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Efficacy of Pelargonium Sidoides Extract in the Treatment of Acute Bronchiolitis in Infants

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Abstract:

Introduction: During the winter months, acute bronchiolitis is the leading cause of hospitalizations for children younger than two years old, contributing to significant rates of infant sickness and mortality. In certain nations, EPs, a herbal remedy made from *Pelargonium sidoides* roots, are authorized to treat acute respiratory tract infections (ARTIs).

Aim of the study: The purpose of the study was to determine how well *P. sidoides* extract relieved infants' acute bronchiolitis symptoms.

Subjects and Methods: From December 2017 to March 2018, we performed a randomized controlled trial on 100 patients who were admitted with acute bronchiolitis to pediatric departments at Fayoum University and health insurance hospitals in Fayoum, Egypt. Two groups of 100 patients were formed. Group 2 got *P. sidoides* extracts for seven days in addition to supportive measures, while Group 1 comprised fifty infants who received standard supportive therapy for bronchiolitis. The cases were categorized as mild, moderate, and severe based on the Wang score, which was used for follow-up at admission and after 2, 4, and 6 days.

Results: Regarding the Wang score follow-up after 2, 4, and 6 days of therapy, we discovered a statistically significant difference between the two study groups with a p-value less than 0.05. Group II had a lower mean, suggesting a better reaction and improvement.

Conclusions: Treatment of infants admitted for bronchiolitis with *P. sidoides* extract helps in a good prognosis and faster improvement.

Keywords: Bronchiolitis; *Pelargonium sidoides;* extracts.

1. Introduction

The most common reason for children under two to attend the emergency room during the winter is acute bronchiolitis. This leads to a significant use

of healthcare resources and adds to the growing challenges faced by outpatient practices, Emergency Departments, and hospitals [1].

Children who experienced respiratory syncytial virus (RSV) illness in infancy are more likely to develop asthma or wheezing in their later years [2].

A natural remedy prepared from the roots of *Pelargonium sidoides* is called *P. sidoides* extract. Reducing the needless use of antibiotics may be the upshot of *P. sidoides*' effective treatment of acute bronchitis or other mild respiratory tract infections [3].

When antibiotics are not technically necessary, a herbal remedy called EPs 7630, which is made from the roots of *P. sidoides*, has been licensed for use in treating acute bronchitis in children aged ≥1 year in Germany. According to studies, EPs 7630 and its separated constituents have immunomodulatory and mild direct antiviral and antibacterial effects in vitro [4].

One of the most often prescribed drugs for children in Germany is a liquid version of P. sidoides, which was approved in December 2005 for the treatment of acute bronchitis. Despite these doubts, it was later accepted in other countries [5].

2. Subjects and methods

2.1. Subjects

Patients with acute bronchiolitis who were admitted to the pediatric departments at Fayoum University and health insurance hospitals in Fayoum City, Egypt, were the subjects of this randomized controlled research from December 2017 to March 2018.

One hundred patients were involved in the study and split into two groups. 50 infants (32 boys and 18 girls) in Group 1 got standard supportive therapy for bronchiolitis, which included humidified oxygen inhalation delivered according to the severity of the case (simple mask with flow 5 to 6 L, or nasal cannula with flow 1 to 2 L), frequent suctioning of nasal and oral secretions, and care of feeding or parenteral fluids if there was a risk of aspiration with respiratory distress. Group 2 consisted of 50

infants (32 males and 18 females) who received *P. sidoides* extracts for seven days in addition to the supportive measures.

Inclusion criteria

Inclusion criteria were patients aged from 1 month to 2 years old, presenting with acute bronchiolitis, and of both sexes. Exclusion criteria were children with congenital heart disease (CHD), congenital lung anomalies, and wheezy infants due to other causes.

2.2. Methods

All patients were subjected to a comprehensive evaluation, which included full history taking, clinical examination, and investigations. The history taking focused on personal history (age, sex, weight), perinatal history (full-term or pre-term, cesarean section or natural vaginal delivery, history of maternal illness during pregnancy, history of NICU admission), history of present illness (duration of illness, analysis of symptoms such as cough, dyspnea, fever, feeding difficulties, irritable crying, lethargy, apnea, and symptoms affecting other systems), history (previous admissions for the same condition or other conditions), developmental history, and family history (similar conditions in the family, history of asthma, consanguinity).

The clinical examination included a general examination where O2 saturation was recorded by pulse oximetry, anthropometric measures (weight, length, head circumference), and a systemic examination (cardiac, abdominal, and neurological examination). In addition to auscultation findings (prolongation of the expiratory phase of breathing, wheezes, and fine crackles), the chest examination evaluated the level of respiratory distress (Grades 1–4: tachypnea, intercostal retraction, grunting, and cyanosis).

The investigations included a standard chest X-ray as well as standard laboratory tests like C-reactive protein (CRP) and complete blood count (CBC). Age between 1 and 24 months, a history of upper respiratory tract viral infection a few days before the illness (as evidenced by symptoms like catarrhal runny nose, sneezing, and cough), examination results (signs of respiratory distress, expiratory wheezes, and fine crackles), and Wang's clinical score for diagnosis and follow-up were the criteria used to diagnose acute bronchiolitis **(Table 1).**

Table 1: Wang et al. clinical severity score.

Variables	Score			
	0	1	2	3
RR	<30	31-45	46-60	>60
Wheezing	None	Terminal expiration/only with a Stethoscope	Entire expiration or audible on exo. Without a stethoscope	Inspiration and expiration without a stethoscope
Retraction	None	Intercostals	Tracheostoma	Severe with nasal flaring
General condition	Normal			Irritable, lethargic, poor feeding

Significance: 0-4 (mild), 5-8 (moderate), and 9-12 (Severe).

Every patient was monitored for seven days, and the results were compared using Wang's clinical score. On a scale of 0 to 3, this score assigns a grade to the four symptoms and indicators: general condition, wheezing, retraction, and respiratory rate. At admission and on days 2, 4, and 6 after admission, scores were noted.

A clinical severity score of equal to or less than 3, the absence of tachypnea, the capacity to feed well orally, oxygen saturation above 92% in room air, no side effects, and a recorded duration of stay were all requirements for discharge.

2.3. Statistical analysis

The investigation report form was used to document all of the material. The statistical package for social sciences (SPSS) for Windows release 10.0 will be used to evaluate these data, and descriptive and analytical statistics will be obtained.

3. Results

Our study involved 100 patients who were split up into two groups. 50 infants in Group 1 received standard supportive therapy for bronchiolitis, while Group 2 received *P. sidoides* extracts (Kalobin 5–10 drops, three times a day) for seven days in addition to supportive measures. Regarding age, weight, and sex, there was no statistically significant difference between the two study groups (p-value >0.05), indicating that the two study groups were

properly matched in these categories **(Table 2).**

Table 2: Comparisons of demographic characteristics in different study groups

Variables		Group I (n=50)		Group II (n=50)		*P*-value
Age (months)		5.8	3.8	6.5	3.6	0.3
Weight (gm)		6666	2107.6	7178	1913.7	0.2
Sex	Male	32	64%	32	64%	0.9
	Female	18	36%	18	36%	

Regarding neonatal history (gestational age and mode of birth), there was no statistically significant difference between the two study groups (P >0.05), indicating that the two study groups were well matched in these factors **(Figures 1,2).**

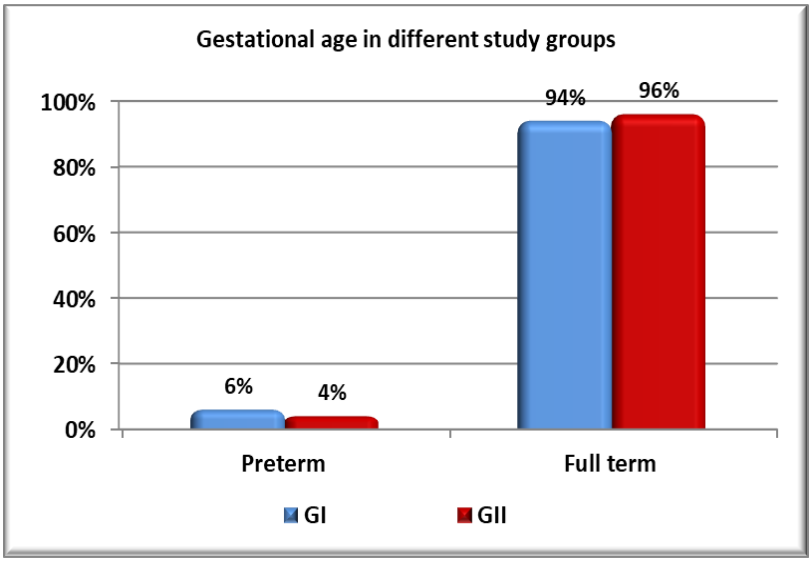

Figure 1: Gestational age in different study groups.

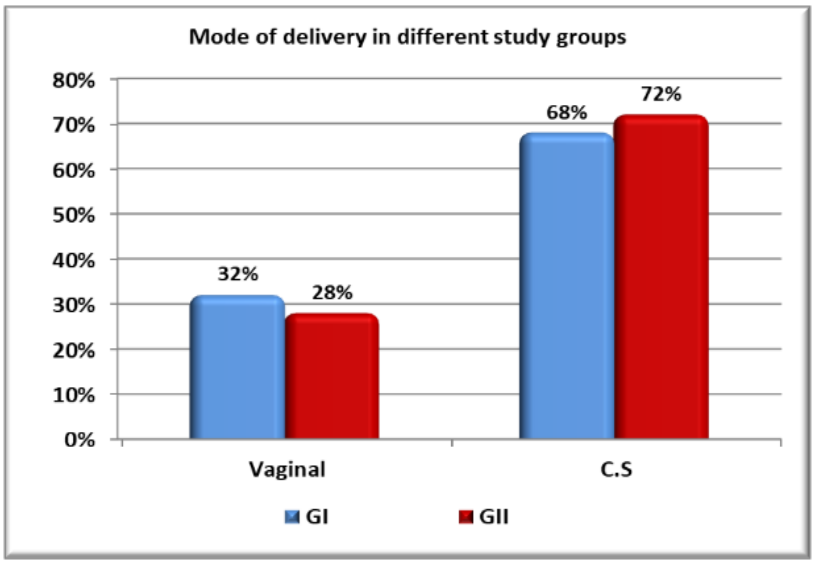

Figure 2: Mode of delivery in different study groups

Regarding patient medical history (developmental history, history of asthma, history of prior hospitalization, and history of NICU admission), there was no statistically significant difference (P >0.05) between the two study groups, indicating appropriate matching between the two study groups in these variables **(Table 3).**

Table 3: Comparisons of patient medical history in different study groups.

Variables		Group I (n=50)		Group II (n=50)		*P*-value
		No.	%	No.	%	
History of asthma in family	No	30	60%	30	60%	1
	Yes	20	40%	20	40%	
History of previous hospital admission	No	35	70%	38	76%	0.7
	Yes	15	30%	12	24%	
Cause of hospital admission	Same condition	10	66.7%	11	91.7%	0.2
	Other conditions	5	33.3%	1	8.3%	
History of previous NICU admission	No	34	68%	43	86%	0.06
	Yes	16	32%	7	14%	
Cause of NICU admission	RD	9	56.3%	4	57.1%	0.9
	Jaundice	3	18.8%	2	28.6%	
	Infant of a diabetic mother	1	6.3%	0	0%	
	Preterm	1	6.3%	1	14.3%	
	HIE	1	6.3%	0	0%	
	RD &LBW	1	6.3%	0	0%	

Comparisons of clinical signs and symptoms in different study groups have shown cough and Dyspnea, i.e., 54% were presented with fever, 50 % were presented with Refusal of feeding, 60 % with irritable crying, 28 % with other systemic affection; this affection mostly included vomiting, 78.6%. in group 2, 100% of infants presented with Cough and Dyspnea, 50 % with fever, 64% with Refusal of feeding, 74 % with irritable crying, 36% with Other systemic affection; this affection mostly included vomiting, 94.4%.

There was no statistically significant difference with *P*>0.05 between the two study groups as regards clinical signs and symptoms, which indicated a proper matching between both study groups in these variables **(Figure 3).**

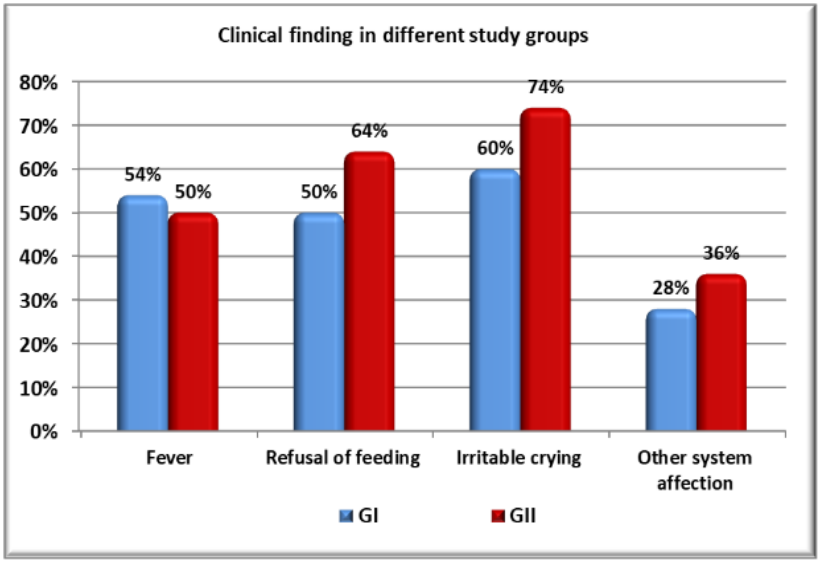

Figure 3: Clinical findings in different study groups.

As regards comparisons of the Wang score in different study groups, there was no statistically significant difference between the two study groups as regards the Wang score on admission, which indicated proper matching between both study groups in these variables. On the other hand, there was a statistically significant difference between the two study groups as regards the Wang score follow-up after 2, 4, and 6 days of treatment, with a low mean among group II **(Figures 4, 5).**

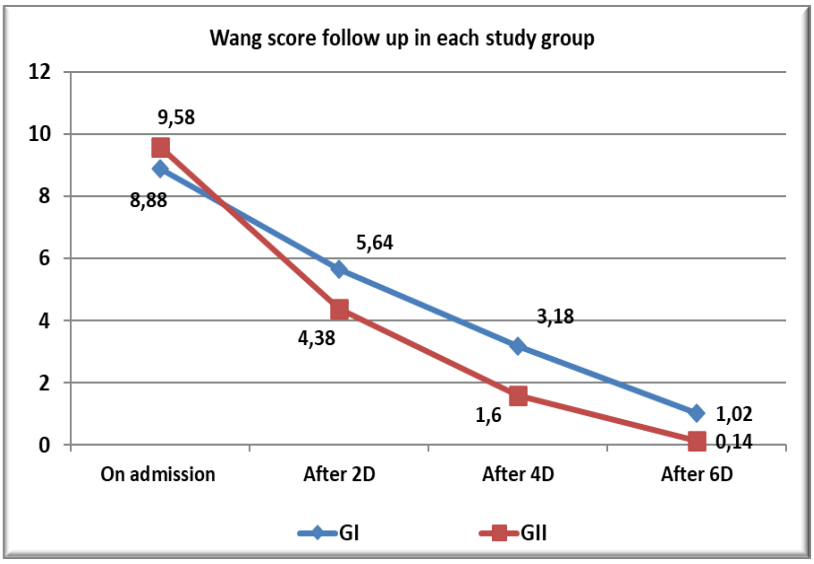

Figure 4: Wang Score follow-up in each study group.

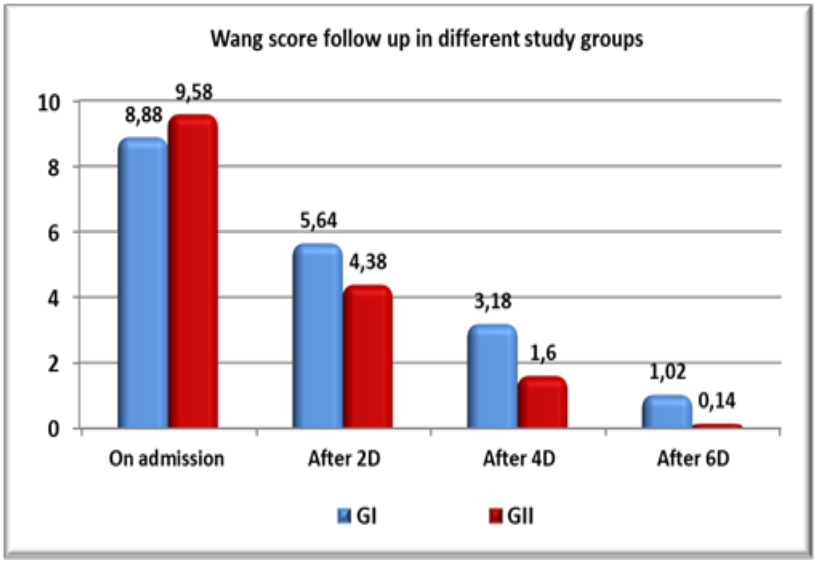

Figure 5: Wang Score degrees follow-up in different study groups.

4. Discussion

Acute bronchiolitis is a common reason for hospitalization of young children. About 3% of children with bronchiolitis need to be admitted to the hospital, even though the majority do not [6]. In affluent nations, 18% of pediatric hospital admissions for bronchiolitis occur in infants less than one year [7].

In everyday clinical practice, the primary focus in treating acute bronchiolitis is to alleviate symptoms. Different drug treatments have been tested, such as inhaled bronchodilators (Beta-2 agonists, epinephrine), corticosteroids (inhaled and systemic), inhaled hypertonic saline, and antiviral medication [8]**.**

This study looked into EPs, a herbal remedy derived from *P. sidoides* roots, as a possible ARTI treatment. EPs 7630 has shown mild antiviral and antibacterial actions and has immune-modulating capabilities, primarily through stimulating the synthesis of interferon-β, increasing natural killer cell activity, and causing the release of nitric oxide and tumor necrosis factor-α [9].

The purpose of our study was to determine whether *P. sidoides* extract was effective in reducing infants' acute bronchiolitis symptoms. Age, weight, and sex did not differ statistically significantly between the two study groups. Males were more affected than females, aligning with a study by Ghazaly & Nadel (2018), where 63% of patients were males [10]. In our study, premature infants accounted for 6% in Group 1 and 4 % in Group 2, contrasting with Ghazaly's study, where preterm infants accounted for 46% of PICU admissions with bronchiolitis, suggesting that prematurity is a risk factor for the severity of the illness.

Regarding perinatal history, 86% of mothers in Group 1 had no illness during pregnancy, while 14% had various illnesses (anemia 42.9%, HTN 14.3%, PROM 14.3%, placenta previa 14.3%). In Group 2, 90% of mothers had no illness during pregnancy, while 10% had various illnesses (anemia 40%, HTN 20%, PROM 20%, placenta previa 20%).

As for NICU admission, 32% of infants in Group 1 were admitted to NICU, with 56.3% of these admissions due to respiratory distress. In Group 2, 14% were admitted to NICU, with 57.1% due to respiratory distress. A previous study found that 31% of patients had a history of NICU admission, which correlates with our study [10].

Regarding previous hospital admissions, 30% in Group 1 and 24% in Group 2 had a history of previous admissions, with 66.7% in Group 1 and 91.7% in Group 2 admitted for the same condition (acute bronchiolitis). This agrees with Luo et al. (2010), who found that 40-50% of severely infected infants with acute

bronchiolitis develop wheezing episodes years after infection [11].

Comparing clinical signs and symptoms, 100% of infants in Group 1 presented with cough and dyspnea, 54% with fever, 50% with feeding refusal, 60% with irritable crying, and 28% with other systemic affection (mostly vomiting, 78.6%). In Group 2, 100% presented with cough and dyspnea, 50% with fever, 64% with feeding refusal, 74% with irritable crying, and 36% with other systemic affection (mostly vomiting, 94.4%).

When comparing Wang scores, the two study groups at admission did not differ statistically significantly, indicating proper matching. However, there was a significant difference in Wang scores after 2, 4, and 6 days of treatment, with Group 2 showing better improvement. Regarding disease severity, 54% in Group 1 had severe disease at admission, decreasing to 8% after 2 days, and none after 4 and 6 days. In Group 2, 70% had severe disease at admission, decreasing to 2% after 2 days, and none after 4 and 6 days. Mild disease in Group 1 increased from 2% at admission to 100% after 6 days, and in Group 2 from 2% at admission to 100% after 6 days, indicating both groups improved to mild severity. There was a significant difference in Wang scores after 2 and 4 days, with Group 2 showing better response and improvement.

The effectiveness of *P. sidoides* extract in reducing the symptoms of acute bronchiolitis in newborns has not yet been the subject of comparable research. Its effectiveness in treating various acute respiratory tract infections, such as acute bronchitis, acute sinusitis, and nasopharyngitis, has been the subject of numerous studies.

5. Conclusion

P. sidoides extract seems to help infants with clinically confirmed acute bronchiolitis have a better prognosis and recover more quickly. However, before suggesting its regular usage in individuals with acute viral bronchiolitis, further extensive research is required to validate its advantages and safety.

Acknowledgment

We would like to thank all of the medical experts and researchers who helped with the diagnosis and therapy, and care of the infants involved in this study. Their

dedication and expertise were invaluable in conducting this research.

Ethical Approval and Consent to Participate

All required ethical permissions were acquired from the relevant institutional review boards, and the study was carried out in compliance with ethical norms and guidelines. Before the newborns were included in the study, their parents or legal guardians gave their informed consent.

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Conflicts of Interest

For this study, no specific grant from a nonprofit, commercial, or public funding agency was secured.

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