

Original Research Article

A Prospective Observational Study- Assessment and Categorization of Urological Operative Complications as Per ClavienDindo Classification in Our Institution

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Abstract: At present main methods of assessing quality of surgical results & audits are mortality and morbidity. In 1992 Pierre Alain Clavien proposed a therapy oriented classification of post-operative complication. This grading system is well accepted worldwide as it is simple, reliable and valid. Our objectives are to assess and categorize urological operative complications as per Clavien-Dindo classification and to assess complication rates in reference to age, body mass index, American society of Anesthesiology score and comorbidities (Diabetes, Hypertension) and laparoscopic versus endourological versus open procedures. We prospectively observed total 310 urological operations conducted in our institute, aged 13-80 yrs, 190 male (61.3%) 120 female (38.7%), open procedure (n 122), laparoscopic procedure (n 35), endourological procedure (n 153). We have assessed and categorized operative complications as per ClavienDindo classification by detailed history, clinical examination and relevant investigations as required and also influence of predictors like age, BMI, ASA score, comorbidities (Diabetes & Hypertension) and laparoscopic versus open surgical procedures have been calculated. We observed total 64 complications (20.6%); gr I 62.5%, gr II 15.6%, gr III 12.5%, gr IV 3.1%, gr V 6.2%; and complications in laparoscopic (17%) and endourological procedure (17.6%) are significantly less than open (35%). Age, BMI and comorbidities (Diabetes and hypertension) have significant influence on complication rates. Most of the complications are grade- I. Laparoscopic and endourological procedures have fewer complications than open procedure. Age, BMI and comorbidities (Diabetes and hypertension) have great influence on complications.

Keywords: mortality, morbidity, Diabetes, hypertension

INTRODUCTION:

The lack of consensus on how to define and grade the adverse post-operative events has greatly hampered the evaluation of surgical procedures. At present, the main methods of assessing surgical results for quality assurance and audit remains mortality and morbidity. The measurement of morbidity requires an accurate definition of surgical complications used as a marker of quality of surgical work.

A new classification of complications, initiated in 1992, ClavienDindo classification [1], based on the type of therapy needed to correct the complications. This grading system is well accepted worldwide as it is simple, reliable and valid. This grading system categorizes uro- surgical complications and assesses the quality of surgical procedures as well as planning to reduce complications, mortality, morbidity and health related costs.

The previous classification [1, 2, 3] consisted of 4 severity grades. Grade 1 included minor risk events not requiring therapy (with exceptions of analgesic, antipyretic, antiemetic, and anti-diarrheal drugs or drugs required for lower urinary tract infection). Grade 2 complications were defined as potentially life-threatening complications with the need of intervention or a hospital stay longer than twice the median hospitalization for the same procedure. Grade 2 was divided into 2 subgroups based on the invasiveness of the therapy selected to treat the complication; grade 2a complications required medications only and grade 2b an invasive procedure. Grade 3 complications were defined as complications leading to lasting disability or organ resection, and finally, a Grade 4 complication indicated death of a patient due to a complication.

The modified classification [4] is based on the therapy used to correct a specific complication remains the cornerstone to rank a complication. Significant

modifications were made compared with the previous classification and increased the number of grades from 5 to 7, including 2 subgroups for grades 3 and 4.

The rationale to divide some grades into 2 subgroups is that these types of complication are likely to be often pooled due to small numbers. Grades I and IIa complications in the initial classification correspond to grades I and II complications in the modified version. Grade IIb events (need for invasive procedures) in the former classification are now listed as a separate entity (grade III complications), further subdivided into grades IIIa and IIIb depending on the need for general anesthesia.

The length of hospital stay as a criterion to rank grade 2 complications was eliminated. Life-threatening complications such as an acute respiratory distress syndrome (ARDS) with the need for mechanical ventilation, listed as grade IIb complications in the initial classification, are now recognized as a higher grade (grade IV complications). Finally, disability, as defined as any impairment of a body function (such as neurologic deficits of an extremity due to positioning of the patient during surgery or hoarseness after thyroid surgery), is no longer a grade on its own (grade III in the previous version), but is now highlighted by the suffix "d" (for "disability"). Thus, any grade of complication may be supplemented with this information.

CLAVIEN- DINDO CLASSIFICATION- Grades Definition

Grade I: Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions. Allowed therapeutic regimens are: drugs such as anti-emetics, antipyretics, analgesics, diuretics, electrolytes and physiotherapy. This grade also includes wound infection opened at the bedside.

Grade II: Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.

Grade III: Requiring surgical, endoscopic or radiological intervention

Grade III-a: Intervention not under general anesthesia

Grade III-b: Intervention under general anesthesia

Grade IV: Life-threatening complication (including CNS complications: brain haemorrhage, ischaemic stroke, subarachnoid bleeding, but excluding transient ischaemic attacks) requiring ICU management.

Grade IV-a: Single organ dysfunction (including dialysis)

Grade IV-b: Multi-organ dysfunction

Grade V: Death of a patient

MATERIAL AND METHODS

Study area: Dept. of urology, IPGMER, Kolkata.

Study period: February 2014 - November 2015

Sample size: 310

Sample design:

Inclusion criteria:

Patients aged 13-80yrs who had undergone urological procedures in urology department.

Exclusion criteria:

1. Age below 13yrs and above 80yrs.
2. Bleeding disorders
3. Patients having UTI.
4. Renal transplantation.

Study Design: A prospective observational study.

Measurement Tools:

1. Detail history.
2. Clinical examination.
3. Investigations

Plan for analysis of data:

Standard statistical analysis and chi-square test was used for analysis and result. We prospectively observed total 310 urological operations conducted in our institute of patients of age group 13-80 yrs, 190 were male(61.3%) and 120 were female (38.7%). Open surgical procedures done in 122 cases, laparoscopic procedures done in 35 cases and endourological procedures done in 153 cases. We have assessed and categorized operative complications as per ClavienDindo classification by detailed history, clinical examination and relevant investigations as required and also predicts the influence of predictors like age, BMI, ASA score, co-morbidities (like Diabetes & Hypertension) and mode of surgical procedures.

RESULT:

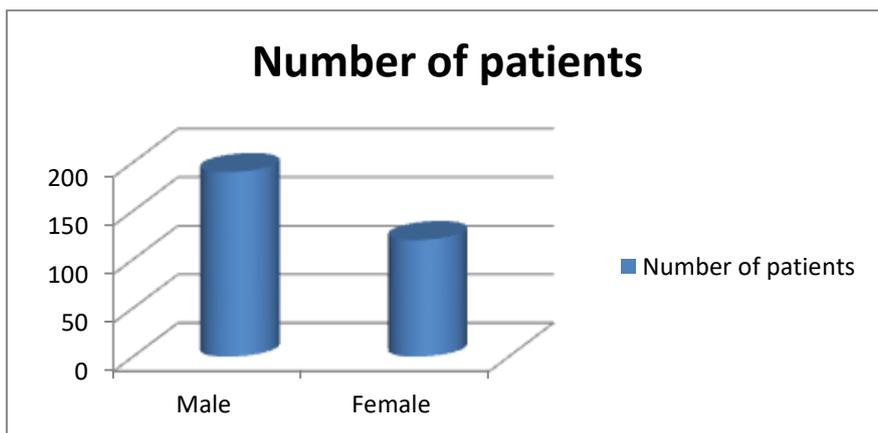
We have included 310 patients (male-190, and female-120), number of complications: grade-I-62.5 %, grade II- 15.6%, grade-IIIa-6.25%, grade-IIIb-6.25%, grade-IVa-1.5%, grade-IVb-1.5% and grade-V-7.8%. As per age number of patients and complications are: in 13-40 year group complications 12 in 88 patients, in 41-60 year age group 20 complications among 128 patients, in age group 61-80 years 32 complications among 94 patients(P- value was <0.05). In BMI less than thirty group 62 patients got complications among 248 cases and in BMI <30 group complications are 24 among 40 patients (p-value was <0.05). ASA grade did not affect the complication rate significantly. ASA grade-I develop 32 complications among 178 patients, grade-II develop 18 complications among 91 patients, grade -III develop 14 complications among 41 patients (p-value was not significant). ASA grade IV and grade-V were not included in the study. Open cases develop 43 complications among 122 procedures, in laparoscopic

procedures 6 develop complications in 35 procedures and in 153 endourological procedures 15 develop complications (p-value was <0.05). Comorbid patients

develop more number and higher grade of complications.

Table 1:Sex distribution of cases

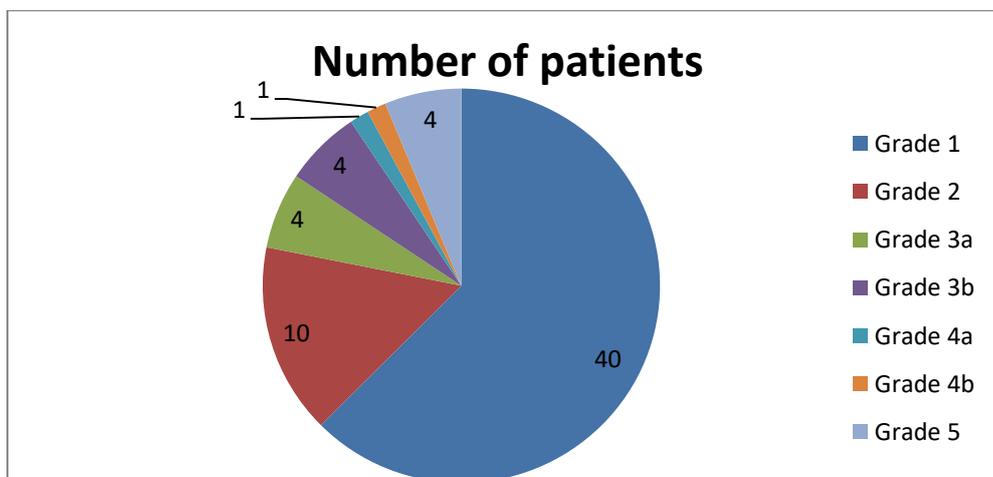
Number of patients	310
Males	190
Females	120
Total complications	64
% complications	20.6%



Graph 1: sex distribution of cases

Table-2-grade of complications

Grade of complications	Number of patients
Grade 1	40
Grade 2	10
Grade 3a	4
Grade 3b	4
Grade 4a	1
Grade 4b	1
Grade 5	5



Graph 2: grade of complications

Table-3-distribution of cases according to age

Age group	Number of patients	Number of complications	Grade 1	Grade2	Grade3a	Grade3b	Grade4a	Grade4b	Grade 5
13-40	88	12	9	2	1	0	0	0	0
41-60	128	20	13	2	2	1	1	0	1
61-80	94	32	18	6	2	2	1	0	3

Table 4: classification according to BMI

BMI	Number of patients	Complications	Grade 1	Grade 2	Grade 3a	Grade 3b	Grade 4	Grade 5
<30	248	40	34	4	1	1	0	0
>30	62	24	6	6	3	3	1	4

Table 5: classifications according to ASA

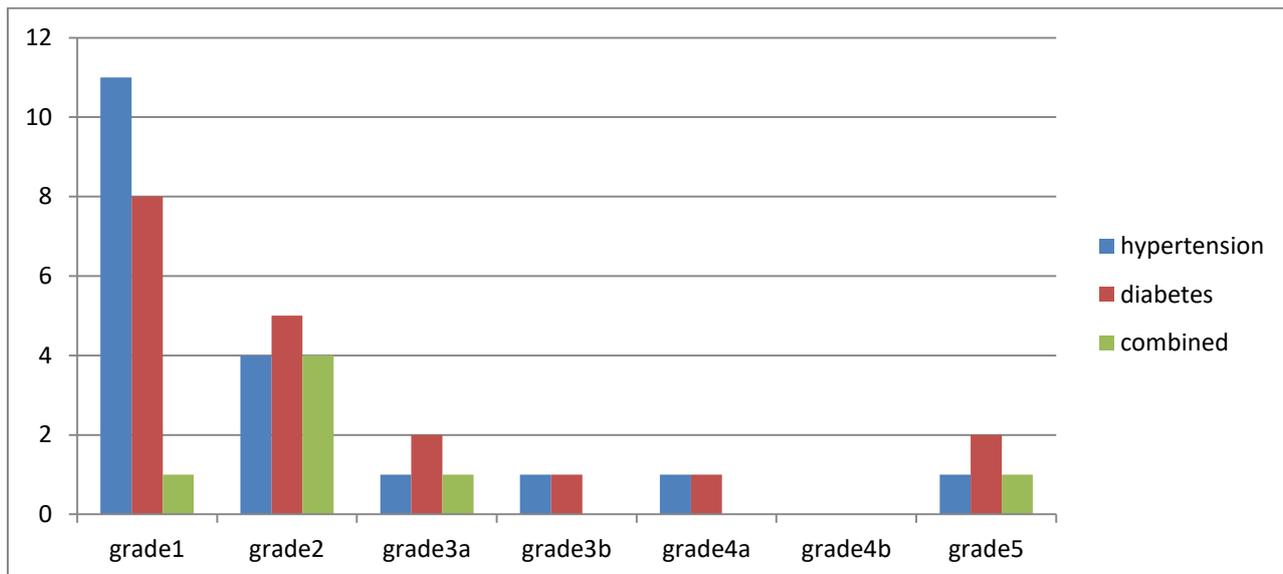
ASA grade	Number of patients	Complications	Grade 1	Grade 2	Grade 3a	Grade 3b	Grade 4a	Grade 4b	Grade 5
1	178	32	22	7	2	1	0	0	0
2	91	18	10	2	2	2	1	0	1
3	41	14	8	1	0	1	1	0	3

Table 6: classification according to type of surgery

	No of patients	No of complications	Grade 1	Grade 2	Grade 3a	Grade 3b	Grade 4a	Grade 4b	Grade 5
Lap	35	6	2	1	0	0	0	0	3
Open	122	43	25	8	3	4	1	1	1
endo	153	15	13	1	1	0	0	0	0

Table 7: classification of cases according to presence of comorbidities

Co-morbidities	No of patients	Complications	Grade 1	Grade 2	Grade 3a	Grade 3b	Grade 4a	Grade 4b	Grade 5
Diabetes	41	19	11	4	1	1	1	0	1
Hypertension	56	20	8	5	2	1	1	0	2
Combined	15	7	1	4	1	0	0	0	1



Graph-3-grade of complications according to presence of comorbidities



Fig-1: Port site wound infection in case of laproscopic simple nephrectomy



Fig-2: Operated site wound infection with inflammatory changes in open ureteric reimplantation



Fig 3-Post PCNL pneumothorax

DISCUSSION:

In 1992 Pierre Alain Clavien proposed a therapy oriented classification of post-operative complication. Daniel Dindo *et al.*; modified the system to include life threatening complications resolved by critical care intervention. The modifications introduced made this classification simple and easy to apply without any confusion for classification of operative complications.

Urology is a super-speciality branch with multiple modalities of surgical management ranging as per their invasive nature [11]. This may lead to variable types of complications unique to the type of surgical procedures[12]. Thus, there is a necessity of a discrete type of system to classify post uro-surgery complications for better management and good post-operative care[13]. This study aims at identifying the patient profile as well as surgical factors which influence the probability of the occurrence of post-operative complications.

Preoperative patient profile is known to affect the post-operative recovery and well-being of the patient. Studies have shown that increasing age of the patient affects the incidence of post-operative complications [14, 15, 16]. It has been seen that increasing age is associated with increased incidence of skin site infections (Grade 1)[17]. There was increased rate of complications following open surgery in elderly patients. Literature has shown that the severity of complications increase with age with an increased

probability of the occurrence of highly morbid complications in older population [18, 19].

However, elderly patients did not have an increased complications following laparoscopic surgery[20]. Overall, complication rate was seen to be higher in older patients (>80) but there was no significant increase in the mortality post-surgery. Studies have age to be having no effect on post-operative morbidity in patients undergoing TURP [21].

BMI has an influence on surgical complications[22]. Body mass index has been shown statistically to be a significant predictor of mortality within 30 days of surgery, even after adjusting for the contribution to mortality risk made by type of surgery and for a specific patient's overall expected risk of death. The grade of complications has also been shown to increase with higher BMI with the risk of highly morbid complications occurring with increased BMI[23, 24]. However, studies have also shown BMI alone have no effect on surgical complication rates especially in open surgeries [25]. BMI does not showing effect on laparoscopic surgeries [25].

ASA class is strongly associated with medical problems in the per-operative period especially in the elderly. Patients identified as being at higher risk (in ASA class 3 or 4) preoperatively should be closely managed medically so that per operative medical complications can be managed and evolving medical issues can be addressed in a timely fashion. Their grade

of the complications also rises with an increase in the ASA class [26].

In spite of literature reporting the association of ASA, age and BMI with perioperative complications, studies have also reported contrary with age and BMI having little or no impact on operative complications. ASA score and co-morbidities are strong predictors of operative complication rates and grades in all the studies.

Conventional thinking is that open surgery is associated with a higher complication rate of all grades and types compared to laparoscopic surgery. Studies have shown the incidence of grade 3, 4 and 5 complications being higher following open surgeries. However, a few studies have shown no such difference in the complications rate. Atif Khan *et al.*; (Urology Annals Dec 7, 2013) reported that there is no statistically significant difference in rate and grade in open vs laparoscopic nephroureterectomy [27].

In the initial years of endoscopic surgery complications were rampant with highly morbid post-operative recovery periods and occasional mortality. Subsequent to refinement of surgical principles and further experience complications have become sparse provided surgical principles are followed. However, studies do show significant complications each specific to a particular endoscopic procedure. Most of the complications which occurred were minor and non-life threatening with minimal morbidity. The complications were mostly of grade 1 and 2 in nature and did not require any aggressive intervention.

Thus it can be seen that multiple factors influence the occurrence of complications in the post-operative period. Both patient as well as surgical factors play a pivotal role in determining the probability of complication occurrence in an index case. The nature of the complications which occur is also influenced by multiple factors.

Surgical complications are inevitable. It is essential to make a system to classify surgical complications so that uniformity in medical record keeping. In case of inter institutional transfer of a patient; a uniform classification system will help in precise data communication between the treating teams in both the institutions. The CalvienDindo classification addresses the same and is a universally accepted classification of surgical complications. Urology is a diverse branch with multiple procedures varying in their level of invasiveness. Thus, the number and variety of surgical complications are innumerable. This study aims at classifying complications post urological surgery as per the CalvienDindo classification.

Multiple factors influence the probability of occurrence of complications. It is essential to identify these factors so that the operating surgeon anticipates a specific complication in a specific index patient. The ability to predict complication occurrence also helps in patient counselling prior to surgery.

This study aims at identifying potential patient as well as surgical factors which influence the occurrence of complication in urological surgeries. The patient factors studied in this study are age, BMI, ASA score, presence of comorbidities. The nature of the procedures performed and the associated complications have also been analysed. In our study, it was seen that increasing age was associated with a higher complication rate. Statistical analysis showed age to be a significant factor influencing the incidence of complication occurrence. The grade of complications also increased with increasing age with a higher incidence of grade 4, 5 complications in the 61-80 year age group.

The possible reason for this was that the younger patients had none or minimal medical comorbidities. The younger patients mainly underwent minimally invasive procedures for relatively benign indications. In contrast older patients had multiple existing medical comorbidities and many underwent extensive long procedures for indications such as malignancy. This possibly predisposed older patients to complications in contrast to younger patients.

Our findings are in corroboration to the existing literature which also states that age is a significant risk factor. Thus, it can be concluded that an older patient is at a higher risk of post-operative complication of all types and grades in comparison to a younger patient for any given procedure. In our study it was seen the incidence of complications were higher in patients with BMI > 30. Statistical analysis showed BMI to be a significant factor influencing complication rate. The grade of the complications also increased in patients with BMI > 30.

The possible reason for this is that patients with BMI > 30 had significantly higher number of medical comorbidities like diabetes and hypertension. Obesity is a known risk factor for wound dehiscence, thus predisposing to grade 1 complication. Obese patients also have an increased incidence of respiratory and Cardiological co-morbidities such as obstructive sleep apnoea and CAD. These factors result in a prolonged morbid post-operative period which may require intensive care and monitoring. ASA physical health status is being determined by presence or absence of systemic disease, functional capacity and overall medical illness. Literature shows that an

increasing ASA is associated with an increased complication rate.

In our study it is seen that ASA did not significantly affect the incidence of complications. The possible reason for this is that the maximum ASA grade included in our study was grade 3 (systemic disease which is not incapacitating). Good preoperative optimization of the patient along with concomitant care by the allied specialties possibly lead to a minimally morbid outcome in our patients with ASA grade 3.

Comorbidities associated with higher complication rate as expected. Diabetes is an independent risk factor for wound infection, delayed wound healing and cardiovascular comorbidity. Hypertension also leads to higher chances of cardiological co-morbidity. In our study there is increased risk of post-operative complications in patients having comorbidity.

Open surgery was associated with an increased complication rate compared to minimally invasive surgery. Statistical analysis has shown a significantly higher complication rate following open surgery. The longer incision, increased blood loss and the prolonged time under anesthesia are possibly the factors which result in a higher complication rate. Laparoscopic and minimally invasive surgery is associated with reduced convalescence, decreased analgesic requirement and shorter hospital stay. 3 deaths were seen post laparoscopic surgery in our study. The probable cause of death in these patients was associated comorbid conditions which resulted in complications during intra-operative period, iatrogenic injury to bowel with resultant peritonitis and septicemia.

Studies have shown that in older and obese patients laparoscopic surgery was associated with minimal post-operative morbidity. Thus, the conclusion of our study is that age, BMI>30 and coexisting medical comorbidities are risk factors for complications when patient related factors are considered. Open surgery is associated with a higher complication rate compared to minimally invasive surgery. The pitfall of our study is that although risk factor-complication relationship has been established, the grade of the complication-risk factor relationship has not been established by our study.

CONCLUSION:

Thus, the conclusion of our study is that age, BMI>30 and coexisting medical comorbidities are risk factors for complications when patient related factors are considered. Open surgery is associated with a higher complication rate compared to minimally invasive surgery. Most of the complications in our study are of grade-1 requiring bed side management. Death occurred

in our study due to extreme ages associated with comorbidities and prolonged operative periods. More number of death following laparoscopic surgery than open surgery was due to associated comorbidities along with increased operating time.

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