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Original Article

Efficacy of Sublingual Atropine to Minimize Drooling in Children with Cerebral Palsy: A Double-Blind Randomized Controlled Trial

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ABSTRACT

Objective: To determine the efficacy of sublingual Atropine in reducing drooling episodes compared to placebo, thereby improving the quality of life of patients, and potentially offering a noninvasive treatment modality.

Study Design: Randomized Controlled Trial (Registered with Thai Clinical Trials Registry TCTR20241022002)

Place and Duration of Study: Department of Developmental & Behavioral Pediatrics, The Children's Hospital & University of Child Health Sciences, Lahore, Pakistan, from Sep 2024 to Mar 2025.

Methodology: A total of 116 participants enrolled, with 58 participants in each group. Two patients withdrew due to significant side effects in the intervention group. During a predetermined period, participants were randomized to receive either sublingual Atropine (intervention group-A, n = 56) or a placebo (Group-B, n = 58). The primary outcome was the composite score of the Drooling Impact Scale (DIS).

Results: Baseline Drooling Impact Scale (DIS) scores were comparable between intervention and placebo groups, with median (IQR) of 77.0(70.0–82.0) and 74.5(65.0–83.5), respectively (p = 0.686). Baseline median Drooling Impact Scale (DIS) score decreased from 77.0(IQR 70.0–82.0) to 54.5(IQR 36.8–78.0) to post-intervention (p<0.001). The median reduction in total DIS scores from baseline was −22.5 (−35.2 to −12.0) in the intervention group compared with −2.5 (−10.0 to +5.0) in the placebo group (p<0.001), indicating a significant reduction in drooling severity.

Conclusion: Sublingual Atropine is a safe, effective, and non-invasive treatment for drooling in children with cerebral palsy, offering significant clinical and quality-of-life improvements.

Keywords: Atropine, Cerebral Palsy, Drooling, Randomized Controlled Trial, Sublingual.

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INTRODUCTION

Drooling, the unintentional loss of saliva from the mouth, is considered abnormal after age four and is commonly seen in children with cerebral palsy due to oromotor dysfunction and impaired swallowing.[1,2] The prevalence of drooling among kids with cerebral palsy (CP) has been reported to range from 10% to 78% worldwide.[3] In Pakistan, prevalence data are lacking; however, available studies and small case series suggest that drooling represents a considerable clinical burden among children with CP.[4]

Drooling is classified as anterior (visible saliva loss from the lips and chin) or posterior (saliva flowing into the pharynx), both of which have significant complications.[2] Anterior drooling may lead to perioral skin infections, dehydration, and psychological distress for both patients and caregivers.[4] Posterior drooling increases the risk of aspiration and recurrent chest infections.[2] There are different treatment modalities available for drooling, which can be behavioral modification, pharmacological intervention, or surgical intervention.[5] However, behavioral approaches require a long time interval, cognitive ability, and training, while surgical methods such as salivary gland ligation or Botulinum toxin injections carry a significant risk of complications.[6] Whereas pharmacologic management includes Anticholinergic agents like Glycopyrrolate and Scopolamine, which are effective, but their use is restricted due to systemic side effects.[7]

Recent publications show novel intervention in the form of sublingual administration of Atropine sulphate to controlled drooling with less side effects.[5] Despite its non-invasive nature and cost-effectiveness, research on sublingual Atropine is scarce, especially in low-resource settings like Pakistan. Dias *et al.*, conducted a prospective clinical trial in 33 children with CP 25 completed the protocol, showed significant reduction in drooling measured by Drooling Impact Scale (DIS) following sublingual Atropine

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administration.[8] Azapagasi *et al.,* reported a retrospective trial of sublingual Atropine administration of 25 hospitalized patients showed significant reduction in drooling rate measured by Teacher Drooling Scale (p value <0.001).[9] To date, no randomized double-blinded placebo-controlled trial has evaluated its efficacy in Pakistan. Therefore, this study aims to provide strong evidence for sublingual Atropine as a viable and safe treatment option for drooling in children with CP, potentially improving patient care and resource allocation.

METHODOLOGY

This was a randomized, double-blind, placebo-controlled clinical trial, conducted at the University of Child Health Sciences, Lahore, Pakistan, from Sep 2024 to Mar 2025. Sample size was calculated for comparison of two independent groups (intervention and control) using the Sample Size Determination in Health Studies Practical Manual, assuming 5 % significance level (two-tailed), 90 % statistical power, a clinically meaningful difference of 10 points(Δ)in the Drooling Impact Scale (DIS) score between the intervention and control groups and anticipated population standard deviation of 16.59, resulting 58 participants per group, a total sample size of 116.2 Hospitalized participants were recruited using a random sampling technique.

Inclusion Criteria: Children aged 4–15 years with cerebral palsy and excessive drooling who had never received prior treatment for drooling. Weighed more than 10 kg and had a normal electrocardiogram (ECG) were included.

Exclusion Criteria: Participants for whom Atropine was contraindicated and were on medications that could interfere with Atropine's effects.The study was approved by the Institutional Ethical Review Board (IERB) of the University of Child Health Sciences, Lahore, Pakistan (IERB No. 941/CH-UCHS/20-09-2024). Written informed consent was obtained from parents/guardians. Participants who developed severe adverse effects were immediately withdrawn and managed accordingly. The trial was registered with the Thai Clinical Trials Registry (TCTR20241022002).

Eligible participants were randomized by using a computer-simulated random sequence created by an independent biostatistician not engaged in recruitment or data analysis. A simple randomization method with a 1:1 allocation ratio was exercised to allocate either the Intervention group (Group-A) or Control group (Group-B). Allocation concealment was warranted using chronologically numbered, opaque envelopes, prepared in advance by a third party. Each envelope included the treatment task and was opened only after the patient had been enrolled and baseline assessments were completed. To maintain blinding, identical packaging and labeling were used for Atropine and placebo solutions (0.9% Normal Saline). Principal investigators, outcome assessors, and caregivers were blinded to treatment allocation throughout the study period. The sequence of randomization was securely stored and only accessed after data analysis was finalized. Sublingual Atropine was administered using a commercially available 1% Atropine ophthalmic solution (10 mg/mL) in the intervention group. For calculation purposes, one ophthalmic drop was assumed to equal 0.05 mL, corresponding to 0.5 mg of Atropine per drop. The prescribed regimen was 20 µg/kg/dose, administered 3 times daily at 8-hour intervals. Drops were administered by staff nurses according to the prescribed schedule. Vital signs were monitored 30 minutes post-administration. Parents were counseled about adverse events, including dry mouth, urinary retention, facial flushing, and hallucinations.

Drooling severity and its impact on daily life were measured using the Drooling Impact Scale (DIS), a validated 10-item parent-reported questionnaire, and each question reflects a 1 to 10 point-scale, in which higher scores indicate a greater impact of drooling on quality of life. Reliability of the scale was found to be 0.91.[8] Drooling Impact Scale (DIS) scores were recorded for all participants as a baseline measure. Post-treatment DIS scores were measured on Day 7.

Data were entered into IBM SPSS (Statistical Package for Social Sciences) Statistics for Windows, Version 27. Qualitative variables (e.g., gender, symptom presence) were analyzed using frequencies and percentages. Quantitative variables (e.g., drooling total scores) were analyzed using median (interquartile range [IQR]). The composite drooling scores were calculated both pre- and post-intervention (pre-DIS and post-DIS scores, respectively). Non-parametric tests were used due to non-normal distribution of variables. Wilcoxon Signed-Rank Test was used for within-group analysis (Changes in DIS scores pre- vs post-intervention), and Mann–Whitney U Test was used for between-group, intervention versus control, for post-intervention comparison

(independent samples). A *p*-value ≤ 0.05 was considered statistically significant.

RESULTS

Out of 114 children, 56 patients were enrolled in intervention group, and 58 patients were in control group-B. (Fig) The majority of children were males and belonged to low socioeconomic status. Major indications for hospitalization were lower respiratory tract infections. Spastic diplegic 39(34.2%) and quadriplegic cerebral palsy 37(32.5%) were the predominant types. In intervention group, most participants had moderate motor impairments, classified as GMFCS level III 27 (48.2%), and in control group, most of the participants 25(43.1%) had severe motor impairments classified as GMFCS level IV (see Table-I).

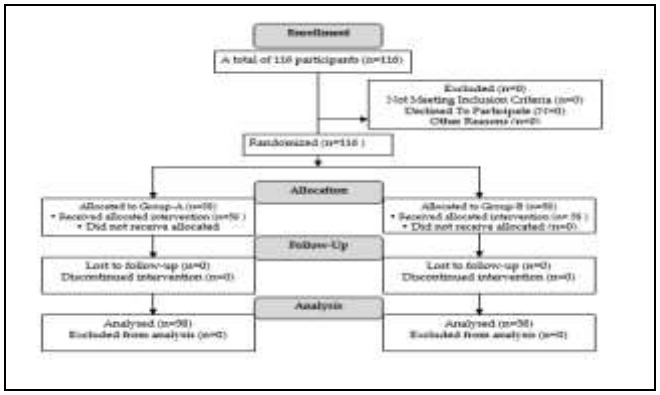

Figure: Flow chart of the participants through the clinical trial.*Two patients from the intervention group withdrew from the study due to significant side effects.

The majority of participants experienced side effects in Intervention group. Some of the participants 9(16.1%) reported constipation in intervention group, followed by flushing 8(14.3%), hallucinations 5(8.9%), and fever 5(8.9%). In Control group, constipation 5(8.6%) and fever 3(5.2%) were the most common reported side effects (Table-II). However, two participants in the intervention group discontinued in the early phase due to intolerable side effects (tachycardia and urinary retention) and were excluded from the final analysis.

Baseline DIS scores were comparable between intervention and control groups, with median (IQR) values of 77.0(70.0–82.0) and 74.5(65.0–83.5), respectively (p = 0.686). At baseline, there was no statistically significant difference between the two groups. However, post-intervention, intervention group showed a significantly lower median DIS score of 54.5 (IQR 36.8–78.0) as compared to control group 72(IQR 61.0–84.0). Post-intervention scores were lower in the intervention group compared to controls (p<0.001). The median reduction in total DIS scores from baseline was −22.5 (−35.2 to −12.0) in the intervention group compared with −2.5 (−10.0 to +5.0) in the control group (p<0.001). This indicates a significant reduction in drooling severity in the intervention group (Table-III).

Table-I: Demographic and clinical characteristics of participants (n=114)

Variable	Intervention group (n = 56)	Control group (n = 58)
Gender		
Male	35(62.5%)	29(50.0%)
Female	21(37.5%)	29(50.0%)
Socioeconomic Status		
Low	25(44.6%)	44(75.9%)
Middle	19(33.9%)	14(24.1%)
High	12(21.4%)	0(0.0%)
Hospitalization Indication		
Low Respiratory Tract Infection	26(46.4%)	15(25.9%)
CNS Infection	14(25.0%)	24(41.4%)
Seizure Disorder	10(17.9%)	13(22.4%)
Other	6(10.7%)	6(10.3%)
Types of Cerebral Palsy (CP)		
Spastic Quadriplegia	24(42.9%)	13(22.4%)
Spastic Diplegia	16(28.6%)	23(39.7%)
Spastic Hemiplegia	14(25.0%)	19(32.8%)
Dyskinetic	2(3.6%)	3(5.2%)
GMFCS Level		
Level 2	2(3.6%)	2(3.4%)
Level 3	27(48.2%)	24(41.4%)
Level 4	18(32.1%)	25(43.1%)
Level 5	9(16.1%)	7(12.1%)

**CNS- Cerebral Nervous System, GMFCS - Gross Motor Function Classification System*

Table-II: Adverse effects reported by participants (n=114)

Adverse Effect	Intervention group (n = 56)	Control group (n = 58)
Flushing	8(14.3%)	1(1.7%)
Constipation	9(16.1%)	5(8.6%)
Hallucinations	5(8.9%)	1(1.7%)
Fever	5(8.9%)	3(5.2%)
Vomiting	2(3.6%)	0(0.0%)
Urinary Retention	2(3.6%)	1(1.7%)
Facial Rash	1(1.8%)	0(0.0%)
Allergy	1(1.8%)	0(0.0%)
Irritability	0(0.0%)	2(3.4%)
No Side Effects Reported	23(41.1%)	45(77.6%)

As shown in Table-IV, all DIS items exhibited significant improvement post-intervention. Median DIS scores decreased significantly across all domains (p<0.001). Compared to the control group, demonstrating the efficacy of sublingual Atropine in children with cerebral palsy.

Table-III: Comparison of DIS scores within and between groups (n=114)

Variable	Intervention group (n=58)	Control group group(n=56)	*p*-Value
Pre-DIS score, median (IQR)	77.0 (70.0–82.0)	74.5 (65.0–83.5)	0.686
Post-DIS score, median (IQR)	54.5 (36.8–78.0)	72.0 (61.0–84.0)	<0.001
Change from baseline, median reduction	−22.5 (−35.2 to −12.0)	−2.5 (−10.0 to +5.0)	<0.001

**DIS- Drooling Impact Scale, IQR – Interquartile Range*

Table-IV. Comparison of Pre- and Post-Intervention Drooling Impact Scale (DIS) item scores in Intervention and control groups (n=114)

DIS Item	Intervention group (n = 56) Median (IQR)		*p*-value	Control group (n = 58), Median (IQR)		p-Value
	Pre-intervention	Post-intervention		Pre-intervention	Post-intervention	
Drooling frequency	8 (7–9)	4 (3–6)	< 0.001	8 (7–9)	7 (6–8)	0.180
Drooling severity	7 (6–8)	3 (2–5)	< 0.001	7 (6–8)	6 (5–7)	0.655
Bib change frequency	8 (7–9)	4 (3–5)	< 0.001	8 (7–9)	6 (5–8)	0.083
Saliva smell	8 (7–9)	4 (3–6)	< 0.001	8 (7–9)	7 (6–8)	1.000
Skin irritation	7 (6–8)	3 (2–4)	< 0.001	7 (6–8)	6 (5–7)	0.317
Mouth wiping frequency	8 (7–9)	4 (3–5)	< 0.001	8 (7–9)	7 (6–8)	0.317
Embarrassment level	8 (7–9)	3 (2–5)	< 0.001	8 (7–9)	6 (5–7)	1.000
Household cleaning frequency	8 (7–9)	4 (3–5)	< 0.001	8 (7–9)	6 (5–8)	0.317
Child life impact	8 (7–9)	3 (2–5)	< 0.001	8 (7–9)	6 (5–7)	0.092
Family life impact	8 (7–9)	3 (2–5)	< 0.001	8 (7–9)	6 (5–7)	0.317
Total DIS score	77.0 (70.0–82.0)	54.5 (36.8–78.0)		74.5 (65.0–83.5)	72.0 (61.0–84.0)	

DISCUSSION

The study showed meaningful reductions in drooling severity with use of sublingual Atropine, with a median post intervention DIS score of 54.5(IQR 36.8–78.0)compared to 72 (IQR 61.0–84.0)in the control group (p < 0.001). These results are comparable to Brown *et al.*, who reported a median DIS reduction of 24 points with individualized sublingual Atropine dosing around four weeks in 42 children with CP. In our fixed-dose trial, the median reduction was −22.5 (−35.2 to −12.0), with parallel short-term tolerability. The slightly smaller effect may relate to our shorter follow-up and non-titrated dosing.[10]

These findings also align with Dias et al., who reported a mean DIS reduction from 61.5±16.6 to 32.1±16.6 after thirty days of sublingual Atropine among 25 children with CP.2 In this study, the median DIS score decreased from 77.0(70.0–82.0) to 54.5(36.8–78.0), showing a comparable improvement trend. The small effect size in our study reflects differences in dose and follow-up duration, but overall results confirm the short-term efficacy and tolerability of intervention.

Petkus *et al.*, assessed 178 cases with neurodevelopmental disabilities and showed inconsistent dosing of sublingual Atropine, with 89% using it as first-or second-line therapy.[11] Notably, they explained no standardized monitoring of adverse effects, which limits direct comparison with our controlled assessment of side effects and withdrawals. On the contrary, the prospectively monitored adverse effects, with 2(3.4%) patients withdrawing due to side effects, were lower than the 12.1% rate reported by Dias et al. This suggests good tolerability with our dosing and monitoring protocol.

Walshe et al., stated that Glycopyrrolate, Botulinum toxin, and Scopolamine reduce drooling but have high discontinuation rates due to side effects.[12] In contrast, our study highlights sublingual Atropine to be effective, well-tolerated, and with a low withdrawal rate (3.4%), showing a more favorable balance of efficacy as compared to other traditional agents.

Phipps et al., reported efficacy of sublingual Atropine in a pediatric palliative care center, resulting in a reduction in drooling with nominal side effects, with ease in administration, comparable to us.[13]

Whereas they did not quantify their actual reductions in drooling intensity, however, above 80% of guardians reported a meaningful reduction in drooling. In contrast, we used to validate DIS tools to quantify outcomes.[8]

Lin et al., showed a significant reduction in drooling with sublingual Atropine in 58 neurodiverse children (mean –2.70), with 7% experiencing adverse events, mostly irritability and flushing. The effect was less pronounced compared to our study, likely due to their large neurodiverse cohort. This study focused on cerebral palsy, which allowed for more standardized outcomes.[14] Davis *et al.,* reported that sublingual Atropine improves caregiver outcomes, aiding in feeding, hygiene, socialization, and ease of use.[15]

Similarly, Norderyd *et al.,* reported significant improvement in drooling severity after sublingual Atropine in neurodiverse children using validated visual analogue scale (VAS) scores, mostly with a dosage of 1–2 drops of 0.5% Atropine once or twice a day.[16] Park *et al.,* reported post pediatric stroke with sialorrhea, that 1% sublingual Atropine administered three times daily significantly reduced drooling scores from 5.12 to 3.94 ($p < 0.01$), without major adverse effects as compared to placebo.[17] Correspondingly, Heine *et al.,* retrospectively studied 35 neurodiverse children, treated with sublingual Atropine (20 µg/kg/dose) and found statically significant reduction in the median Teacher Drooling Scale score from 5 to 3 within two days; all reported dosing regimens remain comparable to our study as well.[18]

In addition, Parrot *et al.,* reported that mucoadhesive sublingual Atropine gel gets effective results in local drug absorption with salivary suppression and low systemic effects, aligning with our results.[19]

Nationally, Ashraf *et al.,* revealed that the use of anticholinergic medications improved drooling symptoms in Pakistani children with cerebral palsy but highlighted caregiver burden and poor adherence due to adverse effects.[20] In contrast, our study achieved treatment completion and caregiver-reported improvement in quality of life, indicating better acceptability. Whereas no previous similar clinical trial has been conducted in Pakistan. This randomized controlled trial is the first of its kind, not only in Pakistan but also globally in this specific clinical context.

The results are mainly consistent with prior studies showing the efficacy of sublingual Atropine in controlling drooling, but differ in broader improvements across all DIS domains. These divergences may be clarified by differences in dosing regimen, restriction of our population with cerebral palsy, and stricter monitoring intensity that probably improved adherence and safety.

Despite these strengths, this study has limitations. A somewhat short follow-up duration may not reflect the sustainability of the intervention, or delayed onset of side effects, and restricted generalizability of results to outpatient settings. The exclusion of two children post-randomization could result in minor bias as well. However, the use of drooling impact tool strengthens internal validity, but caregiver-reported outcomes could introduce subjective bias. Finally, the study was conducted at a single center, itself a limitation.

Forthcoming research with longitudinal follow-up and a large multicenter clinical randomized controlled trial, dose optimization is recommended to validate these results and guide on long term outcomes, and importantly, to determine subgroups that may benefit.

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CONCLUSION

In conclusion, sublingual Atropine showed a statistically significant short-term reduction of drooling severity and its impact among children with cerebral palsy, with good tolerability and slight adverse events. Its efficacy and safety profile recommend that sublingual Atropine can serve as a practical, low-cost alternative to other anticholinergics for drooling control.

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Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

HMMN & HA: Data acquisition, data analysis, critical review, approval of the final version to be published.

MM & AF: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

AH & AA: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity

of any part of the work are appropriately investigated and resolved.

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