

A PALATABILITY STUDY OF A FLAVORED DEXAMETHASONE PREPARATION VERSUS PREDNISOLONE LIQUID IN CHILDREN WITH ASTHMA EXACERBATION IN A PEDIATRIC EMERGENCY DEPARTMENT

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ABSTRACT

Background

Palatability is an important factor in medication compliance for children where the acceptability of a liquid medication and its ease of administration will be greatly affected by its taste.

Objectives

The objective of this study was to determine which, if any of two steroid preparations, oral dexamethasone or oral prednisolone, was more palatable to children requiring steroid treatment for asthma.

Methods

A single-blind taste test of 2 different steroid suspensions, liquid prednisolone (1mg/ml) versus liquid dexamethasone (1mg/ml), was conducted in children aged 5-12 years, presenting to the pediatric emergency department with an exacerbation of asthma requiring steroid treatment. Children received 2.5mls of either prednisolone or dexamethasone and were asked to score their impression of taste on a 10 cm visual analog scale. After cleansing of the palate they were given the other steroid and scored its taste.

Results

Thirty-nine children (54% male) were enrolled in the study. The mean age was 7.1 years (SD=2.0). The median visual analog scale measurement for dexamethasone was 8.2 cm (IQR= 5.2) whilst the median measurement for prednisolone was 5.0 cm (IQR= 7.3), $p=0.03$. Male children were more likely to prefer dexamethasone than females with a median score of 9.9 cm (IQR=3.8) for males vs. 5.9 cm (IQR=9.3) for females, $p=0.005$. There was no gender preference for prednisolone.

Conclusions

There was a statistically significant difference between the taste of dexamethasone and prednisolone, with dexamethasone being the preferred steroid among pediatric patients with asthma. Males were much more likely to prefer dexamethasone than females.

Key words: *Corticosteroids, taste, asthma, children*

Asthma is a common disease, occurring in approximately 12% of the pediatric population in Canada and is a common presenting problem in the pediatric emergency department.¹ Asthma is an inflammatory disorder of the airways associated with airflow obstruction that is

variable and often reversible.² Systemic corticosteroids should be considered a crucial aspect of treatment to address the inflammatory component of the disease process. For use in children who are too young to swallow pills, two liquid steroid preparations, dexamethasone (DEX)

and prednisolone (PRED), are readily available. In a pediatric population, the acceptability of a liquid medication, and hence its ease of administration, is important to consider to maximize patient compliance. A substance that is palatable is one that is pleasant to taste.³ Palatability is believed to be an important factor in medication compliance in children where acceptability of a liquid medication will be greatly affected by taste. The purpose of this study was to determine if an oral DEX or oral PRED preparation was most palatable to children requiring steroid treatment for mild to moderate asthma exacerbation.

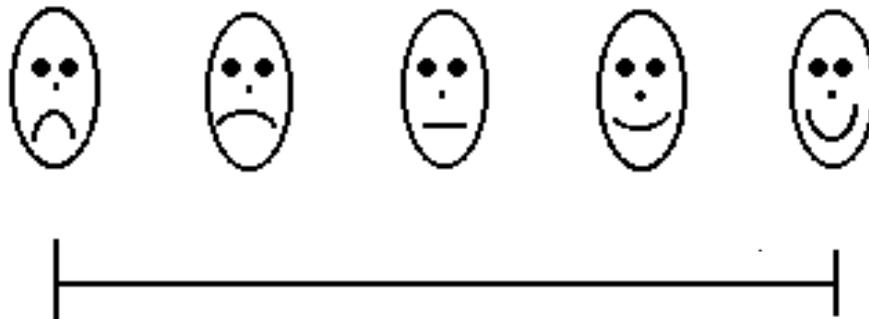
METHODS

A single-blind taste test of liquid PRED versus liquid DEX was conducted in children presenting to the Pediatric Emergency Department at the Children's Hospital of Western Ontario between July 2004 and November 2005, with an exacerbation of asthma requiring steroid treatment based on the judgment of the attending physician. Exclusion criteria included: children younger than age 5 years or older than age 12 years, previous participation in this study, and children with severe symptoms requiring intravenous steroid treatment. DEX was prepared as a liquid suspension (1mg/ml) as follows: 10mL (100mg/10mL) Dexamethasone with 45mL Ora-

Sweet and 45 mL Ora-Plus. This preparation is not available commercially but has been described previously.⁴ Prednisolone (1mg/mL) is commercially available as the formulation Pediapred, which contains disodium edetate, sodium phosphide, methylparaben, flavor raspberry and sorbitol among its listed components.

Patients meeting inclusion criteria were approached to participate, and participation was voluntary. Each preparation was identified to the children by letter only and was given in an orange coloured syringe to mask any colour differences. Each participant received 2.5mls of either PRED or DEX, then was immediately asked to score their impression of taste on a 10 cm Visual Analog Scale (VAS) (Figure 1),⁵ incorporating a previously described facial hedonic scale,⁶ which ranges from a score of 0 (representing least favorable taste) to 10 (most favorable taste). The order of which steroid preparation was received first was randomly assigned. Children placed a mark anywhere on the 10 cm line indicating their taste preference. After cleansing of the palate with a cracker and water the children were given 2.5mls of the remaining steroid and subsequently asked to score its taste on a VAS. This taste testing method has previously been used with antibiotic preparations in young children.⁵ The remainder of their dose was then given using the oral steroid of choice of the attending physician.

FIG. 1 Visual Analog Scale



Data were entered and analyzed in SPSS, version 14.0. Data were reported as mean \pm SD for continuous variables, or when necessary, median (interquartile range, IQR) for skewed continuous variables. Percentages were used for categorical variables. The Wilcoxon Signed Ranks Test was used to detect differences in taste preferences between prednisolone and dexamethasone. The Mann-Whitney Test was used to compare differences between males and females with respect to the palatability of the two steroid preparations. The Pearson product moment correlation coefficient was used to assess the relationship between age and patient steroid preference. A statistically significant difference was noted at $P < 0.05$.

To have a power of 80% to detect a difference of 0.5 cm on the 10 cm VAS, at the 0.05 level of significance (assuming a standard deviation of 1 cm), the power analysis a priori showed that 32 children would be needed in the study.

The Research Ethics Board for Health Sciences Research Involving Human Subjects at the University of Western Ontario approved the protocol. Written consent was obtained from the parent or guardian of all children who participated in this study.

RESULTS

Thirty-nine children were enrolled in the study. Twenty-one (54%) were male. The mean age was 7.1 years (SD=2.0). Twenty-two children tasted DEX first, and seventeen children tasted PRED first. The median VAS measurement for DEX was 8.2 cm (IQR=5.2) whilst the median VAS measurement for PRED was 5.0 cm (IQR=7.3). The difference between the median VAS measurement for DEX and PRED was statistically significant ($p=0.03$). Male children were more likely to prefer DEX than females with a median VAS score of 9.9 cm (IQR=3.8) for males tasting DEX vs. 5.9 cm (IQR=9.3) for females tasting DEX ($p=0.005$). There was no gender preference for PRED with median VAS scores of 5.1cm (males) vs. 5.0 cm (females).

There was no significant correlation between age of patient and preference for either DEX ($r=0.03$) or PRED ($r=0.04$) using the Pearson correlation coefficient. The order the steroids

were tasted was not important in determining preference. Mean scores for DEX were 6.4 cm (SD= 3.5) and 7.2 cm (SD= 4.2) if tasted first or second respectively, while the mean scores for PRED were 5.5 cm (SD= 3.9) and 5.2 cm (SD= 3.8) if tasted first or second respectively.

DISCUSSION

In this study, we found that dexamethasone was the preferred steroid over prednisolone in terms of taste among pediatric patients with asthma. The differential preference of flavored dexamethasone preparation was most pronounced between males and females.

Palatability is believed to be an important factor in the compliance of children taking oral medication and there are many studies addressing the palatability of medications used in a pediatric population.⁵⁻¹¹ While many studies focus on the palatability of antibiotic suspensions, studies addressing the palatability of corticosteroid preparations are fewer. Palatability of corticosteroids has been examined using healthy adult subjects.^{9,12,13} A previous study in children examined the acceptability of two liquid corticosteroid preparations, prednisolone and Orapred in young children, with vomiting as the primary outcome, and palatability as an outcome in those old enough to use the facial hedonic scale.⁸ Another study examined the use of crushed prednisolone tablets versus liquid solution in children, also using a visual analog scale.¹⁰ However, a literature search revealed no studies in children directly comparing dexamethasone liquid to prednisolone liquid.

Oral dexamethasone (tablets) has been shown to be equally effective to oral prednisone/prednisolone in treating children with an exacerbation of asthma, both in terms of improving symptoms and preventing relapse.¹⁴ A recent randomized double-blind trial demonstrated that a single dose of oral dexamethasone is no worse than 5 days of twice-daily prednisolone in managing mild to moderate asthma exacerbations in children.¹⁵

Dexamethasone liquid is not available commercially, but is prepared locally in a preparation determined by the hospital pharmacy. The preparation of dexamethasone used at our centre was chosen as it has been described in the literature.⁴ This preparation is not uncommon and

is used at other major Canadian centres such as The Hospital for Sick Children in Toronto and Children's Hospital of Eastern Ontario in Ottawa. However, other centres may use a slightly different preparation of dexamethasone, which may affect the generalizability of the results.

A second potential limitation of our study is that participants were asked to sample relatively small quantities of each steroid preparation (2.5mls of each), when in reality, the dose they would be receiving as a treatment would often be much larger. As DEX is available in a more potent formula, a smaller dose (0.3mg/kg) is required compared to PRED (1mg/kg). Isa *et al* demonstrated that at least when parental preference was examined, taste was more important than volume in terms of preference of medication for their child.¹³ Our study assessed single dosing of each preparation. Whether multiple daily doses would have had an effect on palatability, as judged by children, was not assessed in this particular study.

The results of this study suggest that an oral dexamethasone preparation may be better tasting than an oral prednisolone preparation in young children with asthma.

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