



EFFECT OF CYSTOSCOPY AND URETHRAL DILATATION VS CYSTOSCOPY ALONE WITH TAMSULOSIN IN WOMEN WITH VOIDING DYSFUNCTION: A RETROSPECTIVE COMPARATIVE STUDY

Urology

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ABSTRACT

Background: To analyze the data of cystoscopy and urethral dilatation with tamsulosin therapy in comparison to cystoscopy alone with tamsulosin in women with voiding dysfunction and overactivity. **Methods:** Retrospective data of women with overactive bladder symptoms and a maximum flow rate of <15 mL/sec on a voided volume of over 150 mL and/or a postvoid residual volume >100 mL who underwent dilatation and tamsulosin therapy were compared with the patients who had undergone cystoscopy and tamsulosin. Symptom assessment and urodynamic evaluation was done at baseline, 6 weeks and 6 months postoperatively. **Results:** In total, 67 patients (34 in dilatation and tamsulosin [group A] and 33 in cystoscopy and tamsulosin [group B]) were included in this study. After 6 weeks and 6 months, the American urological association symptom score decreased by 12.46 and 9.84 in group A and by 8.88 and 6.55 in group B. Changes in voided volume, maximum flow rate and post-void residual volume at 6 weeks and 6 months were significant in both the groups ($P=0.001$). On comparing both the groups, improvements in all the parameters were numerically higher in group A at 6 weeks. Mild bleeding was seen in five cases of group A, no other adverse events were noted. **Conclusion:** A significant improvement in clinical as well as urodynamic parameters was seen in both the groups individually at both 6 weeks and 6 months post-treatment. However, the intergroup comparison revealed that the addition of urethral dilatation to cystoscopy fares better than cystoscopy alone but for short term.

KEYWORDS

Hypertension, lactic dehydrogenase, lymphocyte count, mechanical ventilation, type-2 diabetes mellitus

INTRODUCTION

Female voiding dysfunction is a broad terminology with no clear consensus on its definition with a relatively low prevalence. Lack of diagnostic criteria and studies pertaining to it also limit its understanding. It can either be related to detrusor underactivity or bladder outlet obstruction (BOO). The International Continence Society (ICS) defined overactive bladder (OAB) syndrome as "urinary urgency, usually accompanied by frequency and nocturia, with or without urgency urinary incontinence (UUI), in the absence of urinary tract infection or other obvious pathology" [1]. Specifically, the bladder storage symptoms that make up OAB syndrome consist of symptoms of increased day time frequency, nocturia, urgency, urge incontinence [2]. Often storage and voiding symptoms coexist, making the diagnosis and management all the more difficult. The prevalence varies from 2.7% to 23% across various studies [3-8]. It can also be considered that OAB in women might be secondary to BOO or increased urethral resistance as seen in men with prostatic enlargement. However, there is limited evidence in favor of the fact that OAB symptoms may improve by decreasing the urethral resistance. Urethral dilatation (UD) is one procedure used as an empirical treatment for female lower urinary tract symptoms (LUTS). A published survey in 2006 showed that voiding dysfunction (72%) was the second most common indication for UD practiced across United Kingdom with urethral stenosis being the most common (97%) [9]. In spite of this, there is lack of studies evaluating the effectiveness and the outcomes of UD in females with voiding dysfunction and OAB. Voiding is dependent on both detrusor contractility and outflow resistance. Alpha blockers are one of the most commonly used medications for primary bladder neck obstruction. The reduction of outflow resistance by alpha blockers can decrease the work needed by detrusor, leading to improved outflow with lesser pdet at Qmax (detrusor pressure at maximal flow rate) [10]. Costantini et al [11] reported an improvement in voiding symptoms in 71.4%, a decrease in postvoid residual (PVR) in 62.5% and an improvement in both voiding and storage in 66.7% women with functional BOO who were treated with tamsulosin.

The present study aimed to conduct a comparison of cystoscopy with

UD vs cystoscopy alone in females with OAB and voiding dysfunction along with alpha blocker therapy. In this study, data of patients who underwent UD, in addition to cystoscopy and alpha blocker therapy (tamsulosin) was compared and analyzed retrospectively with the patients who underwent only cystoscopy and alpha blockers with OAB and voiding dysfunction. Furthermore, symptomatic and objective improvement in voiding parameters was also compared in these women.

METHODS

This was a single center, retrospective study conducted at Vardhaman Mahavir Medical College and Safdarjung Hospital, New Delhi including women between 20-65 years of age having subjective and objective evidence of OAB with voiding dysfunction, who underwent either cystoscopy alone or along with UD and tamsulosin therapy during March 2018 to February 2020. American urological association symptom score (AUASS), urgency perception scale (UPS), urodynamic parameters and ultrasonographic study were utilized to classify the pre and post procedural improvement analysis. The patients were divided into two groups (group A – cystoscopy and UD with tamsulosin and group B-cystoscopy alone with tamsulosin).

All procedures were carried out under local anesthesia with intravenous ceftriaxone injection at induction. Cystoscopy was done with rigid 17Fr scope for both group A and group B. A systematic inspection of urethra and bladder was done. Bladder was filled up to the capacity or until saline leaked around the cystoscope, emptied immediately and then re-examined for any glomerulations or hemorrhagic patches. The bladder was completely emptied after this. In addition to this, patients in group A also underwent sequential UD till 24 Fr with Hegar's dilator. Both the groups were started on tamsulosin 0.4 mg HS from the same day.

Post procedure outcomes were assessed on an outpatient basis at 6 weeks and 6 months and the results of both the groups, A and B were compared postoperatively. Expected outcomes were a decrease in AUASS, an improvement of UPS and urodynamic parameters.

INCLUSION CRITERIA

Patients with OAB symptoms such as more than eight voids per day on

a three-day frequency volume chart with episodes of nocturia urgency perception scale of 1-3 [12] and AUA symptom [13] score >15 were included in the study. Also, patients with maximum flow rate of less than 15 mL/sec on a voided volume of more than 200 mL, with a pdet at Qmax >20mL/cm of H₂O or PVR of 150 mL or over were included.

EXCLUSION CRITERIA

Patients with concurrent urodynamic stress incontinence (USI), symptomatic pelvic organ prolapse, urinary tract infection or hematuria under investigation were excluded from the study. Patients with neurological disorders, those unwilling to undergo procedure under local anesthesia and those having spinal trauma were also excluded.

Pressure flow study was performed using 6F catheter at a filling rate of 20 mL/min, filled until 500 mL or when requested by patient for severe pain/urgency.

Primary endpoints

Efficacy of cystoscopy plus UD and tamsulosin vs cystoscopy and tamsulosin in patients with voiding dysfunction and OAB on symptom complex and objective parameters.

Secondary endpoints

Peri-procedure morbidity and complications (blood loss, post-operative hospital stay, complications as graded by Clavien-Dindo classification) [14].

STATISTICAL ANALYSIS

Patient data was collected from hospital records and retrospectively analyzed. For data analysis Microsoft excel 6.5 version software used. Data was presented in the form of mean, standard deviation, and percentage. The student t test was applied. Mean of different groups were compared and their significance was assessed with p value. A P value of <0.05 was considered as significant.

Table 2. Pre-operative and post-operative procedure parameters of patients from group A and B

Parameters	Pre-operative		6 weeks		P value		6 months		P value	
	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B
UPS	2.24	2.23	0.57	0.78	0.001	0.001	1.03	0.9	0.001	0.001
AUASS	24.96	24.36	12.5	15.48	0.001	0.001	15.12	17.81	0.001	0.001
PVRU (mL)	141.06	145.75	105.9	111.96	0.001	0.007	88.48	85	0.001	0.001
Voided volume (mL)	206.06	220	273.93	283.33	0.001	0.001	255.72	267.87	0.001	0.001
Qmax (mL/s)	9.01	9.47	17.86	15.43	0.001	0.001	14.79	15.96	0.001	0.001
pdet at Q max (cm/H ₂ O)	53.95	44.34	47.78	34.19	0.068	0.002	49.07	36.75	0.139	0.015

AUASS, American urological association symptom score; pdet, detrusor pressure; PVRU, bladder post void residual volume; Qmax, maximum flow rate; UPS, urgency perception score.

Table 3. Inter group comparison of Group A vs Group B

Parameters	Mean difference between postop 6 weeks and preoperative		P value	Mean difference between postop 6 months and preoperative		P value
	Group A	Group B		Group A	Group B	
UPS	1.67 (0.47)	1.51 (0.66)	0.355	1.20 (0.53)	1.36 (0.65)	0.163
AUASS	12.41 (3.30)	8.87 (2.79)	0.001	9.79 (3.53)	6.54 (2.10)	0.001
PVRU (mL)	35.14 (11.77)	33.78 (12.99)	0.329	52.50 (14.98)	60.75 (16.15)	0.031
Voided volume (mL)	-68.52 (42.79)	-63.33 (36)	0.27	-49.38 (46.50)	-47.87 (33.42)	0.748
Qmax (mL/s)	-8.76 (2.58)	-5.09 (2.08)	0.001	-5.69 (3.13)	-6.49 (2.49)	0.294
pdet at Qmax (cm/H ₂ O)	6.13 (1.77)	10.15 (2.58)	0.001	4.86 (1.45)	7.59 (2.05)	0.001

Data shown as mean (SD).
AUASS, American urological association symptom score; pdet, detrusor pressure; PVRU, bladder post void residual volume; Qmax, maximum flow rate; UPS, urgency perception score.

On comparing both the groups, improvements in all the parameters

RESULTS

Data of 67 patients meeting the eligibility criteria was analyzed (34 in group A and 33 in group B). None of the patients had evidence of urethral stricture. Both the groups were well matched in terms of mean age (51.12 [6.16] years vs. 52.14 [7.92] years), parity (3.18 [1.00] vs. 3.30 [0.81]), menopausal status (64.7% vs. 54.5%), UPS (2.24 [0.70] vs. 2.36 [0.58]) and AUASS (24.76 [4.49] vs. 24.68 [4.19]). Other clinical characteristics such as PVR, voided volume, Qmax (maximum flow rate) and pdet at Qmax of the patients in group A and B were comparable. The baseline demographic and clinical characteristics of patients from each group are displayed in Table I.

Table 1. Baseline patient characteristics

Parameters	Group A (n = 34)	Group B (n = 33)
Age (years)	51.12 (6.16)	52.14 (7.92)
Parity	3.18 (1.00)	3.30 (0.81)
Post-menopausal	22 (64.7)	12 (54.5)
Proven do	25 (73.5)	17 (77.3)
Prior antimuscarinic therapy	24 (70.6)	17 (77.3)
UPS	2.24 (0.70)	2.36 (0.58)
AUASS	24.76 (4.49)	24.68 (4.19)
PVRU (mL)	140.15 (40.76)	150.91 (49.05)
Voided volume (mL)	206.18 (53.37)	218.64 (51.02)
Qmax (mL/s)	9.11 (3.38)	8.63 (4.00)
pdet at Qmax (cm/H ₂ O)	53.55 (13.92)	45.51 (12.64)

Data shown as mean (SD).
AUASS, American urological association symptom score; pdet, detrusor pressure; PVRU, bladder post void residual volume; Qmax, maximum flow rate; UPS, urgency perception score.

Both the groups showed a statistically significant difference compared to the pre-operative and post-operative procedure parameters at both 6 weeks and 6 months as shown in table 2. In group A, pdet at Qmax (P=0.139) did not differ significantly post cystoscopy along with UD.

were numerically higher for group A compared to group B at 6 weeks assessment, with improvements in mean AUASS and mean urodynamic parameters being clinically significant (P<0.05). However, the benefits of UD in addition to the cystoscopy were not initiated at 6 months. Mean AUASS and pdet at Qmax were statistically significant at 6 months in addition to an improvement in PVR (Table 3). Objective improvement in flow rates were not found at 6 months post dilatation. Rest of the parameters were found to be numerically better in group B, however not clinically significant.

Mild bleeding was seen in dilatation and tamsulosin group (group A) in five cases, no other adverse events were noted. Both the procedures were safe with patients being discharged on first post-operative day. None of the patients developed retention of urine on catheter removal the next day.

DISCUSSION

Urethral dilation as a means for treatment of OAB lacks much of objective evidence. However, it is one of the most commonly employed techniques in various settings. The rationale behind its use is that a decrease in urethral resistance might ameliorate the underlying BOO symptoms responsible for the voiding dysfunction in OAB patients.

The results of the present retrospective study demonstrated an improvement in clinical parameters in both the groups comprising of cystoscopy and tamsulosin with and without UD at 6 weeks and 6 months post treatment. However, addition of UD showed better short-

term outcomes as compared to cystoscopy alone. Failure of the short-term benefits to replicate at the 6 months follow up suggests that the clinical benefits of UD even though significant may only be for brief period. Except for mild bleeding in few cases, no other adverse events were observed in both the groups indicating favorable safety in women with OAB.

In a similar study by Basu et al., 2014 [15], 50 women with OAB symptoms with objective evidence of voiding dysfunction were randomized to undergo UD plus cystoscopy or cystoscopy alone. It was found that urgency was cured in 45% of women in UD group vs 17% in non-UD group at 6 weeks but only 17.85% and 14.28% respectively at 6 months. Similar to the present study, Basu et al., 2014 [15] concluded that UD offers short-term subjective improvement without any change in voiding parameters over cystoscopy alone, but no significant benefit in long term. The present study showed symptomatic as well as objective improvement in voiding parameters at 6 weeks of follow up. Even though the patients continued to experience the subjective response and decreased voiding pressures at 6 months, the improvement in flow rate was not seen. This short-term improvement in flow rate might be due to a temporary increase in the urethral caliber post dilatation. However, the reason for persistent improvement in detrusor pressure cannot be stated definitely.

A review article published by Bazi et al. in 2013 on UD showed that Hegar's dilator were the most commonly used [16]. In practice, both the UK and the American surveys found that most urologists dilate up to 32 F, whereas 86% of the surveyed pediatric urologists who performed UD in 2006 dilated between 20 and 26 F. Also, they found no evidence supporting an appropriate role for UD in girls and women with recurrent urinary tract infection and dysfunctional voiding. Urethral dilatation was claimed to be beneficial for treating urethral intramural obstruction in two retrospective reviews [17,18].

The UK survey published in 2006 revealed that 61 % of urologists who responded had performed UD in female patients more than seven times in the previous year, and 15% reported its use ≥ 30 times in the same year. Most urologists (69%) reported that less than 25% of their patients had stenosis, less than half of their patients showed long-term improvement, and more than 50% of cases experienced improvement. Additionally, dilatation was repeated frequently in less than 25% cases, whereas one-third of urologists reported that up to half of the cases required repeated procedure. Most urologists (45%) tend to dilate up to 32 F as compared to only 9% urologists dilating beyond 36 F [18]. However, in this study the patients were dilated up to 24 Fr and none of the patients required repeat dilatation till 6 months of follow up.

Despite the fact, that UD has short term benefits, studies also report the beneficial effect of alpha adrenoreceptor blocker such as tamsulosin in women with voiding difficulty. In contrast to other alpha blockers such as terazosin that has no benefit in enhancing storage symptoms, tamsulosin has improved voiding as well as storage symptoms when administered alone or in combination with tolterodine [19-21]. A comprehensive review of seven trials showed a significant improvement in urinary symptoms, quality of life and sleep quality with use of tamsulosin in women with voiding dysfunction. Tamsulosin was reported to be an effective, well-tolerated and safe drug [22]. In a prospective multicenter analysis on female voiding dysfunction, it was found that BOO accounted for 80% or higher in all female patients with voiding difficulty, a significantly higher number than detrusor underactivity patients. These results suggest that an alpha blocker may be an effective treatment option in female voiding difficulty due to functional BOO [23]. In this study, both the groups of patients received tamsulosin; however, the extent of its benefit over and above the intervention performed was not studied. The present study did find a persistent symptomatic improvement at 6 months contrary to Basu et al [15] which might be attributable to the concurrent tamsulosin therapy.

The most important advantage of this study was the follow up done with additional objective assessment of voiding parameters at both 6 weeks and 6 months instead of with a postal questionnaire leading to a better and a more reliable outcome assessment with no loss to follow up. The author acknowledges few study limitations. First of all, even though tamsulosin was given to both the groups, its effect and role in improvement of symptom scores and urodynamic parameters was not objectively assessed, distinctly from the cystoscopy and UD. Rather a

comparison with placebo would have added to our present knowledge. This confounding role, however can safely be eliminated as no one group received it solely. Moreover, this is a single center study with limited sample size; hence, results should be generalized cautiously.

Despite the ambiguity surrounding the benefits of female UD, it is by no means a procedure of the past. Observations from this study does not offer confirmatory evidence in support of tamsulosin as compared to UD. Hence, more prospective studies are needed for definitely proving the role of UD and tamsulosin separately in various subsets of female patients under the vast spectrum of female voiding dysfunction

CONCLUSIONS

This study demonstrated a significant improvement in clinical as well as urodynamic parameters in both the groups individually at both 6 weeks and 6 months post treatment. On comparing both the groups, it was found that the addition of UD to cystoscopy fares better than cystoscopy alone in terms of flow rate, but only for short time. However, it does not improve voiding pressures even at 6 months. Thus, the long-term benefits of UD need to be explored.

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