ABSTRACT

Objective: Assessment of the tympanic membrane (TM) is often impeded by the presence of cerumen. We compared the ceruminolytic effects of triethanolamine polypeptide (TP) and docusate sodium (DS) in patients with cerumen.

Methods: We conducted a prospective, randomized, controlled, double blind trial on a convenience sample of cooperative patients presenting to a university based emergency department that required removal of cerumen to visualize the TM. Structured data collection was performed and the physician determined whether visualization of the TM was partially or totally obscured by cerumen (inter-observer agreement, rho=0.79). Patients received intra-aural instillation of 1-mI of either DS or TP in a liquid form. If not completely cleared, the external ear canal was irrigated with 100-mI of NS and an additional attempt to visualize the TM was made. The main outcome was the proportion of ears in which the TM could be totally visualized after ceruminolytic instillation and irrigation. This study had 90% power to detect a 40 percentage difference between groups in the proportion of totally visualized tympanic membranes (x test, alpha=0.05).

Results: Of 50 enrolled patients, 23 received TP and 27 received DS. Mean age was 40, 35% were female. Groups were similar in age, gender, and proportion of completely obscured TMs at presentation (78%). The ability to completely visualize the TM was significantly greater after treatment with DS versus CX (81% vs 35%, x2 p<0.004) particularly in children aged 5 or less (90% vs 0%, x2 p<0.009).
Conclusion: DS solution is a more effective ceruminolytic than TP allowing complete or partial visualization of the TM in most patients after a single application when followed with irrigation. Use of DS as a ceruminolytic should be encouraged, particularly in children.

INTRODUCTION

Accumulation of cerumen in the external ear canal is a common problem.¹ The presence of cerumen not only interferes with the clinician's view of the tympanic membrane, but may also result in hearing loss and vertigo as well as contribute to infection. Evacuation of cerumen may be performed by manual instrumentation or frequent copious syringe irrigation. However, both these procedures are uncomfortable and may result in injury to the external ear canal and the tympanic membrane and even death.²⁻⁴ Removal of cerumen is facilitated by the use of a variety of cerumenolytics or wax solvents. Several studies have evaluated the cerumenolytic effects of a wide range of solvents such as olive oil, sodium bicarbonate, distilled water, glycerine, acetone, triethanolamine polypeptide, hydrogen peroxide, dichlorobenzene and various forms of docusate sodium.⁵⁻¹⁰ However many of these studies were conducted in-vitro, lacked adequate controls or formal statistical analysis, or were conducted in the outpatient setting where patients were instructed to apply the solvent over the course of several days.

The current study was designed to evaluate the cerumenolytic effects of a single brief application of docusate sodium in the emergency setting and to compare these effects with those of a commonly prescribed cerumenolytic, triethanolamine polypeptide, in a randomized, double-blind fashion.

METHODS
**Design**

A prospective, randomized double blind controlled trial design was used to compare the cerumenolytic effects of docusate sodium solution and triethanolamine polypeptide drops. This project was approved by the Institutional Review Board.

**Setting & Patient Selection**

The trial was conducted on a convenience sample of patients who presented to the Emergency Department (ED) of the State University of New York at Stony Brook, a tertiary care center with an annual census of 55,000. Patients were eligible for enrollment if they were 1 year or older, their medical condition required visualization of the ear canal (e.g., earache, hearing loss, fever), and their ear canal was partially or totally occluded by cerumen. Patients were excluded if they had a known or suspected tympanic membrane (TM) perforation, overt infection of the ear, were uncooperative, or were allergic to any of the solvent agents.

For each eligible patient, the next in a series of opaque, consecutively numbered 2-mI syringes was used. Syringes were prepared by hospital pharmacy personnel not connected to the ED or enrollment process and assignments were generated by a computerized random number program. Syringes contained even proportions of 1-mI sodium docusate (Colace®, Richwood Pharmaceutical Company Inc., Florence, KY) or 1-mI triethanolamine polypeptide (Cerumenex®, Purdue Frederick Company, Norwalk, CT) solutions.

**Intervention and Study End Points**

For each patient, a structured closed-question data sheet was used to record patient demographic and clinical information. Visualization of the TM was classified as partially or
completely obscured. The physician then applied 1-mI of the study solution in the affected ear and the patient was instructed to lay on his or her side with the affected ear facing upwards for 10-15 minutes. The physician then determined whether the TM was totally obscured, partially obscured, or completely visualized. If the TM was still not completely visualized, the physician then irrigated the external ear canal with up to 100-ml lukewarm normal saline. The study endpoint was either complete visualization of the TM or irrigation of the ear with 100 ml of irrigant. Patients (or guardians) were also asked to indicate the presence of any adverse events such as pain, vertigo, nausea, or hearing loss during the procedures.

**Primary Outcome Measures**

The primary outcome in this study was the proportion of ears in which complete TM visualization was achieved after application of the wax solvent and irrigation. On an independent subset of 20 patients, this outcome had good inter-observer agreement (Spearman’s rho=0.79). A secondary outcome measure was the presence of any adverse events.

**Analysis**

Data were entered into Access 97 (Microsoft, Inc., Redmond, WA) and imported into SPSS 8.0 for Windows (SPSS, Inc., Chicago, IL) for statistical analysis. For both pretreatment characteristics and outcomes, categorical variables were compared using $\chi^2$ tests and continuous variables were compared using Student’s $t$ tests. Sub-group analysis based on patient age was also performed. This study had 90% power to detect a 40 percentage difference between groups in the proportion of totally visualized tympanic membranes (alpha=0.05).
RESULTS

During the study period 50 eligible patients were enrolled. Their mean age was 40+/- 18 years and 35% were female. Twenty patients 20 (40%) were children less than age 5. Of all patients, 23 were randomized to TP and 27 received DS. Comparison of baseline characteristics indicated that groups were similar in age, gender, and the proportion of initially completely obscured TMs (Table 1).

Immediately after ceruminolytic instillation, the TM was completely visualized in 5 of 27 patients (19%) that received DS and in 2 of 23 (9%) assigned to TP (P=0.32). However, after irrigation with normal saline, the ability to completely visualize the TM was significantly greater after treatment with DS versus TP (81% vs 35%, p= 0.004). The ability to completely visualize the TM after irrigation in the subgroup of children aged 5 years or less was also significantly greater after treatment with DS versus TP (90% vs 0%, p=O.009). No adverse events were reported in either of the groups.

DISCUSSION

Docusate sodium is a commonly prescribed stool softener. Its surfactant properties also make it an effective agent for dissolving earwax. Although prescribed in the United Kingdom, the cerumenolytic effects of docusate sodium are less widely known in the United States. Several in-vitro studies have concluded that of all agents tested, docusate sodium is one of the most effective wax solvents. In 1965 the General Practitioner Research Group first reported that an oil-based docusate sodium solution was more effective than the oil base alone in dissolving earwax in 150 patients. The same group compared a water-miscible docusate sodium solution with a p-dichlorobenzene and benzocaine solution in 107 patients and concluded that the docusate solvent was better than
the control since a smaller volume of water was required for syringing in order to completely remove wax. In this study, the solvents were applied each night over two successive nights prior to assessment. Despite the low cost and relative effectiveness of docusate sodium as an earwax solvent, only 6 of 233 surveyed British general practitioners reported routinely prescribing it as a cerumenolytic.\textsuperscript{10}

The results of the current study clearly demonstrate the superiority of docusate sodium over triethanolamine polypeptide (one of the most commonly prescribed cerumenolytics in the United States) as a cerumenolytic in the acute setting. This is evidenced by a more than two-fold increase in the proportion of ears in which the tympanic membrane was completely visualized after docusate sodium was used. The superiority of docusate sodium as a cerumenolytic was even more pronounced in children aged 5 or younger, in whom most tympanic membranes could be completely visualized.

The cerumenolytic effect of docusate sodium after a single brief application is particularly well suited for the ED setting where rapid visualization of the TM is required. Since ear solvents do not need to be sterile, a multidose bottle of docusate sodium (usually prescribed as a stool softener) may be kept in the ED without refrigeration allowing an easy and economical method of dissolving earwax.

Our study was a convenience sample and therefore we cannot exclude a selection bias whereby patients with particularly hard and impacted cerumen may have not have been included. Also, while colored syringes were used to minimize bias, the two ear solvents had different appearances, which may have affected investigator assessments. Finally, our study lacked the power to detect any between-group differences in the rate of adverse events.

In conclusion, the current study demonstrates that docusate sodium is a better cerumenolytic than triethanolamine peptide particularly in young children. The effectiveness of docusate sodium after a single brief application makes it an ideal cerumenolytic in the ED.
REFERENCES


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