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ORIGINAL RESEARCH

Intra-Procedure Adverse Events and Cardiovascular Changes During Ear Syringing

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Abstract

Background: Ear syringing is a common and relatively safe procedure in ENT practice. Vertigo, vomiting, and discomfort have been reported, but no study has deliberately documented the changes in cardiovascular parameters.

Objective: To assess the frequency of adverse events and changes in cardiovascular parameters during ear syringing.

Methods: This was an observational study of consecutive participants aged ≥ 18 years who underwent ear syringing at the Ear, Nose, and Throat (ENT) Clinic of Obafemi Awolowo University Teaching Hospitals Complex, Ile-Ife, Nigeria, between April and October 2023. Patients with a history of ear discharge or surgeries and those on cardiac pacemakers were excluded. Questionnaires were administered, and pre-and post-procedure vital signs were recorded.

Results: Fifty-seven participants with a male-to-female ratio of 1.19:1 completed this study. Unilateral ear syringing was done in 37 (64.9%) patients. The changes between pre-procedure baseline body temperature, pulse rate, respiratory rate, blood pressure and the post-procedure values of the same parameters were all significantly different but remained within clinically normal limits. The baseline pulse rate and SpO₂ were not influenced by the presence of pre-existing hypertension and the laterality of syringing. There was no significantly elevated baseline respiratory rate in patients who had bilateral ear syringing compared to those with unilateral procedure. However, the changes between pre-procedure body temperature, pulse rate, respiratory rate, and blood pressure and post-procedure values were not influenced by the laterality of the procedure or pre-existing hypertension.

Conclusion: Ear syringing may be associated with minimal changes in cardiovascular parameters, which are not clinically significant.

Keywords: Cardiovascular changes, Ear Syringing, Syncopal attacks, Tympanic membrane, Vasovagal stimulation.

Introduction

Ear syringing is a common procedure in the clinical practice of ear, nose, and throat (ENT).^[1] This procedure involves instilling water at body temperature into the external auditory canal (EAC) to evacuate insoluble, non-hydrophilic materials from the EAC.^[1] The commonest indication for ear syringing is the evacuation of impacted wax, while other indications include removing relatively small, non-vegetative foreign bodies and debris from the EAC.^[2] Although ear syringing is a relatively safe procedure in experienced hands, occasional transient vertigo, vomiting, and discomfort have been reported, especially when the temperature of the irrigating solution significantly differs from the patient's body temperature, leading to caloric stimulation.^[3] Other less common adverse events include tympanic membrane perforation and infections. In Nigeria, Adedeji et al.^[1] reported a 5% overall complication rate, with vertigo (0.7%), abrasion of the external auditory canal (2.2%), and treatment failure (2.2%) being the complications recorded. Another study on the ear syringing experience of South West Nigeria reported vertigo (2.4%), otalgia (3.1%), bradycardia (1.7%), ear infection (1.3%), and external auditory canal injury (1.0%) as the complications recorded in their study.^[4]

A branch of the vagus nerve known as Arnold's nerve supplies sensory innervation to parts of the tympanic membrane and the EAC, and the irritation of this nerve can potentially lead to vasovagal stimulation, resulting in changes in cardiovascular parameters like the pulse rates and blood.^[5] Additionally, a patient who suffered bradycardia after having the posterior wall of the left external auditory meatus stimulated with a cotton-tipped ear probe was shown to have an auriculocardiac reflex.^[6] These irritations can result in a frank vasovagal attack presenting with syncope. The potential dangers of these rare but dangerous situations have raised safety concerns, necessitating the

availability of resuscitation equipment wherever ear syringing is being performed.^[7]

Although risks from ear syringing were documented locally^[1,4], no studies have deliberately documented the frequency of adverse events concerning changes in cardiovascular parameters in patients undergoing ear syringing. This study aimed to document the frequency of intra-procedure adverse events and changes in cardiovascular parameters in patients who had ear syringing in our practice environment.

Methods

Setting

This is an observational study of consecutive patients undergoing ear syringing in the ENT Outpatient Clinic of Obafemi Awolowo University Teaching Hospital Complex, Ile-Ife, Nigeria.

Study population

All adult (≥ 18 years of age) patients scheduled for ear syringing at the ENT Clinic were included in the study. Patients with a history of previous ear surgery, ear discharge, or those with cardiac pacemakers were excluded from the study.

Ethical considerations

Before the study commenced, ethical clearance was obtained from our Institutional Ethics and Research Committee (ERC/2023/12/18). Written informed consent was also obtained from all participants who met the inclusion criteria; however, only consenting participants were included in the study.

Sample size and sampling technique

The sample size was calculated using the formula for a cohort study to detect the difference between means over time.^[8] In the absence of previous research on the impact of ear syringing on cardiovascular parameters and the relative rarity of ear syringing-related adverse events, we assumed a conservative

estimate of incidence of 15%, giving a sample size of 49 at a 95% confidence interval and a margin of error of 10%. Assuming a 10% non-response rate, a calculated minimum sample size of 55 was used for the study.

Data collection

At the commencement of the survey, an interviewer administered a questionnaire to each participant. The questionnaire included questions on the patient's sociodemographic details, laterality of the procedure, previous diagnosis of cardiovascular disease, and drug history. A baseline sitting blood pressure, pulse rate, respiratory rate, body temperature, and percutaneous saturation of peripheral oxygen (SpO₂) were recorded before ear syringing commenced. Ear syringing was performed as per the clinic protocol, using manual ear syringes and water at body temperature, with observation for adverse events. After the procedure, enquiries about adverse events or sensations were made and documented. Post-procedure blood pressure, pulse rate, and SpO₂ were measured and recorded afterwards. The endpoint of the procedure was defined by the successful evacuation of EAC debris, the emergence of unacceptable adverse events, or a diagnosis of failed evacuation by the operator. The blood pressure, temperature, and pulse rates were taken using a single electronic blood pressure machine, a hand-held infrared thermometer, and a pulse oximeter in all patients.

Data management

The data were sorted, coded, and entered into SPSS (Statistical Package for the Social Sciences) version 22 for analysis. Variables of interest included patient sociodemographic details, previous history of cardiovascular diseases, usage of drugs, laterality of procedure, presence and type of intra-procedure adverse events, and the baseline and post-procedure blood pressure, pulse rates, and SpO₂. The mean pre- and post-procedure blood pressure, pulse rates, and SpO₂ were calculated, and the significance of the difference between the pre-

and post-procedure values was determined using the Student's t-tests. Repeated measures of Analysis of Variance (ANOVA) were used to assess the effect of time on the various variables. The level of statistical significance was set at $p \leq 0.05$.

Results

Fifty-seven participants, comprising 31 males and 26 females (male-to-female ratio of 1.19:1), completed the study, with a mean age of 35.13 ± 13.38 years. In Table I, 37 (64.92%) had unilateral ear syringing, while 20 (35.08%) had bilateral ear syringing. Only three (5.26%) were known hypertensive patients with well-controlled blood pressure. Figure 1 shows the lateralisation of ear syringing, where 22 (38.60%) had syringing on the right ear, and 15 (26.32%) participants had left-sided ear syringing done.

Table II shows the pre- and post-syringing haemodynamic parameters. The baseline pulse rate ($p = 0.5$) and SpO₂ ($p = 0.25$) were not influenced by the laterality of the procedure or the presence of pre-existing hypertension. There was no significantly elevated baseline respiratory rate in patients with bilateral ear syringing compared to patients with unilateral ear syringing ($p = 0.07$).

Table I: Characteristics of the participants

Variable	Frequency	Percent (%)
Presence of Comorbidities		
None	54	94.74
Systemic hypertension	3	5.26
Indications for Ear Syringing		
Impacted wax	50	87.72
Fungal debris	6	10.53
Laterality of ear syringing		
Single ear	37	64.91
Both ears	20	35.09

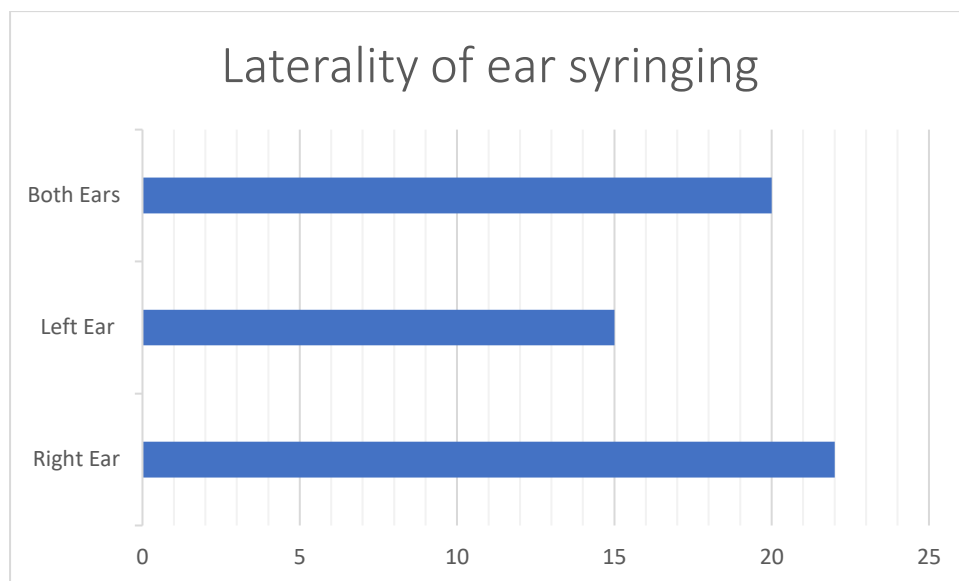


Figure 1: Lateralisation of ear syringing among participants

The mean systolic blood pressure was not significantly different between the hypertensive and non-hypertensive patients ($p = 0.11$). The baseline diastolic blood pressure

was higher in the hypertensive patients ($p = 0.01$), although the blood pressure was still within clinically normal limits in these patients (Table III).

Table II: Comparison of the mean values of pre- and post- syringing haemodynamic parameters

Baseline Parameters	Post Procedure Parameters	p-value
Body temperature 36.76 $\pm$ 0.52 $^{\circ}$ C	Body temperature 36.88 $\pm$ 0.47 $^{\circ}$ C	0.011
Pulse Rate 77.16 $\pm$ 8.82 bpm	Pulse Rate 79.05 $\pm$ 7.16 bpm	0.006
Respiratory Rate 19.47 $\pm$ 1.54 cpm	Respiratory Rate 20.14 $\pm$ 1.48 cpm	≤ 0.001
Systolic Blood Pressure 117.17 $\pm$ 14.24 mmHg	Systolic Blood Pressure 119 $\pm$ 13.20 mmHg	0.32
Diastolic Blood Pressure 72.48 $\pm$ 9.68 mmHg	Diastolic Blood Pressure 74.10 $\pm$ 9.68 mmHg	0.038
SpO ₂ 99.56 $\pm$ 0.57 %	SpO ₂ 99.26 $\pm$ 0.64 %	≤ 0.001

bpm: beats per minute; cpm: cycles per minute; p value < 0.05

The changes in pre-procedure body temperature, pulse rate, respiratory rate, blood pressure, and post-procedure values were not influenced by the laterality of the procedure or pre-existing hypertension. Participants who

had undergone bilateral ear syringing had a significantly higher post-procedure respiratory rate ($p < 0.001$) and a significant reduction in the SpO₂ ($p = 0.03$); however, the values were within clinically normal limits. Only one

participant (1.75%) had a transient period of tinnitus after the procedure. No other adverse event was reported during the study.

Table III: Comparison of Pre-procedure Blood Pressure profile between Hypertensive and Non-Hypertensive participants

Participants Blood pressure	Non-Hypertensive participants (Mean $\pm$ SD)	Hypertensive participants (Mean $\pm$ SD)	p-value
Baseline Diastolic	71.38 $\pm$ 9.07	86.67 $\pm$ 5.78	0.01
Baseline Systolic	115.65 $\pm$ 13.40	136.67 $\pm$ 11.55	0.11

Discussion

Ear syringing is a common procedure often performed in primary care settings. [9,10] Despite occasional reports of adverse cardiovascular events in patients undergoing ear syringing, studies seeking to document the actual frequencies and directions of cardiovascular perturbations in patients undergoing ear syringing are rare. [11,12] This study established a significant increase in the measured cardiovascular parameters post-ear syringing associated with a statistically significant decline in SpO₂. Despite the foregoing, all the estimated changes in cardiovascular parameters and SpO₂ are within clinically normal values. This study confirms the safety of ear syringing within the regular outpatient setting. Given the rarity of adverse cardiovascular events, the requirements for additional safety precautions beyond what is usually available at a routine outpatient clinic in a well-selected patient group cannot be justified.

Reports of syncopal attacks during ear syringing have been attributed to irritation of the auricular branch of the vagus nerve. [5,6,13] This irritation is associated with bradycardia and hypotension, all related to the parasympathetic nervous system stimulation. [4,5,14,15] In this study, the observed cardiovascular changes were in the opposite direction, suggesting sympathetic system stimulation. This implies that parasympathetic

nerve stimulation during ear syringing is a rare event. From the foregoing, this sympathetic activation is likely linked to the patient's apprehension, which may be a much more common phenomenon in patients undergoing ear syringing.

Generally, anxiety and apprehension are more likely to correlate with symptom severity in patients undergoing medical procedures. This study did not attempt to quantify symptom severity; however, a greater decline in SpO₂ and an increase in post-procedure respiratory rates observed in patients undergoing bilateral syringing likely point to a higher degree of apprehension due to increased symptom intensity. Studies focusing on the impact of symptom severity and apprehension on cardiovascular changes in patients undergoing ear syringing may be a worthwhile endeavour in the future. With the foregoing, measures to alleviate patients' apprehension before and during ear syringing should be implemented to enhance the patient experience during ear syringing.

Studies have shown a higher incidence of adverse events in patients using Jet irrigation with devices designed for dental procedures. [16] The higher incidence of such adverse events is attributed to the higher irrigating pressure of such devices. [10] In our study, manual ear irrigating syringes were used in all cases. These syringes cannot generate high pressure, which partly explains the rarity of adverse events in our study. The foregoing notwithstanding, our study design cannot determine the impact of

irrigating pressure on adverse events in patients undergoing ear syringing. Similarly, whereas it is possible that the volume of irrigating solution can influence the incidence of adverse events, there are no clear recommendations for the ideal volume of irrigating fluid for ear syringing. Consequently, this study did not attempt to standardise the volume of irrigating solution. Instead, a clinical endpoint determined by successful evacuation, failure of evacuation, or appearance of adverse events as triggers for termination of the procedure was adopted for this study. Based on this, a variable but unmeasured fluid volume was used during the procedure. This study cannot, therefore, determine the impact of irrigating fluid volume on the incidence of adverse events. Experimental studies to determine the relationship between the volume of irrigating fluid and changes in cardiovascular parameters can be an interesting area of future research

This study included only a small number of hypertensive patients, all of whom are already on medications and are stable. Therefore, the outcomes of this study should not be extended to unstable patients. The routine determination of baseline cardiovascular parameters before ear syringing should be done, and only patients with stable and normal parameters should be offered ear syringing within the primary care level. Physicians should review patients with significant derangements in their baseline parameters before syringing.

Conclusion

Routine ear syringing in the carefully selected patient population should be considered safe, as the observed cardiovascular changes are not clinically significant. The cardiovascular changes observed in this study are apparently benign and are generally not linked to vasovagal stimulation. However, training in the management of acute vasovagal attacks with

regular drills should be encouraged to avoid disasters of this rare but dangerous occurrence.

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Authors' Contributions: AA conceived the study and designed it with ASO, while AA, ASO, and OCE did the literature review. AA, ASO, and NBU analysed and interpreted the data. ASO and OCE drafted the manuscript, while AA and OCE revised the draft for sound intellectual content. All the authors approved the final version of the manuscript.

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