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Post Transvesical Prostatectomy (TVP) Complications, Risk Assessment Using Clavien–Dindo System in Kassala Teaching Hospital, Kassala, Sudan

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Abstract **Background:** Open surgery is the main treatment option for Large Volume (LV) BPH. We preferentially used a standardized system; the Clavien-Dindo grading system that was highly recommended by the European Association of Urology in 2014. The aim of this study was to identify the type and rate the complications following TVP. **Methods:** A prospective descriptive analytical study done in Kassala Teaching Hospital (Eastern Sudan) in a General Surgery Unit from January 2013 through December 2015. All patients [188] with a clinical problem of Benign Prostatic Hyperplasia (BPH) have been involved. Designed questionnaire was synchronously filled from the hospital records. Variables were: Age, ASA, Co-morbidities, Size of the prostate, Complications of BOO, duration of Catheterization pre-op, Duration of surgery, Hospital stay, Duration of irrigation, Removal of the catheter, Removal of the drain, renal impairment, Surgeon, Blood loss, SSI, Fistulae. **Results:** One hundred and eighty eight patients were included in the study over two years. Mean age 69.4 ± 8.5 SD. All the patients had a prostate > 80 ml by US scan. The size of the prostate has been categorized to 80-100 (135 patients 71.8%), 101-200 (48 patients 25.5%), and 201-250 (6 patients 3.2%). Complication rates according to Clavien-Dindo were 99 (52.6%) no complications, 81 (43%) grade II, 3 (1.6%) grade Iva, and 5 (2.6%) with grade V. **Conclusion**: Most complications occur in our setting is consistent with the literature except the SSI (Surgical Site Infection) rate. The Clavien-Dindo classification system promises to be a good system for assessing complications following prostatectomy. As a recommendation patients tracing for long term follow up of late complications, absence of national registry for most of them was a determinant limitation of our study.

Keywords: *LV-BPH, TVP, Clavien-Dindo grading system, Sudan*

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1. Introduction

BPH has been known for several centuries to be a cause of urinary dysfunction. A recent study of aging among normal volunteers found a 51% clinical incidence of BPH in men 60 to 69 years. Symptoms of BPH may be thought of as obstructive in nature [1,2]

Prostate volume is an important factor that affects the treatment of benign prostatic hyperplasia (BPH) [3]. Surgical treatment of large-volume BPH (LV-BPH) poses a challenge to urologists. Although transurethral resection of the prostate (TURP) is considered the "gold standard" for surgical treatment of BPH [4], the relatively long operative time, low efficiency of resection, and high incidence of postoperative complications (e.g., intra-operative and postoperative bleeding, postoperative hyponatremia, and urethral stricture) have limited its application in the treatment of LV-BPH [5]. Although HOLEP (Holmium Laser Enoculation of the Prostate) is the evolving procedure for big prostates [6], open surgery remain treatment option for LV-BPH where this option is not available. TVP remain a viable option because of its shorter operative time, complete gland removal, and significant postoperative improvement in lower urinary tract symptoms [7,8,9]

TURP is a procedure done only in the capital of the Sudan (Khartoum) and only a few other cities, where general surgeons are performing open prostatectomy.

We preferentially used a standardized system; the Clavien-Dindo grading system is used for grading complications of various oncological, renal, and endourological procedures [9]. The aim of this study was to identify the type and rate the complications following TVP, to apply the Clavien- Dindo grading system to classify the complications, to compare the grade of complications between the operators, to compare the grade

of complication with the literature (the accuracy of the Clavien-Dindo in Sudanese patients), to compare the grade of complications between different groups of patients allows earlier recognition of the pattern of complications, thereby allowing for pre-emptive changes in care in an effort to decline the incidence.

2. Methodology

A prospective descriptive analytical study done in Kassala Teaching Hospital (Eastern Sudan) in a General Surgery Unit from January 2013 through December 2015. All patients [188] with a clinical problem of Benign Prostatic Hyperplasia (BPH) have been involved. Designed questionnaire was synchronously filled from the hospital records.

Patients included in the study have big prostates with genuine indication of prostatectomy. All patients received medical treatment in form of alpha blockers and finasteride at one stage of their follow up in our clinic.

Patients were followed after discharge in an outpatient setting for 2–4 weeks after discharge.

The American Society of Anesthesiologists (ASA) to evaluate the degree of a patient's "sickness" or "physical state" before selecting the anesthetic or before performing surgery. Describing patients' preoperative physical status is used for record keeping, for communicating between colleagues, and to create a uniform system for statistical analysis. The grading system is not intended for use as a measure to predict operative risk [11].

Blood loss: The volume of intra-operative blood loss is measured by volume in the sucker container after subtraction of normal saline volume used for flushing. Bleeding considered when blood loss more than 500 ml.

2.1. Procedural Description

Transvesical prostatectomy was performed in the standard fashion. The patient was placed supine. A transverse supra-pubic incision was made through skin, subcutaneous tissues down to the sheath. Rectus muscles splitted longitudinally. The bladder exposed and opened longitudinally. Cavity was explored and the ureteric orifices identified. The appropriate plane between the adenoma and the prostate capsule was developed and the adenoma gently dissected from the capsule. The dissection was completed using the index finger until only the distal urethra attachment remained; this was finally cut using curved scissors or fine tips diathermy with low energy, and the adenoma freed. A 22 F three-way urethral catheter was placed transurethrally so that the tip of the catheter and the balloon remained in the bladder filling the prostatic bed. Haemostasis secured and irrigation started using Normal Saline. Urinary bladder then closed in two layers using 2/0 vicryle suture. Size 18 tube drain is placed in the retro-pubic area. Wound closed in layers.

Ethical clearance: verbal consent for the study was obtained from the patients and relatives for the study and an informed consent was obtained from the patients and relatives according to the Federal Ministry of Health rules and patients' pathway.

Study Design: A prospective descriptive analytical study done in Kassala Teaching Hospital in a General Surgery Unit from January 2013 to December 2015.

2.2. Study Population

All patients with a clinical problem of Benign Prostatic Hyperplasia (BPH) who were planned for prostatectomy have been involved. The inclusion criteria is huge prostate with indication of prostatectomy

2.3. Data Collection

Designed questionnaire was filled from the hospital records. Variables were: Age, ASA, Co-morbidities, Size of the prostate, Complications of BOO, duration of Catheterization pre-op, Duration of surgery, Hospital stay, Duration of irrigation, Removal of the catheter, Removal of the drain, renal impairment, Surgeon, Blood loss, SSI, Fistulae.

2.4. Data Analysis

The data have been fed to Statistical Package for Social Sciences (SPSS) Inc., Chicago, IL, USA; version 19.0. Significance level has been taken for values at $P \leq 0.05$ with 95% confidence interval.

2.5. Ethical Clearance

This study has been approved by ethical clearance committee, Ministry of health, Kassala State, Sudan.

2.6. Conflict of Interest

None declared.

3. Results

188 patients were included in the study over two years. Mean age 69.4 ± 8.5 SD. 44 (23.4%) patients had co-morbidities like Diabetes, Hypertension, Asthma and one patient had previous Ischemic Heart Disease. All patients were planed for surgery,the indication was urine retention despite medical treatment in 171 patient, urolethiasis was the indication in 10 patients, obstructive uropathy was the indication in 5 patients while severe LUTS (lower urinary tract symptoms) was the indication in 2 patients.

All the patients had a prostate > 80 ml by US scan. The size of the prostate has been categorized to 80-100 (135 patients 71.8%), 101-200 (48 patients 25.5%), and 201-250 (6 patients 3.2%). Complications occurred were: significant bleeding > 750 ml was in 61 (32.4%), renal failure 20 (10.6%), 3 of them needed hemodialysis, SSI 44 (23.4%) third of them were superficial, and vesico-cutaneous fistulae in 27 (14.4%).

On application of the Clavien-Dindo (C/D), there were five deaths, with combined complications. 80% of them had renal failure as a part of multi-organ dysfunction (Table 1).

Table 1. Shows the Frequency and percentage of complications and the C/D

Complication	C/D grade	Frequency	Percent %	Death= 5
Bleeding	II	61	32.4%	1
SSI	I	44	23.4%	0
Renal impairment**	I / IVa	17/3	9/1.6%	2
Fistulae	I	27	14.4%	0
Others (MI)	Iva	1	0.53%	2
Death	V	5	2.6%	0
Total		158		5 (2.6%)

*C/D= Clavien-Dindo. SSI= Surgical Site Infection. MI= Myocardial Infarction. ** Renal impairment: Treated conservatively/needed hemodialysis.

Table 2. Summation of Grades of Clavien-Dindo in our Patients

Clavien-Dindo	Frequency	Percent %
No Complications	99	52.65
II	81	43.08
Iva	3	1.59
V	5	2.65
Total	188	100.0

Table 3. Shows the correlation between the Size of the Prostate and the Clavien-Dindo grade

		Clavien-Dindo grade					Total
		0	I	III	Iva	V	
Size of the Prostate	80-100	2	130	0	0	2	134
		1.5%	97.0%	.0%	.0%	1.5%	100.0%
	101-200	0	44	1	1	2	48
		.0%	91.7%	2.1%	2.1%	4.2%	100.0%
	201-250	0	4	1	0	1	6
		.0%	66.7%	16.7%	.0%	16.7%	100.0%
Total		2	178	2	1	5	188
		1.1%	94.7%	1.1%	.5%	2.7%	100.0%

38 (20.2%) of the patients have no complications, but the Clavien-Dindo grade II given for those who were transfused blood post operatively when the blood loss during irrigation (bladder wash) cannot be measured accurately. **No complications** with no blood transfusion was noted in only two patients, **grade II** Clavien-Dindo means either the patient has been transfused or had one of the three other complications (SSI, Fistulae or renal impairment not necessitating haemodialysis). **Grade IVa** is a patient with renal impairment necessitating haemodialysis. **Grade V** is death (Table 2).

Cross tabulation of the Clavien-Dindo grade with the operator was insignificantly showing no deaths in patients operated by MO (surgery residents), 3 deaths (60%) happened with registrars and 2 (40%) happened with the consultants, that may be due to more frequent surgeries done by the registrars (ratio 1.4:1). 94.7% of the cases had the rank of II. It was insignificantly reversed percentages between the residents, registrars and consultants by 100%, 96.1% and 92% respectively. Data correlation was not significant by Pearson Chi square test but significant by Goodman and Kruskal tau test for nominal categories in independent variables (Table 3).

Correlation between the Clavien-Dindo grades of complications with the co-morbidities of the patients was insignificant; where only two patients who died (grade V) had co-morbidities (Diabetes and the other had Hypertension). Another diabetic patient (grade IVa), developed renal failure and Haemodialysis. As well, correlation with the ASA was insignificant. 75% of the patients were ASA 1 and fifth of them were ASA 2 and the rest (around 5%) were ASA 3. Fortunately, all the ASA 3 patients were graded by the Clavien-Dindo as I. ASA 2 patients were 36, three (8.3%) of them died (grade V), 1 (2.8%) was grade IV and, the rest 32 (88.9%) were grade I. Of course, the two only patients with grade 0 Clavien-Dindo were ASA 1.

4. Discussion

BPH is a common burden for men worldwide. Open transvesical prostatectomy (TVP) and transurethral resection of the prostate (TURP) are two old surgical procedures performed for patients with benign prostatic hyperplasia (BPH). Currently, TURP is considered as the reference or standard treatment for the prostate less than 70 to 80 g [12,13,14]

Nevertheless, TVP is still being performed for operations of the prostates that are candidate for TURP in

many developing and even developed countries, as the percent of TVP in the late 1990's and early 2000 in Sweden [15], France [16], Italy [17] and the Mediterranean coasts ranged from 14% to 40% [18].

In 1992, Clavien et al. proposed a classification for complications of surgery and introduced a severity grading system called T92 [19], which was based on the main criterion of the intervention needed to resolve the complication. T92 Modification by Dindo et al was performed in 2004 to add further precision and to characterize whether an intervention due to the complication led to general anaesthesia, intensive care unit admission, or organ failure, and again, it was based on the type of therapy required to treat the complication [20]. This modified classification, which is known as the Clavien-Dindo system, was validated and tested for inter-observer variation in 10 centers around the world [21].

In our study the mean age of the patients was 69.4 ± 8.5 in between studies done by A. G Hill et al from Kenya (72.8 ± 0.8) [22] and C. K Oranusi et al from Nigeria (66.3±9.4) [22] year old. Also the range of co-morbidities 23% was in the range of the literature as of Hill's 25% [22].

Our patients had a prostate size more than 80 ml, and third of them had a size between 100 and 250, that was bigger than that mentioned in the literature. In contrast to that reported by Hill's which were 70.4 ±4.5ml. Significant amount of blood loss and the need for blood transfusion (intra and post operative) was noted in more than 20% in the study done by Oranusi et al [23], and higher (27%) in the AUA guide line report [25], where the rate was as high as 32% in our study, and that was relatively significant in correlation with the bigger size of the prostate volume, but no severe bleeding was not more than one liter.

SSI was higher (23%) in our study in comparison with the literature reported by Oranusi et al 6.9%. SSIs in our study were all superficial and treated at bedside with only one patient developed localized necrotizing fasciitis. As a result of that, 14% of our patients developed vesico-cutaneous fistulae extended the duration of catheterization. Correspondingly it was as low as 4.7%; [22] and 0.8% [23] as reported in the literature. Renal impairment was distinguished in 20 patients (10.6%), only 1.6% needed renal dialysis and the rest were treated conservatively.

Total complication rate was 47.6%, in 22.3% of the total, only one of the four complications was happened and 87.7% were multiple. The highest complication rate reported in the literature in was happened by Lund BL et al as 46.5% [25] but it was done on only 67 patients (i.e. only 35% of our patients).

In application of the Clavien-Dindo grading system of complications, grades II, IVa and V were only implicated in our patients. Grade V is death that happened in 2.6% of our patients. One of them developed myocardial infarction, and the others were occurred as a consequence of renal impairment in two and as a part of multi-organ dysfunction, one due to bleeding and the other due to sepsis. The rate was 0.9% by of Hill's [22]. Most importantly, the huge size of the prostate that we are dealing with for the time being is the biggest series in the literature with this prostatic size.

5. Conclusion

TVP still remains a valid surgical option in contemporary environments where advanced techniques for TURP and laparoscopic prostatectomy are unavailable. Most complications occur in our setting is consistent with the literature except the SSI (surgical site infection) rate. The Clavien–Dindo classification system promises to be a good system for assessing complications following prostatectomy. As a recommendation patients tracing for long term follow up of late complications, absence of national registry for most of them was a determinant limitation of our study.

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