CLINICAL PRACTICE

Problems in the management of asthma in young children — a potential role for montelukast

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Quality-of-life assessments in children with asthma have enabled us to understand the significant impact of asthma on their lives. In addition, and possibly more importantly, they enable us to evaluate the therapy we use in asthmatic children. Such assessments indicate that we, as clinicians, are not doing as well as we would hope in the control of asthma using current therapeutic strategies.

All treatment interventions in asthma management have two objectives. Patients want improvement in their quality of life (absence of morbidity and mortality), and the funders want cost-effective care. These objectives are reflected in the goals of asthma management in all local and international guidelines (Table I).

From time to time we need to check on how well we are doing in achieving these goals. Unfortunately such analysis is seldom performed and the studies conducted reveal a pessimistic picture.[2,3] Management of the young (preschool) asthmatic needs critical evaluation as the evidence presented suggests that disease control is especially poor in this subpopulation.

Table I. The goal of asthma management is that the asthmatic is able to lead a normal and physically active life

For a normal life the aim is to:

- Be completely free of any symptoms, i.e. cough, wheeze and breathlessness
- Attend school regularly and participate fully in all school activities, including sport
- Have restful sleep free from nighttime cough and/or wheeze
- Minimise the number of asthma attacks
- Avoid hospital admissions
- Grow normally

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Although most paediatric asthma management guidelines recognise the special nature of asthma in young children, they fail to acknowledge the limitations of current therapies in controlling inflammation in this age group. Recent studies have revealed that asthma prevalence is on the increase,[4] and that the prevalence in South Africa is significant.[5,6] This is one of the commonest chronic conditions in childhood and requires our full attention. In addition to this background picture, there is evidence that the prevalence is increasing at a greater rate in young children.[7] There is also evidence that 50 - 80% of asthmatics develop the disease before the age of 5 years.[8]

We know today that the pathology of asthma is similar, if not identical, in young children and adults;[9] because of this, it has been stressed that effective therapy necessitates anti-inflammatory drugs. How well are we doing then in controlling this disease?

At the most basic level of assessment, namely mortality, evidence of success has until recently been very disappointing. Mortality from asthma has been increasing and very significantly so in children.[10] However, studies of quality of life show a disappointing outcome in morbidity control. Remarkably, different studies reveal similar results. On average one-third of children are waking up at night at least once a week due to asthma[2,3] and missing school at an alarmingly significant rate.[3,11]

In view of this lack of success in asthma control it is not surprising that the disease is resulting in spiralling costs. In a recent analysis of total inpatient costs (as a marker of uncontrolled asthma and exacerbations) in Scandinavia, the young asthmatic was found to be responsible for a disproportionately high percentage of this bill (Fig. 1).[12] This evidence must suggest a failure of current preventive therapeutic approaches in this age group.

For a treatment strategy to be effective, there must be synergy between efficacy of a product and adherence to that product in real, day-to-day life. Although clinical trials suggest efficacy of many products, many factors influence adherence (Fig. 2). There are a number of limitations to inhaled anti-inflammatory therapy in asthma management. In general, and at best, only 20 - 25% of the delivered dose reaches the lower airway.[13] In reality, however, compliance with inhaled therapy is poor[14] (Fig. 3), even in South Africa. For the majority of older children and adults the inhaled route is the preferred delivery route and patients need to be educated to use their therapy correctly and regularly. It is for this reason that most countries have asthma education bodies.

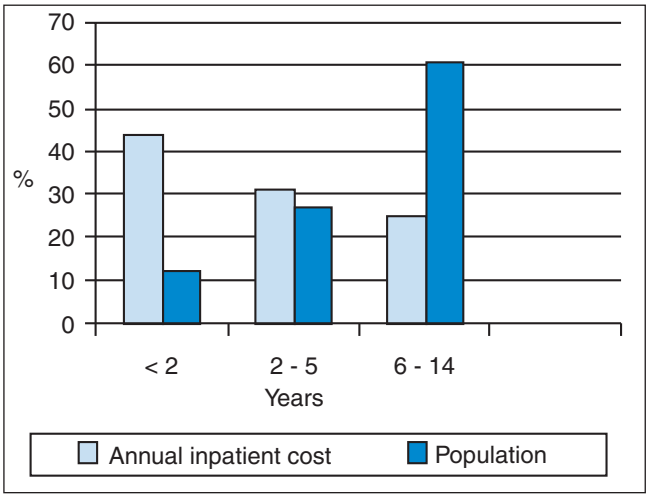

Fig. 1. Scandinavian figures for asthma hospitalisations.

However, in young children quality-of-life assessments and spiralling inpatient costs testify to failure of attempts to implement therapy via the inhaled route. Most clinicians working with parents of young asthmatics can relate stories of unhappy attempts to get toddlers to use spacer devices. Our endpoint assessments suggest that this is the rule rather than the exception.

Lastly it should be noted that most of the inhaled therapies recommended in guidelines are in fact not registered for use in young children (Fig. 4). Although this lack of registration does not attest to lack of efficacy or safety, it does suggest the difficulty in assessing these endpoints in this age group.

Where to then, in this worrying situation? Recently an oral anti-inflammatory drug was registered for use in 2 - 5-year-old asthmatics. Montelukast (Singulair) is a leukotriene receptor antagonist now licensed for use in young asthmatics. In clinical trials this drug has shown dramatic results in controlling the symptoms and disease that is asthma.[15] It is available as a pleasant-tasting chewable tablet for once-a-day administration and has no significant safety issues. A safe and effective oral anti-inflammatory preparation for controlling asthma in the young child is now available. The advantages of this preparation are

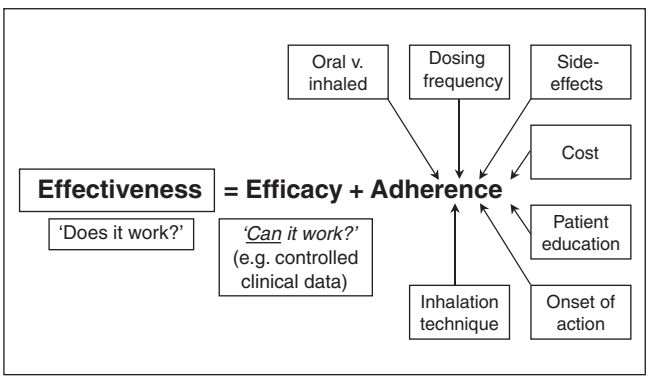

Fig. 2. Determinants of effectiveness of drug therapy.

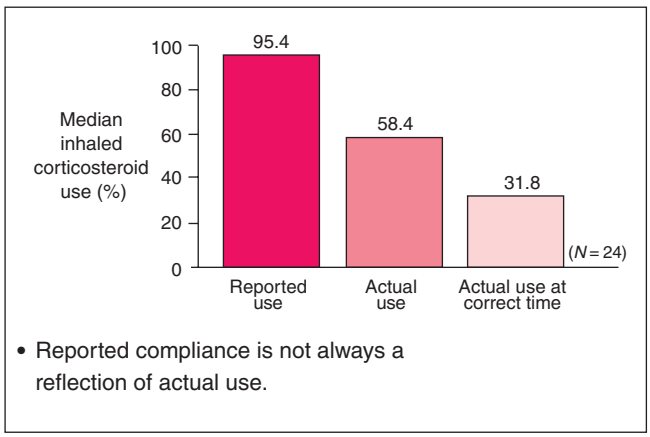

Fig. 3. Adherence/compliance problems.

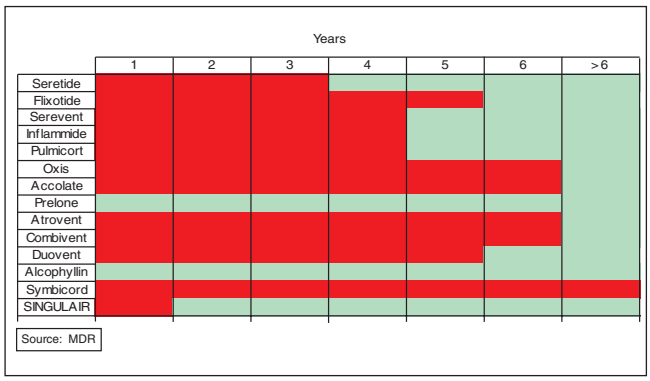

Fig. 4. Indicated age profile of commonly used therapies in the paediatric market.

obvious (Table II), but in the face of the unhappy picture of asthma control, the preparation may offer a truly unique breakthrough in pre-school asthma.

Despite this optimism, montelukast should be used in a responsible and controlled way. This drug is advocated as monotherapy for mild to moderate asthma in the pre-school age group only. Standard inhaled therapy is still recommended for older children and for failure to control all symptoms of asthma in the young age group.

In most young children, asthma control is determined by symptom control, as most patients will not be able to perform lung function testing. The availability of montelukast will, it is hoped, lead to success in quality-of-life and cost-effectiveness parameters,

Table II. Advantages of monteleucast

- Oral therapy (compliance)
- Single daily dose
- Safe therapy (not a steroid)
- No food/drug interactions
- Registered for young children
- Anti-inflammatory

but this is a long-term goal. In the short term monteleucast offers the opportunity to refocus on the goals of asthma management as set out by the South African Childhood Asthma Working Group (SACAWG) (Table I).

Montelukast is not a panacea for asthma. Recommendation for its use, as a new therapeutic strategy, carries a huge responsibility. In order to meet this challenge certain guidelines are suggested for determining the ideal patient and for safeguarding both the patient and the reputation of the product (Table III).

We feel that the time is right for a shift in our recommendations for the management of young asthmatics and hope that this treatment approach will be adopted in future guidelines, but more importantly, improve the quality of life of our patients and reduce the enormous financial burden resulting from poor control of this common illness in young children.

Table III. Indications for montelukast

In a child 2 - 5 years of age with asthma:
1. Diagnosis: Chronic cough or wheeze responsive to a bronchodilator or 7 - 10-day course of oral steroids (prednisolone 1 mg/kg/day)

'The modified bronchodilator response test': Document symptoms and signs of asthma (e.g. audible wheeze, hyperinflated chest, prolonged expiration) and then give two puffs of a bronchodilator/nebuliser. Assess the response objectively at 10 - 15 minutes.

2. Four-week trial of montelukast

3. Response to montelukast as indicated by a significant reduction in symptoms or use of bronchodilators

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