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Assessment of use of spacer devices for inhaled drug delivery to asthmatic children

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In the treatment of bronchial asthma, inhaled therapy with both bronchodilators and corticosteroids represents the basis for acute and long-term management. Drug therapy in asthma is predominantly by pressurized metered dose inhalers. The impact of treatment on the disease morbidity and mortality depends to a large extent on appropriate delivery of drug to the lungs by means of a spacer device. We performed an audit on spacer use in 200 children and showed that 99% owned a spacer, 2% owned but did not use their spacer, 11% were using a spacer which was not ideal for their age, 17% had a poor technique, and 24% were not following the recommendations given on previous visits to wash the spacer only with a soapy solution. Although physicians frequently associate poor control of asthma with inadequate doses of drugs, many factors must be considered before increasing the dose of inhaled medications to children. We should all ensure that the drugs we prescribe are delivered in the best possible manner, thus improving control of asthma, reducing side effects and offering a more cost-effective therapy.

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The prevalence of chronic bronchial asthma and other allergic conditions is on the increase and more emphasis is being placed on the underlying chronic inflammatory processes responsible for asthma (1). Indeed, drug therapy is jointly aimed at symptom relief and control of chronic airway inflammation (2, 3). Inhaled bronchodilators and corticosteroids are the basis of the acute and chronic treatment of bronchial asthma. The drugs available today have been shown to be very effective in reducing the morbidity and mortality associated with this chronic condition (2, 3).

In the setting of a busy outpatient clinic, insufficient attention may be given to drug administration and compliance. In fewer medical conditions this is more important than in asthma where most medications are delivered directly into the bronchial tree using devices that require training for their use. The impact of treatment on the disease morbidity and mortality depends entirely on appropriate drug delivery to the target organ i.e. the lungs (4). Patients often do not follow guidelines for appropriate drug delivery and may discontinue medication when feeling better.

Almost all drugs used in the management of asthma are available in the form of pressurized metered dose inhalers (pMDI). These preparations deliver a dose of active drug accompanied by a propellant agent. The concept of lung dose as opposed to nominal dose is of extreme importance in asthma. The nominal or prescribed dose may differ greatly from the amount of drug that actually reaches the target organ (5).

In asthma, this gap has been partially bridged with the use of spacer devices that allow better and more effective delivery of drug to the lung (4). These devices are required for children and adults alike and their use has made treatment more effective but more complicated.

Spacers come in a wide variety of shapes, materials, volumes and may include a face mask for administration in younger children. Conventionally, spacers have been manufactured from plastic. However, problems caused by electrostatic charges have encouraged manufacturers to

produce devices made of metal or carbon black to bypass this problem. Spacer volume should also be appropriate for patient size and hence patient tidal volume. In infants and young patients who are unable to inhale through a mouthpiece, a mask should be interposed between the spacer and the child. However, the inappropriate use of a spacer with mask in an older child will inevitably decrease the lung dose. Spacer care is of utmost importance. Apparently harmless practices – such as excessive washing of spacer devices – have been found to be counter-productive by decreasing drug delivery. Spacer devices are usually marketed with little or no documentation on use or performance, and it is therefore crucial for the prescribing physician to meticulously explain the use of such devices. In this prospective study, a cohort of children with asthma were individually assessed in the use of their spacer device and in their compliance with medication in an attempt to explore methods to improve spacer use and care.

Methods

St Luke's Hospital is the regional hospital for Malta and caters for the follow-up of all asthmatic children. Two hundred children attending at the outpatient department for follow-up of chronic bronchial asthma were consecutively selected and were individually assessed for compliance with medication and spacer technique. Patients were seen every 3–4 months depending on severity and control of their asthma and compliance with treatment. Correct spacer usage and the importance of compliance with treatment had been explained during virtually all previous visits to the clinic.

One or both parents were present during the examination. Assessment and questionnaire were performed by the same individual (C.V.). In older children who administer the medication themselves, all stages of administration were carried out by the child. In younger children one of the parents, usually the mother, was assessed for technique of administration. Special emphasis was made on agitation of the canister containing the pMDI prior to use as this maneuver is essential to ensure that subsequent doses contain consistent amounts of drug and propellant agent.

Assessment was carried out in the following way: spacer ownership, spacer appropriateness for age (including use or otherwise of mask), compliance with spacer use, spacer care, inhaler agitation prior to use and inspiratory effort through spacer device. Failure to agitate the pMDI or a poor inspiratory effort constituted an overall poor technique. The use of a spacer device with a face mask beyond the age of 4 yr was considered to be inappropriate. One of the parents – or in older patients, the children themselves – were asked to explain how the spacer device was washed and how frequently. Any deficiencies in compliance or spacer technique were noted and corrected.

Results

Two hundred patients with a known diagnosis of chronic bronchial asthma attending for routine follow-up at a general children's out patients clinic under the care of a single consultant (C.V.) were assessed for spacer technique and a questionnaire was completed (Appendix). The patient age ranged from 2 to 14 yr with a mean age of 9 yr. One hundred and sixteen patients were males and 84 were females. Two patients did not own a spacer device at all while 99% of all patients owned a device. Four patients (2%) did not use their device despite owning one.

Of those patients using a device regularly, 89% had a device which was appropriate for their age while 11% of patients were still using a spacer with face mask beyond the age of four. No patients <4 yr of age were using a spacer without a mask.

In 43.5% of all patients the administration of the medication via the spacer device was carried out by the parent, usually the mother. Parental administration was more likely in patients <7 yr of age. The overall technique for spacer use was good in 83% of all patients assessed while 17% had a poor technique. Poor technique was because of failure to agitate the inhaler prior to use (13.5%) or poor inspiratory effort (14.5%) or both. A poor overall technique was not dependent on the administrator with 59% of those with a poor technique administering the drug themselves while 41% were administered the drug by their parents.

With regard to spacer care, 24% were not following the recommendations given on previous visits to only infrequently wash the spacer with a soapy solution without rinsing and letting it drip-dry. This was not dependent on whether the treatment was administered by the child or the parents.

Discussion

Physicians frequently associate poor control of asthma with inadequate doses of drugs. The most

important factors which determine effective pMDI dosing are electrostatic charge and the appropriate use of a spacer device. Therefore many factors must be taken into consideration before increasing the dose of inhaled medications in children.

Pharmacokinetics of drugs delivered by pMDI

The actual dose delivered by each actuation of a pMDI depends on several factors including canister agitation prior to dosing, ambient temperature and humidity, and actual dose remaining in the canister (6). It is crucial that the canister be agitated well prior to each and every actuation in order to minimize dose variation. Although pMDI were initially designed for direct use, it became clear that in view of the high velocity of propulsion of the drug, a significant proportion of the active ingredient was being deposited in the mouth and oropharynx rather than in the target peripheral airways (7, 8). Several techniques of inhalation were advised but most were inappropriate for use in children due to problems with coordination. Deposition of active drug in the oral cavity also has the added disadvantage of increased systemic absorption increasing the likelihood of side effects, and an unpleasant taste that may result in noncompliance (7). These dosing variations prompted the development of spacer devices, which allow for more standardized dosing and better compliance with treatment (7, 8). Several spacer devices have been developed over the last decade, some specifically made for certain age groups. The dynamics and behavior of pMDI delivered through spacer devices has been the subject of various studies which have concluded that pMDI in children should always be delivered through an appropriate spacer to maximize drug delivery to the lung and decrease side effects (7).

Spacer devices

A spacer is a device which allows effective passage of a drug in the form of a suspended particle, from the pMDI to the patient. Most spacers have a basic design consisting of a holding chamber and a mouthpiece with a valve mechanism. Spacers for use in infants and children under 4 yr of age have a facemask between the valve mechanism and the patient.

There are several factors in the design of a spacer, which determine what percentage of the prescribed (nominal) dose actually reaches the lung (lung dose) and these include (5, 9, 10):

1 volume of holding chamber;
2 material of which spacer is made up and electrostatic charge;
3 volume of dead space in mouth piece;
4 type of valve mechanism;
5 care of spacer device;
6 leaks around port for insertion of pMDI.

Most spacer devices are made of PVC and static charges on the inner aspect of the spacer attract suspended drug particles and deposits them on the spacer's interior, reducing the lung dose (4, 6). It is our experience that most parents who use spacer devices to administer pMDI to their children tend to wash their device very frequently for perceived hygienic purposes. When a plastic device is washed and dried, an electrostatic charge builds on the device and it has been estimated that to neutralize the charge from a single wash requires the equivalent of 30 doses of pMDI. Simple precautions such as washing the spacer in a mild soapy solution and allowing it to drip-dry coats the spacer with an insulating layer, drastically reducing electrostatic charges. It has been estimated that this simple procedure improves drug delivery through the device by up to 60% (11). The problems caused by electrostatic charges have recently encouraged manufacturers to produce devices made of metal or carbon black, excellent electrical conductors that are grounded to earth when held and hence bypass these problems (11, 12).

Some spacer devices are deliberately designed by manufacturers to only accept inhalers produced by their company. The rigid shape of such inhaler connection ports therefore precludes a good seal between the spacer and certain other inhalers. The connection port of some spacers is made of rubber and therefore provides an almost universally good seal for all inhalers.

Use of handout for parents

Five years ago, we prepared a handout for parents of children using spacer devices outlining all of the above in lay terms along with guidelines for the proper use and care of inhalers and spacers. Although it is not possible to quantify the impact of introducing this handout on compliance with spacer use and care, it is our impression that there has been a significant improvement in compliance.

From this audit it is clear that the message for using a spacer device has been accepted with 99% of all patients having a spacer. Unfortunately, spacer care and technique of administration were not as good as expected. An unexpected 24% of

patients were not following simple instructions given on previous visits and highlighted on handouts, and future explanations and handouts must stress this further. At follow-up visits, patients should be constantly reminded that a spacer is essential and their technique should be routinely reassessed and any faults corrected. Assessment of the use of a spacer is not time consuming and a variety of spacer devices and pMDI should be available for demonstration at such clinics.

Although we were disappointed to find that a significant proportion (17%) of patients were not adhering to our instructions, this figure compares favorably with other studies where this proportion was much higher (4, 15, 16). We attribute this to our repeated instructions as to the proper use of pMDI and spacers, and this is corroborated by studies that have shown that such repetition improves technique (17).

Conclusions

Spacer devices are essential tools for the adequate delivery of drugs in asthmatic patients. Although compliance with the use of a spacer does not seem to be a problem locally it is clear from the results of this audit that a significant number of patients are using spacer devices which are not appropriate for their age and a even larger number of patients are not using their devices properly. We should all do our best to spend a few extra minutes with our young patients and their parents to ensure that the drugs we prescribe are delivered in the best possible manner, thus improving control of asthma, reducing side effects and offering a more cost-effective therapy. Advice on the appropriate use of spacers should include proper agitation, correct timing of the actuation of the pMDI, single actuations and not multiple pMDI actuations and correct spacer care (5, 13, 14). The use of handouts to patients or their parents are essential. Finally patients who persistently refuse to use a spacer device should be changed to a dry powder preparation thus avoiding the need for a spacer.

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Appendix

Sample of questionnaire

Age of patient:
Sex:
Type of inhaled medication: Reliever/Prophylactic steroid
Who deliver drug? Parent/Child
Spacer device type: _____
Appropriate for age: Yes/No
Compliance with use of spacer: Yes/No
Spacer care: Good/Poor
Height:
Weight:
PEFR: _____l/min (children above 8 yr).

Observation of technique

Inhaler agitation before use: Yes/No
Inspiratory effort: Good/Poor
Overall technique: Good/Poor