

# Clinical Efficacy of “Modified Clavien Grading Classification” for Analysis of Post Surgical Morbidity in Male Urethral Stricture Disease & Its Clinico-Pathological Profile: An Ambispective Observational Study

Running Title: *Demographic-Etiological & Morbidity in Male Urethral Stricture Surgery*

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**Abstract:** ***Background & Aim:** Male urethral stricture disease (MUSD) is a prevalent urological condition characterized by fibrotic narrowing of the urethral lumen, often resulting in recurrent urinary symptoms and complications. Surgical management remains the definitive treatment, with variable outcomes based on technique, stricture characteristics, and patient factors. **Methods:** This observational study included 100 patients with MUSD treated either by internal optical urethrotomy (OIU) or urethroplasty (excision and primary anastomosis or substitution) at a tertiary care centre. Clinico-demographic, intraoperative, and post-operative data were collected retrospectively (n=84) and prospectively (n=16). Morbidity was assessed using the Modified Clavien-Dindo classification, and recurrence was defined by the need for any re-intervention within 2 months postoperatively. **Results:** The most common aetiology was infectious (33%), followed by trauma (27%) and iatrogenic causes (21%). Weak urinary stream (74%) and acute retention (60%) were the predominant symptoms. OIU was performed in 60% of patients, with a recurrence rate of 26.7%, significantly higher than EPA (7.1%) and substitution urethroplasty (8.3%) (p=0.024). Stricture length >2 cm was a significant predictor of recurrence in the OIU group (p<0.001). Most complications were Clavien-Dindo Grade I or II, with longer hospital stays observed in urethroplasty patients. **Conclusion:** OIU remains a feasible short-term option but is associated with high recurrence in long or complex strictures. Urethroplasty, especially EPA, offers superior outcomes with acceptable morbidity. Surgical planning guided by stricture characteristics is essential to optimize long-term success.*

**Keywords:** Male urethral stricture, urethroplasty, internal optical urethrotomy, surgical outcomes, stricture recurrence

## 1. Introduction

Male urethral stricture disease (MUSD) is a chronic urological condition characterized by narrowing of the urethral lumen due to fibrotic scarring of the subepithelial tissues within the corpus spongiosum[1]. This fibrotic process, known as spongiofibrosis, arises primarily from trauma, infection, or iatrogenic causes and results in obstructive voiding symptoms that significantly impair quality of life. Histologically, strictures are marked by replacement of the normal pseudo-stratified columnar epithelium with squamous metaplasia, contributing to luminal compromise and urinary complications[2]. While its

pathology may initially be asymptomatic, progressive fibrosis often leads to urinary retention, recurrent urinary tract infections, bladder decompensation, and in severe cases, upper urinary tract deterioration[3]. MUSD is relatively common, with a reported prevalence of 229–627 per 100,000 men, especially affecting older males. Most strictures are located in the anterior urethra- predominantly bulbar and penile segments- while posterior urethral stenosis, often a result of pelvic trauma or surgical interventions, is less frequent but more complex to manage[4]. In the Indian population, trauma, idiopathic causes, lichen sclerosis, and iatrogenic injuries such as TURP and catheterization are among the leading aetiologies. Notably, lichen sclerosis and traumatic presentations are

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more prevalent in India compared to Western cohorts[5]. Management of MUSD remains challenging due to its chronic nature, high recurrence rates, and procedural complications[6]. Treatment is typically reserved for symptomatic patients or those with complications. Initial management may include minimally invasive techniques such as urethral dilatation or optical internal urethrotomy (OIU); however, urethroplasty remains the gold standard, offering the most durable outcomes[7]. Urethroplasty techniques are tailored according to stricture characteristics that includes excision and primary anastomosis, non-transsecting approaches, and substitution methods using grafts or flaps[8]. Despite advancements, post-operative complications and recurrences remain significant concerns. Reported complications include erectile and ejaculatory dysfunction, fistula formation, and urinary incontinence[9]. Factors such as stricture length, location, degree of fibrosis, and patient comorbidities influence surgical outcomes[10]. Indian literature addressing the clinico-pathological spectrum and morbidity associated with MUSD is limited. This study aims to evaluate the clinico-pathological profile and surgical morbidity of MUSD in a tertiary care setting by analysing a decade-long retrospective dataset, with the goal of informing future surgical strategies and improving patient outcomes.

## 2. Materials and Methods

This observational study was conducted in the Department of General Surgery at UCMS & GTB Hospital over a period of 18 months. The study employed a combined retrospective and prospective design to evaluate the clinico-pathological profile and surgical morbidity associated with male urethral stricture disease (MUSD) managed with internal optical urethrotomy (IOU) or open urethroplasty. Retrospective data were collected for patients operated on between 30th October 2009 and 30th October 2019. Prospectively, patients were enrolled following the resumption of non-COVID clinical operations, with all relevant institutional ethical clearances and informed consents obtained.

Inclusion criteria consisted of male patients aged 18 to 80 years, diagnosed with MUSD, and operated on via IOU or urethroplasty during the specified retrospective or prospective periods. Patients were excluded if medical records were incomplete or if contraindications to either surgical procedure existed. The retrospective component involved reviewing medical records and operative theatre logs from January 2012 to March 2020. Prospectively enrolled patients were assessed with all necessary COVID-19 precautions. Data were collected on demographic details, aetiology, imaging findings (cystoscopy and cystourethrogram), stricture characteristics (site, length, number), surgical notes, and intra/peri-operative complications. Post-operative outcomes, including recurrence and the need for further interventions (dilatation, CIC, or repeat IOU), were assessed up to two months post-surgery. Follow-up data for retrospective cases were gathered via telephone where feasible. The study endpoint was defined as the time of discharge or documented recurrence of stricture requiring intervention within two months post-operatively.

*Sample Size Computation:* The sample size was estimated based on previous literature. For urethroplasty, Navai et al.[11] (2008) reported a 15% complication rate. Using Cochran's formula for sample size calculation at a 95% confidence level and 5% absolute precision, the initial sample size was calculated as 196. After applying Cochran's correction for finite population (assuming 40 eligible patients), the adjusted sample size was determined to be 33. For IOU, lacking existing complication data, a conservative estimate of 50% was used, yielding an initial sample size of 96 at 10% precision. This was adjusted to 37 using the finite population correction (assuming 60 patients). Accounting for potential losses due to incomplete records (10%), follow-up limitations (15%), and pandemic-related disruptions (15%), a buffer of 27.6 cases was added. Thus, the total sample size was rounded to a minimum of 100 patients (40 for open urethroplasty and 60 for IOU), with the possibility of additional recruitment subject to institutional ethics approval.

## 3. Results

The present study included 100 patients diagnosed with male urethral stricture disease (MUSD), of which 84 were retrospective and 16 were prospective cases. The mean age of patients was  $35.9 \pm 13.08$  years, with the majority of cases falling in the 25–45-year age group. Infectious (33%), traumatic (27%), and iatrogenic (21%) causes were the leading aetiologies. Clinically, weak urinary stream (74%) and acute urinary retention (60%) were the most frequent presenting complaints. Strictures were predominantly located in the anterior urethra (57%), with 86% being single and 73% measuring  $\leq 2$  cm. Partial strictures were more common (68%) than complete strictures. Table 1 depicts and summarizes the key clinico-demographic characteristics relevant to disease profile:

Patients were managed with either internal optical urethrotomy (OIU, 60%), excision and primary anastomosis urethroplasty (EPA, 28%), or substitution urethroplasty (12%). Duration of hospital stay significantly differed across surgical modalities ( $p < 0.001$ ), with a median of 1.5 days in OIU, 7 days in EPA, and 15 days in substitution urethroplasty. Post-operative complications varied significantly, as depicted in Table 2. OIU was associated with the highest recurrence rate (26.7%), significantly more than EPA (7.1%) and substitution urethroplasty (8.3%). Modified Clavien-Dindo grading showed that urethroplasty procedures were associated with a higher rate of Grade 2 complications (up to 50% in substitution urethroplasty,  $p < 0.001$ ), though most were medically managed. Risk factor analysis as depicted in Table-3, revealed that recurrence was significantly associated with stricture length  $> 2$  cm in patients undergoing OIU ( $p < 0.001$ ). Bulbomembranous location was significantly associated with a **lower** recurrence rate ( $p = 0.004$ ). No significant associations were found between recurrence and age, hypertension, comorbidity score, or aetiology.

In conclusion, OIU was associated with shorter hospital stays but higher recurrence, especially in long strictures. Urethroplasty, particularly EPA, offered better long-term outcomes but was associated with longer hospitalization and

a higher rate of early post-operative morbidity. Proper stricture assessment, particularly length and location, is critical in selecting the optimal surgical approach to reduce recurrence and complications.

#### 4. Discussion

Male urethral stricture disease (MUSD) remains a prevalent urological condition with significant morbidity due to its chronic nature and high recurrence rates. In this study, we evaluated the clinico-pathological profile and post-operative outcomes of 100 patients treated for MUSD at a tertiary care centre, aiming to identify complication patterns and predictors of recurrence across different surgical modalities.

The present study findings were consistent with earlier reports that show infectious, traumatic, and iatrogenic aetiologies as the predominant causes of urethral stricture [12,13]. In our cohort, infectious aetiology was the most common, reflecting regional variation in disease patterns, as also seen in the multicentric analysis by Stein et al. [14] (2013), which highlighted a higher burden of traumatic and LS-related strictures in India compared to the West.

The anterior urethra was the most frequently involved site, particularly the bulbar region, corroborating findings from Harraz et al. [15] (2015), Meeks et al. [16] (2009), and Pal et al. [17] (2015). Partial strictures were more common, and the majority were short ( $\leq 2$  cm). These anatomical characteristics directly influenced the choice of surgical management in our study, which included internal optical urethrotomy (OIU) in 60% of patients and urethroplasty (either excision and primary anastomosis [EPA] or substitution) in the remainder.

OIU is a widely performed intervention for select MUSD patients, due to its simplicity and low peri-operative morbidity [18,19]. However, our study found that OIU was associated with significantly higher recurrence rates (26.7%) compared to urethroplasty (10%). This aligns with prior research by Zehri et al. [20] (2020) and Pansadoro et al. [21] (1999), who observed recurrence rates of 37% and 68% respectively following OIU, particularly in long, multiple, or complex strictures. Mandhani et al. [22] (2011) also emphasized the importance of stricture severity—particularly luminal narrowing—as a predictor of adverse OIU outcomes, even when adjusted for stricture length and location.

The present study data revealed that stricture length  $>2$  cm was a significant predictor of recurrence in OIU cases ( $p < 0.001$ ), consistent with findings from Levy et al. [23] (2020) and Steenkamp et al. [24] (1997), who reported increased failure rates with longer strictures. In contrast, recurrence following urethroplasty was not significantly associated with length, number, or aetiology, suggesting the relative durability of reconstructive surgery in appropriate candidates.

Amongst urethroplasty types, EPA showed better long-term outcomes compared to substitution urethroplasty, which had higher rates of complications and a slightly elevated recurrence risk. Andrich et al. [25] (2003) similarly observed

that while anastomotic urethroplasty outcomes remain stable long-term, substitution urethroplasty deteriorates over time, with over 50% requiring reintervention by 15 years. In our cohort, early postoperative complications such as urinary tract infections were significantly more common in substitution urethroplasty (41.7%) compared to EPA (28.6%) and OIU (3.3%).

While urethroplasty is associated with longer hospital stay—averaging 9.18 days for EPA and 14.33 days for substitution procedures—it demonstrated significantly lower recurrence rates and was thus more cost-effective in the long term. These findings echo conclusions from Barbagli et al. [26] (2015) and Meeks et al. [16] (2009), who both highlighted the superior long-term outcomes of urethroplasty compared to endoscopic treatments.

Regarding post-operative morbidity, the majority of complications in our cohort were Clavien-Dindo Grade 1 or 2, consistent with complication profiles reported in studies by Hebert et al. [27] (2014) and Kolukcu et al. [28] (2021). Lumen et al. [29] (2013) similarly noted low-grade complications with non-transecting EPA, while D'hulst et al. [30] (2020) found only 2.1% Grade 2 and 4.2% Grade 3b complications, indicating the relative safety of reconstructive approaches. Though stricture recurrence was not significantly associated with most comorbidities, a notable exception was stricture location. Bulbomembranous strictures showed a significantly lower recurrence rate ( $p = 0.004$ ), as also observed by Lumen et al. [31] (2013), suggesting this location may be more amenable to surgical correction.

Recent studies reinforce the versatility of buccal mucosal grafts (BMGs) across urological reconstructive procedures. In a prospective single-centre study by Nasef et al. [8], the use of oral BMG for onlay urethroplasty in managing long-segment proximal ureteric strictures and recurrent ureteropelvic junction obstruction (UPJO) yielded an 85.7% stricture-free rate at a mean follow-up of 16.3 months. Despite involving complex cases, the approach maintained a favourable safety profile, with complications limited to Clavien-Dindo grade II and III events in under a third of patients. These findings support the adaptability of BMGs for upper tract reconstructions, particularly where traditional methods had failed.

A prospective randomized trial by Alrefaey et al. [1] comparing BMG and penile skin grafts (PSG) for anterior urethral augmentation urethroplasty, both techniques showed high and statistically comparable success rates (97.9% for BMG vs. 93.2% for PSG) over a median follow-up of 20 months. Functional outcomes—including IPSS, USS-PROM, IIEF, MSHQ-EJD, and Qmax, were also likewise similar. This reinforces the clinical equivalence of both graft types in long-segment anterior strictures, underscoring that graft selection may be tailored based on individual patient factors, graft availability, and surgeon expertise.

Finally, in the context of evolving management practices, Cabral et al. [2] observed a population-wide increase in urethroplasty rates and a corresponding decline in repeated endoscopic interventions following the 2016 AUA

guidelines. Their analysis of over 65,000 patients indicates a growing recognition of urethroplasty's durability and supports its integration earlier in the treatment pathway, particularly following initial endoscopic failure.

In summary, our study reinforces the prevailing consensus that while OIU offers short-term symptom relief with minimal hospitalization, it carries a substantial risk of recurrence- especially for long and complex strictures. Urethroplasty, particularly EPA, remains the gold standard for durable repair of anterior urethral strictures, with a favourable balance between recurrence and morbidity. Selection of surgical modality must therefore be individualized based on stricture characteristics, patient comorbidity, and resource availability.

**Limitations:** This study, while comprehensive, has a few limitations. First, its retrospective design for the majority of cases may have introduced selection and recall bias due to incomplete or missing records. Second, the sample size of prospectively followed patients was limited due to the COVID-19 pandemic, potentially affecting the generalizability of postoperative outcomes. Third, long-term follow-up beyond two months was not uniformly available for all patients, limiting the assessment of late recurrences. Lastly, certain variables such as sexual dysfunction and quality of life post-surgery were not included, which could have provided deeper insight into the functional outcomes of different surgical modalities.

**Conclusions:** Male urethral stricture disease remains a significant cause of morbidity, with infectious, traumatic, and iatrogenic aetiologies being most prevalent in our cohort. Internal optical urethrotomy, although simple and commonly performed, is associated with higher recurrence, particularly in strictures longer than 2 cm. Urethroplasty, especially excision and primary anastomosis, demonstrated superior long-term outcomes with fewer recurrences and acceptable morbidity. Proper selection of surgical technique based on stricture characteristics is critical to optimize patient outcomes. This study emphasizes the need for timely intervention, appropriate surgical planning, and long-term follow-up to improve success rates in the management of MUSD.

## 5. Ethical Statements

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**Author Contributions:** The authors confirm their contribution as follows: Study conception, Design & Supervision: IS ; Data collection: MC, IS ; Draft manuscript preparation: IS, HA, NP, MC ; Data Analysis & Statistics & References: NP, MC ; Review of the results & approval of the final version of the manuscript: All authors.

**Availability of Data and Materials:** The data that support the findings of this study are available from the corresponding author (IS) upon reasonable request.

**Ethics Approval:** The Institutional Ethics Committee – Human Research (IEC-HR) of University College of Medical Sciences, University of Delhi, Delhi – 110095, vide No **IECHR/2020/PG/47/23** dated 21.12.2020, approved the study protocol from ethical angle. All patients participating in the study gave written and informed consent.

**Conflicts of Interest:** The authors (s) individually declare that they have no conflicts of interest for the present study.

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### Legends For Figure & Tables

**Figure- 1:** Depicting flow of current study protocol

**Table I:** Clinico-Demographic Profile of Male Urethral Stricture Disease(MSUD) Patients

**Table II:** Post-operative Morbidity of MUSD–Operative Procedure wise

**Table III:** Significant Risk Factors For Post-Op Recurrence of MUSD

**Table IV:** Review of Important Published Studies MSUD

**Table-I:** Clinico-Demographic Profile of 100 Patients with MUSD

VARIABLE	FREQUENCY (%)
<b>ETIOLOGY</b>	
Infectious	33 (33.0%)
Trauma	27 (27.0%)
Iatrogenic	21 (21.0%)
Idiopathic	12 (12.0%)
<b>CLINICAL PRESENTATION</b>	
Weak Stream	74 (74.0%)
Acute Urinary Retention	60 (60.0%)
Increased Frequency	43 (43.0%)
Burning Micturition	16 (16.0%)
<b>STRICTURE CHARACTERISTICS</b>	
Anterior Location	57 (57.0%)
Length ≤2 cm	73 (73.0%)
Partial Type	68 (68.0%)

**Table-II: Post-Operative Morbidity by Surgical Modality**

COMPLICATION TYPE	OIU (N=60)	EPA (N=28)	SUBSTITUTION (N=12)	P-VALUE
<b>IMMEDIATE</b>				0.021
No Complication	78.3%	96.4%	75.0%	
Hematuria	20.0%	0.0%	16.7%	
<b>EARLY (UTI, FEVER)</b>				<0.001
No Complication	96.7%	67.9%	58.3%	
UTI	3.3%	28.6%	41.7%	
<b>LATE (RECURRENCE)</b>				0.024
Recurrence	26.7%	7.1%	8.3%	

**Table-III: Significant Risk Factors for Post-Operative Recurrence**

RISK FACTOR	RECURRENCE RATE (%)	P-VALUE
Stricture Length >2 cm (OIU only)	100.0%	<0.001
<b>Bulbomembranous Location</b>	5.0%	0.004
Charlson Comorbidity Score ≥1	No significant association	0.349
Age, Hypertension, Etiology	No significant association	>0.05

**Table IV: Summary of IMP Published Studies**

Author	Title / Topic	Type	Size	Focus/Aim	Salient Conclusions
Pansadoro, 1999	Post-OIU Recurrence	PS	224	Anterior SU	68% recurrence after 1st OIU; repeat OIU not effective
Andrich DE, 2003	Anastomotic vs Substitution Urethroplasty	RS	200	Long-term efficacy comparison	Substitution deteriorates over time; higher complications
Steenkamp JW,1997	OIU vs Dilation	RCT	210	Comparative outcomes	Long strictures associated with higher recurrence
Santucci R, 2007	Efficacy of repeat OIU	RS	136	Repeat OIU outcomes	Stricture-free rate drops with each repeat procedure
Meeks JJ, 2009	Stricture recurrence & complications	SR	86	Recurrence post-urethroplasty	15.6% recurrence higher with long penile strictures
Barbagli G, 2015	Transsecting vs Non-transsecting EPA	SR	926	Surgical outcomes in non-traumatic strictures	Comparable success (90–98.6%)
Harras NA, 2015	Site-specific stricture analysis	RS	430	Stricture location & symptoms	Most common site, bulbar urethra
Pal A, 2015	OIU outcomes in Anterior SU	RS	186	Site, cause, predictors of recurrence	Bulbar strictures most common; inflammation key etiology
Zehri AA, 2020	Recurrence predictors post OIU	RS	148	Demographics and outcomes	37% recurrence; mean 4.5 months to recurrence
Levy M, 2020	Predictors of success in urethroplasty	RS	MIS	Predictors of graft success	Short strictures (<2.5 cm) more likely to succeed
Lumen N, 2013	Non-transsecting EPA for short bulbar strictures	PS	75	Complication & recurrence	8% recurrence; UTI, extravasation as predictors
D’hulst C, 2020	Complications in EPA	PS	-	Grading of post-op complications	Grade 2: 2.1%, Grade 3b: 4.2%
Hebert K, 2014	Clavien-Dindo complications in urethroplasty	PS	57	Post-op complication spectrum	24% had complications; mostly Grade 1 or 2
Kolukcu A, 2021	BMG complications graded	PS	62	Post-op morbidity in BMG	Mostly Grade 1 or 2; rare Grade 3a
Mandhani A, 2011	Predicting OIU outcomes with RGU	PS	105	Lumen narrowing and outcomes	% Narrowing predicts failure better than length alone
Lumen et al, 2013.	Etiology-location correlation	PS	268	Location vs cause	Idiopathic and iatrogenic common; regional patterns
Barbagli G, 2015	Substitution urethroplasty outcomes	RS	359	Graft success in substitution	Oral mucosa superior to penile skin over time
Song L, 2020	National registry analysis	RS	4764	Stricture patterns & surgical choice	Trauma and iatrogenic most common; OIU most used
Nasef AS, 2025	BMG in Onlay Ureteroplasty	PS	21	Recurrent proximal ureteric strictures	85.7% stricture-free; safe and effective
Alrafeay A	BMG vs PSG in AU	RCT	98	Graft type comparison	Success: BMG (97.9%) vs PSG (93.2%)
Cabral JD, 2025	Trends post-AUA guidelines	RS	65,333	AUA guidelines impact	Urethroplasty use ↑ post-2016; repeat OIU ↓
Present Study	OIU Vs End to End Anastomotic/Substitution Urethroplasty	AS	100	Morbidity Comparison using Modified Clavien Dindo Score	OIU -Associated with ↓hospital stay but ↑recurrence, esp in long strictures. Urethroplasty (EPA), offered better long-term outcomes but was assoc with ↑ hospital stay & ↑ Early Post-Op Morbidity

PS: Prospective Study; RS: Retrospective Study, RCT: Randomised Controlled Trial, SR: Systematic Review MIS: Multi-Institutional Study; ASA: Abispective Study

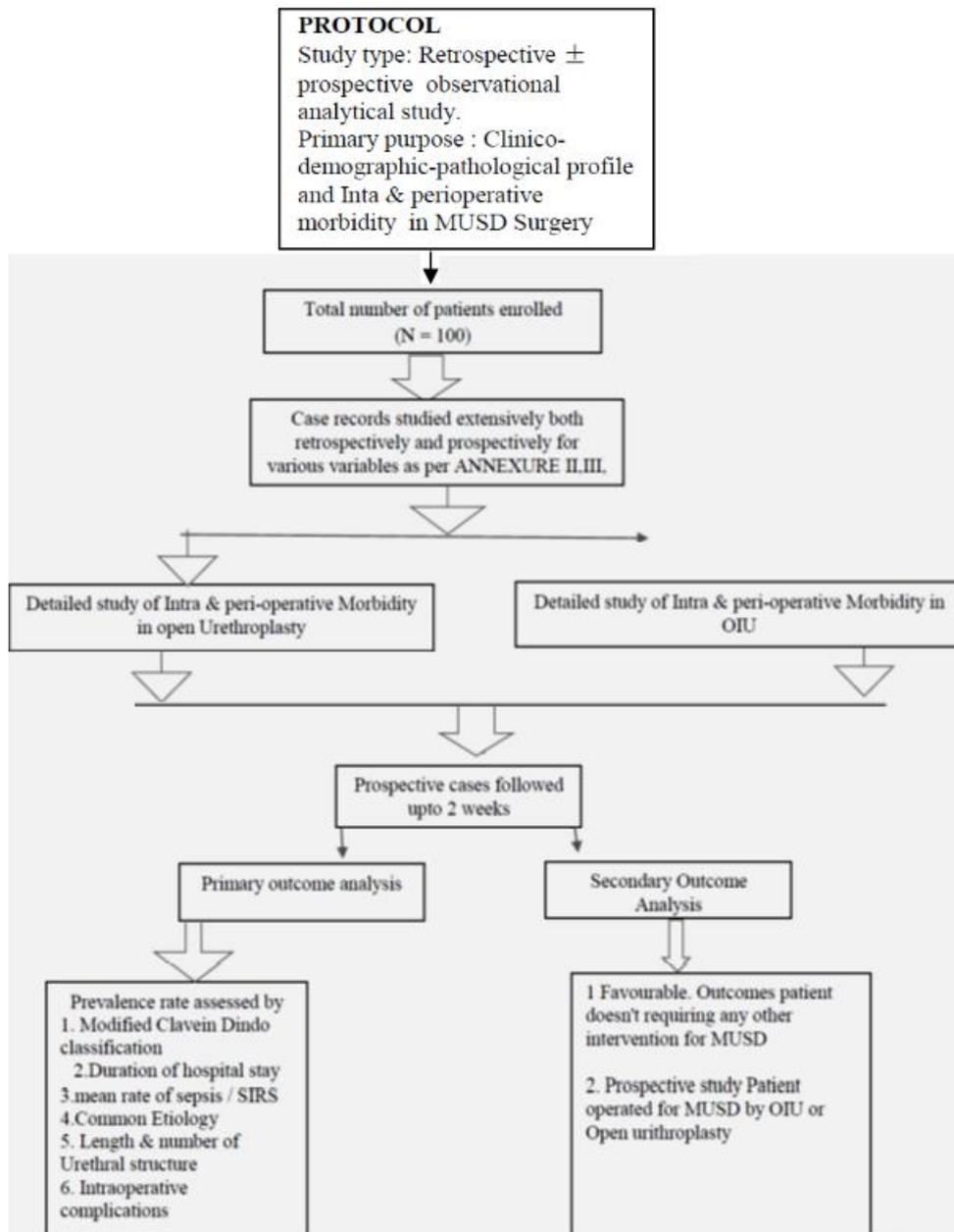


Figure 1: Figure Depicting Flow of the Current Study Protocol