COMPARATIVE STUDY OF CERUMINOLYTIC EFFECT OF DISTILLED WATER AND 2% PARA DICHLOROBENZENE

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ABSTRACT
Background: Cerumen impaction is a common condition encountered in ENT practice. There are many treatment options available for removal of impacted ear wax. The ceruminolytic effect of distilled water and 2% para-dichlorobenzene ear drops has been compared in this study.

Aims & Objective: (1) To compare the ceruminolytic effect of distilled water and commercially available 2% para-dichlorobenzene ear drops; (2) To observe and analyze the complications during the usage of these agents.

Materials and Methods: A total of 103 patients who attended the ENT OPD and were diagnosed to have impacted ear wax completely occluding the ear canal were included in the study. They were divided into two groups – Group D and Group P. Group D patients were advised to use distilled water as ear drops and Group P patients were advised to use commercially available 2% para-dichlorobenzene ear drops. A total of 72 ears were studied in each group.

Results: From the results it is clear that using distilled water as ear drops does lead to significantly more complications and pain during removal than 2% Para dichlorobenzene ear drops. The results also point that removal becomes significantly easier when distilled water is used compared to 2% Para dichlorobenzene. No statistically significant difference has been noted in the number of attempts required to achieve complete removal between the two groups.

Conclusion: The results indicate that the usage of distilled water on a regular basis as a ceruminolytic ear drop cannot be recommended.

Key Words: Cerumen Impaction; Ceruminolytics; Distilled Water; 2% Para-dichlorobenzene

Introduction

Cerumen or ear wax is a mixture of the glandular secretions from the lateral third of the ear canal and exfoliated squamous epithelium. It lubricates the ear canal, acts as a trap for dust, hair and insects. Normally cerumen is eliminated or expelled by self-cleansing mechanism which causes it to migrate out of the ear canal assisted by jaw movements.[1]

Cerumen or wax impaction is defined as accumulation of cerumen that causes symptoms, prevents a needed assessment of ear canal/tympanic membrane or audiovestibular system or both. Symptoms associated with cerumen impaction vary from simple itching to hearing loss to tinnitus and vertigo.[2] Impacted cerumen is a major cause of primary care consultation and common co-morbidity in ENT patients[3] and people with mental retardation[4]. The optimal and effective treatment of cerumen is time consuming in many cases, delays the required assessment in some and moreover has remained a controversial subject for many centuries. There are many treatment options available for cerumen impaction including observation, ceruminolytic agents, irrigation or manual removal other than irrigation and also combination of ceruminolytic agents with either irrigation or manual removal.[5] The concept of softening ear wax with the intention of facilitation of its removal dates back to 18th century. In the early 18th century, Grace in his dissertation on wax, described use of olive oil in treatment of wax impaction.[6] From then on various authors have recommended various preparations for treatment of impacted wax. These preparations can be widely classified into water based and oil based.

Many studies have compared the efficacy of these preparations. One of the most detailed meta-analysis and systemic review of effectiveness of topical preparations concluded that on current evidence, there is little evidence to choose between water based and oil based preparations, non-water, non-oil based preparations appear promising at both clearing and facilitating successful syringing.[6] Another study by Eekhof et al concluded that water instilled in the affected ear 15 minutes prior to syringing is effective as a quick dispersant for persistant ear wax.[7] Some in vitro studies have proved that water which was originally intended as a control substance, surprisingly proved to be one of the fastest working and most effective agent.[8,9]
But so far there are no studies comparing the effectiveness of water used as ear drops in a similar fashion to commercially available ear drops or if water can actually be an alternative for commercially available ceruminolytic ear drops or is there any additional adverse effects of using water in this manner. Hence these parameters have been studied by comparing the use of distilled water and commercially available 2% para-dichlorobenzene ear drops in a similar way.

Materials and Methods

The ethical clearance was obtained from the institutional ethical committee before the start of the work.

Patients

A total of 103 patients who attended the ENT OPD between September 2013 to December 2013 and diagnosed to have impacted ear wax completely occluding the ear canal were included in the study. The patients were in the age 1yr to 80 years of both sexes. An informed consent was obtained from the patients in a prescribed form at the time of inclusion in the study. They were divided into two groups – Group D and Group P. Group D patients were advised to use distilled water as ear drops and Group P patients were advised to use commercially available 2% para dichlorobenzene ear drops. A total of 72 ears were studied in each group. The patients were randomized and not the ears because this was more practical. Randomization was done based on the OPD number of the patients – even numbers to Group D and odd numbers to Group P.

All patients with previous history of ear discharge or any otological surgery were excluded from the study. Also patients who had pain, otitis externa or otomycosis at presentation were excluded from the study.

Methodology

Method of administering the ear drop was same in both groups. They were advised to lie with the affected ear top most and instil 4 drops and exert inward pressure over the tragus 8-10 times. They were advised not to use cotton plugs and to remain in that position for 5 minutes. If the patient had bilateral wax he/she was advised to follow the same procedure for the other ear after 30 minutes. They were advised to use the ear drops 4 times every day for 5 days and return on the 6th day for wax removal.

Study of Parameters

Each patient was explained about the possibility of any complication developing during the usage of these medications and was asked to report in case of any such occurrence. They were treated fully for the complications also. During review visit each patient was assessed for any complication which was not reported earlier and recorded accordingly.

Suction was used as the main method of wax removal and in some cases instrumentation was required in addition to suction. Each ear was scored based on this system and recorded. End point was complete removal of wax allowing full visualization of tympanic membrane. If this was not achieved during first review (6th day), then patient was instructed to continue same medication in the same fashion for another 5 days and review again for removal and this procedure followed till the end point was achieved. During removal presence of pain was noted and recorded. The number of attempts required for complete removal in each ear was also recorded.

All the results were subjected to Wilcoxon rank sum test using SPSS v17 to determine the statistical significance of the differences between Group D and Group S.

Results

General Parameters

In the present study patients were in the age group 1-80yrs. Maximum number of patients was in 1-10 years of age in both the groups - 44.44% in Distilled water group (Group D) and 40.27% in 2% Para dichlorobenzene group (Group P).

The age distribution of subjects selected for the present study is shown in Figure 1. This is comparable to studies by Nair et al[5], where they had maximum number of patients in the age group 1-10 years. Also a study on age related changes in ear wax secretion by Jacobsen observed that there is reduction in sebum production in males and females almost to the same degree as age advances.[10]

There were 39 males and 33 females in Group D and 43 males and 29 females in Group P (Figure 2). Similar finding of more incidence of ear wax in male patients has been noted by Stone and Falghum in their study [11]. This has been attributed to the larger and coarser hairs in the external auditory canal of males. However many
studies [5, 10, 12] did not find any significant difference in the sex incidence of cerumen impaction.

In Group D there were 17 patients with right ear cerumen impaction, 21 with left ear cerumen impaction and 17 more patients with bilateral wax impaction. In Group P there were 6 patients with right ear wax impaction, 18 with left ear wax impaction and 24 had bilateral impaction (Figure 3). Therefore there were 34 right and 38 left ears in Group D (total 72) and 30 right and 42 left ears in Group P (total 72). Though there were a total of 55 patients in Group D and only 48 patients in Group P in effect 72 ears were studied in each group.

**Specific Parameters**

First specific parameter studied was development of any complication during usage of the medication. The complications encountered were increase in ear block, otitis externa and otomycosis. About 9 patients in Group D and 2 patients in Group P developed complications. The details are given in Table 1. Study showed that there is a significant increase in the incidence of complications while using distilled water as ear drops (p < 0.05).

The next parameter studied was ease of removal. It was considered easy removal if only suction was required and difficult if instrumentation was required in addition to suction (score 2). It was observed that after using distilled water it was easier to remove wax using only suction. The results have been tabulated in Table 2. These results were analyzed to see if this difference is statistically significant and it was observed that there is a statistically significant difference in the ease of removal between the two groups (p < 0.05).

The third parameter studied was pain during removal. There were 6 patients who experienced pain in one of the ears (total 6 ears) during removal in Group D, whereas no patient experienced pain in Group P. This difference was found to be statistically significant (p < 0.05).

The fourth parameter that has been analyzed in the efficacy was number of attempts at complete removal. The results are shown in Table 3. There was only one patient who required a total of 3 attempts for complete removal in Group P whereas maximum attempts required in all other ears were either 1 or 2 in both groups. However analysis of these results did not show any statistically significant difference between the two groups (p > 0.05).

### Table 1: Complications

<table>
<thead>
<tr>
<th>Complications</th>
<th>Group D (N = 72 ears)</th>
<th>Group P (N = 72 ears)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increase ear block</td>
<td>1 ear</td>
<td>1 ear</td>
</tr>
<tr>
<td>Otitis externa</td>
<td>6 ears</td>
<td>1 ear</td>
</tr>
<tr>
<td>Otomycosis</td>
<td>2 ears</td>
<td>Nil</td>
</tr>
</tbody>
</table>

### Table 2: Ease of removal

<table>
<thead>
<tr>
<th>Ease of Removal</th>
<th>Group D (N = 72 ears)</th>
<th>Group P (N = 72 ears)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Only suction</td>
<td>45 ears</td>
<td>28 ears</td>
</tr>
<tr>
<td>Suction + instrumentation</td>
<td>27 ears</td>
<td>44 ears</td>
</tr>
</tbody>
</table>

### Table 3: Attempts at complete removal

<table>
<thead>
<tr>
<th>Attempts</th>
<th>Group D (N = 72 ears)</th>
<th>Group P (N = 72 ears)</th>
</tr>
</thead>
<tbody>
<tr>
<td>One</td>
<td>66</td>
<td>61</td>
</tr>
<tr>
<td>Two</td>
<td>6</td>
<td>10</td>
</tr>
<tr>
<td>Three</td>
<td>Nil</td>
<td>01</td>
</tr>
</tbody>
</table>
Discussion

From the results it is clear that using distilled water as ear drops does lead to significantly more complications than 2% Para-dichlorobenzene ear drops. Distilled water dispensed in sterile packing available in any medical setup was used to avoid introduction of any infected material into the external auditory canal and so these results are comparable.

However the results also point that removal becomes significantly easier when distilled water is used compared to 2% Para-dichlorobenzene. Chosen method of choice for removal in both groups was suction because any effect of water/ saline used during syringing in Group P has been successfully eliminated by this. This has allowed a comparison of the exclusive effect of distilled water against that of 2% Para dichlorobenzene. Water has been shown to have a ceruminolytic action whereas 2% Para-dichlorobenzene is a wax softening agent and so the disintegration of wax after using water may be more effective.

There is also significantly more pain during removal in patients who used distilled water. The reason for this may be that when water collects in the ear canal especially when trapped by wax, the skin can become soggy and this may render the area more sensitive to pain. Though this is a theoretical possibility, the post removal appearance of canal skin has not been included in this study and hence is difficult to conclude. The other reason may be due to more patients with complications like otitis externa and otomycosis in Group D.

No statistically significant difference has been noted in the number of attempts required to achieve complete removal between the groups. However the only patient who required three attempts for complete removal belonged to the Group P. Certain general parameters like age, sex and ear distributions of wax impaction observed during this study have been tabulated but a detailed analysis of these factors has not been carried out because this was beyond the purview of this study.

Considering all these factors, though distilled water is as effective as 2% Paradichlorobenzene ear drops and is in fact a better ceruminolytic facilitating easier removal, regular usage of this as ear drops cannot be recommended based on this study. At the same time, further detailed study will be needed with respect to each and every complication seen during this study for a better understanding of their actual clinical impact.

Conclusion

Distilled water used as ear drops is as effective as 2% Para-dichlorobenzene and in fact makes removal of impacted wax easier. However since the complication rate while using distilled water is more compared to 2% Para-dichlorobenzene, the usage of distilled water on a regular basis as a ceruminolytic ear drop canot be recommended.

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References