Original Article A nurse-led hierarchical management model for the out-of-hospital management of children with bronchial asthma: a prospective randomized controlled study

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Abstract: Objective: To explore the effects of a nurse-led hierarchical management model for managing the out-ofhospital asthma control and quality of life in children with bronchial asthma. Methods: A prospective randomized controlled study was designed. Children with bronchial asthma treated in our hospital were recruited as the study cohort and randomly divided into a test group (n=60) and a control group (n=60). After their discharge from the hospital, the children with bronchial asthma in both groups underwent out-of-hospital management led by nurses. In addition to this management, the test group underwent hierarchical management according to the results of their social living ability and temperament type evaluations. The levels of control of the asthma within 6 months after discharge were compared between the two groups. The changes in the asthma control test (ACT) scores, the daily variation rates in the peak expiratory flows (PEF), the pulmonary functions, the changes in the airway inflammation indicators, and the two groups' quality of life were compared. In addition, univariate and multivariate logistic regressions were used to analyze the factors influencing the acute asthma attacks in children. Results: Compared with the control group, the number of acute asthma attacks, the emergency medical treatment and hospitalization rates in children with acute asthma attacks within 6 months were significantly decreased in the test group (P<0.05). After 3 and 6 months of the nursing, the test group had better ACT scores, better daily PEF variation rates, better pulmonary function, better serum inflammatory factors, better Medication Adherence Report Scale for Asthma (MARS-A) scores, and better pediatric asthma quality of life questionnaire (PAQLQ) scores than the control group (all P<0.05). A multivariate logistic regression analysis showed that acute asthma attacks in childhood asthma were associated with the age of the first attack ≤f years (OR=3.635), a family history of rhinitis/asthma (OR=1.425), poor medication adherence (OR=1.855), the baseline IgE level (OR=1.305), and the hierarchical nursing management (OR=0.593). Conclusions: A nurse-led hierarchical management model can effectively improve the level of out-of-hospital asthma control in children with bronchial asthma and can improve their pulmonary function and quality of life as well.

Keywords: Bronchial asthma, nurse-led, hierarchical management, pulmonary function, airway responsiveness, quality of life

Introduction

Bronchial asthma mainly occurs in young children and has an 8%-28% incidence and prevalence globally, and it is increasing yearly [1, 2]. Recurrent attacks, multiple exacerbations, and poor clinical control have a huge impact on the physical and mental health of children. In severe cases, suffocation or even death may occur [3, 4]. The treatment and management of childhood asthma has become one of the most vital clinical and public health tasks around the world. The current clinical treatment goal for childhood asthma is to achieve complete control of the asthma and to carry out its long-term maintenance, including controlling the clinical symptoms and improving the inflammation and pathophysiological indicators [5]. The clinical treatment procedure is to switch to degraded treatment after at least 3-months of the initial treatment, gradually reducing the drug dose to the lowest effective dose, and maintaining the regular treatment for at least one year without any recurrence or worsening of the symptoms. That is to say, withdrawing the drugs can be

Items	Test group (n=60)	Control group (n=60)	χ²/t	Р	
Gender (n, %)			0.147	0.702	
Male	38 (63.33)	40 (66.67)			
Female	22 (36.67)	20 (33.33)			
Age (years)	4.4±1.4	4.2±1.5	0.828	0.410	
Age of first attack (n, %)			0.600	0.439	
≤3 years	42 (70.00)	38 (63.33)			
>3 years	18 (30.00)	22 (36.67)			
Disease course (years)	2.78±1.45	2.35±1.50	1.597	0.113	
Family history of rhinitis/asthma (n, %)	40 (66.67)	43 (71.67)	0.352	0.553	
Hierarchical management (n, %)			0.318	0.853	
Common level	22 (36.67)	25 (41.67)			
Intermediate level	28 (46.67)	26 (43.33)			
Enhanced level	10 (16.67)	9 (15.00)			

Table 1. Comparison of the general data (n, $\%/\overline{x} \pm sd$)

considered when the asthma is fully controlled. Studies have shown that it takes at least two years from the beginning of a regular diagnosis and treatment regimen to the actual complete control of asthma in children, but a large number of clinical cases have revealed that the actual treatment often takes much longer [6, 7]. Children's poor out-of-hospital compliance and their lack of self-management abilities are confirmed to be the main reasons why the treatment takes so long [8]. Thus, how to achieve the effective out-of-hospital management of children with asthma has always been an important clinical research topic.

In recent years, nurse-led nursing management has been proven to have significant effects in the treatment of clinical diabetes, hypertension, and many other chronic diseases [9]. It has also achieved good results in the out-ofhospital management of children with asthma, but some children still fail to effectively achieve an ideal control of their asthma. Recent studies have revealed that children with different temperament types and children with different social abilities have significantly different outcomes in the management of their asthma [10, 11]. Children with difficult temperaments and low social life abilities are prone to difficult management of asthma and poor asthma control. Thus, this study used the nurse-led hierarchical management model in children with bronchial asthma outside the hospital to investigate the effect of its application in asthma management and control and to provide a clinical reference.

Materials and methods

General data

Children with bronchial asthma (n=120) treated in our hospital from March 2018 to March 2019 were recruited as the study cohort. Inclusion criteria: (1) Children who met the diagnostic criteria for childhood asthma according to the 2018 Global Initiative Guidelines for Bronchial Asthma (GINA) [12]. (2) Children who were all in preschool and who ranged in age from 3 to 7 years old. (3) Children whose course of the disease was >1 year and who were in the clinical remission period. (4) Written informed consents were obtained from the family members of the children and the families agreed to carry out the follow-up. Exclusion criteria: (1) Children with primary neurological disorders. (2) Children were with severe heart, lung, liver, kidney, and other organ dysfunctions or with systemic diseases. (3) Children with severe consciousness disorders, mental retardation and other neurological diseases who cannot communicate and cooperate. (4) Children who withdrew from the study for any reason. (5) Children who had incomplete followup data. Using to the random number table method, the children were randomly divided into a test group and a control group with 60 cases in each group. The general clinical data of the two groups are shown in Table 1. This study was approved by the Ethics Committee of Huzhou Hospital of Traditional Chinese Medicine Affiliated Zhejiang University of Traditional Chinese Medicine.

Nursing methods

The children in both groups received a nurseled nursing plan, with the details as follows [13].

Establishment of a nursing team: A nursing team led by nurses was established. One chief head in charge of the head nurse of the department was responsible for the overall work coordination. The department included five asthma specialist nurses with more than five years of work experience who had completed advanced training in asthma treatment management. They took charge of the implementation of the main tasks of child nursing management. One key nurse had more than 5 years of rich work experience and asthma professional knowledge and was mainly responsible for giving lectures about health knowledge to children and their families, answering questions in WeChat groups, giving free clinic activities about asthma, managing the online software for asthma, and participating in the coordination with the doctors. In addition, there was also one research nurse responsible for collecting and managing the children's treatment and follow-up data.

Establishment of the health files for the children with asthma: The treatment, management, and follow-up data of all the children, including the sociodemographic data such as the ages, genders, clinical examination, and treatment data at the initial admission, information on the family caregivers for the asthma management after the discharge, the responsible nurses, the follow-up data, and the checkup data during the follow-up visits were recorded and updated using online management software, and the data were backed up to a local computer for storage.

The implementation of the out-of-hospital nursing management measures: The health education content mainly includes basic asthma knowledge, the prevention methods, the drug inhalation treatment methods, diet and exercise guidance such as exercises, and exercise intensity and frequency and exercise precautions.

A health lecture was given once a month, and questionnaires were used to improve the teaching outcomes. Asthma handbooks were distrib-

uted to all the family members, and one-on-one instruction on how to use it was provided. The handbook started with the English letters A to F and consisted of 6 parts with relevant knowledge. A, B, C, D, and E were the initials of Asthma, Bring, Children, Deal, and Evaluate. The basic facts about asthma, the home environment settings, the management of children with asthma, the management guidance of children with asthma, the asthma drugs and treatment methods, and the evaluation of the asthma control were introduced respectively. The cooperation of the family members and their requirements and the nurses in the management and treatment of childhood asthma are given in part F. All the family members were placed in an exclusive WeChat group and were advised to follow the WeChat public account for asthma prevention and treatment. In the WeChat group, the medical staff took turns providing online consultations and answered medical questions from the patients' families. A database of information related to asthma prevention and treatment was set up in the WeChat public account, displayed by means of videos, pictures, and text, to make it convenient for family members to learn.

Standardized outpatient review and follow-up plans were developed. All the children underwent and outpatient review every three months to measure their pulmonary function and their serum inflammatory factor levels, and to assess their asthma control and quality of life. For children who failed to undergo the review in time, their family members were contacted via phone or WeChat to inquire about the situation and to urge them to promptly do the follow up. The Follow-ups were carried out by the specialist nurses using WeChat or the telephone once a month. For individuals with abnormal conditions or poor treatment compliance, home follow-up was carried out to determine the specific situation of the child, and solutions would be discussed with family members, while the family members were encouraged to do a good job of self-management.

The mini programs in WeChat were used to implement remote services and the supervision of children with asthma. The mini programs include the server and the client, which can be used for online consultations, medication record forms, asthma attack record forms

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and other related continuous nursing forms. All the family members were required to register, fill in their personal account information and the corresponding information such as the responsible nurse, and the family members were required to fill in the records of the children's medication use, their PEF daily variation rate measurements, and whether there was an asthma attack each day. The server was managed and coordinated by the hospital staff. According to the recorded data, the children were provided with diet and exercise guidance (customized by the nursing team and approved by the medical experts). When there was an abnormality in the a child's data, timely feedback was given to the doctor, who would communicate with the family members of the children online to provide solutions.

Hierarchical management: The children in the test group underwent the above nursing plan, and they also underwent additional hierarchical management [14].

The "Chinese Preschool Children's Temperament Quality Scale of 3~7 Years Old" was used to evaluate the children's temperament types [10]. The specific types include easy temperament, which was assigned a score of 5 points, middle-easy temperament, which was assigned a score of 4 points, slow start temperament, which was assigned a score of 3 points, middle-difficult temperament, which was assigned a score of 2 points, and difficult temperament, which was assigned a score of 1 point. And the "Infant-Junior High School Students Social Living Ability Scale" was used to evaluate the children's social living abilities. and the scale divided the children into excellent (5 points), high (4 points), normal (3 points), marginal (2 points), and low (1 point) [15]. After that, the above two scores were added together, and according to their total scores, the children were placed into 3 levels, that is, the common level, with a score of 8-10 points, the intermediate level, with a score of 5-7 points, and the enhanced level, with a score of 2-4 points.

As for the common level, no additional management was carried, out so this group underwent the same management as the control group. As for the intermediate level, apart from the monthly follow-up visits via phone or WeChat, home visits were conducted every two months to evaluate the temperature, humidity, and ventilation of the children's home environment, to exclude adverse external stimuli. At the same time, the children's symptoms and problems with the self-management during the period were determined and evaluated, and then targeted nursing measures were formulated to promptly deal with the problems.

In addition, the children's overall statuses and existing problems were analyzed based on the examination results during the subsequent visit and the recorded data in the mini program. Corresponding intervention measures were carried out for the children with abnormal symptoms. And every 3 months, the family members would be given relevant information and the operation centralized the education and guidance to ensure that each family member had fully grasped the information and could solve the existing problems. As for the enhanced level, on the basis of the intermediate-level children, the nursing level was improved and the frequency of the home follow-up (once a month) was increased. Relying on the children's medication records, asthma attack records, and other continuous nursing form fillings, an analysis was performed once a week. And for the children with problems, targeted nursing measures were developed and communication with their families was conducted promptly to promote the effective implementation of the nursing measures.

Outcome measures

The number of the acute asthma attacks, emergency medical treatments, and hospitalizations were recorded: The asthma control test (ACT) was used to assess the asthma control in the children [16]. The assessment was conducted on the day of discharge, and at 3 months and 6 months after their discharge. There are 5 items in the ATC scale. Each item has a score that ranges from 0 to 5, with a total possible score of 25, of which 25 points indicates complete asthma control, 20-24 points indicates the asthma is well controlled but not completely controlled, and a score of less than 20 points indicates poor control.

All the children were equipped with a household peak flow meter (Beijing Jina High-tech Medical Equipment Co., Ltd., model: 232-6,000) to measure the daily variation rates of the peak expiratory flows (PEF). Professionals guided the family members to learn how to use the devices. The children were monitored twice a day, once upon waking up in the morning and again 10 hours later. They were also measured the 3 times before their bronchodilator use. Then the average value was calculated. PEF mutation rate = $2 \times$ (evening PEF value - morning PEF value)/(evening PEF value + morning PEF value) × 100%. The daily variation PEF rates on the day of discharge, and at 3 and 6 months after discharge were recorded.

The Medication Adherence Report Scale for Asthma (MARS-A) was used for the evaluation of the medication adherence [17]. MARS-A includes 10 items, each with a score of 1 to 5, and the total score is the average of all the items. A total score of 4.5 points or more indicates good medication adherence, but a score lower than 4.5 indicates poor medication adherence.

The pulmonary function was recorded on the day of discharge, and at 3 and 6 months after discharge, including the forced vital capacity (FVC%), the ratio of forced expiratory volume in the first second to FVC (FEV1%/FVC%), and the expiratory peak flow rate (PEF%).

The serum inflammatory factor levels were record on the day of discharge, and at 3 and 6 months after the discharge, including IL-4, IL-5, and IgE: Fasting peripheral venous blood (5 mL) was collected from the children in the morning and was measured using enzymelinked immunosorbent assays. The IL-4 and IL-5 kits were purchased from China 124 Jingmei Bioengineering Co., Ltd., and the human specific IgE antibody was purchased from FOOKE, Germany.

The children's quality of life scores were assessed using the Pediatric Asthma Quality of Life Questionnaire (PAQLQ) on the day of discharge, and at 3 and 6 months after the discharge [18]. The PAQLQ scale has a total of 35 items, involving five dimensions of assessing the asthma symptoms, including activity limitation, response to stimuli, psychological conditions, and self-health care. Each item has a score that ranges from 0 to 4 points, and the assessment has a total possible score of 0 to 140 points. The higher the score, the higher the quality of life.

Statistical analysis

SPSS 23.0 was used for the statistical analysis. The count data were represented as (n, %). χ^2 tests or Fisher's exact tests were performed. All the measurement data in the study that conformed to a normal distribution were expressed as the mean \pm standard deviation ($\overline{x} \pm$ sd). Independent sample t tests were used for the comparisons between groups; the test level was two-sided α =0.05. Age, gender, age of the first attack, family history of rhinitis/asthma, whether to carry out hierarchical care management, medication adherence, and the baseline IL-4, IL-5, and IgE levels were regarded as independent variables; the number of each child's acute asthma attacks was considered a dependent variable. Univariate and multivariate logistic regression analyses were used for the relevant factors of the childhood asthma attacks. P<0.05 indicated that the results were statistically significant.

Results

Comparison of the general data

In the test and control groups, most of the children were male, accounting for 63.33% and 66.67%, respectively. The children with an age of first attack \leq 3 years old accounted for 70.00% and 63.33%, respectively, while the number of children with a family history of rhinitis/asthma in both groups exceeded 66.00%. There were no significant differences between the two groups in terms of their baseline data such as age, gender, or disease course, so they were comparable (P>0.05). See **Table 1** for details.

Comparison of the number of acute asthma attacks and hospitalizations

Compared with the control group, the number of acute asthma attacks, the emergency medical treatment, and the hospitalizations in the children with acute asthma attacks within 6 months decreased significantly in the test group (P<0.001). See **Table 2** for details.

Comparison of the ACT score and PEF daily variation rate changes before and after the nursing

The ACT scores in the two groups of children after the nursing showed a gradually increasing

Table 2. Comparison of the number of acute onsets, emergency medical treatments, and hospitalizations within 6 months ($\bar{x} \pm sd$, time)

Group	Case (n)	Acute onsets	Emergency medical treatments	Hospitalizations
Test group	60	1.25±0.35	1.02±0.28	0.75±0.23
Control group	60	2.30±0.42	2.55±0.45	1.54±0.36
t		14.877	22.361	14.324
Р		0.000	0.000	0.000



Figure 1. Changes in the ACT scores and daily variation rates of PEF before and after the nursing. A: Changes in the ACT scores. B: Changes in the daily PEF variation rates. Compared with the control group, *P<0.05, **P<0.01, ***P<0.001. ACT: asthma control test. PEF: peak expiratory flow.

trend, and the daily variation rate of PEF showed a decreasing trend (**Figure 1**). After 3 and 6 months of nursing, the test group had higher ACT scores (P<0.05 or P<0.001). Compared with the control group, the daily variation rates of PEF after 3 and 6 months of the nursing was significantly reduced in the test group (P<0.01 or P<0.001).

Changes in the FVC%, FEV1%/FVC%, and PEF% levels before and after the nursing

The FVC%, FEV1%/FVC%, and PEF% levels were gradually increased in the two groups of children after the nursing, and the differences in the test group were significant (P<0.05 or P<0.001). The FEV1%/FVC% and the PEF% levels in test group after 6 months of nursing were also significantly higher than they were in the control group (all P<0.01). See **Figure 2**.

Changes in the IL-4, IL-5, and IgE levels before and after the nursing

Figure 3 shows a decreasing trend in the IL-4, IL-5, and IgE levels in the test group after the

nursing, but there was no significant change in the control group. Compared with the control group, the IL-4, IL-5, and IgE levels after 3 and 6 months of nursing were significantly reduced in the test group (P<0.01 or P<0.001).

Changes in the medication adherence rates and quality of life

As shown in **Figure 4**, the MARS-A and PAQLQ scores in the two groups after nursing showed a gradual upward trend. Specifically, the MARS-A and PAQLQ scores in the test group after 3 and 6 months of the nursing were significantly higher than the corresponding scores in the control group (both P<0.05).

Relevant factors of the acute exacerbation of childhood asthma

Fifty-five children had 2 or more acute asthma attacks

within 6 months after their discharges. A univariate logistic regression analysis showed that an age of the first attack ≤ 3 years old (OR=3.853), a family history of rhinitis/asthma (OR=1.453), poor medication adherence (OR= 1.842), the baseline IL-4 levels (OR=1.236) and the baseline IgE levels (OR=1.328) were correlated with the number of acute asthma attacks (P<0.05). And the hierarchical management (OR=0.525) was beneficial for reducing the acute asthma attacks (Table 3). In the multivariate logistic regression analysis, after controlling for other potential confounding factors, an age at first attack was ≤3 years old (OR=3.635), a family history of rhinitis/asthma (OR=1.425), poor medication adherence (OR= 1.855), the baseline IgE level (OR=1.305), and the hierarchical management (OR=0.593) remained statistically significant (all P<0.05, Table 4).

Discussion

Repeated asthma attacks and frequent and long-term treatment not only seriously affect children's physical and mental health, but they



Figure 2. Changes in the two groups' pulmonary function. A: FVC%; B: FEV1%/FVC%; C: PEF%. Compared with the control group, *P<0.05, **P<0.01. FVC%: the forced vital capacity; FEV1%/FVC%: the ratio of forced expiratory volume in the first second to FVC; PEF%: expiratory peak flow rate.



Figure 3. Changes in the IL-4, IL-5, and IgE levels before and after the nursing in the two groups. A: IL-4; B: IL-5; C: IgE. Compared with the control group, **P<0.01, ***P<0.001.



Figure 4. Changes in the medication adherence and quality of life between the two groups. A: MARS-A; B: PAQLQ scale. Compared with the control group, *P<0.05, **P<0.01, ***P<0.001. MARS-A: Medication Adherence Report Scale for Asthma; PAQLQ: pediatric asthma quality of life questionnaire.

also bring a huge medical burden to the children's family and to society [19]. In this study, the implementation of a nurse-led hierarchical management model effectively reduced the acute asthma attacks, improved children's medication adherence and asthma control levels, reduced their inflammatory factor levels, and effectively improved their pulmonary function and quality of life, which are of great significance for children to achieve complete control of their asthma

Relevant factors	OR	95% CI	Р		
Gender (male vs. female)	1.031	0.856~1.289	0.265		
Age (years)	0.958	0.656~1.139	0.135		
Age of first attack (≤3 years vs. >3 years)	3.853	2.048~5.589	0.009		
Disease course (years)	1.022	0.749~1.189	0.085		
Family history of rhinitis/asthma (yes vs. no)	1.453	1.056~3.789	0.006		
Hierarchical management (yes vs. no)	0.525	0.168~0.963	0.026		
Medication adherence (poor vs. good)	1.842	0.958~2.889	0.031		
Baseline IL-4	1.236	0.839~2.158	0.037		
Baseline IL-5	1.189	0.805~1.956	0.092		
Baseline IgE	1.328	0.905~2.456	0.027		

Table 3. Univariate logistic regression analysis

Table 4. Multivariate logistic r	regression analy	sis
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Relevant factors	OR	95% CI	Р
Age of first attack (≤3 years vs. >3 years)	3.635	1.848~5.156	0.002
Family history of rhinitis/asthma (yes vs. no)	1.425	1.102~3.436	0.014
Hierarchical management (yes vs. no)	0.593	0.248~0.973	0.008
Medication adherence (poor vs. good)	1.855	0.896~2.786	0.033
Baseline IL-4	1.036	0.796~1.858	0.155
Baseline IgE	1.305	0.9856~2.385	0.040

as soon as possible and to reduce the burden on the family and society.

Adhering to regular treatment is the key to complete asthma control. Studies have confirmed that most asthma can be completely treated by the regular inhalation of glucocorticoids (ICS) for 1 to 2 years [20, 21]; however, the actual clinical treatment shows that the current medication adherence rate of ICS medication in children with asthma is far from ideal, and more than half of the children have no medication adherence [22-24]. It was reported that non-adherence to ICS medication is one of the main reasons for the deterioration of asthma control in children [24, 25]. Therefore, determining how to improve the medication adherence of children with asthma is still an important challenge for clinical asthma management. Social life ability is an important manifestation of children's ability to independently handle daily affairs and their self-control management [15, 26]. The higher the social life ability, the higher the degree of cooperation of the child in nursing and education. On the contrary, children with low social life abilities show low cooperation with nursing work and daily guidance, and significantly reduced compliance. The temperament is closely related to the personality and psychological characteristics of children, especially for younger children, who are greatly affected by the external environment, and the performance of the children with different temperaments in nursing work has significant differences [10]. Previous studies demonstrated that children with difficult temperament characterized by emotional irritability, strong reactions to external affairs and stimuli, negative and avoiding attitudes, and poor life regularity, led to poor compliance, and increased the difficulty of the nursing work [11].

In this study, the children were classified according to the comprehensive scores

of their social life abilities and temperament scale scores, and the children at the intermediate and enhanced levels were treated with stepwise strengthened management. The results of the study showed that after the hierarchical management, compared with the control group, the children in the test group had a significant improvement in the medication adherence, especially after 6 months of management. We believe that it can be analyzed from two aspects. On one hand, implementing hierarchical and strengthened management, such as increasing the number of follow-ups after treatment, improving the follow-up methods and the timely evaluation and analysis, can promptly help to discover the psychological and medical changes of the children and their family members, as well as the problems in the nursing process. Accordingly, effective nursing intervention measures and guidance methods can be used to solve the existing problems promptly, so as to ensure the rapid recovery of the children's condition. On the other hand, health education is the focus of asthma prevention and management. Research from Inkelas et al. reveals that patients' knowledge and awareness of asthma are closely related to medication adherence and asthma control

[27]. In this study, health education was carried out in multiple ways and forms such as health lectures, asthma handbooks, WeChat group knowledge popularization and question answering, and WeChat public account knowledge columns, so that children and their families can quickly learn and master information about asthma, which is consistent with the results of previous research [28]. In addition, for children classified at the intermediate and enhanced levels, further strengthened education on asthma-related prevention and treatment knowledge, including centralized education guidance and online guidance, has been carried out to further ensure that the children's family members have a full understanding and mastery of the relevant information, improving the level of cognition which plays an important role in the management of children with asthma.

In a multivariate analysis, an age of first attack \leq 3 years old was associated with frequent acute asthma attacks in children (OR=3.635). The related interferences which may be related to the younger the child, the worse the social life ability, the greater the difficulty of management, the lower compliance [29]. In addition, hierarchical management (OR=0.593) was beneficial to reducing acute asthma attacks in children, which further verified the advantages of implementing a nurse-led hierarchical management of asthmatic children.

In summary, the results of this study demonstrate that the nurse-led hierarchical management model can effectively improve the medication adherence of children with bronchial asthma, improve their level of asthma control, and significantly improve their pulmonary function and quality of life. It has significant advantages in the out-of-hospital management of children with asthma.

Disclosure of conflict of interest

None.

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