Study objective: Assessment of the tympanic membrane is often impeded by the presence of cerumen. We compared the ceruminolytic effects of triethanolamine polypeptide and docusate sodium in patients with cerumen.

Methods: We conducted a prospective, randomized, controlled, double-blind trial on a convenience sample of cooperative adult and pediatric patients presenting to a university-based emergency department who required removal of cerumen to visualize the tympanic membrane. Structured data collection was performed, and the physician determined whether visualization of the tympanic membrane was partially or totally obscured by cerumen (interobserver agreement, \( \rho = 0.79 \)). Patients received intra-aural instillation of 1mL of either docusate sodium or triethanolamine polypeptide in a liquid form. If not completely cleared within 15 minutes, the external ear canal was irrigated with 50 or 100 mL of normal saline solution and additional attempts to visualize the tympanic membrane were made. The main outcome was the proportion of ears in which the tympanic membrane could be totally visualized after ceruminolytic instillation with or without irrigation. This study had 80% power to detect a 40% difference between groups in the proportion of totally visualized tympanic membranes (\( \chi^2 \) test, \( \alpha = 0.05 \)).

Results: Of 50 enrolled patients, 23 received triethanolamine polypeptide and 27 received docusate sodium. Mean patient age was 40 years (range 1 to 81 years); 35% were female. Groups were similar in age, sex, and proportion of completely obscured tympanic membranes at presentation (78%). The ability to completely visualize the tympanic membrane was significantly greater after treatment with docusate sodium versus triethanolamine polypeptide (81% versus 35%; difference in proportions 47%; 95% confidence interval [CI], 22 to 71) particularly in children aged 5 or less (90% versus 0%; difference in proportions 89%; 95% CI 50 to 100).
Conclusion: Docusate sodium solution is a more effective ceruminolytic than triethanolamine polypeptide, allowing complete or partial visualization of the tympanic membrane in most patients after a single application when followed with irrigation. Use of docusate sodium 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 of these procedures are uncomfortable and may result in injury to the external ear canal and the tympanic membrane.2,3 There have even been rare deaths associated with syringe irrigation.4 Removal of cerumen is facilitated by the use of a variety of ceruminolytics or wax solvents. Several studies have evaluated the ceruminolytic effects of a wide range of solvents such as olive oil, sodium bicarbonate, distilled water, glycercine, 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 ceruminolytic effects of a single brief application of docusate sodium with or without irrigation in the emergency setting and to compare these effects with those of a commonly prescribed ceruminolytic, triethanolamine polypeptide, in a randomized, double-blind fashion.

METHODS

A prospective, randomized, double-blind controlled trial design was used to compare the ceruminolytic effects of docusate sodium solution and triethanolamine polypeptide drops. This project was approved by the institutional review board.

The trial was conducted on a convenience sample of patients who presented to the emergency department 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 (eg, 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 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-mL 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 numbers program. Syringes contained even proportions of 1 mL of sodium docusate (Colace) or 1 mL of triethanolamine polypeptide (Cerumenex) solutions. Both solutions are highly viscous yet differ in color. Docusate sodium is a light pink solution, whereas triethanolamine polypeptide is a pale yellow solution. At our institution, most physicians use a curette to remove cerumen and do not routinely use either of the ceruminolytic solvents involved in this study.

For each patient, a structured closed-question data sheet was used to record patient demographic and clinical information. Visualization of the tympanic membrane was classified as partially or completely obscured.7 The physician then applied 1 mL of the study solution in the affected ear and the patient was instructed to lie on his or her side with the affected ear facing upward for 10 to 15 minutes. The ceruminolytic agent was allowed to drain by gravity and any remains were gently absorbed with a cotton-tipped applicator. The physician then determined whether the tympanic membrane was totally obscured, partially obscured, or completely visualized.8 If the tympanic membrane was still not completely visualized, the physician then irrigated the external ear canal with 50 mL of lukewarm normal saline solution at which point a second attempt to visualize the tympanic membrane was repeated. Irrigation was performed using a 50-mL syringe with an 18-gauge angiocatheter at the tip. If the tympanic membrane was still incompletely visualized, the physician repeated irrigation of the external canal with another 50 mL of normal saline solution. The study endpoint was either complete visualization of the tympanic membrane 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 hear-
CERUMINOLYTIC EFFECT OF DOCUSATE SODIUM
Singer, Sauris & Viccellio

RESULTS
Fifty eligible patients were enrolled during the study period. Their mean age (±SD) was 40±18 years (range 1 to 18 years), and 35% were female. Thirteen (26%) patients were children aged 5 or younger. Of all patients, 23 were randomly assigned to receive triethanolamine polypeptide and 27 received docusate sodium. Comparison of baseline characteristics indicated that groups were similar in age, sex, and the proportion of initially completely obscured tympanic membranes (Table 1).

Immediately after ceruminolytic instillation, the tympanic membrane was completely visualized in 5 (19%) of 27 patients who received docusate sodium and in 2 (9%) of 23 assigned to receive triethanolamine polypeptide. This difference was not significant (Table 2). After irrigation with 50 mL of normal saline solution, the tympanic membrane was completely visualized in another 10 patients who received docusate sodium and another 2 patients who received triethanolamine polypeptide (Figure). After irrigation with the second 50-mL aliquot of normal saline solution, the tympanic membrane was completely visualized in an additional 7 and 4 patients receiving docusate sodium and triethanolamine polypeptide, respectively. Thus after instillation of the ceruminolytic, with or without irrigation with normal saline solution, the ability to completely visualize the tympanic membrane was significantly greater after treatment with docusate sodium than of the control solvent, 40% of the tympanic membranes would be completely visualized, this study had 80% power to detect a 40% difference between groups in the proportion of totally visualized tympanic membranes (α=.05).

Table 1. Baseline characteristics.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Docusate Sodium (n=27) No. (%)</th>
<th>Triethanolamine Polypeptide (n=23) No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean age (y±SD)</td>
<td>38.7±30.7</td>
<td>46.1±29.1</td>
</tr>
<tr>
<td>Females</td>
<td>11 (41)</td>
<td>7 (30)</td>
</tr>
<tr>
<td>Children ≤5 y</td>
<td>9 (33)</td>
<td>4 (17)</td>
</tr>
<tr>
<td>Completely occluded ears</td>
<td>21 (78)</td>
<td>18 (78)</td>
</tr>
</tbody>
</table>

Table 2. Outcomes.

<table>
<thead>
<tr>
<th>Patient Group</th>
<th>Docusate Sodium (n=27) No. (%)</th>
<th>Triethanolamine Polypeptide (n=23) No. (%)</th>
<th>% Difference Docusate Sodium-Triethanolamine Polypeptide (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Completely visualized ears after solvent only</td>
<td>5 (19)</td>
<td>2 (9)</td>
<td>9.8 (-8.8 to 28.5)</td>
</tr>
<tr>
<td>Completely visualized ears after solvent with or without irrigation</td>
<td>22 (82)</td>
<td>8 (35)</td>
<td>46.7 (22.3 to 71.1)</td>
</tr>
<tr>
<td>Children ≤5 y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Completely visualized ears after solvent with or without irrigation</td>
<td>8 (90)</td>
<td>0 (0)</td>
<td>88.9 (50.5 to 100)</td>
</tr>
<tr>
<td>Patients &gt;5 y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Completely visualized ears after solvent with or without irrigation</td>
<td>14 (78)</td>
<td>8 (42)</td>
<td>35.7 (6.3 to 65.0)</td>
</tr>
<tr>
<td>Adverse events</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (-7.8 to 7.8)</td>
</tr>
</tbody>
</table>

The primary outcome in this study was the proportion of ears in which complete tympanic membrane visualization was achieved after application of the wax solvent with or without irrigation. On an independent set of 20 patients who did not participate in this study, this outcome had good interobserver agreement (Spearman's ρ=0.79). A secondary outcome measure was the presence of any adverse events.

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 pretreatment characteristics, categorical variables were compared using χ² tests, and continuous variables were compared using Student's t tests. For outcomes, results are presented as point and interval estimates with the difference in proportions and the 95% confidence interval (CI) for that difference. Post hoc subgroup analysis based on patient age was also performed. Assuming that after application
dissolving earwax. Although prescribed in the United Kingdom, the ceruminolytic 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 because a smaller volume of water was required for syringing to

D I S C U S S I O N

Docusate sodium is a commonly prescribed stool softener. Its surfactant properties also make it an effective agent for
completely remove wax. In this study, the solvents were applied each night over 2 successive nights before assessment. Despite the low cost and relative effectiveness of docusate sodium as an ear wax solvent, only 6 of 233 surveyed British general practitioners reported routinely prescribing it as a ceruminolytic.10

The results of the current study clearly demonstrate the superiority of docusate sodium over triethanolamine polypeptide (one of the most commonly prescribed ceruminolytics in the United States) as a ceruminolytic in the acute setting. This is evidenced by a more than twofold 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 ceruminolytic was even more pronounced in children aged 5 or younger, in whom most tympanic membranes could be completely visualized.

The ceruminolytic effect of docusate sodium after a single brief application is particularly well suited for the ED setting where rapid visualization of the tympanic membrane is required. Because 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. However, use of any non-sterile solution (eg, docusate sodium) should be avoided if tympanic membrane perforation is strongly suspected.

Our study was a convenience sample; therefore, we cannot exclude a selection bias whereby patients with particularly hard and impacted cerumen may have not have been included. Also, although colored syringes were used to minimize bias, the 2 ear solvents had different colors, which may have introduced an observer bias that could have exaggerated the differences between the groups. Ideally, an independent observer and not the physician cleaning the ear would have performed assessment of tympanic membrane visualization. However, because most of our physicians routinely use a curette to clean ears, the majority were unfamiliar with the appearance of both solvents used in this study and therefore were blinded to the treatment assignment.

Our study also did not include a third control group, in which patients’ ears were cleaned by irrigation alone without any solvents. Thus, it is possible that use of the ceruminolytics may actually have reduced the efficacy of irrigation by solubilizing the cerumen. Although we found that docusate sodium was especially effective in children aged 5 or younger, the small number of young children included in the study may limit any age-specific conclusions regarding the efficacy of the ceruminolytics.

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 ceruminolytic than triethanolamine peptide, particularly in young children. The effectiveness of docusate sodium after a single brief application makes it particularly well-suited for use as a ceruminolytic in the ED.

REFERENCES