival (%)	68.7	73.2		
5-year overall survival (%)	69.8	71.2		
Length of stay	8.7	14	0.047	0.07-10.6
Days to mobilization	3.8	4.8	0.13	−0.3-2.2
BMI % (high)	63	37	0.0005	1.63-5.14
ASA grade 3 or above (%)	48	52	0.57	0.48-1.48

BMI: Body Mass Index, ASA: American Society of Anesthesiologists, RCC: Renal cell carcinoma, TCC: Transitional Cell Carcinoma

basal atelectasis, wound infections to ischemic stroke and cardiac arrest. There was no death recorded. Of these, 59% of complications were seen in the open group and 41% in the laparoscopic group.

Grade I complications accounted for 25.6% of all the complications. Grade II complications were encountered the most in the overall population group (41.1%). Grade IIIa 7.7%, Grade IIIb 7.7%, Grade IVa 17.9 % with no complications in the Grade IVb and no recorded deaths i.e. no Grade V complications.

The complications are outlined in Table 3 with their respective *P* values and confidence intervals. As a secondary observation statistical analysis comparing post-operative complications in both groups according to the Clavien-Dindo system showed no extra risks in the laparoscopic group compared to the open group in octogenarians. The study also showed a higher T stage of the disease was associated with a significantly higher complication rate with T3 accounting for 44.7% of all complications [Figure 1]. Similarly, patients with a high BMI accounted for most of the complications in the two groups. A BMI >24.5 resulted in 50% of the overall complications in the two groups [Figure 2].

Table 2: Overall complications according to the Clavien-Dindo classification system

Complications	Total (%) *N*=39
Grade I	10 (25.6)
Atrial fibrillation	2
Post operative confusion	2
Bradycardia (settled conservatively)	1
Atelectasis	2
Ileus	2
Diarrhea–non infectious	1
Grade II	16 (41.1)
Clostridium difficile	2
Pneumonia	3
Wound infection	4
Urinary tract infection	1
MRSA	2
Pulmonary embolism	1
Blood transfusion	3
Grade IIIa	3 (7.7)
Pleural effusion requiring chest drain	1
Subphrenic abscess requiring radiological drainage	1
Pneumothorax requiring chest drain	1
Grade IIIb	3 (7.7)
Splenectomy	2
Small bowel injury	1
Grade IVa	7 (17.9)
Renal failure requiring dialysis	2
Cerebrovascular accident	3
Cardiac arrest (survived)	1
Sepsis	1
Grade IVb	Nil
Nil	
Grade V	Nil
Nil	

MRSA: Methicillin-resistant *Staphylococcus aureus*

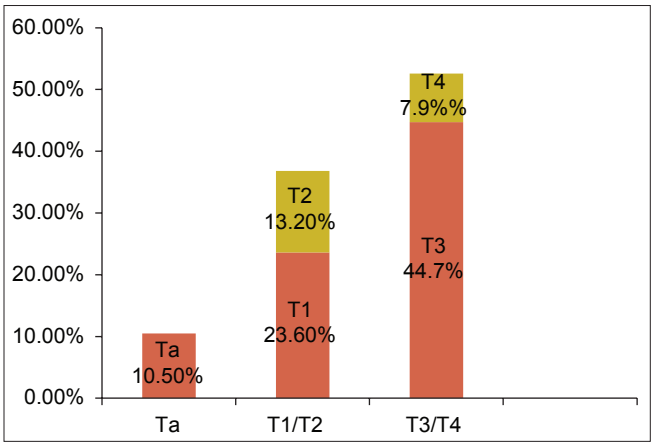

Figure 1: Complications according to histological grades

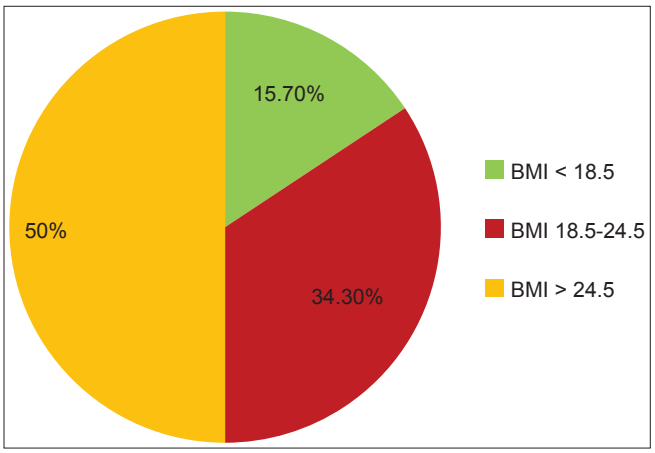

Figure 2: BMI and complications in laparoscopic and open groups combined

Table 3: Incidence of complications in open and laparoscopic group according to the Clavien-Dindo classification system

Grade	Total *N*=39 (%)	Open *N*=23 (59.0%)	Laparoscopic *N*=16 (41.0%)	Confidence interval	*P* value	OR (odds ratio)
Grade I	10 (25.6)	6	4	0.2-4.5	0.93	1.05
Grade II	16 (41.1)	9	7	0.2-3.0	0.773	0.8
Grade IIIa	3 (7.7)	2	1	0.1-17.2	0.77	1.4
Grade IIIb	3 (7.7)	2	1	0.1-17.2	0.77	1.4
Grade IVa	7 (17.9)	4	3	0.1-4.7	0.91	0.9
Grade IVb	0	0	0	NA	NA	NA
Grade V	0	0	0	NA	NA	NA

DISCUSSION

Procedure specific complications are an important indicator for measuring quality in health care. Although quality assessment is gaining widespread recognition, there is still no consensus about grading post-operative complications in urology. Various studies have reported complications in kidney operations, which include studies in octogenarians. Surgery in octogenarians has always posed major challenges to the operating surgeon in various fields of surgery.[11-13] An increase in life expectancy in the field of medicine has led to more and more patients in this age group being offered surgery for cancer as well as benign conditions.[12] Thomas *et al.* compared laparoscopic partial nephrectomy in octogenarians and non-octogenarians and concluded age should not be a contraindication to surgery.[14] In another study, by Vasudev *et al.*, the conclusion was that chronological age itself should not be the only determining factor and in octogenarians laparoscopic radical nephrectomy had fewer complications than open radical nephrectomy.[16] Pareek *et al.* also concluded that laparoscopic renal surgery is safe in octogenarians, associated with a reduced hospital stay and leads to early mobilization.[17]

The challenge in this group lies in having a valid negative outcome data so as to decide which patients would benefit from surgery. Nevertheless, inconsistency prevails to a large extent in surgical literature when it comes to complications reporting both short-term and long-term complications. Martin *et al.* identified 10 critical elements of accurate and comprehensive reports of complications in randomized controlled trials. Their study showed a strong inconsistency in data reporting and favored the creation of a generalized and standard reporting system.[8,9]

Clavien *et al.* first described the use of a standard reporting system for post-operative complications in 1992. It was re-evaluated in 2004 in a cohort of 6336 patients to improve its acceptability and accuracy. Results were obtained from an international survey sent out to ten surgical centers worldwide. In 2009 the classification system was further critically evaluated to show its reliability and credibility in complications reporting worldwide.[1-3]

In the field of urology the use of this grading system is slowly gaining impetus. Various centers have started to grade their complications according to the Clavien-Dindo system to improve quality assessment and standardize data for comparison between different centers.[10-15,18-22] However, some modifications when reporting specific complications in some urological operations are necessary. Intra-operative complications can significantly alter the normal post-operative course. There is some confusion in the interpretation of how particular intra-operative complications should be graded. Stolzenberg *et al.*[19] grade rectal injury during laparoscopic RP as a Clavien grade I complication, whereas Murphy *et al.*[23] grade it as a Clavien III complication. In our series due to severity of complications we have classified bowel injury as IIIb. Our study reported a total of 10 grade I complications, which is a total of 25.6% of the overall complications. The complications included various complications like atrial fibrillation, post-operative confusion, non-infectious diarrhea and basal atelectasis. The complication rate reporting of grade I complication in other urological surgeries seemed to be higher in comparison to other grades. As our study was a retrospective study of case notes we suspect a shortcoming of under reporting and under realization of these minor complications in patient notes.[12]

Our study showed mostly grade 2 complication ($N = 16$) accounting for overall 41.1 % complications. Similarly, Grade 3 and 4 complications accounted for 14.4 % and 17.9% respectively. In our study a higher BMI was associated with an increased percentage of complications. 50% of complications were seen in patients with a BMI of 24.5 Kg/m^2 or above [Figure 2] compared to other groups. Kapoor *et al.* in their study demonstrated a longer operative time but comparable complications rate between obese and non-obese patients.[21]

Using a standardized system to grade complications has a number of benefits in the surgical literature.[8,17,22,24,25] It will lead to a uniform negative outcome data reporting system in various centers which could subsequently be used between centers to compare their results, inform patients of the efficacy of various treatment modalities and as a whole lead to improving the quality of care based on reliable data worldwide.

The Clavien system offers all the advantages of a system, which has been extensively evaluated and used since 1992 in many fields of surgery.[24] Despite this there has been limited data regarding its use in urology. We, however, acknowledge the small numbers in this study and the fact that this is retrospective data collection. This effectively limits the statistical validity. There could be also some difference in management between various centers and surgeons, which could limit the way various complications are graded. Also difference in availability of various treatment modalities in developing and developed countries could affect the way various complications are managed may have an effect on how complications are graded. The main drawback is, however, non-inclusion of intraoperative events for example splenctomy or bowel injury during nephrectomy. We have published a proposal to incorporate intraoperative complications as a separate group with Suffix I.[26] This will ensure simple

reporting of such events without unnecessary complicating grading system. Further large prospective multi-centric studies with Clavien-Dindo grading needs to be undertaken in urology.

CONCLUSIONS

We believe that in elderly patients, laparoscopic renal surgery can be applied safely. The length of stay and hospital stay were short, demonstrating that laparoscopic nephrectomy/nephroureterectomy is a reliable approach that allows patients to benefit from the advantages of minimally invasive surgery without further increasing the surgical risks.

In our view the Clavien-Dindo system is the way forward and should be adopted in all urological surgeries and should be the gold standard for reporting complications. The Clavien-Dindo system has been extensively analyzed and critically evaluated for its acceptability and credibility. It seems an easy system, which can be used by all grades of surgeons and should form the basis of all discharge summaries following all elective urological surgical work.

Monthly morbidity and mortality discussions should also be based on using the Clavien-Dindo system as a methodology of reporting negative outcomes. Junior doctors who normally produce discharge summarizes and form the majority of documentation in case notes should be familiarized with the Clavien-Dindo system for better outcome reporting. Furthermore work also needs to be done by the urological community to further strengthen this system and formulate it in the context of urological surgery for better reporting.

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