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Comparative clinical efficacy and procedural efficiency of nebuliser vs valved holding chamber in paediatric obstructive bronchitis

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Abstract. Obstructive bronchitis remains a frequent cause of acute respiratory distress in paediatric care. While bronchodilators remain the standard therapeutic approach, the choice between a nebuliser and a pressurised metered-dose inhaler (pMDI) with a valved holding chamber continues to be a subject of clinical debate, particularly regarding younger children. In this prospective observational study, a cohort of 30 children aged 2-8 years was examined to compare the clinical efficacy and usability of these delivery methods. Group A (n = 16) received salbutamol via a jet nebuliser, while Group B (n = 14) utilised a pMDI with a Vortex-type spacer. Despite comparable baseline characteristics ($p > 0.05$), Group B demonstrated accelerated clinical stabilisation, higher levels of child cooperation, and a reduction in the total number of required inhalations. Notably, the incidence of repeat medical consultations and hospitalisations was lower in the spacer group (7.1% for each outcome) compared to the nebuliser group (25.0% and 12.5%, respectively). These findings suggested that a pMDI with a spacer is a highly effective primary tool for managing mild-to-moderate episodes in outpatient and home settings. Nebuliser therapy should be reserved for severe clinical presentations or patients with significant hypoxia and coordination difficulties, typically requiring supervised clinical observation. Integrating spacers into primary care protocols can optimise treatment efficiency and alleviate the burden on hospital facilities by providing reliable management of less severe obstructions

Keywords: bronchial obstructive syndrome; respiratory conditions; bronchodilators; spacer

Introduction

Obstructive bronchitis is one of the most common acute respiratory conditions in early childhood, accounting for a significant proportion of visits to paediatric emergency departments. A.A.B. Wolters *et al.* [1] found that in some countries the prevalence of wheezing in preschool children reaches 30-50%, with a substantial proportion of these children subsequently exhibiting recurrent episodes of obstruction. The pathogenetic basis of bronchial obstructive syndrome includes bronchospasm, mucus hypersecretion, and oedema of the bronchial mucosa, which leads to impaired pulmonary ventilation and an increased risk of respiratory failure.

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C. Schorlemer & E. Eber [2] demonstrated that short-acting β_2-agonists, particularly salbutamol, remain the first-line treatment for obstructive bronchitis in children. Inhalation therapy is the main method of delivering bronchodilators in bronchial obstructive syndrome in paediatric practice. The two principal delivery methods are nebuliser therapy and the use of a pressurised metered-dose inhaler (pMDI) with a spacer. A. Emeryk *et al.* [3] demonstrated that the clinical effectiveness of nebuliser therapy in children is significantly influenced by the technical characteristics of the device and the patient's breathing pattern, as both factors directly determine pulmonary drug deposition and, consequently, the bronchodilator response. E. Bhatt & R.A. Malkin [4] demonstrated that errors in MDI technique remain highly prevalent among children despite prior in-person instruction: 81% of paediatric patients used their inhalers incorrectly, with the most frequent errors being rapid shallow breathing, inadequate breath-holding, and excessive actuations, all of which significantly reduce the amount of medication reaching the airways.

The comparative effectiveness of these two delivery methods has been investigated in a number of randomised controlled trials. C. Lemaçon & A.A. Lopes [5], in a two-centre study conducted in paediatric emergency departments, demonstrated that salbutamol delivered via pMDI with a holding chamber was as effective as nebulisation for mild to moderate asthma exacerbations, with significantly lower hospitalisation rates, fewer side effects, and shorter emergency department visits in the pMDI group – particularly pronounced in children under 6 years of age. C. Graybill *et al.* [6], in a retrospective study of paediatric patients with asthma exacerbations at a primary care centre, found that albuterol delivered via MDI with a spacer was more effective than nebulisation in reducing follow-up visits: none of the MDI-treated patients returned to care within 30 days, compared with 61% of those who received nebulised treatment ($p < 0.00001$). P.K. Gleeson *et al.* [7] emphasised that improper inhaler technique in persistent asthma is a widespread problem, and standardised checklists for assessing inhalation technique are still lacking. In this context, the choice of a specific spacer model is important. In this context, the choice of a specific spacer model carries direct clinical relevance.

L. Ojanperä *et al.* [8], in an *in vitro* study simulating paediatric breathing patterns in children aged 4 and 6 years, demonstrated that salbutamol fine particle dose (FPD, 1-5 μm) differed substantially between devices: EasyChamber delivered a median FPD of 30.7 μg in the 6-year-old profile and 25.0 μg in the 4-year-old profile, compared with 8.2-13.5 μg and 6.8-11.6 μg, respectively, for the remaining spacers ($p < 0.001$). Under simulated obstructive breathing, FPD declined markedly across all devices, with EasyChamber still outperforming others (6.4 μg vs 1.4-1.7 μg; $p < 0.001$), reinforcing that findings from one spacer model cannot be extrapolated to another. M.M. Alotaibi *et al.* [9] demonstrated that the majority of asthma patients do not use their inhalers appropriately, with poor technique observed in 67% of participants, and emphasised that prescribing an inhaler device matched to the patient's ability to generate adequate inspiratory flow is essential for optimal drug delivery to the airways and effective disease management. M. Ruszczyński *et al.* [10], in a systematic review, assessing the quality of guidelines on preschool wheezing and asthma using the AGREE II instrument, demonstrated considerable variability in methodological rigour across available recommendations, with particularly low scores in the domains of applicability and stakeholder involvement, highlighting the need for higher-quality evidence to inform clinical decision-making in this patient population.

Despite the available data on the comparable effectiveness of pMDIs with spacers and nebulisers, the question of the optimal delivery method for specific age groups and degrees of obstruction remains insufficiently studied, particularly regarding Vortex-type spacers in children with obstructive bronchitis in real-world clinical practice. Therefore, the purpose of this study was to conduct a comparative evaluation of the clinical effectiveness, ease of use, and safety of nebuliser therapy and pMDIs with a Vortex-type spacer in children with obstructive bronchitis by analysing the dynamics of clinical parameters (degree of obstruction, oxygen saturation), the frequency of adverse effects, and the convenience of device use depending on the child's age.

Materials and Methods

This prospective observational cohort study was conducted in the outpatient paediatric department of Municipal Non-Profit Enterprise "City Children's Clinical Hospital No. 16" of Kharkiv City Council between February 2024 and May 2025. The study protocol was approved by the Institutional Ethics Committee (reference No. 2023/06) and was carried out in full accordance with the principles of the Declaration of Helsinki [11]. Written informed consent was obtained from the parent or legal guardian of each participant following a comprehensive explanation of all study procedures. Out of 32 children aged 2-8 years consecutively screened with a clinical diagnosis of obstructive bronchitis, 30 patients fulfilled all per-protocol criteria and were retained in the final analysis; two children were excluded due to post-enrolment protocol deviations. The enrolled cohort comprised three age strata: 9 children (30.0%) aged 2-3 years, 12 children (40.0%) aged 4-5 years, and 9 children (30.0%) aged 6-8 years, with a mean age of 5.0 ± 1.8 years for the total sample. The overall sex distribution was 18 males and 12 females (60.0% and 40.0%; $p > 0.05$). Inclusion criteria were: clinical diagnosis of obstructive bronchitis, age 2-8 years, and written parental/guardian consent. Diagnosis was established based on productive cough, diffuse expiratory wheeze, tachypnoea, expiratory dyspnoea, and accessory muscle recruitment; chest radiography was performed when clinically indicated in accordance with R. Axinte *et al.* [12], Ministry of Health of Ukraine [13-14], Global Initiative for Asthma Management and Prevention [15]. Baseline SpO_2 ranged from 90-94%. Exclusion criteria included bronchial asthma, congenital

cardiopulmonary disease, cystic fibrosis, severe central nervous system pathology, immunodeficiency, gastroesophageal reflux disease, systemic corticosteroids within the preceding four weeks, and salbutamol hypersensitivity.

All patients were treated per current clinical guidelines and were initially seen on an outpatient basis; hospitalisation during the follow-up period was recorded as a primary outcome measure rather than a baseline condition. Allocation was based on clinical severity and the physician's assessment of the child's ability to cooperate with the device. Disease severity at presentation was classified as mild (SpO_2 92-94%, dyspnoea absent or minimal) or moderate (SpO_2 90-91%, expiratory dyspnoea present); no severe cases (SpO_2 <90%) were enrolled. In Group A, 10 patients (62.5%) presented with mild and 6 (37.5%) with moderate disease; in Group B, 9 patients (64.3%) presented with mild and 5 (35.7%) with moderate disease. Severity distribution was comparable between groups ($p > 0.05$). Group A (n = 16; 53.3%) received salbutamol (2.5 mg/mL) via jet nebuliser; Group B (n = 14; 46.7%) received salbutamol via pMDI with a Vortex valve-controlled spacer. Primary outcomes included: session duration, number of sessions to full resolution, repeat visit rate, hospitalisation rate, and overall clinical improvement (resolution of dyspnoea, SpO_2 ≥96%, absence of wheeze, and meaningful cough reduction). Secondary outcomes comprised post-treatment changes in respiratory rate, dyspnoea, SpO_2, cough grade, and auscultatory findings.

A structured questionnaire was administered to 34 paediatricians with experience of both devices, evaluating five domains – ease of use, procedure duration, child cooperation, technique error rate, and tolerability – each on a five-point Likert scale. Continuous data were expressed as mean ± SD or median interquartile range. Between-group comparisons used the Mann-Whitney U test and Fisher's exact test for continuous and categorical variables, respectively. The Holm-Bonferroni correction was applied for multiple comparisons; 95% CIs were estimated by bootstrap resampling (1,000 iterations). Statistical significance was set at $p < 0.05$. Analyses were performed in SPSS v26.0 and Python 3.x (SciPy). Baseline characteristics were comparable between groups ($p > 0.05$ for all parameters).

Results

Baseline characteristics. Detailed demographic, clinical, and laboratory parameters for both cohorts are presented in Table 1. Two baseline asymmetries of potential clinical relevance warrant explicit commentary. First, Group B exhibited a more pronounced male predominance (64.3%) compared with Group A (56.3%), which, although not statistically significant, merits acknowledgment given that male sex is a recognised modifier of airway reactivity in early childhood and may have introduced a subtle directional influence on Group B outcomes. This observation is consistent with the findings of M. Attanasi *et al.* [16], who reported that boys demonstrated consistently higher odds of wheezing than girls from birth through age 13 years (OR 0.86, 95% CI 0.74-0.98) in a multi-ethnic population-based cohort of 3,418 children. Second, the distribution of prior episode history differed noticeably between groups: only 6.3% of Group A patients were experiencing their first obstructive episode versus 21.4% in Group B – a 15.1-percentage-point differential carrying potential clinical implications, as first-episode patients may exhibit a more pronounced initial bronchodilator response. Conversely, Group B contained a nominally higher proportion of patients with three or more prior episodes (35.7% vs 25.0% in Group A), suggesting a greater burden of recurrent airway disease in the spacer cohort. These distributional nuances are reported transparently to support unbiased interpretation of the efficacy data. Beyond these specified asymmetries, formal statistical testing confirmed cohort parity across all remaining parameters at baseline (all $p > 0.05$).

Table 1. Baseline demographic, clinical, and laboratory characteristics of study participants

Characteristic	Total (n = 30)	Group A – Nebuliser (n = 16)	Group B – Spacer (n = 14)	p-value
Sex distribution, M/F	18/12	9/7	9/5	> 0.05
Age, years (mean ± SD)	5.0 ± 1.8	5.2 ± 1.6	4.8 ± 2.0	> 0.05
First episode of obstruction, n (%)	4 (13.3)	1 (6.3)	3 (21.4)	> 0.05
≥3 prior episodes of obstruction, n (%)	9 (30.0)	4 (25.0)	5 (35.7)	> 0.05
Atopic dermatitis, n (%)	3 (10.0)	1 (6.3)	2 (14.3)	> 0.05
Food allergy, n (%)	4 (13.3)	2 (12.5)	2 (14.3)	> 0.05
Allergic rhinitis, n (%)	3 (10.0)	1 (6.3)	2 (14.3)	> 0.05
Family history of allergic diseases, n (%)	8 (26.7)	4 (25.0)	4 (28.6)	> 0.05
Eosinophils > 0.3×10^9/L, n (%)	4 (13.3)	2 (12.5)	2 (14.3)	> 0.05
Lymphocytes > 4.0×10^9/L, n (%)	16 (53.3)	9 (56.3)	7 (50.0)	> 0.05
Elevated CRP (>5 mg/L), n (%)	10 (33.3)	5 (31.3)	5 (35.7)	> 0.05
Leukocytosis (>10×10^9/L), n (%)	14 (46.7)	7 (43.8)	7 (50.0)	> 0.05
Recurrent URTIs, n (%)	26 (86.7)	14 (87.5)	12 (85.7)	> 0.05
Passive smoking exposure, n (%)	11 (36.7)	6 (37.5)	5 (35.7)	> 0.05
Dyspnoea before treatment, n (%)	24 (80.0)	13 (81.3)	11 (78.6)	> 0.05
SpO_2 before treatment (mean, %)	91.7	91.8	91.5	> 0.05

Continued Table 1

Characteristic	Total (n = 30)	Group A – Nebuliser (n = 16)	Group B – Spacer (n = 14)	p-value
Moderate/severe cough, n (%)	27 (90.0)	14 (87.5)	13 (92.9)	> 0.05
Auscultatory wheezing, n (%)	27 (90.0)	14 (87.5)	13 (92.9)	> 0.05

Note: PM/F – male/female; SpO_2 – oxygen saturation; CRP – C-reactive protein; URTI – upper respiratory tract infection; SD – standard deviation. All $p > 0.05$ (Mann-Whitney U/Fisher's exact tests with Holm-Bonferroni correction)
Source: compiled by the authors

Collectively, the data in Table 1 confirm that Groups A and B entered the study with broadly equivalent disease burden and clinical presentation profiles. The absence of statistically significant differences across all 18 assessed baseline parameters provides a valid analytical foundation for attributing observed inter-group differences in clinical outcomes to the inhalation modality rather than to pre-existing cohort heterogeneity. The two qualitative asymmetries identified above – the higher proportion of first-episode patients in Group B and the mild male predominance in that cohort – constitute acknowledged observational features of the pragmatic allocation design and should be considered in the contextual interpretation of subsequent efficacy findings.

Atopic and allergic profiles. Allergic predisposition profiling was undertaken systematically in all 30 participants; group-level prevalence figures for each condition are provided in Table 1. Notably, the recorded allergic conditions were not mutually exclusive. Two children with concurrent atopic dermatitis and allergic rhinitis were both from Group B (6.7% of the total cohort; 14.3% of Group B), and one child with co-existing atopic dermatitis and food allergy was from Group A (3.3% of the total cohort; 6.3% of Group A). No child presented simultaneously with allergic rhinitis and food allergy, and no case of all three conditions co-occurring was documented. In total, three children (10.0%) carried two simultaneous allergic diagnoses – a pattern consistent with early-stage atopic march progression, as highlighted by Y.D. Bondarenko *et al.* [17], who reported frequent allergic comorbidities in children with allergic rhinitis, including bronchial asthma (28%), allergic conjunctivitis (32%), and atopic dermatitis (4.7%), underscoring the concept of allergic multimorbidity as a hallmark of the atopic march. Accounting for overlap, children with any form of allergic predisposition constituted approximately 23-27% of the cohort. Although none of the inter-group differences in allergic conditions reached statistical significance (all $p > 0.05$; Table 1), the marginally higher aggregate atopic burden in Group B warrants acknowledgment as a potential modulatory factor when interpreting treatment response data, given that allergic airway inflammation may independently influence bronchodilator responsiveness. Concomitant non-allergic comorbidities – primarily acute rhinitis – were identified in 6 children across the cohort (20.0%). Symptom duration prior to initiation of bronchodilator therapy ranged from 1 to 4 days, with 2-3 days being the most frequently reported interval, reflecting an acute clinical presentation at enrolment. All patients were managed in accordance with the current clinical guideline for children with acute expiratory airway obstruction and bronchial asthma exacerbation.

Clinical outcome. Both inhalation modalities produced clinically meaningful improvements across all assessed respiratory parameters (Fig. 1). The magnitudes of symptomatic improvement were broadly similar between groups across all five parameters (Table 2), confirming that both delivery systems achieve effective acute bronchodilation. The clinically decisive differentiation lies not in the quality of therapeutic response but in the efficiency with which it is achieved. As shown in Table 2, spacer use resulted in a two-fold reduction in mean session duration ($p < 0.001$), accompanied by a significantly lower total number of sessions required to reach complete symptom resolution ($p = 0.038$). Together, these parameters indicate a dual efficiency advantage with direct implications for outpatient clinical throughput and caregiver treatment burden.

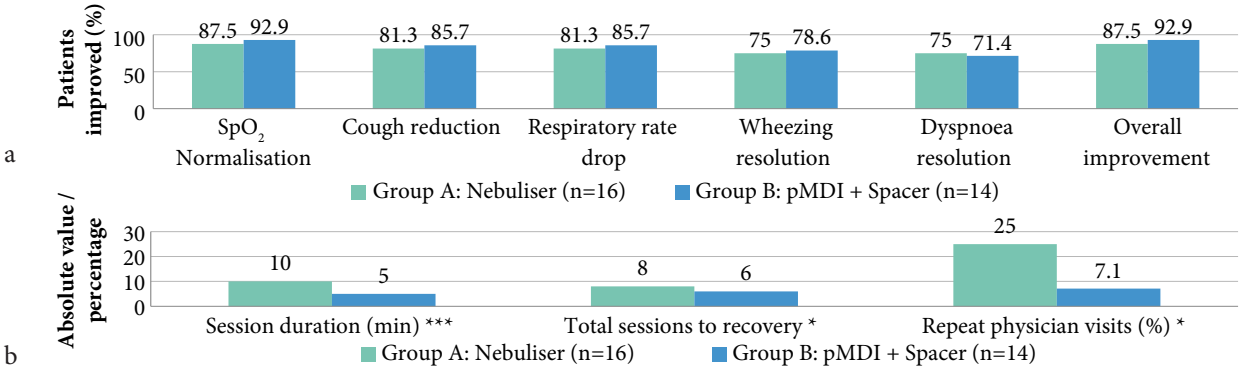

Figure 1. Comparison of paediatric treatment effectiveness
Note: a – clinical effectiveness (equivalence between groups); b – treatment efficiency and burden (advantage of spacer); clinical outcomes: Group A (nebuliser, n = 16) vs Group B (pMDI+Vortex, n = 14): respiratory rate, SpO_2, dyspnoea, cough, and wheezing. Values = % of patients improved; * $p < 0.05$, *** $p < 0.001$ (statistical significance for procedural advantage)
Source: compiled by the authors

Table 2. Clinical outcomes and procedural efficiency by inhalation modality

Parameter	Nebuliser		Spacer		Δ (%) A vs B	p-value
	Before	After	Before	After		
Respiratory rate (RR), elevated, n (%) / MD ± SD	16 (100) / 32 ± 4	3 (18.7) / 20 ± 3	14 (100) / 31 ± 5	2 (14.3) / 19 ± 2	-81.3 vs -85.7	> 0.05
Dyspnoea, n (%)	13 (81.3)	1 (6.3)	11 (78.6)	1 (7.1)	-75.0 vs -71.4	> 0.05
SpO_2 <96%, n (%) / MD ± SD	16 (100) / 91.8 ± 2.1	2 (12.5) / 97.0 ± 1.2	14 (100) / 91.5 ± 2.3	1 (7.1) / 97.5 ± 0.8	+87.5 vs +92.9	> 0.05
Moderate/severe cough, n (%)	14 (87.5)	3 (18.7)	13 (92.9)	2 (14.3)	-81.3 vs -85.7	> 0.05
Auscultatory wheezing, n (%)	14 (87.5)	2 (12.5)	13 (92.9)	2 (14.3)	-75.0 vs -78.6	> 0.05
Duration of inhalation (min, MD ± SD)	10.0 ± 1.2		5.0 ± 0.8		–	< 0.001
Total sessions to recovery (MD ± SD)	8.0 ± 1.6		6.0 ± 1.2		–	0.038
Repeat physician visits, n (%)	4 (25.0)		1 (7.1)		-17.9 pp	< 0.05
Hospitalisations, n (%)	2 (12.5)		1 (7.1)		-5.4 pp	> 0.05
Overall clinical improvement, n (%)	14 (87.5)		13 (92.9)		+5.4 pp	> 0.05

Note: SD – standard deviation; n – absolute number of patients. Mann-Whitney U test for continuous variables. Fisher's exact test for categorical variables with Holm-Bonferroni correction. Overall clinical improvement defined as composite endpoint: SpO_2 ≥96%, resolution of dyspnoea and auscultatory wheezing, and clinically meaningful reduction in cough severity

Source: compiled by the authors

Secondary healthcare utilisation outcomes reinforced this pattern. Repeat physician visits were significantly less frequent in Group B ($p < 0.05$), while hospitalisation rates, though numerically lower in the spacer group, did not reach statistical significance – a finding attributable to limited statistical power for this infrequent outcome. Overall clinical improvement rates were comparable between groups, with a numerically – though not significantly – superior composite response in the spacer group (Table 2). The data in Table 2 delineate a consistent clinical pattern in which the pMDI + Vortex spacer confers statistically significant and clinically meaningful advantages in treatment efficiency – specifically in session duration ($p < 0.001$), total session count ($p = 0.038$), and unscheduled return visit rate ($p < 0.05$) – without compromising the quality of therapeutic response relative to jet nebuliser therapy. The non-significant difference in hospitalisation rates may reflect adequate clinical safety provision in both arms rather than genuine equivalence in the most severely affected patients; this question warrants evaluation in adequately powered future studies.

Usability and paediatricians' satisfaction. The structured usability questionnaire administered to 34 paediatric physicians yielded a domain-specific performance profile providing critical context for interpreting the aggregate scoring differential between modalities (Table 3). Notably, both devices received identical physician ratings for ease of use and frequency of inhalation technique errors – confirming that physicians perceive the two modalities as equally straightforward to prepare and operate, with an equivalent margin of procedural error. The aggregate advantage of the spacer ($p < 0.001$) therefore cannot be attributed to differences in device complexity or physician familiarity with the equipment. Statistically significant between-device differences were identified exclusively in three domains: procedure duration, child cooperation, and child tolerability (all $p \leq 0.05$). The procedure duration differential is the most objectively grounded of the three, directly corroborating the two-fold session time reduction. The cooperation and tolerability domains, in contrast, reflect physician-perceived behavioural and experiential assessments. In children aged 2-8 years, responses to inhalation procedures are substantially modulated by developmental stage, anticipatory anxiety, sensitivity to the nebuliser's motor noise, and physical encumbrance of the mask – factors that cannot be fully disentangled from device-specific performance characteristics in an observational design. These ratings therefore represent important observational signals regarding the paediatric patient experience, and should be interpreted as such rather than as strictly objective device performance metrics.

Table 3. Paediatric physician ratings of inhalation device usability

Criterion	Group A Nebuliser	Group B Spacer	Difference (Δ)	Statistical significance
Ease of device use	5	5	0	n.s.
Procedure duration	1	5	4	$p < 0.01$
Child cooperation during procedure*	2	5	3	$p < 0.05$
Child tolerability*	1	5	4	$p < 0.01$
Frequency of inhalation technique errors	3	3	0	n.s.
Total mean score	2.4	4.6	2.2	$p < 0.001$

Note: *domains of child cooperation and tolerability reflect physician observational assessments in children aged 2-8 years and contain an inherent subjective component attributable to age-dependent behavioural variability and developmental stage

Source: compiled by the authors

The domain-level analysis of Table 3 reveals that the aggregate physician preference for the pMDI + Vortex spacer is driven by a combination of objectively faster procedure delivery and the perceived superiority of the spacer in terms of child tolerability and cooperation – with no contribution from device-complexity differences, as evidenced by the identical ease-of-use and technique-error scores. These findings support the preferential use of pMDI + Vortex spacer therapy as the first-line bronchodilator delivery modality in cooperative paediatric outpatients with obstructive bronchitis, while affirming the continued clinical utility of jet nebuliser therapy in patients with more severe respiratory distress or inadequate inhalation coordination – a stratified deployment model aligned with current evidence-based recommendations – Order of the Ministry of Health of Ukraine No. 00129 and No. 00613 [13-14] and Global Initiative for Asthma Management and Prevention [15].

Discussion

The present study evaluated jet nebuliser therapy versus pMDI with a Vortex-type valved holding chamber for bronchodilator delivery in children aged 2-8 years with mild-to-moderate obstructive bronchitis. Both modalities produced clinically equivalent therapeutic responses across all assessed respiratory parameters. On the other hand, the spacer-based approach conferred statistically significant advantages in procedural efficiency and secondary healthcare utilisation.

*Equivalence of therapeutic response***.** Overall clinical improvement was achieved in 87.5% and 92.9% of patients in Groups A and B respectively ($p > 0.05$), with all individual parameter response rates likewise statistically equivalent (all $p > 0.05$). This aligns with the growing evidence base confirming pharmacological equivalence of the two delivery platforms. K. Sugiura *et al.* [18] demonstrated that pMDI with a spacer was comparable to nebuliser in clinical effectiveness among children aged 4-16 years with moderate-to-severe acute asthma exacerbations (MPIS reduction: 4.3 vs 3.7; $p = 0.13$), while being associated with a significantly shorter length of stay (61 vs 94 min; $p < 0.001$) and a lower incidence of adverse events. C. Graybill *et al.* [6] similarly confirmed the superiority of pMDI with spacer in reducing unscheduled follow-up visits, with zero MDI-treated patients returning within 30 days compared to 61% in the nebuliser group ($p < 0.00001$). The present data confirm that this equivalence in therapeutic response – alongside the efficiency advantage of the spacer – holds in a real-world outpatient cohort using the Vortex device specifically.

Procedural efficiency: the decisive differentiator. Mean session duration was reduced by 50% in Group B (5.0 ± 0.8 vs 10.0 ± 1.2 min; $p < 0.001$), and total sessions to full recovery were significantly fewer (6.0 ± 1.2 vs 8.0 ± 1.6; $p = 0.038$), yielding cumulative time savings of 24-40 minutes per treatment course. The reduced session count suggests more efficient bronchial deposition per dose – consistent with cost-effectiveness data from J. Witnalakorn *et al.* [19], who demonstrated that MDI with spacer incurred lower direct medical costs than nebulisation in children with asthma exacerbation (ICER: −4.60 USD per one-point asthma score improvement; −20.07 USD per hospitalisation averted), and with resource utilisation data from S.A. Alhaider *et al.* [20], who reported a 48% reduction in treatment delivery time and up to 87% medication cost savings following conversion from nebuliser to MDI-spacer in hospitalised children. These efficiency advantages persisted under outpatient conditions in children as young as 2 years, including those with no prior device familiarity.

Secondary healthcare utilisation and implications for outpatient management. One of the most clinically significant findings of this study was the substantially lower rate of unscheduled repeat physician visits in Group B. Four of 16 Group A patients (25.0%) required a repeat visit due to clinical deterioration, compared with only 1 of 14 Group B patients (7.1%) – a statistically significant 17.9-percentage-point reduction ($p < 0.05$). Hospitalisation rates, while numerically lower in Group B (7.1% vs 12.5%), did not reach statistical significance ($p > 0.05$), a finding attributable in part to the limited statistical power for this low-frequency outcome in a 30-patient cohort. Taken together, these utilisation data suggest that superior procedural efficiency and better child tolerance in the spacer group contribute to more sustained therapeutic adherence at home, reducing clinical rebound. The directional finding on hospitalisations, though non-significant, is consistent with findings in the literature: O. Nomura *et al.* [21], in a prospective observational study of 158 paediatric ED patients, similarly found no statistically significant difference in admission rates between MDI-delivered ipratropium and non-MDI groups (25.9% vs 31.5%; $p = 0.67$), suggesting that detection of hospitalisation differences in real-world outpatient cohorts is inherently limited by event frequency and sample size. But it is worth mentioning that parental perception of device efficacy is a key mediator of home adherence: A.A. Alzayed *et al.* [22], in a cross-sectional survey of 1,021 Saudi caregivers, found that 70.2% suggested there is a therapeutic difference between MDI and nebuliser, with 45.2% considering the nebuliser more effective, despite evidence to the contrary; moreover, parents who received adequate device education reported significantly higher satisfaction scores (6.38 vs 5.28; $p < 0.001$). Proper inhaler technique further conditions home-based outcomes – B.A. Almomani *et al.* [23] reported that correct MDI use was observed in only 13.4% of paediatric patients, and that higher parental knowledge was independently associated with a greater number of correct inhaler steps (OR = 1.066; 95% CI = 1.010-1.125; $p = 0.020$). Institutional barriers to MDI adoption also affect utilisation patterns at the system level: N.F. Sakrani *et al.* [24] demonstrated that targeted physician education at a tertiary paediatric ED increased MDI + spacer prescribing from 28% to 41% ($p = 0.046$), and raised the proportion of physicians confident in convincing parents to accept spacer-based therapy from 35% to 66% ($p < 0.0001$). The Vortex spacer's advantages –

portability, absence of power-source requirements, and shorter procedure duration – make it particularly suited to home-based maintenance therapy in resource-limited outpatient contexts, aligning with the practical recommendations of Ukrainian Ministry of Health clinical guidelines [13-14].

Child cooperation, tolerability, and the paediatric patient experience. The paediatrician usability survey (n = 34) revealed that aggregate preference strongly favoured the spacer (mean score 4.6 vs 2.4; $p < 0.001$), with significant between-device differences in procedure duration ($p < 0.01$), child cooperation ($p < 0.05$), and tolerability ($p < 0.01$) – while ease of use and technique error rates were identical. The nebuliser's lower ratings reflect its well-documented behavioural stressors: continuous motor noise, prolonged mask contact, and substantial drug losses during crying – factors disproportionately affecting toddlers and pre-schoolers, who comprised 70% of this cohort. As A. Ari [25] noted in a narrative review of aerosol delivery in children, lung deposition in crying infants receiving nebulised therapy was approximately fourfold lower than in cooperative patients, and up to 49% of children do not tolerate facemasks during treatment, with fussing and crying substantially reducing the inhaled dose. The Vortex spacer eliminates the noise source, halves session time, and requires only a few cooperative breaths, substantially lowering the behavioural threshold for effective inhalation. An additional practical advantage relates to the device interface: S.H. Chen *et al.* [26] demonstrated in an in vitro infant and paediatric model that aerosol drug delivery efficiency is significantly influenced by the degree of enclosure sealing and the delivery interface used, confirming that device configuration directly determines the inhaled dose available to the child.

Interpretation of baseline asymmetries and allocation design. Allocation was based on clinical severity and assessed cooperation capacity, reflecting real-world outpatient practice. Two baseline asymmetries warrant consideration: a higher proportion of first-episode patients in Group B (21.4% vs 6.3%), and greater recurrent obstruction burden in the same group (≥3 episodes: 35.7% vs 25.0%). These forces are directionally opposing and difficult to quantify in a cohort of this size. The allocation design – directing more severely affected or uncooperative children toward nebuliser therapy – may itself account for Group A's higher session count and repeat visit rate, independent of any pharmacological inferiority. This allocation-severity confound is the primary study limitation and should be addressed through prospective randomisation in future research.

Device selection context: the role of clinical severity. The Vortex spacer is a valved holding chamber that temporarily retains the pMDI aerosol cloud, eliminating the coordination requirement and selectively delivering the 2-5 μm therapeutic fraction to the distal bronchi. O.A. Sayed *et al.* [27] demonstrated in an in-vitro model that conventional spacers significantly enhance the delivery of fine particles (<5 μm) and improve aerodynamic distribution compared to using a pMDI alone. This mechanism presupposes a minimum level of respiratory effort and cooperation, which is reliably available in children with mild-to-moderate obstruction but becomes compromised under conditions of marked respiratory distress, hypoxia-driven reduction in β_2-receptor sensitivity, or impaired consciousness. E. Poplicean *et al.* [28] reported that up to 70-80% of asthma patients do not use their inhalers correctly, with technique errors such as incorrect inhalation speed directly contributing to poor asthma control and increased emergency department visits. The nebuliser, by contrast, enables passive aerosol delivery independent of patient effort, making it the appropriate default in severe obstruction with desaturation (SpO_2 <90%), pronounced intercostal retractions, or inability to sustain mask contact. J.M. Lizzo *et al.* [29] emphasised that because paediatric asthma severity can range from intermittent symptoms to life-threatening airway compromise, treatment decisions must be strictly guided by symptom intensity and exacerbation risk. R. Chu & P. Bajaj [30] noted that a stepwise approach to management is essential, ensuring that the escalation of medication and device selection matches the severity of the patient's presentation and their physical capacity to use the delivery device.

In the present cohort, baseline SpO_2 was comparable across groups (91.8% vs 91.5%), and all enrolled children fell within the mild-to-moderate severity range – a design condition that appropriately isolated the efficiency and tolerability dimensions of the comparison rather than the pharmacological ceiling of either device. The current Global Initiative for Asthma Management and Prevention [15] states that "the preferred device is a pressurised metered-dose inhaler (pMDI) and spacer, with face mask for <3 years and mouthpiece for most children aged 3-5 years, highlighting that in children, pMDI should always be used with a spacer as delivery of short-acting beta-agonist via a pMDI and spacer or a DPI leads to a similar improvement in lung function as delivery via nebuliser (Evidence A).

Conclusions

Both nebuliser therapy and pMDI with a Vortex-type spacer demonstrated comparable clinical efficacy in the treatment of mild-to-moderate obstructive bronchitis in children aged 2-8 years, with statistically equivalent improvements across all assessed respiratory parameters (overall clinical improvement: 87.5% in Group A vs 92.9% in Group B; $p > 0.05$), confirming pharmacological equivalence of both delivery platforms. The Vortex spacer demonstrated a significant advantage in procedural efficiency: mean session duration was two-fold shorter (5.0 ± 0.8 vs 10.0 ± 1.2 min; $p<0.001$), total number of sessions required for full recovery was lower (6.0 ± 1.2 vs 8.0 ± 1.6; $p = 0.038$), and the rate of unscheduled repeat visits markedly reduced (7.1% vs 25.0%; $p < 0.05$). Hospitalisation rates were lower in Group B (7.1% vs 12.5%), though non-significant due to limited sample power. Physician usability ratings strongly favoured the spacer (4.6 vs 2.4; $p < 0.001$), with superiority in procedure duration, child cooperation, and

tolerability – most pronounced in children aged 2-5 years. No severe adverse effects were recorded in either group. Baseline asymmetries – higher male proportion in Group B (64.3% vs 56.3%) and more first-episode cases (21.4% vs 6.3%) – and the absence of formal severity stratification within groups represent methodological limitations. Future prospective multicentre RCTs stratified by age, sex, and severity grade with standardised caregiver technique assessment are needed to confirm these findings and to determine whether the spacer's efficiency advantage translates into a significant reduction in hospitalisation rates.

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Conflict of Interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Порівняльна клінічна ефективність та процедурна результативність небулайзера та клапанної утримувальної камери при дитячому обструктивному бронхіті

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Анотація. Обструктивний бронхіт залишається частою причиною гострого респіраторного дистресу в педіатричній практиці. Хоча бронхолітики є «золотим стандартом» лікування, вибір між небулайзером і дозованим аерозольним інгалятором під тиском (pMDI) із клапанною утримувальною камерою й надалі є предметом клінічних дискусій, особливо щодо дітей молодшого віку. У цьому проспективному обсерваційному дослідженні було обстежено когорту з 30 дітей віком 2-8 років з метою порівняння клінічної ефективності та зручності використання цих методів доставки. Група А (n = 16) отримувала сальбутамол через струминний небулайзер, тоді як група В (n = 14) використовувала pMDI зі спейсером типу Vortex. Попри зіставні вихідні характеристики (p > 0,05), у групі В спостерігалися швидша клінічна стабілізація, вищий рівень співпраці дітей та зменшення загальної кількості необхідних інгаляцій. Примітно, що частота повторних медичних звернень і госпіталізацій була нижчою у групі спейсера (по 7,1 % для кожного показника) порівняно з групою небулайзера (25,0 % і 12,5 % відповідно). Отримані результати свідчили, що pMDI зі спейсером є високоефективним основним засобом для лікування епізодів легкої та середньої тяжкості в амбулаторних і домашніх умовах. Небулайзерну терапію доцільно резервувати для тяжких клінічних випадків або пацієнтів зі значною гіпоксією та труднощами координації, які зазвичай потребують клінічного нагляду. Інтеграція спейсерів у протоколи первинної медичної допомоги може оптимізувати ефективність лікування та зменшити навантаження на стаціонари, забезпечуючи надійне ведення менш тяжких обструктивних станів

Ключові слова: бронхообструктивний синдром; респіраторні захворювання; бронхолітики; спейсер