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Comparative Evaluation of Urodynamic Study in Women With and Without Uterovaginal Prolapse

Dr. Ayindrila Das[1], Dr. Usha Rani[2], Dr. Paridhi Garg[3], Dr. Soumit Dey[4]

[1]Post Graduate Resident, Department of Obstetrics and Gynaecology, Rama Medical College, Hospital and Research Centre, Hapur, Uttar Pradesh, 245304
Email: *ayindrila2011[at]gmail.com*

[2]Assistant Professor, Department of Obstetrics and Gynaecology, Rama Medical College, Hospital and Research Centre, Hapur, Uttar Pradesh 245304
Email: *usha2k3medico[at]gmail.com*

[3]Professor, Department of Obstetrics and Gynaecology, Rama Medical College, Hospital and Research Centre, Hapur, Uttar Pradesh 245304
Email: *dr2pir[at]gmail.com*

[4]DrNB Trainee, Department of Burns, Plastic & Microvascular Surgery, Maulana Azad Medical College and Lok Nayak Hospital, New Delhi, 110002
Email: *drsoumitdey100[at]gmail.com*

Abstract: ***Introduction: Pelvic organ prolapse (POP) is the descent of vaginal walls, uterus, or vaginal apex and is classified using the POP-Q system. POP often affects urinary function, causing incontinence or obstruction. Urodynamic study (UDS) provides objective insight into bladder and urethral function which are essential in the assessment and diagnosis of patients presenting with lower urinary tract dysfunction. This study compares the UDS in women with and without prolapse. Aim: To study and compare the prevalence of urodynamic changes in women with and without uterovaginal prolapse. Objectives: 1) To evaluate urodynamic study profile in women with uterovaginal prolapse. 2) To correlate degree of prolapse (POP-Q Classification) with urinary incontinence. 3) To compare urodynamic study profile in women with and without uterovaginal prolapse. Methodology: Case control study conducted at Rama Medical College Hospital and Research Centre from April 2023 to September 2024, recruiting 40 women with 2°/3° uterovaginal prolapse and 40 women without uterovaginal prolapse of any age and parity seeking care in this hospital. Data collected by semi- structured interviews, pre-designed questionnaire, physical examination, laboratory tests, pelvic ultrasound and urodynamic study was analysed in SPSS software version 29. A p value <0.05 was considered significant. Results: In this study, pelvic organ prolapse patients (mean age 53.9)—mostly aged 51–60, had higher parity (70% ≥3), and more advanced POP-Q stages: Stage III in 43.75%. They experienced urinary hesitancy (27.5%), incomplete bladder evacuation (25%), lower peak voiding flow (~18.9 ml/s), reduced bladder compliance (~30.8 ml/cm H_2O), elevated post-void residual (~91.8 ml), lower bladder capacity and altered detrusor pressures—contrasting sharply with younger, lower-parity, healthier controls. Conclusion: Prolapse patients had higher parity, lower compliance, reduced peak flow rate, and increased hesitancy (27.5%) and incomplete evacuation (25%). Significant differences in detrusor pressure, urge volumes, and incontinence rates highlight the need for further research.***

Keywords: Uterine Prolapse, Urodynamic study, Uroflowmetry, Cystometry

1. Introduction

Prolapse literally means 'to fall out of place'. Pelvic organ prolapse (POP) is defined as the downward displacement of one or more of the anterior or posterior vaginal wall, the uterus (cervix) or the apex of the vagina (vaginal vault or cuff scar in post- hysterectomy individuals). This descent may lead to the protrusion of the vaginal walls or uterus, or both. The uterine support system and the vaginal support system are different from each other, based on three different levels. Level I, comprises of the uterosacral ligament and cardinal ligament complex. This complex keeps the vaginal length and direction. At level II, support comes from the lateral vaginal ligaments and the endopelvic fascia connecting to the arcus tendinous. The vagina stays in the midline position. The level III support which includes the muscles and connective tissue that covers the support to the distal vagina and the perineum.

A method called POP-Q, which stands for Pelvic Organ Prolapse Quantification, is being backed by the International Continence Society right now. There are six reference points along the vagina that are used for the labeling process. Two of these reference points are on the front, middle, and back sections, and they are measured in relation to the hymen. The six sites must be measured in millimeters, with a negative value indicating closer to the hymen and a positive value indicating farther away from the hymen. The plane at which the hymen lies must be used as the reference point where the measurement starts at zero. The extra measures that are part of the POP-Q system are genital hiatus, perineal body, and total vaginal length.

STAGES OF PELVIC ORGAN PROLAPSE

Stage 0	Prolapse is not demonstrated. The points Aa, Ap, Ba, Bp are all at -3cm, and the point C is between the total vaginal length (TVL) and -(TVL- 2 cm).
Stage I	Most distal portion of the prolapse is greater than 1 cm above the level of hymen.
Stage II	The most distal portion of the prolapse is less than 1 cm proximal or distal to the plane of hymen.
Stage III	The most distal portion of the prolapse is less than 1 cm below the plane of the hymen but no further than 2cm less than TVL.
Stage IV	Complete to nearly complete eversion of the vagina. The most distal portion of the prolapse protrudes to greater than TVL - 2cm.

Pelvic organ protrusion and urinary complaints are hard to understand. The bladder and urethra are held up by the front wall of the vaginal canal. Not having enough support can make the urethra very mobile and cause a cystocele to form, which can cause stress urinary incontinence. According to prior researches, a lot of women with moderate prolapse have problems with stress urine leakage. Patients with serious prolapse are more likely to develop obstructive symptoms but not urine incontinence because their lower urinary tract is skewed. Women who have higher degrees of pelvic organ prolapse may not realize they have stress incontinence because of the way their bladder is curved or compressed. Once the prolapse is reduced, the leakage may become clear . Urge incontinence has been linked to both anterior vaginal wall prolapse as well as posterior vaginal wall prolapse in several studies conducted. However, symptoms such as frequency or urgency or urge incontinence may not always be related to pelvic organ prolapse in females and need different tailored treatment. Anterior wall prolapse or vaginal wall prolapse can block the urethra or cause the bladder trigone to collapse, which can lead to signs of an overactive bladder (OAB). A bladder that exerts excessive effort to compensate for increased resistance may eventually alleviate the obstruction. Lower urinary tract symptoms (LUTS) and female pelvic organ prolapse (POP) may be caused by the same etiology, which explains why they often happen together. The ICS has broadly grouped LUTS into three categories, related to their timing within the bladder (voiding) cycle as follows**.**

Storage	Voiding	Post-Micturation
Urgency	Hesitancy	Feeling of incomplete emptying
Increased daytime frequency	Intermittency	
Nocturia	Slow stream	
Altered bladder sensation	Splitting or spraying	Post-micturition dribble
	Straining	
	Terminal dribble	

Urodynamic studies (UDS) are special diagnostic tests that can help in evaluating the lower urinary tract dysfunction. UDS is a helpful tool for better understanding of the etiology of lower urinary tract dysfunction providing objective information regarding the normal and abnormal function. So UDS can be beneficial in the assessment and diagnosis of patients presenting with lower urinary tract dysfunction. It can help in the diagnosis of storage or emptying problems such as urinary incontinence, voiding dysfunction, obstruction, etc in patients presenting with these symptoms. The clinical applications of UDS can give broader perspective in diagnosing and guided treatment options in these category of individuals. However, consensus is lacking on which patients and for which particular voiding symptoms UDS should be routinely performed and various guidelines, e.g., NICE have reflected on the matter.

The information received from accurate interpretation and well-performed urodynamic studies can be used to diagnose the underlying cause of the lower urinary tract dysfunction, characterizing the lower urinary tract dysfunction, formulating treatment strategies may improve therapeutic outcomes and educate patients regarding their problems.

In addition to UDS, Uroflowmetry can be done for measurement of the rate of flow of urine expelled via the urethra (the external urinary stream) during voiding. This gives an assessment of voiding in a simple, non-invasive, and relatively inexpensive way compared to UDS. Residual volume is the volume in the bladder immediately

Cystometry monitors bladder pressure and voiding function simultaneously, allowing it to identify the malfunction to the bladder or bladder outlet/urethra, unlike uroflowmetry. Cystometry can provide a pathophysiological diagnosis for lower urinary tract symptoms (LUTS) and valuable information regarding how the bladder cycle works during storage and voiding.

Pressure/flow cystometry is split into two phases mirroring the normal bladder cycle. The urethral and the detrusor function should be evaluated in both phases.

Aim

To study and compare the prevalence of urodynamic changes in women with and without uterovaginal prolapse**.**

Objectives

1) To evaluate urodynamic study profile in women with uterovaginal prolapse.
2) To correlate degree of prolapse (POP-Q Classification) with urinary incontinence.
3) To compare urodynamic study profile in women with uterovaginal prolapse and women without uterovaginal prolapse.

2. Methodology

Study Design

This study was a Case control study.

Study Area

The study was conducted on women attending Gynaecology OPD in Rama Medical College Hospital and Research Centre, Hapur-245304

Study Population

A minimum of 40 women with 2°/3° uterovaginal prolapse and 40 women without uterovaginal prolapse of any age and

parity seeking care in Rama Medical College Hospital & Research Centre between April 2023 and October 2024 were enrolled into the study.

Sample Size: 80

Proportion (n) = Z21-α P (1-P)/d2 P – Estimated proportion
d – desired precision
n = (1.96)2 x 0.15 x 0.85 / (0.08 x 0.08)
= 3.8416 x 0.1275 / 0.0064
= 76.53

Study Period
The study period was 18 months (April 2023-September 2024).

Inclusion Criteria
Cases- Women with 2°& 3° uterovaginal prolapse of all age group and parity.
Controls- women without any uterovaginal prolapse of all age group and parity.

Exclusion Criteria
Women with 1° uterovaginal prolapse
Urinary tract infection.
Any urinary tract anomaly such as diverticula.
Bladder calculi.
Major degrees of hydronephrosis.
Stenosis or strictures of urethra.
Any related medical conditions like Diabetes Mellitus or Neurological diseases.
Vaginal surgery in the past.

Statistical Evaluation:
Data collected was subjected to statistical analysis and then relevant statistical tests was applied, then was entered in MS Excel and was analyzed in SPSS software version 29. P value <0.05 was considered significant during data analysis.

Ethical Consideration
This study was conducted after the approval from the institutional ethics committee and all the collected data used for the purpose of this study was kept strictly confidential. Written informed consent (in English/Hindi) was taken from the subjects and/or their attendants before the recruitment of the subjects in the study.

Figure 1: Urodynamics Machine (Advin Healthcare)

Figure 2: Uroflowmeter

3. Results

Patients Characteristics:

Table 1: Age (In Years)

Age in Group	Prolapse	%	Without Prolapse	%	Total
≤30	0	0	17	42.5	17
31-40	1	2.5	23	57.5	24
41-50	12	30	0	0	12
51-60	19	47.5	0	0	19
61-70	8	20	0	0	8
Total	40	100	40	100	80

The mean age of the group of patients with prolapse was 53.9 years while the mean age of the group of patients without prolapse was 32 years. Majority of patients with prolapse

belong to age group 51-60 years and patients without prolapse mostly were in the age group 31-40.

The prevalence of prolapse in our study was 6.5 % (30-40 years), 15 % (41-50 years), 23.75 % (51-60 years), 10 % (61-70 years).

Table 2: Parity

Parity	Prolapse	%	Without Prolapse	%	Total
1	0	0	1	2.5	1
2	3	7.5	19	47.5	22
3	9	22.5	11	27.5	20
4	14	35	6	15	20
5	9	22.5	3	7.5	12
6	3	7.5	0	0	3
7	1	2.5	0	0	1
8	1	2.5	0	0	1
Total	40	100	40	100	80

70 % patients with prolapse had parity ≥3 whereas 50% patients without prolapse had parity ≤2.

Odds Ratio: 1.0000 (0.1894, 5.2801

Table 3: Stage of Prolapse (POP-Q SYSTEM)

Stage of Prolapse	Prolapse	%	Without Prolapse	%	Total	%
0	0	0	36	90	36	45
1	0	0	4	10	4	5
2	5	12.5	0	0	5	6.25
3	35	87.5	0	0	35	43.75
Total	40	100	40	100	80	100

Distribution of patients according to POP-Q system is as follows: Stage 0= 45%, Stage I= 5%, Stage II=6.25% & Stage III= 43.75%

Urinary Complaints

Table 4: Prevalence of SUI

SUI	Prolapse	%	Without Prolapse	%	Total
Absent	37	92.5	37	92.5	74
Present	3	7.5	3	7.5	6
Total	40	100	40	100	80

This study shows that stress incontinence as presenting symptoms in 3 patients (7.5%) with prolapse and also in patients without prolapse.

Chi-square value: 0.0000; p-value: 1.0000
Odds Ratio: 1.0000 (0.1894, 5.2801)

Table 5: Prevalence of UI

UI	Prolapse	%	Without Prolapse	%	Total
Absent	37	92.5	39	97.5	76
Present	3	7.5	1	2.5	4
Total	40	100	40	100	80

Urge Incontinence was seen in 3 patients with prolapse (7.5 %) and only in 1 in patient without prolapse (2.5 %).

Chi-square value: 1.0526; **p-value:** 0.3049
Odds Ratio: 0.3162 (0.0315, 3.1779)

Table 6: Prevalence of Hesitancy

Hesitency	Prolapse	%	Without Prolapse	%	Total
Absent	29	72.5	40	100	69
Present	11	27.5	0	0	11
Total	40	100	40	100	80

Hesitancy was present in 11 patients in prolapse group of patients (27.5 %) whereas no patients in without prolapse group had complaints of hesitancy.

Chi-square value: 12.7536; **p-value: 0.0003**

Table 7: Prevalence of Incomplete Evacuation

Incomplete Evacuation	Prolapse	%	Without Prolapse	%	Total
Absent	30	75	40	100	70
Present	10	25	0	0	10
Total	40	100	40	100	80

In this study it showed that complaints of incomplete bladder evacuation was found in 10 patients (25%) compared to no complaints of incomplete evacuation in without prolapse group of patients.

Chi-square value: 11.4286; **p-value: 0.0007**

Uroflowmetry

Table 8: Peak Flow Rate (Qmax) on Uroflowmetry

Qmax (ml/s)	Prolapse	%	Without Prolapse	%	Total
0-10	8	20	0	0	8
11-20	20	50	27	67.5	47
21-30	8	20	11	27.5	19
31-40	4	10	2	5	6
Total	40	100	40	100	80

The mean peak flow rate was 18.90ml/sec in patients with prolapse and 21.025 ml/sec in patients without prolapse.
Chi-square value: 11.4286; **p-value: 0.0007**

Cystometry -Filling Phase

Table 9: Filling /Storage Detrusor Pressure (Pdet(S))

Pdet(s)	Prolapse	%	Without Prolapse	%	Total
0-5	9	22.5	2	5	11
6-10	19	47.5	16	40	35
11-15	7	17.5	8	20	15
16-20	5	12.5	14	35	19
Total	40	100	40	100	80

In the present study mean maximum filling detrusor pressure was 9.025 cm H2O in patients with prolapse as compared to 12.375 in patients without prolapse.

Table 10: Compliance

Compliance (ml/cm H2O)	Prolapse	%	Without Prolapse	%	Total
0-15	3	7.5	0	0	3
16-30	17	42.5	2	5	19
31-45	15	37.5	29	72.5	44
46-60	4	10	7	17.5	11
61-90	1	2.5	2	5	3

In this study the compliance in the prolapse group was 30.80 ml/cm H2O as compared to 43.60 ml/cm H2O in patients without prolapse.

Table 11: Leakage of Urine

Leakage	Prolapse	%	Without Prolapse	%	Total
Absent	36	90	40	100	36
Present	4	10	0	0	4
Total	40	100	40	100	40

In present study 4 patients were diagnosed to have incontinence during cystometrography

Table 12: First Urge to Void

First Urge to Void (ml)	Prolapse	%	Without Prolapse	%	Total
0-100	3	7.5	0	0	3
101-200	8	20	0	0	8
201-300	14	35	29	72.5	43
301-400	11	27.5	11	27.5	22
401-500	4	10	0	0	4
Total	40	100	40	100	80

In the present study, the mean volume at first urge to void was 257.8750 in patients with prolapse and 295.3750 in patients without prolapse.

Table 13: Strong Urge to Void

Strong Urge to Void (ml)	Prolapse	%	Without Prolapse	%	Total
0-100	2	5	0	0	2
101-200	4	10	0	0	4
201-300	4	10	2	5	6
301-400	17	42.5	26	65	43
401-500	10	25	11	27.5	21
501-600	3	7.5	1	2.5	4
Total	40	100	40	100	80

Strong urge to void was seen at 354.1250 ml in patients with prolapse, whereas it was 390.6250 ml in patients without prolapse.

Table 14: Maximum Cystometric Capacity (MCC)

Max Capacity (ml)	Prolapse	%	Without Prolapse	%	Total
0-100	1	2.5	0	0	1
101-200	1	2.5	0	0	1
201-300	5	12.5	0	0	5
301-400	8	20	5	12.5	13
401-500	11	27.5	22	55	33
501-600	11	27.5	13	32.5	24
601-700	1	2.5	0	0	2
701-800	2	5	0	0	2
Total	40	100	40	100	80

The mean MCC in patients with prolapse was 439.625 ml and that in patients without prolapse was 481.00 ml.

Table 15: Unstable Detrusor Contractions

Unstable Detrusor Contractions	Prolapse	%	Without Prolapse	%	Total
Absent	38	95	40	100	78
Present	2	5	0	0	2
Total	40	100	40	100	80

Unstable detrusor contractions were seen only in 5% patients in association with urinary incontinence in the prolapse patients and none in without prolapse group in this study.
Chi-square value: 2.0513; **p-value:** 0.1520

Cystometry -Voiding Phase

Table 16: Peak Detrusor Pressure (Pdet (v))

Pdet (v) cm H_2O	Prolapse	%	Without Prolapse	%	Total
0-20	0	0	0	0	0
21-40	26	65	21	52.5	47
41-60	14	35	19	47.5	33
Total	40	100	40	100	80

In this study significant changes was seen in peak detrusor pressure during voiding with p value of 0.0034. The mean Pdet(v) was 38.0750 in patients with prolapse whereas it was 43.2500 in patients without prolapse.

Table 17: Detrusor Pressure at Peak Flow Rate

Pdet at Qmax (cm H2O)	Prolapse	%	Without Prolapse	%	Total
0-20	0	0	0	0	0
21-40	26	65	21	52.5	47
41-60	14	35	19	47.5	33
Total	40	100	40	100	80

In the present study the detrusor pressure at peak flow was 31.1500 cm H2O in the patients with prolapse and 31.8250 cm H2O in patients without prolapse with p value of 0.7349. This variation in findings was not significant.

Table 18: Peak Flow Rate (Qmax)

Qmax (ml/s)	Prolapse	%	Without Prolapse	%	Total
0-10	6	15	0	0	6
11-20	17	42.5	27	67.5	44
21-30	14	35	11	27.5	25
31-40	3	7.5	2	2	5
Total	40	100	40	100	80

During voiding studies Qmax was 20.8250 ml/sec in patients with prolapse and 20.4 ml/sec in patients without prolapse. The p value being 0.7863 with no significance in the present study.

Table 19: Average Flow Rate (Qav)

Qav (ml/s)	Prolapse	%	Without Prolapse	%	Total
0-10	26	65	8	20	34
11-20	13	32.5	32	80	45
21-30	1	2.5	0	0	1
Total	40	100	40	100	80

The mean Qav for patients with prolapse is 11.3250, whereas the mean is 13.9750 in patients without prolapse. The p value being **0.0034**. This tend to suggest that overall micturition time is better in patients without prolapse.

Table 20: Post-Void Residual Volume

PVR	Prolapse	%	Without Prolapse	%	Total
0-50	17	42.5	38	95	55
51-100	6	15	2	5	8
101-150	9	22.5	0	0	9
151-200	6	15	0	0	6
201-250	2	5	0	0	2
Total	40	100	40	100	80

In this study the mean PVR in prolapse group was 91.7750, whereas the mean PVR in patients without prolapse was 28.50 with a p value- **<0.0001**. This confirms improper bladder evacuation in patients with prolapse.

Summary of Results of Urodynamic Studies

	Prolapse Mean+/- S.D	Without Prolapse Mean+/- S.D	p-value
Qmax(Uroflowmetry) -mL/s	18.90 +/- 7.8309	21.0250+/-4.7203	0.1456
Max. Pdet(s) - cm H2O	9.0250 +/- 4.3352	12.3750+/-4.3364	**0.0009**
Compliance - mL/cm H2O	30.80 +/- 11.3662	43.60 +/- 9.1534	**<0.0001**
First urge to void - mL	257.875 +/-113.6227	295.3750 +/-41.9002	0.0538
Strong urge to void - mL	354.1250+/-115.5360	390.6250 +/-54.7042	0.0748
MCC – mL	439.625+/-139.6212	481.00 +/- 60.9666	0.0898
Max Pdet (v) - cm H2O	38.0750+/-8.3217	43.25 +/- 6.9384	**0.0034**
Pdet at Q MAX - cm H2O	31.15+/-9.5315	31.8250+/-8.1803	0.7349
Qmax(Cystometry) -mL/s	20.8250+/-8.5751	20.40+/-4.9084	0.7863
Qav(Cystometry) -mL/s	11.3250+/-4.8219	13.9750+/-2.7502	**0.0034**
PVR Volume - mL	91.7750+/-70.2933	28.50+/-20.0064	**<0.0001**

4. Discussion

Prolapse of pelvic organ is a noteworthy health related issue affecting lifestyle of women globally, and this study—conducted at Rama Medical College Hospital & Research Centre, Hapur—compared 40 women with 2° and 3° uterovaginal prolapse to 40 without prolapse to investigate urodynamic parameters and clinical characteristics. The prolapse group had a mean age of 53.9 years, mostly in the 51–60 age range, while the non-prolapse group averaged 32 years, predominantly aged 31–40. A notable observation was that 70% of prolapse patients had higher parity (≥3), as opposed to 50% with lower parity (≤2) in the non-prolapse group. POP-Q staging showed more patients in advanced stages in this Indian cohort compared to international studies. Urinary complaints such as hesitancy, incomplete evacuation, and urge incontinence were more common in the prolapse group. While peak flow rate was slightly lower in prolapse patients, statistically significant differences emerged in maximum filling detrusor pressure, bladder compliance, and post-void residual volume, indicating compromised bladder mechanics. Incontinence diagnosed during cystometrography occurred in four prolapse patients, with detrusor overactivity and stress incontinence observed. Though bladder sensations, average flow rate, and detrusor pressures at Qmax showed variable significance, overall the data suggest that advanced prolapse adversely affects bladder function and voiding efficiency. These findings were supported and contrasted with previous research, underlining the need for further investigation into urodynamic behavior in prolapse patients.

5. Conclusion and Recommendations

A total of 40 women with 2°/3° uterovaginal prolapse and 40 women without uterovaginal prolapse of any age and parity seeking care in Rama Medical College Hospital & Research Centre between April 2023 and October 2024 underwent urodynamic evaluation to study the urodynamic changes in these two comparrison groups.

The mean age of the group of patients with prolapse was 53.9 years while the mean age of the group of patients without prolapse was 32 years. Majority of patients with prolapse belong to age group 51-60 years and patients without prolapse mostly were in the age group 31-40.

The study reveals that 70 % patients with prolapse had parity ≥3 whereas 50% patients without prolapse had parity ≤2 and majority of them belonged to POP-Q stage III (43.75%).

This is probably because patients are hesitant to consult at a younger age or at an early stage due to shyness, lack of family support, money, time or lack of availability of heath facilities and more importantly due to lack of awareness.

The statistically significant parameters in urodynamic study in this research work were hesitency (0.0003), incomplete evacuation (0.0007), maximum filling detrussor pressure (0.0009), compliance (0.0001), mean maximum Pdet (0.0034), mean Qav (0.0034), mean PVR (0.0001).

Not much studies have been conducted in patients without prolapse in comparison to studies with prolapse patients. Patients with prolapse must be evaluated with urodynamic studies for better treatment options.

Further more studies are required in future with bigger sample size, blinding at different levels of study.

Advanced modalities for UDS evaluation need to be implemented in patients coming with complaints of LUTS whether they have complaints of prolapse or not.

In future randomised control trial is necessary to determine whom to advise UDS.

Meta analysis studies are also required for more concrete results and advancement in management of LUTS related problems in women with prolapse or without prolapse.

6. Limitations

1) Although the sample size in the study was adequate for some of the statistical analyses, a larger sample size would provide more compelling data, especially when comparing patients with prolapse and without prolapse on the basis of urodynamic studies since very few reseach work has been done on role of urodynamic study on patients without prolapse. Smaller sample size may limit the universality of findings to a larger population.
2) The study design being case control done in a single institution may limit the extensibility of the study findings to different populations or regions. Multicentre studies involving diverse population would help validate these findings and provide a broader perspective.
3) Differences in patient demographic or clinical characteristics between study groups could influence outcomes.
4) Subjective Variability – Patient-reported symptoms and examiner interpretations in urodynamic studies may introduce bias.
5) Technological Limitations – Variations in urodynamic equipment and techniques may affect measurement accuracy.
6) This study was done only on urodynamic findings. Lack of availability of advanced urodynamics machines which includes electromyography is a major limitation. Electrical activity measurement of the muscles and nerves in and around bladder and sphincters could have given better results to this study. Video urodynamics study could have given more accurate findings.
7) Exclusion Criteria – Patients with specific comorbidities may be excluded, limiting real-world applicability. The effect of these factors on the outcome of the UDS findings could not be assessed.
8) Interobserver Variability – Differences in assessment by multiple clinicians may introduce i
9) Ethical Considerations – Invasive nature of urodynamic studies may deter participation, affecting study power
10) Lack of Standardized Protocols – Differences in diagnostic criteria or techniques may affect comparability with other studies.

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