

## ORIGINAL RESEARCH

**A study of effectiveness of drug delivery systems for ear wax removal****Dr. Abha Kumari<sup>1</sup>, Dr. Sayan Dutta<sup>2</sup>, Dr. Sandeep Kumar<sup>3</sup>, Dr. Ujjawal Kumar Dubey<sup>4</sup>,  
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[2013sayandutta@gmail.com](mailto:2013sayandutta@gmail.com)Received: 18<sup>th</sup> Feb, 2024Accepted: 29<sup>th</sup> March, 2024**Abstract:**

**Introduction:** Ear wax is a naturally occurring substance in the external ear having protective functions. However, excess ear wax along with epithelial cells and dirt may sometimes block the ear canal. This impacted ear wax may cause symptoms of ear blockage sensation, hearing loss. Traditionally ear wax softening drops were used to soften the impacted wax followed by procedures like syringing, micro suctioning and instrumental manipulation. In syringing, the external auditory canal is irrigated with lukewarm water, and the ear wax is washed out along with the jet of water. In micro suctioning, the wax is removed with the help of vacuum created by a suction machine. In instrumental manipulation, the wax is removed by manipulation using instruments like ear wax hooks, loops or forceps. Recently, ear wax softening agents in the form of sprays have been manufactured. Our study compares the efficacy of this newer drug delivery system to the traditionally used drops in softening of impacted ear wax followed by removal of wax using syringing.

**Aims:** To compare the efficacy of an ear wax softening agent when applied in the form of spray vs traditionally used drops.

**Materials and Methods: Study design:** Randomized control trial in the ENT department of a tertiary care centre in Jharkhand. **Subjects:** 50 patients with bilateral ear wax were selected from patients visiting the ENT OPD. **Methods:** 50 patients of bilateral ear wax were selected among patients visiting the ENT OPD by the process of purposive sampling. These patients were divided into two groups, Group A having 26 patients and Group B having 24 patients. Patients in group A were advised to apply Sodium bicarbonate ear spray in left ear and Sodium bicarbonate ear drop in right ear. Group B patients were asked to apply Sodium bicarbonate ear spray in right ear and Sodium bicarbonate ear drop in left ear. Patients were asked to follow up on Days 3, 5 and 7 for bilateral external ear syringing. Syringing was performed by a blinded researcher.

**Results and Conclusion:** Ear drops took around 7 days of repeated application to soften the ear wax for complete removal by syringing. Ear spray took a lesser time of around 3-5 days to soften the ear wax for complete removal by syringing.

**Keywords:** Ear wax, Sodium bicarbonate drops, Sodium bicarbonate spray, Syringing.

### **Introduction:**

Ear wax, scientifically called cerumen is naturally produced by the ceruminous glands in the external auditory canal. It has protective functions and also helps in keeping the external auditory canal clean and moisturized. Accumulation of cerumen along with shed epithelial cells and dirt in the external auditory canal can lead to impacted wax resulting in symptoms like conductive hearing loss, ear pain, ear blockage sensation [1]. In these cases, it becomes necessary to remove the impacted wax to relieve the patient of these symptoms. In other cases, when patient is asymptomatic, ear wax removal may be necessary to properly visualize the tympanic membrane or to perform tests like audiometry and tympanometry [2]. Traditionally ear wax softening agents (cerumenolytics) in the form of ear drops have been used to soften the impacted ear wax followed by procedures like syringing, microsuctioning, instrumental manipulation for removal of impacted wax. In syringing, the external auditory canal is irrigated with lukewarm sterile water of body temperature (37 degree Centigrade), using a syringe with the jet of water being directed postero-superiorly in the external auditory canal and the ear wax is washed out along with the jet of water [3]. Syringing is the most frequently used procedure for wax removal [4]. In micro suctioning, the wax is removed under direct vision with suction probes and the help of vacuum created by a suction machine [5]. In instrumental manipulation, the wax is removed by manipulation under proper vision using instruments like ear wax hooks, loops or by help of forceps. Recently, few pharmaceutical companies have manufactured ear wax softening agents in the form of ear sprays.

Ear wax softening sprays have been used in animals by veterinary doctors because of ease of application and uncooperative nature of the animals. Very few studies have been done on the efficacy of wax softeners applied in the form of sprays vs drops in humans. Hence, we have conducted a comparative study to assess the efficacy of these two drug delivery systems in softening of impacted ear wax in case of humans in our institute. Among the commonly used methods for wax removal, we have chosen the procedure of syringing.

### **Materials and methods:**

The study was conducted on patients of bilateral impacted ear wax presenting to the ENT OPD of RIMS, Ranchi. 50 patients of bilateral ear wax were selected by the process of purposive sampling. Patients having no history of previous ear discharge, no history of ear surgery, no history of presence of grommet were selected for the study. 50 patients were divided into two groups, Group A having 26 patients and Group B having 24 patients. Patients in group A were advised to apply Sodium bicarbonate ear spray in left ear and Sodium bicarbonate ear drop in right ear. Group B patients were asked to apply Sodium bicarbonate ear spray in right ear and Sodium bicarbonate ear drop in left ear. The dosage for each patient was : instillation of Sodium Bicarbonate spray: 2 puffs , four times a day in one ear and Sodium Bicarbonate drop: 4 drops, four times a day in the other ear. This was done to rule out variations in hardness and composition of wax in different patients and to rule out any bias that could occur due to the ease of performing syringing of a particular ear. Following this process we had 50 ears on which Sodium bicarbonate ear spray was applied

and 50 ears on which Sodium bicarbonate ear drops were applied. Patients were counselled about the proper method of instillation of drops and spray and the need for follow up.

Patients were recalled on Day 3, Day 5 and Day 7 for bilateral External ear canal syringing. Patients who did not have complete removal of wax by Day 7 were recalled on Day 10. The researcher who performed syringing did not know whether spray or drop was used in a particular ear.

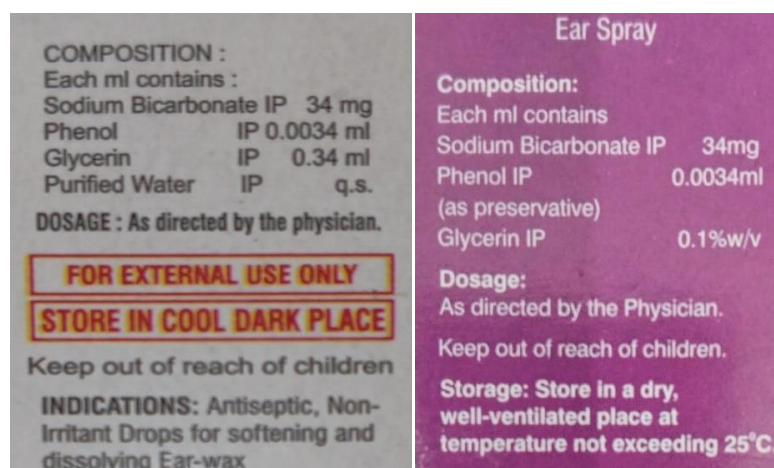
### Inclusion Criteria:

1. Patients of bilateral impacted ear wax
2. No history of ear discharge.
3. No history of application of wax softening agents before attending the ENT OPD.
4. Patients of age group 18-60 years.
5. No history of ear surgery.
6. No history of grommet insertion.

### Exclusion Criteria:

1. Patients having history of ear discharge or ear ache.
2. Patients having Otomycotic debris along with impacted ear wax.
3. Patients who are a known case of Type 2 Diabetes Mellitus.
4. Patients not giving consent for the study.
5. Patients who have already applied any ear drop before attending ENT OPD.
6. Patients who are unable to come for follow up.
7. Patients who know that they have a perforated tympanic membrane.
8. Patients who have experienced vertigo after syringing in the past.

After fulfilling the above criteria, 50 patients were selected for the study. All of the patients were given medications free of cost.



Sodium Bicarbonate drop composition      Sodium Bicarbonate spray composition



Design of the Sodium bicarbonate spray bottle

**Results:**

The study was conducted in the month of August, 2023 in RIMS, Ranchi.

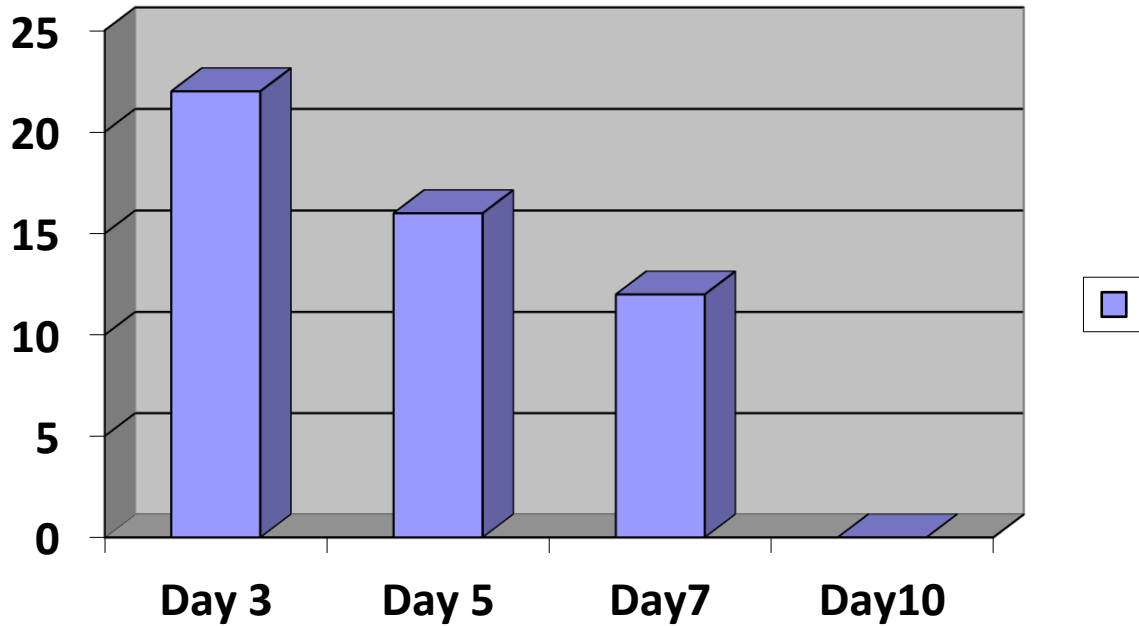
Total number of cases: 50 (50 ears on which spray was applied and 50 ears on which ear drop was applied)

Age group of patients: 18 – 60 years.

Gender Distribution: Male patients: 28, Female patients: 22.

Among the patients who came for bilateral ear syringing, we had 50 ears in which Sodium bicarbonate ear spray was applied. Among those ears, we found that on Day 3, 22 ears had complete removal of ear wax and 28 ears had partial removal of ear wax during syringing. On Day 5, 16 ears had complete removal of ear wax and 12 ears had partial removal of ear wax during syringing. On Day 7, all the remaining 12 ears had complete removal of ear wax during syringing. The chart below shows the ears using ear sprays (n = 50) having complete removal of wax by syringing on Day 3, 5, 7, 10.

Day 3	Day 5	Day7	Day10
22	16	12	0



**Ear spray group (n=50) having complete removal of wax on Syringing**

Among the patients who came for bilateral ear syringing, we had 50 ears in which Sodium bicarbonate ear drops were applied. Among those ears, we found that on Day 3, 0 ears had complete removal of ear wax, 18 ears had partial removal of ear wax and 32 ears had no removal of wax during syringing. On Day 5, 4 ears had complete removal of ear wax and 46 ears had partial removal of ear wax during syringing. On Day 7, 36 ears had complete removal of ear wax during syringing and 10 ears had partial removal of wax during syringing. On day 10, all remaining 10 ears had complete removal of ear wax during syringing.

The chart below shows the ears using ear drops (n = 50) having complete removal of wax by syringing on Day 3, 5, 7, 10.

Day 3	Day 5	Day7	Day10
0	4	36	10

	<b>Ear spray group</b>	<b>Ear drop group</b>
Number of packs needed per patient	1	1
Consistency of wax on removal	Soft, doughy	Brittle, clumpy, fragmented
<b>Post Syringing findings:</b>		
Skin of EAC	Normal.	4 patients had slight congestion over the skin of the EAC
Post Syringing Complications	No post syringing complications observed	No post syringing complications observed
Need for suction or mopping after syringing	No residual wax flakes were observed after syringing.	Few remaining wax flakes were removed by mopping.

### **Eardrop group (n =50) having complete removal of wax on Syringing**

After syringing, the wax expelled out of the external auditory canal was examined. It was found that the wax became soft and doughy on application of ear spray whereas on application of ear drops, it was brittle and fragmented.

Otoscopic examination after syringing revealed that in the ear spray group, the skin of the external auditory canal was normal whereas in the ear drop group, 4 patients had slight congestion over the skin of the external auditory canal. No post syringing complications like vertigo, damage to the external auditory canal, perforation of the tympanic membrane was seen in any patient in either of the two groups.

In the ear drop group, few residual flakes of wax were removed from the external auditory canal by mopping with a sterile cotton ear bud. There were no visible flakes of ear wax in the ear spray group. Hence, no mopping of the external auditory canal was done.

### **Discussion:**

In our study conducted in the month of August 2023, in RIMS, Ranchi on 50 patients, males were 28 and females were 22. The youngest patient was 19 years old and the oldest patient was 58 years old. Among the 50 patients, 26 patients who were in group A were advised to apply ear spray in left ear and ear drop in right ear. 24 patients who were in group B were advised to apply ear spray in right ear and ear drop in left ear. The patients were recalled for bilateral external ear canal syringing on Day 3, 5, 7 and 10. Syringing of bilateral external auditory canals was done by a researcher who did not know about the type of drug delivery system (drops vs spray) that was being used on which ear. Thus we could achieve blinding of the researcher in our study. After syringing, the expelled wax was examined for consistency. Otoscopic examination of bilateral external auditory canals was done and findings noted.

Ear drops after instillation in the external auditory canal gradually gets absorbed in the ear wax. However, in case of hard, impacted wax, the drops take a long time to percolate into the ear wax. This results in the softening of the outer layers of wax and the wax deeper in the external auditory canal remains hard. During syringing on Day 3 and 5, the outer layers of wax which have become soft get removed. Partial removal of wax was possible by syringing as a result. Repeated application for around 7 days was needed to make the ear wax suitable for complete removal by syringing.

On the other hand, ear sprays during application exert some amount of pressure upon the ear wax, which helps in faster penetration into the ear wax. On a single spray puff, we observed that the mist went up to 15 cm in air. There is also a role of surfactant action of glycerine which is achieved as glycerine forms micelles with Sodium bicarbonate and water when delivered in the form of spray. This resulted in faster softening of the ear wax and needed lesser time of around 3-5 days for the ear wax to be suitable for complete removal by syringing.

Ear drops need to be instilled properly in the external auditory canal and the patient should lie down for some time so that the ear drop can penetrate into the hardened ear wax. When the patient gets up, there is also some amount of overflow of the excess liquid that does not get absorbed into the ear wax. There is also a chance of spillage of the ear drops while application. Usually, the patient needs another person who can properly apply the drops in the external auditory canal of the patient.

Ear sprays are fancier compared to traditional ear drops. There is added benefit of easier application of ear sprays and there is no spillage or overflow from the external auditory canal after application. There is also no need for lying down during and after application of ear sprays. The patient did not need another person to apply the spray, there by having the benefit of self application. These qualities make it a very easy to use and it can be carried by patients easily in schools and offices. This also leads to better patient compliance.

Our study was concluded on a small sample size. In our study, we found that ear spray was more effective in removal of ear wax. However, further studies are required on a larger scale to assess the effectiveness of ear sprays compared to ear drops in removal of ear wax.

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