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Research Article

FREQUENCY OF COMPLICATION OF ENDOUROLOGY PROCEDURES AND CLAVIEN GRADING

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Abstract:

Objective: Purpose of this study was to establish supplementary criteria for the Clavien-Dindo classification to standardize the evaluation of postoperative complications.

Methodology: This was a cross-sectional observational study using non-probability consecutive sampling in which 142 patients undergoing endourology procedures from 29th July 2015 to 28th January 2016 at the Department of Urology, Jinnah Postgraduate Medical Center, Karachi after taking ethical approval. Patients between the ages of 30 to 60 years of either gender undergoing endourology procedures in which duration of procedures was ≥ 4 weeks were included for this study after taking informed consent. Known diabetics, hypertensive or patients having cardiopulmonary diseases were excluded from the study. Post procedure patients were followed and the final outcome was recorded in terms of complications and grades of complications were reported. Data were analyzed on SPSS version 20. Descriptive statistics was performed.

Results: Among the total of 142 patients of either gender with age between 30-60 years having a mean age of 48.72 ± 8.71 years, undergoing endourology procedures of 4 weeks or more were evaluated to determine the frequency of complications and different grades of complications using Clavien grading system. The results showed that there were 92 (64.8%) males and 50 (35.2%) female patients. Majority of the patients, i.e. 113 (79.6%) were found to have no complication after undergoing end urology procedures while 29 (20.4%) of the total patients had developed complications. (Figure 1) As far as complication grades according to clavien grading system are concerned, 05 (7.2%) were grade-1, 14 (48.3%) were grade-2, 04 (13.8%) were grade-3, and 06 (20.7%) were observed with grade-4 complications.

Conclusion: The present study concluded that although majority of the patients recorded to have no subjective or objective complications. Those patients who experienced any complication, were classified according to clavien grading system which was beneficial in recognizing and managing the complications with regards to the degree of severity.

Keywords: Clavien-Dindo classification, complications.

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INTRODUCTION:

Evaluation of postoperative complications in surgical trials is as important as the assessment of toxicities in chemotherapy trials. Prior to the proposal of a therapy-oriented classification scheme, by Clavien PA et al. [1], there were no accepted definitions for the grading of surgical complications in clinical practice. This framework proposed by Clavien et al. was not used widely, because there was no system for the grading of severity of surgical complications and no uniform definition of these events. [2] For instance, some surgeons included a body temperature greater than 38 °C on two consecutive days as being “high”, whereas others included intraoperative complications, postoperative complications (within 30 days), and late events such as dumping syndrome. [3] Few randomized controlled trials (RCTs) have used this classification system, with individual parochial definitions of surgical complications being used in most surgical RCTs [4–6]. In cancer clinical trials, adverse events (AEs) are evaluated in accordance with the Common Terminology Criteria for Adverse Events (CTCAE), which is far from exhaustive in terms of surgical complications; thus, some surgeons are not comfortable using grading definitions. The Clavien-Dindo classification, defined a simple classification of postoperative complications, which has been adopted widely in clinical practice. Although this classification categorizes postoperative complications broadly into four major groups, it is often desirable to more clearly define the common AEs to avoid the use of different or less precise terms for the same AEs occurring in different clinical trials. More detailed grading criteria for common AEs would also be helpful for surgeons. [7]

In 2004, the Clavien-Dindo classification was modified to allow for the grading of life-threatening complications and long-term disability caused by a complication. This revised version defines five grades of severity (Grade I, II, IIIa, IIIb, IVa, IVb, and V) and the suffix “d” (for “disability”) is used to denote any postoperative impairment [8]. This refined Clavien-Dindo classification has been used increasingly in clinical practice and also in clinical trials involving surgical procedures, because it is simple, reproducible, and flexible [9]. Rather than providing specific grading criteria for each AE, the Clavien-Dindo classification provides broad-based but general criteria that can be used uniformly for all kinds of surgical AEs.[10] However, several issues have emerged since this classification became more widely used. One controversial issue is that AE terms are not well defined and different AE terms designate the same AEs in different clinical trials. [11] For example, when

intestinal obstruction occurs, some investigators could report this AE as “ileus”, but others refer to it as “small bowel obstruction” or “colon obstruction”. Under such circumstances, the incidence of this AE cannot be counted accurately. [12] A second issue is that only general grading criteria are defined and therefore, grading can be difficult in some cases and subject to bias by the grader. For example, primary non-operative treatment for intestinal obstruction is gastroenteric tube decompression. Nasogastric tube or nasoenteric tube is utilized depending on the severity, but the original Clavien-Dindo classification does not define what grading should be applied for any type of gastroenteric tube placement for decompression. [13]

Purpose of this study was to establish supplementary criteria for the Clavien-Dindo classification to standardize the evaluation of postoperative complications.

METHODOLOGY:

This was a cross-sectional observational study using non-probability consecutive sampling in which 142 patients undergoing endourology procedures were selected for the study for 6 months from 29th July 2015 to 28th January 2016 at the Department of Urology, Jinnah Postgraduate Medical Center, Karachi. Ethical review was sought from the Institutional Review Board of Jinnah Postgraduate Medical Center, Karachi. Patients between the ages of 30 to 60 years of either gender undergoing endourology procedures in which duration of procedures was ≥ 4 weeks were included for this study after taking informed consent. Known diabetics, hypertensive or patients having cardiopulmonary diseases were excluded from the study. Post procedure patients were followed and the final outcome was recorded in terms of complications and grades of complications were reported.

Data analysis:

Data were analyzed on SPSS version 19. Age and duration of disease were presented as Mean \pm SD. Frequency and percentages were presented for complications, grades of complications using Clavien grading system, educational status and economic status.

RESULTS:

Among the total of 142 patients of either gender with age between 30-60 years having a mean age of 48.72 \pm 8.71 years, undergoing endourology procedures of 4 weeks or more were evaluated to determine the frequency of complications and different grades of complications using Clavien grading system. The results showed that there were 92 (64.8%) males and 50 (35.2%) female patients. (Table 1)

Majority of the patients, i.e. 113 (79.6%) were found to have no complication after undergoing end urology procedures while 29 (20.4%) of the total patients had developed complications. (Figure 1) As far as complication grades according to clavien grading

system are concerned, 05 (7.2%) were grade-1, 14 (48.3%) were grade-2, 04 (13.8%) were grade-3, and 06 (20.7%) were observed with grade-4 complications. (Figure 2)

Table 1: Descriptive analysis of patients (n=142)

Variables		Mean±SD/n(%)
Age (years)		48.71±8.71
Duration of disease (months)		5.8±1.33
Gender	Male	92(64.8%)
	Female	50(35.2%)
Education	Illiterate	9(6.3%)
	Primary	12(8.5%)
	Secondary	21(14.8%)
	>= Matric	100(70%)
Salary	< 15,000	22(15.5%)
	15,000 - 50,000	97(68.3%)
	> 50,000	23(16.2%)

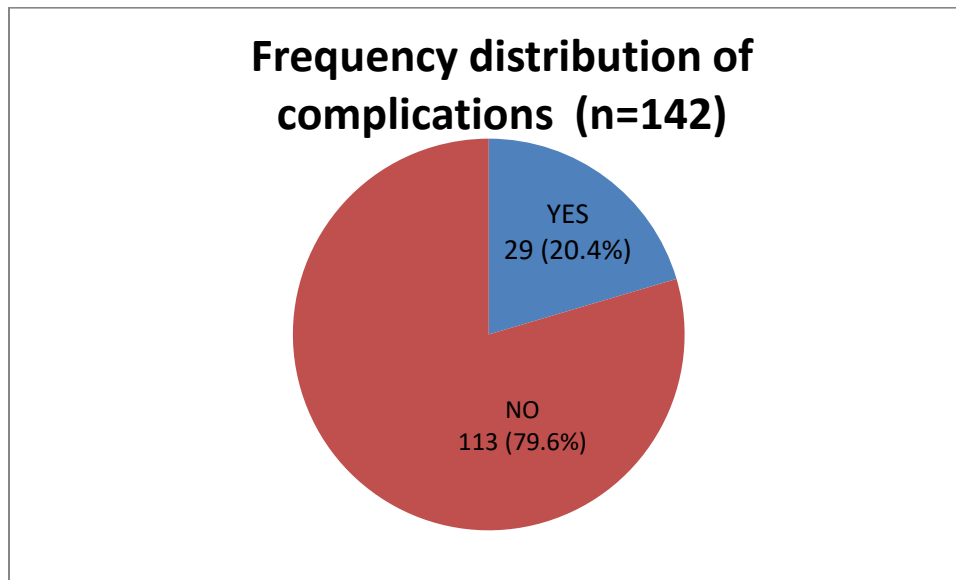


Figure 1: Frequency of complications of patients undergoing end urology procedures

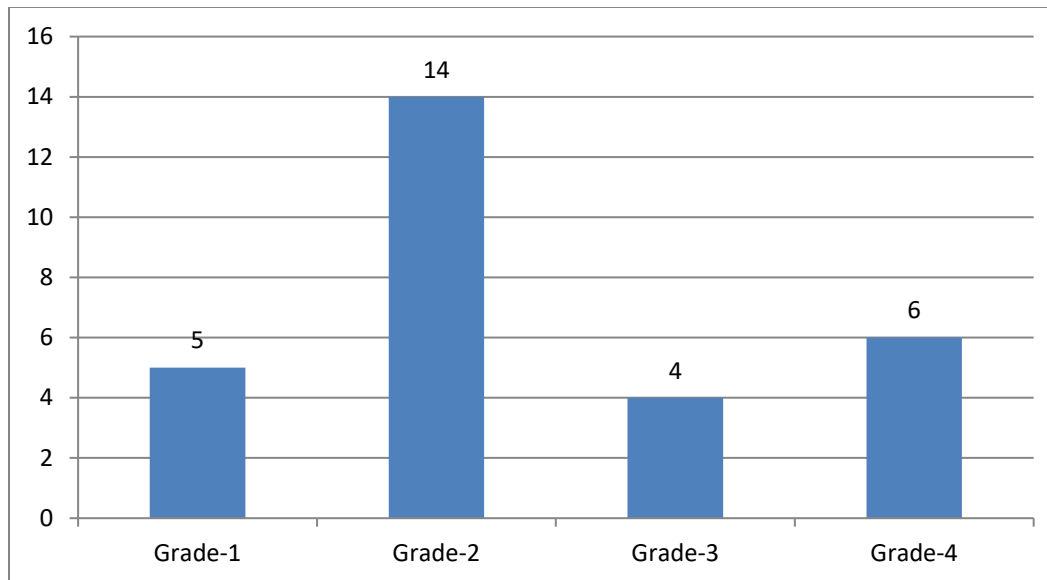


Figure 2: Frequency of complications according to Clavien grading (n=29)

DISCUSSION:

Among the total of 142 patients who had undergone urological procedures, majority of the patients, i.e. 113 (79.6%) out of 142 did not experience any complication after undergoing surgeries while 29 (20.4%) of the patients had developed complications. As far as complication grading according to Clavien grading system was concerned, 05 (7.2%) of complications were grade-1, 14 (48.3%) of complications were grade-2, 04 (13.8%) of complications were grade-3, and 06 (20.7%) of complications were grade-4 complications. In a study by Rassweiler J et al the vast majority of the patients experienced either no complication (167 out of 198; 84.4%) or complications ranked as grade I–II (27 out of 198; 13.6%), which were merely related to persisting bleeding, catheter placement or replacement and urinary tract infections (UTI). Only 3 out of 198 patients (1.5%) experienced life-threatening complications necessitating intensive care unit admission i.e. grade IV (14). Skolarikos A et al have reported that the frequency of major complications after PCNL was 0.9% to 4.7% for septicemia, 0.6% to 1.4% for renal hemorrhage necessitating intervention, 2.3% to 3.1% for pleural injury, and 0.2% to 0.8% for colonic injury (15). Consequently, reported overall rates may include complications that are mostly clinically insignificant, such as minor bleeding or fever, combined with those that are significant, such as urosepsis or organ damage related to access (16). In a study by Rosette JDet al, among 5803 patients included in their study, 4549 (79.5%) of patients did not experience any complications while 634 (11.1%) of patients suffered grade I complications while grade II

complications were observed in 301 (5.3%) of patients. Grade III complication was reported in 210 (3.6%) of patients. Grade IV complication was observed in 28 (0.5%) while 2 (0.03%) of patients experienced grade V complication (17). In another study by De La Rosette J et al, among 11885 patients included in their study, 11,415 (96.0%) of patients did not experience any complications while 169 (1.4%) of patients suffered grade I complications while grade II complications were observed in 159 (1.3%) of patients. Grade III complication was reported in 61 (0.5%) of patients. Grade IV complication was observed in 14 (0.1%) while 5 (0.02%) of patients experienced grade V complication and data about 12 (0.04%) of patients was missing (18). The postoperative complication rate was low at 3.5%; fever was reported in 1.8% of patients and was comparable to that in other studies (19). Mandal S et al who showed a 30% complication rate at a resident training centre; 98% of these were grade 1–3 and <2% were grade 4 (20). Utanğaç et al. showed preoperative complications of grade II and III to be 11.6% and 8.7% respectively with absence of grade IV and V complications (21). In a study by Taha SM et al, among the total of 108 patients selected for their study, the total incidence of complications was 18.5%. Grade I, II and III complications were detected in 10 (9.2%), 4 (3.8%) and 2 (1.9%) of the patients respectively while no complications of grade IV and Grade V were reported. The differences in the success and complication rate between studies can be partially explained by involvements of surgeon experience (consultants) and it is intuitive that the complications are higher during the learning phase. Some surgeons

have a broad experience and others such as residents are acquiring it. The incidence of complications after ureteroscopy performed by consultants and residents in the study were 1.8% (2/108) and 12.9% (14/108) respectively (22). Such results do only reflect the impact of surgeon's experience but also denotes that cases are better to be performed by the consultants.

The qualitative approach of our study has assured that we have assessed the extensive range of complication of patients undergoing endourological procedures. However the study might not be immune from observer and practice bias. Considering the finding of our study and to what extent they are consistent with their experience of the surgeons performing the procedure would be enlightening to establish the gradings of complication in endourological procedures and their better management strategies in the future.

CONCLUSION:

The present study concluded that although majority of the patients recorded to have no subjective or objective complications, those patients who experienced complication, were classified according to Clavien grading system which was beneficial in recognizing and managing the complications with regards to the degree of severity.

CONFLICTS OF INTEREST:

All the authors declare no conflict of interest.

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