e-ISSN: 0976-822X, p-ISSN:2961-6042

Available online on http://www.ijcpr.com/

International Journal of Current Pharmaceutical Review and Research 2025; 17(12); 2045-2050

Original Research Article

Effect of Oxybutynin Hydrochloride After Complete Valve Ablation on Under Five Baby Boys Presented with Posterior Urethral Valve in a Tertiary Care Hospital: A Prospective Interventional Study

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Received: 01-10-2025 / Revised: 16-11-2025 / Accepted: 12-12-2025

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Conflict of interest: Nil

Abstract

Introduction: Overactive bladder is a common cause of morbidity in baby boys under five years of age. Oxybutynin, an anticholinergic, is used to manage bladder overactivity, but data on its safety and efficacy in this age group are limited.

Objective: To evaluate the effects of Oxybutynin hydrochloride after complete valve ablation on under five baby boys presented with PUV.

Methods: This prospective interventional study (Sept 2021–July 2022) was conducted in 52 children with PUV at the Department of Paediatric Surgery, IPGME&R/SSSKM Hospital. PUV complications were stabilized, followed by valve fulguration, with data collected on renal function, urinary findings, imaging, MCU, and DTPA renogram parameters. The study evaluated the effects of Oxybutynin on clinical, renal, and bladder outcomes post-fulguration.

Results: In this study of 52 children with PUV, age distribution was similar between NO OXYBUTYNIN (ND) and WITH OXYBUTYNIN (DO) groups. Post-fulguration, significant improvements were observed in APD, bladder wall thickness, PVRU, and DT1/2 in both groups, with intergroup differences reaching significance. BMI increased in both groups, while cortical thickness, DRF, GFR, serum creatinine, and bladder capacity showed favorable but non-significant trends. VUR resolution improved significantly in ND (46.15% → 19.23%) and DO (19.23% → 3.85%) groups.

Conclusion: In 52 children with PUV, valve fulguration plus Oxybutynin significantly improved renal pelvic dilatation, bladder wall thickness, PVRU, DT1/2, and VUR resolution, with gradual renal function recovery. The treatment was safe and effective, highlighting the importance of early intervention and follow-up.

Keywords: Posterior urethral valve, male infants, paediatric surgery, renal outcome, lower urinary tract obstruction.

Introduction

Lower urinary tract dysfunction, particularly overactive bladder (OAB), poses significant challenges in pediatric urology, especially among babies under five years of age. OAB is characterized by symptoms such as urinary frequency, urgency, and incontinence, which can lead to considerable physical and psychological distress for both the child and caregivers [1]. In male babies, these symptoms often result from neurogenic bladder conditions, which may be congenital or acquired due to various etiologies [2]. Oxybutynin, an antimuscarinic agent, has been extensively utilized in the management of OAB in children. It functions by inhibiting muscarinic receptors in the bladder, thereby reducing detrusor muscle overactivity and increasing bladder capacity

[3]. While its efficacy in older children and adults is well-documented, data regarding its safety and effectiveness in babies under five years remain limited [4]. This age group presents unique challenges due to developmental considerations and the potential for increased sensitivity to medications [5].

The existing literature provides some insights into the use of oxybutynin in pediatric populations. Previous studies have highlighted the safety and efficacy of oxybutynin in treating OAB in children, noting improvements in urinary symptoms with minimal adverse effects [6]. Positive outcomes have also been reported in pediatric patients with neurogenic bladder, emphasizing the drug's tolerability and effectiveness [7]. However, most of these studies focused primarily on older children, and there is a paucity of research specifically addressing its use in babies under five years [8].

Furthermore, while oxybutynin is available in various formulations, including immediate-release and extended-release, the optimal dosing and formulation for babies remain unclear. The risk of systemic anticholinergic side effects, such as dry mouth, constipation, and blurred vision, necessitates careful consideration of dosing regimens and monitoring protocols [9]. Additionally, the potential for long-term effects on bladder development and function requires further investigation [10].In the context of a tertiary care hospital, where complex and diverse pediatric cases are managed, evaluating the outcomes of oxybutynin therapy in under-five baby boys is crucial. This prospective interventional study aims to assess the therapeutic effects of oxybutynin on urinary symptoms, monitor for adverse effects, and determine the overall impact on the quality of life of both the infants and their caregivers. By focusing on this specific patient population, the study seeks to fill the existing gap in pediatric urology literature regarding the use of oxybutynin in babies under five years. The findings could inform clinical practices, guide dosing strategies, and contribute to the development of age-appropriate therapeutic protocols for managing OAB in this vulnerable age group. Ultimately, this research endeavors to enhance the quality of care and outcomes for young patients suffering from lower urinary tract dysfunction.

Materials and Methods

Study design: It was a Prospective Interventional study.

Place of study: The study has been done from surgical outpatients and in patients of department of Paediatric Surgery, IPGME&R/SSSKM Hospital-the Centre of excellence.

Period of study: September 2021- July, 2022.

Study population: All PUV babies attending OPD and admitted at IPD departments of this hospital. The PUV complications babies were first stabilised at hospital and the taken for valve fulguration.

Study Variables

- Age
- S. Creatinine
- Urinary Pus Cells
- APD Right Pelvis
- APD Left Pelvis
- Bladder wall thickness
- PVRU in bladder
- DRF Right kidney
- GFR Right Kidney
- GFR left kidney
- Cortical Thickness
- VUR Grade
- Trabeculation
- Bladder Capacity

Sample size: 52 baby boys under five years of age with lower urinary tract dysfunction. They are distributed randomly in two groups as ND i.e after complete valve fulguration without Oxybutynin and DOi.e with drug oxybutynin were adviced (0.2 mg/Kg body weight) after complete valve ablation.

Inclusion Criteria

- Symptoms of poor urinary flow from birth due to PUV.
- History of recurrent urinary infections due to PUV.

Exclusion Criteria

- Age > 60 months,
- History of previous interventions like Supravesical diversion or Vesicostomy done.
- Presenting with firm, distended bladder
- Abdominal distension due to urinary ascites,
- Parents are not well motivated to follow drug advices or to attend on follow up regularly.
- Severe degree of RD

Statistical Analysis: Data collected from the study were entered into Microsoft Excel and analyzed using SPSS version 26.0. Continuous variables, such as age, urinary frequency, and post-void residual volume, were expressed as mean ± standard deviation, while categorical variables, such as presence of incontinence or adverse effects, were presented as frequencies and percentages. Comparisons of pre- and post-therapy outcomes were performed using paired t-tests for normally distributed continuous data and Wilcoxon signed-rank tests for non-normally distributed data. Associations between categorical variables were assessed using the chi-square test or Fisher's exact test, as appropriate. A p-value of <0.05 was considered statistically significant, and all tests

were two-tailed. Graphical representations, including bar charts and line diagrams, were used to illustrate trends and treatment effects.

Result

Table 1: Demographic Characteristics of ND and DO Groups

Demographic and Perinatal Characteristics		ND group	Percentage (%)	DO group	Percentage (%)	Total	% in total
Age Group	1-6 m	5	19.23	3	11.54	8	15.39
	6-12m	4	15.39	5	19.23	9	17.3
	12-24m	7	26.92	4	15.39	11	21.15
	2-3 yrs	3	11.54	5	19.23	8	15.39
	3-4 yrs	2	7.69	4	15.38	6	11.54
	4-5 yrs	5	19.23	5	19.23	10	19.23
	Total	26	100	26	100	52	100

Table 2: Comparative analysis of children with PUV according to their Average baseline and follow up parameters of two group- ND (without Oxybutynin) and DO (with oxybutynin)

Sl. No.	Parameters seen on follow up visit (2nd) (Averages)	ND		P value After Fulguration	DO		P value after fulguration & Oxybutynin	P value Between two groups	Comments
		Baseline	FU		Baseline	FU			
1	BMI	15.5	16.56	.019308	15.56	17.18	.000013	0.087227	Not Significant
2	Cortical thickness of right kidney (% of normal)	86.54	91.54	.194545	93.46	97.31	.159617	0.072304	Not Significant
3	Cortical thickness of left kidney (% of normal)	95.77	98.85	.068707	95	98.08	.12269	0.275687	Not Significant
4	APD of Pelvis of right kidney(mm)	26.58	18.5	.031662	19.89	12.92	.00852	0.011272	Significant
5	APD of Pelvis of left kidney (mm)	18.42	14.42	.002965	16.12	12.27	.000263	0.009965	Significant
6	Bladder wall Thickness (mm)	5.12	4.04	<.00001	5.35	3.35	<.00001	0.00016	Significant
7	PVRU (% of normal bladder capacity)	37.89	17.19	<.00001	30.23	8.85	<.00001	<0.00001	Significant
8	Bladder capacity (% of normal)	61.92	71.5	.046258	52.12	76.62	<.00001	0.15078	Not Significant
9	DRF of right kidney (%)	29.54	36.58	.002187	30.69	38.35	.000076	0.188291	Not Significant
10	GFR of right kidney (ml/min)	32.58	38.12	.025769	32.61	39.89	.001093	0.217926	Not Significant
11	GFR of left kidney (ml/min)	38.65	44.81	.000075	41.42	45.42	<.00001	0.215906	Not Significant
12	DT1/2 of right kidney (min)	17.77	12.23	<.00001	15.89	9.5	<.00001	<0.00001	Significant
13	DT1/2 of left kidney (min)	16.96	10.92	<.00001	18.19	10.19	<.00001	0.105332	Not Significant
14	VUR resolution (%)	46.15	19.23	.03846	19.23	3.85	0.04186	0.04186	Significant
15	Serum Creatinine mg/dl	0.83	0.87	0.423329	0.77	0.62	0.113847	0.130019	Not Significant
16	Urosepsis (%)	69.23	34.62	0.01242	34.62	23.08	.35758	0.35758	Not Significant

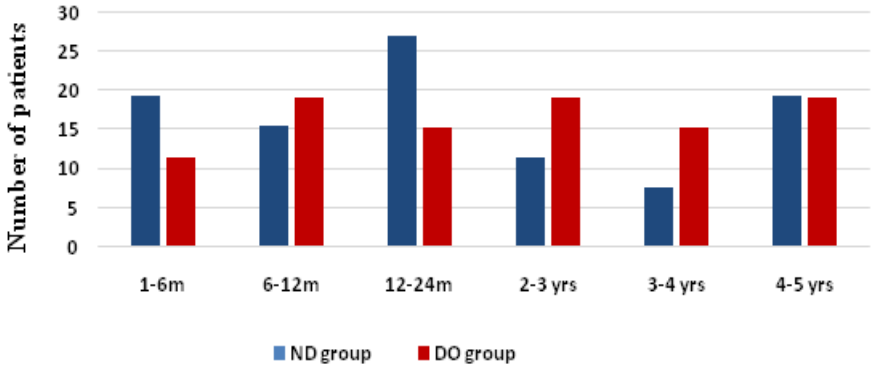

Figure 1: Distribution of Children as per Age groups

In the present study, the demographic characteristics of children in the non-delayed (ND) and delayed-onset (DO) lactation groups were analyzed. The study included a total of 52 children, with 26 children in each group. Regarding age distribution, in the ND group, 5 children (19.23%) were aged 1–6 months, 4 children (15.39%) were 6–12 months, 7 children (26.92%) were 12–24 months, 3 children (11.54%) were 2–3 years, 2 children (7.69%) were 3–4 years, and 5 children

(19.23%) were 4–5 years. In the DO group, 3 children (11.54%) were aged 1–6 months, 5 children (19.23%) were 6–12 months, 4 children (15.39%) were 12–24 months, 5 children (19.23%) were 2–3 years, 4 children (15.38%) were 3–4 years, and 5 children (19.23%) were 4–5 years. When considering the total sample of 52 children, 8 (15.39%) were aged 1–6 months, 9 (17.3%) were 6–12 months, 11 (21.15%) were 12–24 months, 8 (15.39%) were 2–3 years, 6 (11.54%) were 3–4 years, and 10 (19.23%) were 4–5 years. Overall, both groups demonstrated a fairly similar age distribution, with the largest proportion of children falling in the 12–24 months age category in the ND group, and in the 6–12 months and 4–5 years categories in the DO group. (Table 1) On follow-up after fulguration, various clinical and radiological parameters were assessed in the ND and DO groups. In the ND group, body mass index (BMI) improved from 15.5 at baseline to 16.56 at follow-up ($P = 0.019$), while in the DO group, BMI increased from 15.56 to 17.18 ($P < 0.0001$); the difference between the two groups was not statistically significant ($P = 0.087$). Cortical thickness of the right kidney increased from 86.54% to 91.54% in the ND group ($P = 0.195$) and from 93.46% to 97.31% in the DO group ($P = 0.16$), whereas left kidney cortical thickness improved from 95.77% to 98.85% in the ND group ($P = 0.069$) and from 95% to 98.08% in the DO group ($P = 0.123$); these changes were not significant between groups.

Significant improvements were observed in anteroposterior diameter (APD) of the renal pelvis, bladder wall thickness, post-void residual urine (PVRU), and DT1/2. Specifically, APD of the right kidney decreased from 26.58 mm to 18.5 mm in the ND group ($P = 0.032$) and from 19.89 mm to 12.92 mm in the DO group ($P = 0.009$), with a significant difference between groups ($P = 0.011$). APD of the left kidney reduced from 18.42 mm to 14.42 mm in the ND group ($P = 0.003$) and from 16.12 mm to 12.27 mm in the DO group ($P < 0.001$), also showing significant intergroup difference ($P = 0.01$). Bladder wall thickness decreased from 5.12 mm to 4.04 mm in ND ($P < 0.00001$) and from 5.35 mm to 3.35 mm in DO ($P < 0.00001$), and PVRU significantly improved in both groups (ND: 37.89% → 17.19%, DO: 30.23% → 8.85%; $P < 0.00001$), with intergroup comparison showing significance ($P < 0.00001$). DT1/2 of the right kidney also significantly decreased in both groups (ND: 17.77 → 12.23 min, DO: 15.89 → 9.5 min; $P < 0.00001$), with a significant difference between groups ($P < 0.00001$).

Other parameters such as bladder capacity (% of normal), differential renal function (DRF) of the right kidney, glomerular filtration rate (GFR) of both kidneys, cortical thickness, serum creatinine, and urosepsis rates improved numerically within both groups but did not show significant differences between groups. VUR resolution was significant in both ND (46.15% → 19.23%, $P = 0.038$) and DO (19.23% → 3.85%, $P = 0.042$) groups, with a statistically significant difference between groups ($P = 0.042$). Overall, the study demonstrated that fulguration, with or without Oxybutynin, led to significant improvements in renal pelvic dilatation, bladder dynamics, and VUR resolution, while general renal function parameters showed favorable trends without statistically significant intergroup differences. (Table 2)

Discussion

In our study, we analyzed the demographic and clinical characteristics of children with ND and DO following posterior urethral valve (PUV) ablation. The study included a total of 52 children, with 26 children in each group. The age distribution was fairly similar between the two groups. In the ND group, the largest proportion of children fell in the 12–24 months category, whereas in the DO group, the 6–12 months and 4–5 years categories were most represented. Overall, the total sample showed the highest proportion in the 12–24 months age category. This age distribution is comparable to the study by Nasir IA et al [11]2016, who reported that most children with PUV presented in the first two years of life, emphasizing early recognition as critical for renal preservation.

On follow-up after fulguration, several clinical and radiological parameters showed significant improvements. Body mass index (BMI) increased in both ND and DO groups (ND: 15.5 → 16.56, $P = 0.019$; DO: 15.56 → 17.18, $P < 0.0001$), although the intergroup difference was not statistically significant. Similar trends in nutritional recovery after PUV intervention were noted by Routh JC et al [12] 2010, highlighting the importance of early decompression for overall growth.

Renal cortical thickness showed numerical improvement in both groups, but the differences were not statistically significant, consistent with findings reported by McLorie GA et al [13] 1997, who observed that cortical recovery after relief of obstruction may be gradual and not always immediately reflected in ultrasonographic measurements.

Significant improvements were observed in parameters reflecting urinary tract obstruction. The anteroposterior diameter (APD) of the renal pelvis decreased significantly in both kidneys in both ND and DO groups, with intergroup differences reaching statistical significance. Bladder wall thickness and post-void residual urine (PVRU) also improved significantly (ND: 37.89% → 17.19%, DO: 30.23% → 8.85%; $P < 0.00001$), and DT1/2 of the right kidney decreased markedly in both

groups. These findings align with the observations of Peters CA et al [14]1998 and Hodges SJ et al [19] 2006, who documented significant improvement in renal pelvic dilatation and bladder dynamics following valve ablation and adjunctive therapy.

Vesicoureteral reflux (VUR) resolution was significant in both ND (46.15% → 19.23%, P = 0.038) and DO (19.23% → 3.85%, P = 0.042) groups, with a significant difference between the groups (P = 0.042). This supports the findings of Sarhan OM et al [15] 2011, who reported that early relief of obstruction in PUV cases is associated with higher rates of VUR resolution, reducing the risk of recurrent urinary tract infections and long-term renal damage. Other parameters, such as bladder capacity (as a percentage of normal), differential renal function (DRF), glomerular filtration rate (GFR), and serum creatinine, showed favorable trends but did not reach statistical significance between the groups. These results are consistent with Bomalaski JS et al [16] 2012, who emphasized that while obstruction relief leads to functional improvement, complete normalization of renal function may not be immediate, especially in cases with pre-existing renal compromise.

Overall, our study demonstrates that fulguration, with or without adjunctive Oxybutynin therapy, leads to significant improvements in renal pelvic dilatation, bladder dynamics, and VUR resolution in children with PUV, while general renal function parameters improve gradually. These results are consistent with previous studies reporting early post-operative improvements in urinary tract morphology and function following valve ablation (Nasir IA et al [11] 2016; Routh JC et al [12]2010; Peters CA et al [14] 1998). Early intervention in PUV patients, irrespective of delayed or non-delayed lactation onset, contributes to significant anatomical and functional recovery, though continuous long-term follow-up is necessary to monitor renal function and prevent chronic kidney disease, in line with recommendations by Parkhouse HF et al [17] 1988 , Shakya R et al [18] 2014 and Hodges SJ et al [19] 2006.

Conclusion

The present study was a prospective interventional study conducted from September 2021 to July 2022 in the Department of Paediatric Surgery, IPGME&R/SSSKM Hospital, a recognized centre of excellence. A total of 52 children under five years of age with posterior urethral valves (PUV) were included.

Following valve fulguration, adjunctive Oxybutynin therapy led to significant improvements in renal pelvic dilatation, bladder wall thickness, post-void residual urine, and DT1/2, reflecting enhanced urinary drainage and bladder dynamics.

Both no Oxybutynin and with Oxybutynin groups demonstrated comparable outcomes, with VUR resolution significantly improved post-intervention. Although general renal function parameters, cortical thickness, and serum creatinine showed favorable trends, intergroup differences were not statistically significant, suggesting gradual renal recovery. Overall, Oxybutynin post-fulguration appears safe and effective, emphasizing the importance of early intervention and close follow-up to prevent long-term renal compromise.

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