Randomized Clinical Trial of Docusate, Triethanolamine Polypeptide, and Irrigation in Cerumen Removal in Children

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Background: Cerumen obstructing visualization of the tympanic membrane in children is a common and frustrating problem. Docusate sodium, triethanolamine polypeptide, and saline were compared to determine their effectiveness in relieving cerumen obstruction in children.

Methods: A randomized, controlled, double-blind trial was performed on pediatric patients aged 6 months through 5 years with cerumen obstruction. The enrolling physician determined whether the cerumen completely or partially obstructed visualization of the tympanic membrane. One milliliter of docusate sodium, triethanolamine polypeptide, or normal saline as control was placed into the patient's ear canal. If the tympanic membrane was not completely visualized after 15 minutes, the ear was irrigated with 50 mL of tepid water. Irrigation was repeated a second time if needed. The main outcome was the proportion of tympanic membranes that were completely visualized after cerumenolytic agents or control saline, alone or with irrigation if needed.

Results: Of 92 patients enrolled, 34 received docusate sodium; 30, triethanolamine polypeptide; and 28, saline. Mean±SD patient age was 34.7±18.1 months, and 50 (54%) of the patients were girls. Groups were similar in age, race, sex, ear enrolled, wax consistency, and degree of obstruction. There was no significant difference in the proportion of tympanic membranes completely visualized after treatment with docusate (18/34; 53%), triethanolamine polypeptide (13/30; 43%), or saline (19/28; 68%) (P=.17).

Conclusion: Application of docusate sodium or triethanolamine polypeptide did not significantly improve the proportion of tympanic membranes that were completely visualized vs application of the saline control.


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 Ninety-three patients were enrolled during the study period. One patient was removed because of a protocol violation, leaving 92 patients for analysis (Figure). Mean ± SD patient age was 34.7 ± 18.1 months, and 50 (54%) patients were girls. Comparison of pretreatment characteristics indicates that each treatment group was similar in age, sex, race, type of wax (soft, hard, or mixed), and the number of tympanic membranes partially or completely obstructed (Table 1). Compared with the pediatric clinic, a higher percentage of patients enrolled in the emergency department received triethanolamine polypeptide (42% vs 15%) and fewer patients received saline (22% vs 45%). However, patients enrolled in the docusate sodium group at each site were evenly distributed (36% vs 39%). This was the result of chance randomization. The pretreatment characteristics of patients sorted by site were very similar.

Of the analyzed 92 patients, 34 received docusate, 30 received triethanolamine polypeptide, and 28 received saline control. Table 2 presents the degree of obstruction of the tympanic membrane. A $\kappa$ value of 0.72 was obtained, showing a good amount of agreement. Using a computerized random-number program, syringes with 1 mL of docusate sodium, triethanolamine polypeptide, or normal saline were placed in consecutively numbered envelopes by a hospital pharmacist. Each enrolled patient was then assigned the next numbered envelope.

After enrollment, 1 mL of substance was instilled into the patient’s external auditory canal by a trained nurse. Parents were asked to keep children lying with that ear facing upward for 15 minutes. The nurse then had the patient turn the ear downward to drain any remaining fluid. The same physician investigator examined the ear to determine if it was completely or partially obstructed or if complete visualization of the tympanic membrane was possible. If the membrane was not completely visualized, the ear was irrigated by the enrolling physician or nurse with 50 mL of tepid tap water (85°-95°F). A 60-mL syringe with an 18-gauge angiocatheter precut to a length of 1.5 cm was used for irrigation. The angiocatheter was inserted 2 to 3 mm into the ear canal, aimed along the posterior-superior canal wall, and pressure, as allowed by syringe and angiocatheter size, was used to irrigate the canal. After irrigation, the physician investigator again examined the ear to determine if the tympanic membrane could be completely visualized. If not, irrigation was repeated. The physician examined the ear a final time to determine the degree of visualization of the membrane. If at any time during the study patients complained of significant pain, dizziness, nausea, hearing loss, or drainage in their throat, the study was discontinued and an adverse event was recorded on the study form.

The main outcome for this study was the proportion of ears achieving complete visualization of the tympanic membrane after use of the agent and irrigation if necessary. The main outcome and categorical pretreatment variables were statistically analyzed using a $\chi^2$ test or a Fisher exact test. Continuous pretreatment variables were analyzed using an analysis of variance test. A sample size of 90 was estimated to achieve 80% power to detect a 40 percentage-point difference between the treatment groups ($\alpha=0.05$; $\chi^2$ with df=2). A 40 percentage-point difference was considered to be significant based on previous studies. SAS statistical software version 8.02 (SAS Institute, Cary, NC) was used for the analyses, and $P<.05$ was considered statistically significant.
The efficacy of many different cerumenolytics has been studied. Docusate sodium has been shown to be more effective than other agents in the acute removal of cerumen. However, this use in young children has not been well evaluated.

This study looked exclusively at young children with cerumen obstruction. We compared docusate sodium, triethanolamine polypeptide, and normal saline as control, with irrigation if needed, and found no difference between the agents. Despite recent literature recommending the use of docusate sodium prior to ear irrigation in cerumen obstruction, we found this not to be effective in children aged 6 months through 5 years.

A recent study by Singer et al compared the effectiveness of docusate and triethanolamine polypeptide as cerumenolytic agents when applied prior to irrigation. Fifty patients were enrolled, with only 14 patients aged 5 years and younger. Overall, they found that docusate was significantly more effective than triethanolamine polypeptide (82% vs 35%). In pediatric patients aged 5 years and younger, docusate was even more effective than triethanolamine polypeptide (90% vs 0%). However, only a small number of pediatric patients were enrolled and only 4 of 14 received triethanolamine polypeptide. This study did not have enough power to draw a conclusion in the population aged 5 years and younger. It was also limited by the lack of a control agent.

Our study compared docusate and triethanolamine polypeptide in only the young pediatric population (≤5 years of age). A control was also included to help determine whether irrigation alone may be the main reason for improvement. The results of our study do not support the use of either docusate or triethanolamine polypeptide as cerumenolytics prior to ear irrigation.

A limitation to our study was that it was a convenience sample based on the availability of an enrolling physician, although we have no reason to believe that children seen at other times would have had a different outcome. In addition, although the method for ear irrigation was clearly stated in the protocol, physicians and nurses performing the irrigation may have differed in their technique and effectiveness. The color of each of the agents is different, which could potentially allow the investigator to determine which agent a patient received. We tried to minimize this blinding error by having the nurse place the agent in the ear and then have patients turn their heads to drain the agent before the investigator examined the ear a second time. Finally, normal saline was chosen as the control agent, because we wanted a liquid to help maintain blinding. In addition, we wanted a substance that would remain stable and sterile in a syringe for months at a time. There is a possibility that saline could have cerumenolytic properties; however, this is unlikely. It is possible that 1 mL of saline may have loosened the wax, making irrigation more successful. Irriga-

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**What This Study Adds**

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**Table 2. Study Participants With Completely Visualized Tympanic Membranes**

<table>
<thead>
<tr>
<th></th>
<th>Docusate Sodium (n = 34)</th>
<th>Triethanolamine Polypeptide (n = 30)</th>
<th>Saline (n = 28)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clear after agent</td>
<td>4 (12)</td>
<td>4 (13)</td>
<td>1 (4)</td>
</tr>
<tr>
<td>Clear after first irrigation</td>
<td>13 (38)</td>
<td>12 (40)</td>
<td>12 (43)</td>
</tr>
<tr>
<td>Clear after second irrigation</td>
<td>18 (53)</td>
<td>13 (43)</td>
<td>19 (68)</td>
</tr>
</tbody>
</table>

Many different substances have been studied and advocated as cerumenolytic agents. Docusate is commonly prescribed as a stool softener; however, physicians also recommend it as an effective cerumenolytic agent. Chen and Caparosa commented on its use in children seen at other times would have had a different outcome. In addition, although the method for ear irrigation was clearly stated in the protocol, physicians and nurses performing the irrigation may have differed in their technique and effectiveness. The color of each of the agents is different, which could potentially allow the investigator to determine which agent a patient received. We tried to minimize this blinding error by having the nurse place the agent in the ear and then have patients turn their heads to drain the agent before the investigator examined the ear a second time. Finally, normal saline was chosen as the control agent, because we wanted a liquid to help maintain blinding. In addition, we wanted a substance that would remain stable and sterile in a syringe for months at a time. There is a possibility that saline could have cerumenolytic properties; however, this is unlikely. It is possible that 1 mL of saline may have loosened the wax, making irrigation more successful. Irriga-
tion alone was not studied as a separate treatment arm to maintain blinding within the study design.

In conclusion, this study did not find a significant difference in the proportion of tympanic membranes able to be completely visualized after application of docusate or triethanolamine polypeptide vs saline control in the pediatric population.

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REFERENCES