



## AN IN VITRO COMPARISON OF THE EFFICACY OF CERUMINOLYTICS FOR THE DISINTEGRATION OF CERUMEN PLUGS FROM ELDERLY PATIENTS

### YAŞLI HASTALARDAN ELDE EDİLEN SERÜMEN TİKAÇLARININ ÇÖZÜNMESİ ÜZERİNE SERÜMENOLİTİK SOLÜSYONLARIN ETKİLERİNİN İN VİTRO KARŞILAŞTIRILMASI

#### ÖZET

**Amaç:** İlerleyen yaşla birlikte serümen (buşon) birikimlerine sık rastlanmaktadır. Yaşlı hastalardan elde edilen serümen tıkaçlarının çözünmesinde Earex, Waxsol, Xerumenex, hidrojen peroksit'in gliserin içinde % 6'lık solüsyonu, % 10'luk sodyum bikarbonat solüsyonu ve distile suyun etkilerinin karşılaştırılması.

**Materyal ve Metod:** Otuz iki yaşlı hastanın dış kulak yolundan taze buşon örnekleri alındı. Aynı buşon örneğinden 100 mg'lık eşit miktarlar ölçülerek çalışma ortamına yerleştirilerek üzerine serümenolitik solüsyonlar eklendi. Çözünme derecesi beş gün boyunca belli zaman aralıklarında değerlendirildi.

**Sonuçlar:** Tam çözünme bir saat içinde sadece hidrojen peroksit'in gliserin içinde % 6'lık solüsyonu ile meydana geldi. Waxsol ve % 10'luk sodyum bikarbonat solüsyonunun her ikisinde de kısmi çözünme izlendi. Earex ve Xerumenex solüsyonlarının ise buşon çözünmesinde hemen hemen hiç etkisinin olmadığı görüldü.

**Yorum:** Beş serümenolitik solüsyonun kullanıldığı bu invitro çalışmada yaşlı hastalardan elde edilen serümen tıkaçların çözünmesinde hidrojen peroksit'in gliserin içinde % 6'lık solüsyonunun en etkili serümenolitik olduğu belirlenmiştir.

**Anabtar Sözcükler:** Serümen tıkaç, serümenolitik, hidrojen peroksit, gliserin, sodyum bikarbonat.

#### ABSTRACT

**Background:** Cerumen impactions are more common with advancing age.

**Objective:** To compare the efficacy of Earex, Waxsol, Xerumenex, a 6% solution of hydrogen peroxide in glycerin, a 10% solution of aqueous sodium bicarbonate preparations and distilled water for producing disintegration of the cerumen plugs collected from elderly patients.

**Method:** Fresh samples of cerumen were obtained from ear canals of 32 elderly patients. Equal parts of the same piece of the cerumen plug weighed 100 mg were placed into the preparations. The degree of disintegration was observed at specific time intervals for up to five days.

**Results:** Complete disintegration only occurred with hydrogen peroxide 6% in glycerin within one hour. Cerumen plug in both Waxsol and aqueous sodium bicarbonate solution 10% were observed to be substantially disintegrated. We noticed that Earex and Xerumenex had almost no effect on cerumen plug disintegration.

**Conclusion:** The 6% solution of hydrogen peroxide in glycerin appears to be the most effective ceruminolytic preparation for producing disintegration of the cerumen plugs collected from elderly patients among the five ceruminolytics used in this in vitro study.

**Key words:** cerumen plug, ceruminolytic, hydrogen peroxide, glycerin, sodium bicarbonate.

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## INTRODUCTION

Cerumen (Earwax) is a mixture of secretory products of sebaceous glands and ceruminous glands that are located in the cartilaginous part of the external auditory canal (EAC) as well as desquamated epithelial cells and exfoliated hairs (1). Cerumen normally forms within, and spontaneously clears, from the EAC. However, in some individuals cerumen accumulates in the EAC and forms cerumen plugs. When the cerumen plugs obstructs the external auditory canal or touches the tympanic membrane, it can cause discomfort, tinnitus, a sensation of aural fullness, reflex cough, conductive hearing loss, and occasionally vertigo. These plugs also hinder the tympanic membrane inspection of patients with suspected otitis media (1,2).

Cerumen impaction has posed a problem to both patients and otolaryngologists or general practitioners. The prevalence of cerumen impaction is approximately 2% to 6% of general population in America (1,3). Accumulation of cerumen is more common among the elderly and mentally retarded persons (3).

Removal of cerumen impaction is facilitated by means of curetage, irrigation or ceruminolytic agents. Ceruminolytics are primarily used to dissolve and liquefy occlusive earwax plugs before irrigation or direct removal with curette or suction. A variety of ceruminolytics have been used in practice (4-6). Several in vivo and in vitro studies have examined the ceruminolytic effects of a various solvents in children and adults (4,7,8). Since cerumen tends to become drier with advancing age, the ceruminolytics used in adults may not have the same efficacy as in elderly patients. To the best of our knowledge, an in vitro study comparing the efficacy of ceruminolytics for cerumen plugs collected from only geriatric patients is almost lacking.

We therefore designed to evaluate the comparative efficacy of five ceruminolytic solutions for the disintegration of cerumen plugs collected from elderly patients.

## MATERIALS AND METHOD

The in vitro study was carried out in Ear, Nose & Throat and Biochemistry Departments of our Hospital between January 2004 and June 2004. Fresh samples of cerumen were collected from ear canals of 32 elderly patients ranging in age from 65 to 84 years (15 women and 17 men) by means of an ear hook. While the ear wax was being collected, patients with inflammation of the external auditory meatus or middle ear or seborrhoeic dermatitis were excluded from the trial. The cerumen samples were stored at 4°C until the time of analysis. The preparation and analysis of the ceruminolytic agents is similar to that used by Horowitz and Mehta (7,8). The cerumen samples were separately homogenised into one large mass. Then the large cerumen mass was divided into equal parts, which were manually rolled into standard spheres. Each piece of part weighed 100 mg. These parts were then placed into individual numbered test tubes. Ten ml of the ceruminolytic was added into each of the test tubes by a clean pipette, in the following order.

Tube 1: Earex (arachis oil BP 33.3% v/v, almond oil 33.3% v/v, rectified camphor oil BP 33.3% v/v)

Tube 2: Waxsol (docusate sodium 0.5% in a water miscible base)

Tube 3: Xerumenex (triethanolamine polypeptide oleate condensate 10%, chlorbutor 5%, in propylene glycol)

Tube 4: Hydrogen peroxide 6% in glycerin

Tube 5: Aqueous sodium bicarbonate 10%

Tube 6: Distilled water

The tubes were then placed in a vertical perspex holder and left undisturbed in a room temperature during the study period. Ten distinct observers assessed the degree of disintegration of the cerumen in each test tube at 15 min, 1 hr, 6 hr, 12 hr, 1 days, 3 days and 5 days by using the following scale as described in Mehta's report (8) .

- + = Unchanged
- ++ = Slight disintegration
- +++ = Moderate disintegration
- ++++ = Substantial disintegration
- +++++ = Complete disintegration

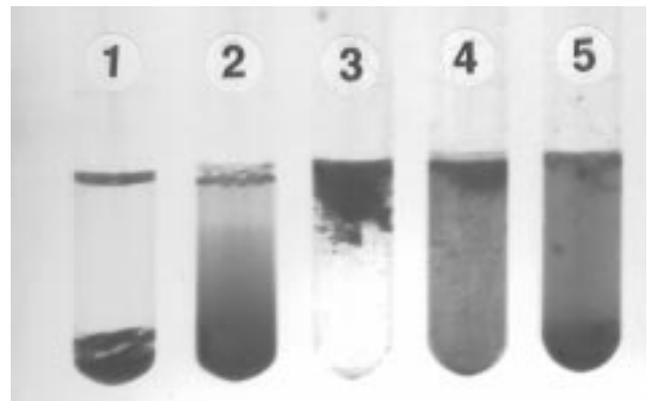
Photographs were obtained to record the results at set time intervals after introducing the ceruminolytics into tubes.

## RESULTS

The results of disintegration of the cerumen was shown at set time intervals in Table 1. Disintegration was observed in test tubes except in tube of earex (Figure 1-3). No change in tube 1 (Earex) was noted during the study period.

The degree of disintegration of the cerumen plug in tube 2 (Waxsol) and 6 (distilled water) was seen to be moderate within fifteen minutes (Figure 1). Substantial disintegration in tube 2 occurred within one hour, which stopped later on (Figure 2). The marked swelling of cerumen plug caused by Waxsol solution was noted in tube 2 (Figure 3). In tube 6, no change for the degree of disintegration was observed after fifteen minutes (Figure 1-3)

Slight disintegration of cerumen plug was observed in tube 3 (Xerumenex) within fifteen minutes (Figure 1).



However, no change was recorded after this. In contrast to  
**Figure 1-** The appearance of the cerumen plug in tubes at 15 minutes.



**Table 1-** Appearance of cerumen plugs from 15 minutes to 5 days

	Tube 1 Earex	Tube 2 Waxsol	Tube 3 Xerumenex	Tube 4 Hydrogen Peroxide 6% in Glycerin	Tube 5 Sodium Bicarbonate 10%	Tube 6 Distilled Water
After 15 minutes	+	+++	++	++++	++++	+++
After 1 hour	+	++++	++	+++++	++++	+++
After 6 hours	+	++++	++	+++++	++++	+++
After 12 hours	+	++++	++	+++++	++++	+++
After 1 day	+	++++	++	+++++	++++	+++
After 3 days	+	++++	++	+++++	++++	+++
After 5 days	+	++++	++	+++++	++++	+++

+ = Unchanged, ++ = Slight disintegration, +++ = Moderate disintegration, ++++ = Substantial disintegration, +++++ = Complete disintegration.

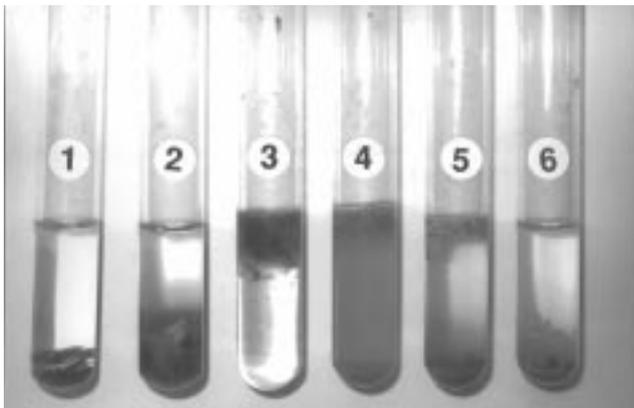
the cerumen plugs in other test tubes, the cerumen plug in tube 3 was surprisingly noted to float during the study (Figure 1-3).

The cerumen plug in tube 4 (hydrogen peroxide 6% in glycerin) and 5 (aqueous sodium bicarbonate 10%) was observed to be substantially disintegrated within fifteen minutes (Figure 1). Despite complete disintegration occurred in tube 4 within one hour, there was no change in tube 5 after fifteen minutes (Figure 2,3).

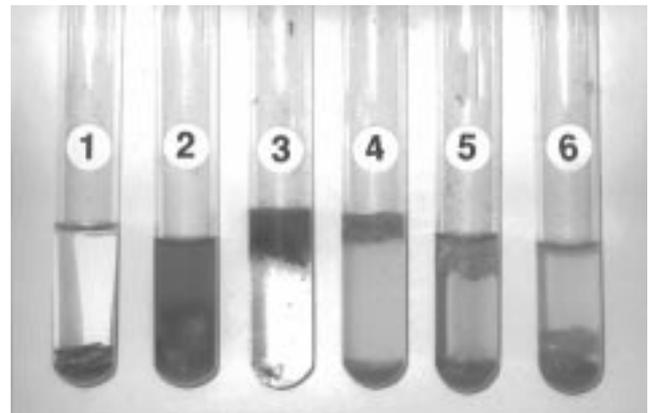
## DISCUSSION

Accumulation of cerumen is more frequent in the older population (1). In the elderly, cerumen accumulation may aggravate a preexisting hearing loss, prompting them to seek care for the obstruction earlier than would younger persons.

Several ceruminolytic preparations are available, but there is no consensus on the effectiveness of the wide variety of ceruminolytics in use (1). Mehta conducted an in vitro comparison of ceruminolytics commonly used in general practice (8). Results showed that waxsol was likely to be the most effective preparation to disintegrate the cerumen plug completely (8). Robinson and Hawke also evaluated ceruminolyt-



**Figure 2-** The appearance of the cerumen plug in tubes at 1 hour.



**Figure 3-** The appearance of the cerumen plug in tubes at 3 days.



ics agents for in vitro efficacy (4). They supported Mehta's observation showing that docusate sodium to be the most effective ceruminolytic. In another in vitro study, sodium bicarbonate, waxsol, cerumol and olive oil were compared for dispersion of cerumen plugs (9). The solution of sodium bicarbonate proved to be the most effective and cheapest ceruminolytic. Waxsol would also seem to be fairly effective in dissolving cerumen plug after sodium bicarbonate (9).

However, in previously described in vitro experiments, it has not been reported that these cerumen plugs were collected from which group of ages such as children, adults and elderly people. We are not aware of a previous in vitro study comparing the efficacy of various ceruminolytic preparations for producing disintegration of the cerumen plugs collected from elderly persons.

Since it has been shown that cerumen seen in the elderly has different biochemical and physical properties than in children and adults (10), a ceruminolytic which is effective in dissolving cerumen plugs of younger population can not have the same efficacy in the elderly. These different properties are: 1) cerumen may be rock-hard may contain exfoliated hairs in elderly persons, 2) with advancing age, there is an slight increase in protein content and a slight decrease in lipid content of cerumen, 3) in the elderly, migration slows down and changes to the cerumen glands in the ear canal tend to make cerumen dry (6,10,11).

Carr and Smith compared the efficacy of sodium bicarbonate and aqueous acetic acid solution in children and adults. Although they could not demonstrate a difference between these two ceruminolytic agents, both solution were significantly more efficacious in children than adults (6).

The result of the present study shows that 6% solution of hydrogen peroxide in glycerin was the most effective ceruminolytic preparation for producing disintegration of the cerumen plugs collected from elderly patients. This was closely followed by a 10% solution of sodium bicarbonate and Waxsol. We did not find earex and xerumenex to be useful in the disintegration of the cerumen plugs. The 10% aqueous solution of sodium bicarbonate would seem to be quicker acting in the disintegration of plug than Waxsol. Waxsol was shown to be effective in a number of in vitro and in vivo studies (5,7,8). It has been reported that waxsol was more effective in children than adults (5). This may explain why Waxsol could not disintegrate the cerumen plug completely as the 6% solution of hydrogen peroxide in glycerin in our in vitro study. The disadvantage of this solution is that it causes marked swelling of cerumen (4). In vivo situations, this may give discomfort sensation to patients. Conversely, no swelling of wax caused by 6% solution of hydrogen peroxide in glycerin was observed in our trial.

Besides the efficacy of ceruminolytic agent, its tolerability, commercially availability and cost effectiveness are of particular significance. Cerumol, as a possible alternative ceruminolytic, has not been included in our study, because it has been shown that it might predispose to otitis externa (12). In our clinical practice with a 6% solution of hydrogen peroxide in glycerin, we did not observe any side effects in both young and adult population. The hydrogen peroxide 6% in glycerin is also a cheap and easily prepared solution. Thus, we would recommend the use of a hydrogen peroxide 6% in glycerin solution as the ceruminolytic of choice particularly in elderly patients.

### CONCLUSION

The 6% solution of hydrogen peroxide in glycerin was the most effective ceruminolytic in the disintegration of the cerumen plugs collected from elderly patients among the five ceruminolytics used in this in vitro study. We think that comparative in vivo studies of ceruminolytics in elderly patients with impacted cerumen will be necessary to confirm our results.

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