FACTORS WITH IMPACT ON ADHERENCE TO TREATMENT IN CHILDREN WITH ASTHMA

PHD THESIS
- SUMMARY -

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General data

Adherence in children with asthma

Nonadherence to treatment is an important influence on the health outcomes of children and adolescents with pediatric asthma, which is the most prevalent childhood chronic illness (up to 7.2% in Romania) [6]. Although extensive research is done in order to understand and promote adherence in paediatric asthma, little progress has been made in reducing the prevalence of nonadherence.

For children with asthma, the average medication adherence rate of 48% was determined by a meta-analysis of 10 studies [8]. The wide-ranging disparity in adherence emphasizes the need to use reliable measures to distinguish between patients who adhere to the therapeutic regimen and those who do not, both in clinical practice and in research. Attention to adherence leads to improved patient management and more accurate interpretation of the results of clinical trials [14,16,17].

To address this need, research concerning the correlates and predictors of adherence to inhaled corticosteroid treatment for pediatric asthma was reviewed. Significant predictors and correlates of treatment adherence identified in this study were consistent with a conceptual model that included family demographic characteristics and functioning, parent and child characteristics, health care system and provider characteristics, and child health outcomes. All guidelines, protocols and recommendations underline the importance of therapeutic education as a key element in asthma management and control [7,9,11]. Considerable evidence supports the efficacy and effectiveness of this measure. Health personnel, as well as patients and their parents, can and should be educated with two main objectives: to achieve the best possible quality of life and to allow self-control of the disease. These goals can be attained through an educational process that should be individually tailored, continuous, progressive, dynamic, and sequential. The process poses more than a few difficulties involving patients, health professionals, and the health systems. Knowledge of the various psychological factors that can be present in asthmatic patients, as well as the factors related
to the highly prevalent phenomenon of non-adherence, is essential. Awareness of the factors influencing physician-patient-family communication is also highly important to achieve the objectives set in therapeutic education \[12,13\].

The clinical management of paediatric asthma would be enhanced by routine assessment of barriers to treatment adherence and anticipatory interventions that address them to prevent nonadherence.

Current guidelines recommend that children with asthma need to know how to manage their own condition \[7\]. There is an increasing body of evidence that educational interventions designed to teach self-management skills among children lead to better asthma control by improvements in lung function, feelings of self-control and reduced number of absences from school, the number of days with restricted activity, and the number of emergency department visits \[14\].

In view of these considerations, we carried out a study to evaluate the importance of active interventions on adherence to asthma self-management in children. This intervention was performed in Craiova Regional Centre for Children with Asthma, using the framework of a complex management program for asthmatic children, described elsewhere \[2-5\]. The results of our study are published or presented at international meetings (see attached \textit{Publications List}).

Specific data

Study I

The randomized, controlled clinical study performed had a duration of 12 weeks and included forty-two children with persistent asthma (age 9.2 +/- 3.1 yrs; 28 boys). All subjects received a written asthma plan and instruction on electronic PEF home-monitoring. Adherence to PEF home-monitoring was assessed using Piko-1 devices and data were downloaded at each monthly visit. The design included the use of both symptom-based and PEF-based plans due to recent data suggesting arbitrariness of peak-flow cut-offs in younger children \[1\].

All co-interventions were similar in the study population. We randomly assigned the subjects to either of 2 groups based on a computer-generated allocation in blocks of 3. Because of the nature of the study, blinding was not possible. Children assigned to the control group followed the usual care recommended by the in-house physician and were given a booklet with basic information on asthma. The booklet had been developed previously for asthmatic children managed in the centre. Children assigned to the intervention group received one-to-one educational intervention on asthma self-management delivered by Centre personnel.

The main outcome measure was change in the number exacerbations after the intervention. Secondary outcome measures included the impact of asthma-related education on the number of admissions to hospital, quality of life, use of oral corticosteroid therapy for exacerbations of asthma, and pulmonary function.

Results

There were no significant differences on the use of PEF-meters at home during the first month between the intervention group and the control group. Nevertheless, at 3 months, the intervention group presented a two-fold better adherence than the controls (Figure 1). Overall, adherence to home PEF monitoring in intervention group was below the targeted adherence (i.e. 61% vs. 80%). Children in either group who were less than 33% adherent to PEF-monitoring were significantly prone to asthma symptoms.

The number of asthma exacerbations decreased in both the control and intervention groups (Figure 2), but we observed a significantly greater reduction in the intervention group i.e. 0.92 vs. 1.3, respectively, (\(p=0.0014\)). Compared with the control group, the intervention group had a lower likelihood of requiring emergency care. (RR 0.59; 95% confidence interval [CI] 0.41-0.78; \(p = 0.0003\)).
Figure 1. Kaplan-Meyer estimation of asthma exacerbations, using as co-variable better (dotted line) or lesser (continuous line) compliance to PEF home-monitoring.

Figure 2. Asthma exacerbation rate in the studied population.

Study II.

Background:
Patient education of children with asthma is of utmost importance for achieving the control of the disease, especially when adherence to controller therapy is challenged by prescription of inhaled medication.

Objective:
To evaluate the effect of age specific targeted education on inhaler technique and knowledge in children with asthma

Methods: Children with moderate persistent asthma (n=28, age=8.3+/-2.9 yrs., 16 boys) who attended a Regional Centre for children with asthma were recruited (Table I). Patients were randomised to receive either standard educational intervention (i.e. one-to-one intervention delivered by study nurse) – group A (n=14), or standard educational intervention plus distribution of an educative package – group B. The educative package consisted in an illustrated book and a short movie, both addressing controller therapy and inhaled medication for asthma in children. Asthma knowledge (score/10) and inhaler technique (score/10) were assessed in all patients before and after 1 month from the intervention.

Results: Both groups of patients had similar asthma knowledge and inhaler technique at baseline. After 1 month both scores improved significantly in the B group, but not in the A group (changes in asthma knowledge scores and inhaler technique +2.3+/-0.3; p=0.024, and +0.9+/-0.2; p=0.038, respectively) (Figures 3-4).
Table I. Patient characteristics at baseline

<table>
<thead>
<tr>
<th></th>
<th>Group A (n=14)</th>
<th>Group B (n=14)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs.)</td>
<td>8,1</td>
<td>8,4</td>
</tr>
<tr>
<td>Sex (Boys/Girls)</td>
<td>7/7</td>
<td>9/5</td>
</tr>
<tr>
<td>Previous use of MDI (y/n)</td>
<td>6/8</td>
<td>5/9</td>
</tr>
<tr>
<td>Disease duration (yrs.)</td>
<td>1,5</td>
<td>1,2</td>
</tr>
<tr>
<td>Score for asthma knowledge*</td>
<td>6,28</td>
<td>6,14</td>
</tr>
<tr>
<td>Score for inhalation technique*</td>
<td>8,64</td>
<td>8,78</td>
</tr>
</tbody>
</table>

*p Scale from 1 to 10. Results are showed as median.

Figure 3. Changes in inhaler technique scores at studied groups

Figure 4. Changes in asthma knowledge scores at studied groups

Study III.

Objective:
To evaluate the impact of local adverse events on adherence to inhaled controller therapy in children with asthma.

Methods:
The database of a Regional centre for children with asthma was retrospectively studied. Medical records of patients aged 5 to 16 years with persistent asthma (n=326) were analyzed by the presence of local adverse events and adherence to inhaled controller therapy. All children were diagnosed and treated according to GINA guidelines and underwent the same educational interventions and had at least 3 prescriptions of ICS in the last 12 months before the analysis. Multivariable linear statistics were used to evaluate the correlation between the variables. The
sample size was set to include all patients fulfilling the inclusion criteria due to the intention to capture certain domains with statistical significance.

**Results:**

Data collected identified 16.2% of the children having at least one local adverse event (figures 5, 6). Among them, 22.8% of the patients presented good adherence to inhaled controller therapy (> or = 80% of medication prescribed) vs. 31.2% in children with no local adverse events. Nevertheless, in the studied group of patients, adherence was not significantly influenced by the presence of local adverse events (concordant with data from other studies). Adherence was 58% in patients with local adverse events vs. 62% in all patients, p = 0.054. Other correlations showed statistically importance (i.e. age of the patients, severity of asthma). Impact of gender was not significant.

![Figure 5. Distribution of local adverse effects by patients (%)](image)

![Figure 6. Adherence to treatment by absence/presence of side effects (%)](image)

**Conclusions**

1. Our data support the positive impact of educational interventions on adherence to asthma self-monitoring in children. Our intervention on asthma self-management for children was found to be effective in significantly reducing the number of exacerbations. Quality of life for the children and their families improved. Opportunities to question, problem-solve and engage in conversation with the educator may serve to promote empowerment. These hypotheses will need to be tested using qualitative analysis. Education about asthma, especially in an interactive, one-to-one format, is an important aspect of self-management and overall care for children with asthma.

2. Children who read the educative story and watched the demonstrative video improved their inhaler technique and knowledge of asthma, which could lead to a better control of the
disease. Educative intervention in children with asthma needs special consideration for age-specific issues regarding playing, maintaining interest and focus attention. Our data suggest that, in asthmatic children treated according to current guidelines, and exposed to educational interventions, the presence of local adverse events does not hamper the adherence to inhaled controller treatment. Further interventions and education resources should rather address other issues of childhood asthma management.

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