The Role of Pseudoephedrine Tablets Versus Xylometazoline Spray in Otic Barotrauma Prevention During Flights

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Otalgia during airplane flights is a common complaint among patients. This occurs due to the changes in air pressure during take-off and landing that affect middle ear and inner ear. The eustachian tube is responsible with equalizing pressure but in many cases, it happens insufficiently leading to mild to severe pain, hearing loss, tympanic membrane rupture and even inner ear lesions. The aim of this paper is to asses the efficacy of two decongestants, oral pseudoephedrine versus topical xylometazoline in preventing otic barotrauma.

Keywords: Otic Barotrauma, Pseudoephedrine, Xylometazoline

Hearing has two main components: bone transmission and air transmission. The sound wave before becoming an impulse passes through the external auditory canal (EAC) to the tympanic membrane (TM) - the borderline between the external and middle ear, then to the ossicle chain situated behind the eardrum afterwards to the round window from where it enters the inner ear's territory. The middle ear (ME) is responsible for a significant part of the hearing process – air transmission and can be affected by several factors among which flying is one of them. The ME normally besides the ossicle chain and other anatomical structures is filled only with air that should have the same pressure with room air. Communication of the ME with the nasopharynx is done through the Eustachian tube (ET) that helps equalise pressure between ME and the back of the nose. When there is a case of air pressure change in the room air like in plane take off or landing ME pressure should be equalizing through the spontaneous or provoked opening of the ET. In some cases, this is not enough, and people feel ear fullness, hearing loss and mild to severe ear pain.

Otic barotrauma represents an injury of the middle ear secondary to pressure differences between atmospheric and intratympanic pressures. According to Teed's classification of middle-ear barotrauma, there are 5 otoscopic detectable degrees of a possible lesion (table 1) [1,2] In severe cases, one can develop a perforation of the TM or even round or oval window membrane rupture. Barotrauma or aerotitis was first described by a French doctor, J.A.C. Charles, in 1783. After his personal experience of flying with the hydrogen balloon, he complained of severe otalgia developed during landing [3].

According to Tingley et al. there have been reported several cases of rupture of oval and round window membrane leading to a fistula[4]. This should be suspected when a patient with a recent history of flying presents with otoscopic barotrauma, vertigo, nausea, vomiting, tinnitus and sensorineural hearing loss. The resolution of this cases stands in surgical intervention for the closure of the fistula with fat or fascia graft.

Table 1

TEED'S CLASSIFICATION OF MIDDLE-EAR BAROTRAUMA

Grade 0	Normal tympanic membrane
Grade 1	Retraction with redness in Shrapnell's membrane and along the manubrium
Grade 2	Retraction with redness of the entire ear drum
Grade 3	Same as grade 2 plus evidence of fluid in the tympanum or hemotympanum
Grade 4	Hemorrhage and perforation of the ear drum

Prevention of both minor and severe complications of flights can be easily done through simple manoeuvres that force the opening of the ET such as Valsalva's manoeuvre, Frenzel's manoeuvre [5], medication if needed or by knowing when it is not advised to fly. When suffering from an acute upper respiratory tract infection flying should be avoided if possible due to the increased risk of aerotitis media. Uncontrolled allergic rhinitis, nasal obstruction due to chronic rhinitis or deviation of nasal septum are common disorders that may lead to otic barotrauma.

According to several scientific figures, it is advisable to give prophylactic treatment to patients who have a history of ear pain, even ear discomfort during ascending or descending of a plane[6-11]. Mostly for preventing aerotitis media in patients complaining of pain during takeoff and landing ENT doctors prescribe pseudoephedrine drugs or nasal sprays with oxy or xylometazoline. Pseudoephedrine is a sympathomimetic amine that acts on α- and β2-adrenergic receptors, resulting in constriction of the blood vessels and relaxation of smooth muscle. By causing vasoconstriction, less fluid leaves the vessels resulting in a volumetric reduction of the nasal mucosa and decreased nasal discharge relieving nasal blockage symptoms. [12,13] Xylometazoline is a nasal vasoconstricting decongestant drug that binds the same receptors as adrenaline. It is usually found in nasal drops or sprays, and it is prescribed to patients complain of nasal obstruction.

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Experimental part

The authors conducted a clinical prospective study on a group of patients who presented in the outpatient department (OPD) of The National Institute of Aeronautical and Spatial Medicine, between May and October 2017, aged between 18 and 60 years old, complaining of moderated to severe pain in one or both ears during most of their airplane flights in order to determine the efficacy of two decongestants, oral pseudoephedrine versus topical xylometazoline.

After a full ENT examination which included micro otoscopy, fiberoptic endoscopy of the nose and nasopharynx and tympanometry a full medical history was requested. Patients who have diabetes, thyroid diseases, high blood pressure, heart failure, prostatitis and current therapy with a monoamine oxidase inhibitor were excluded due to the contraindication of taking pseudoephedrine or xylometazoline. Severe nasal obstruction due to static factors such as deviation of the nasal septum or nasal polyps, perforation of the TM or glue ear were also exclusion criteria. Tympanogram test results were also an important criterion, being accepted only patients with type A results.

After the inconsistent patients were ruled out a group of 90 patients met the inclusion requisite. They were divided into 3 lots as per their presenting time in the OPD. The first group included a number of 32 patients who received nasal sprays with xylometazoline, the second lot, composed of 30 subjects received oral pseudoephedrine and the third one, formed of 28 patients, received both medications. All subjects were adequately informed about the nature of the clinical study and gave written approval for their participation. They all received an envelope with a prescription of the medication they were going to take and written instructions about how to administrate it and how to measure the otalgia. For that, the authors used a visual analogue scale to measure patients' symptoms from 1- no pain to 5- unbearable pain. The dosage for pseudoephedrine was 60mg p.o. in a single dose 30 min before departure, and for xylometazoline hydrochloride 0.1% was 2 puffs in every nostril 15minuts before departure. Administration time was by the indication of the manufacturer. Subjects for instructed not to use any other antihistaminic or nasal decongestant until the end of the flight. After arriving at their destinations, study groups members emailed the investigators the completed questioner - visual analogue scale. All data was gathered together and analysed.

Results and discussion

Gender distribution in all three groups, although unintentionally, was almost equal between men and women with no tendency for any to be more susceptible.

Subjects were aged between 18 and 60 and divided for each group by decade. Age did not influence how subjects responded to treatment.

Otalgia during airplane flights is a common complaint among people. There have been several attempts over time to prevent it and many studies done with different drugs. Pseudoephedrine is commonly found in over the counter cold medication and is proven to have an excellent decongestant effect due to it's direct and indirect action on the adrenergic receptor in the upper respiratory tract [14].Adrenergic vasoconstriction results in reducing oedema and congestion of the nasal mucosa resulting in a better nasal airflow. By extrapolation, the same mechanism should apply to the Eustachian tube soft tissue, increasing its' patency and optimising middle ear pressure.

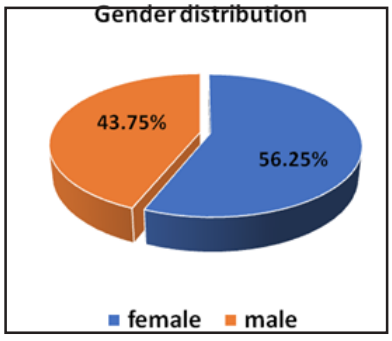

Fig. 1. Gender distribution of the first lot

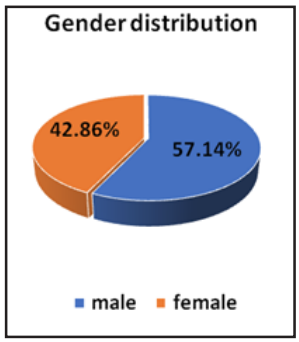

Fig. 2. Gender distribution of the second lot

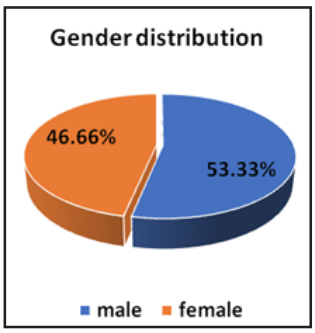

Fig. 3. Gender distribution of the third lot

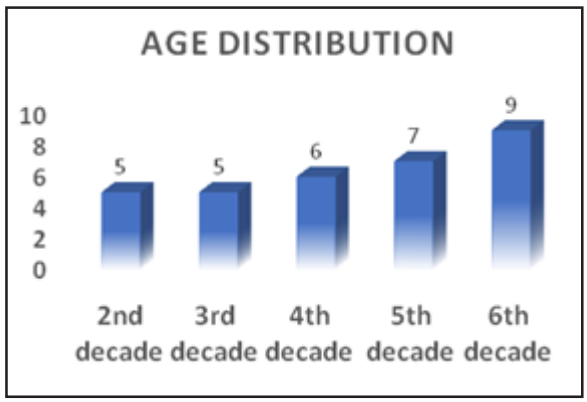

Fig. 4. Age distribution of the first lot

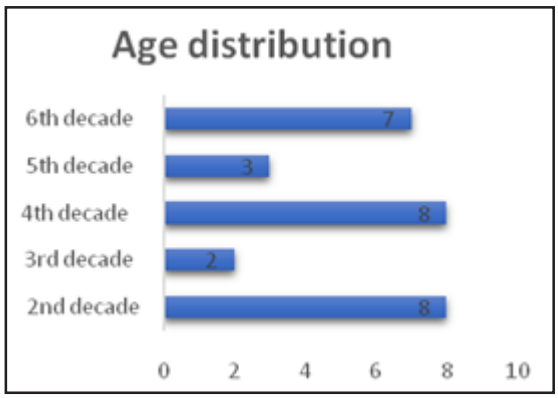

Fig. 5. Age distribution of the second lot

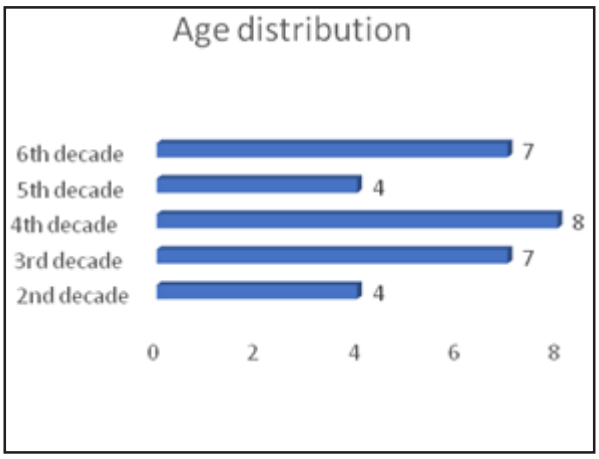

Fig. 6. Age distribution of the third lot

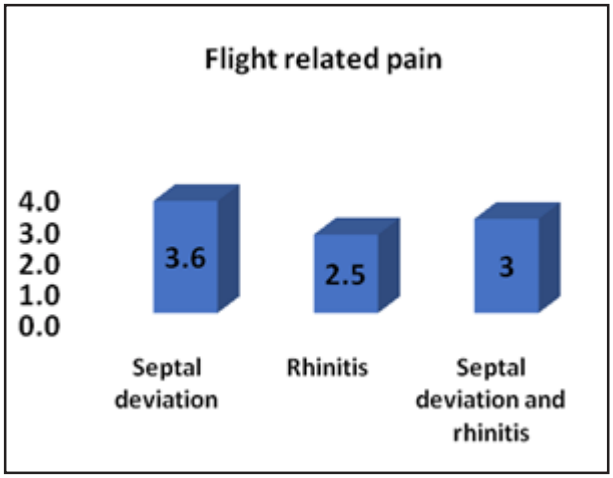

Fig. 7. Pain felt by patients using xylomethazoline 0.1%

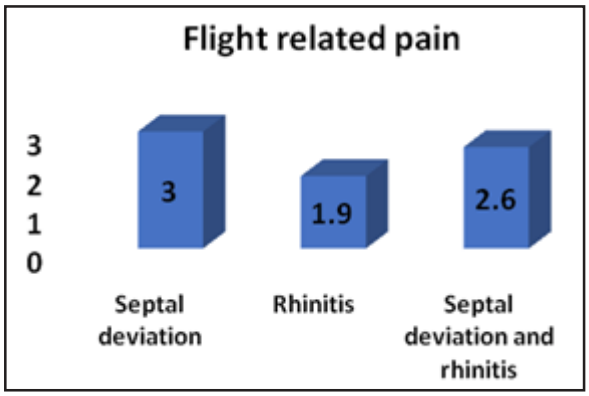

Fig. 8. Pain felt by patients using 60mg of pseudoephedrine p.o.

To ensure accurate research, the authors included in the study only persons who addressed the ENT department for ear conditions developed during airplane flight because usually random people who volunteer to participate in research studies have a different approach and might increase the risk of bias[15]. As seen in the figures above gender and age distribution was random. Patients were enrolled in the study according to their presentation in the OPD, which also induced uneven number of subjects but with no statistical impact. All patients received a visual analog scale: 1- no pain, 3- moderate pain and 5- unbearable pain. First group received nasal xylometazoline 0.1%, 2 puffs in every nostril 15minuts before departure. Second group received 60mg of pseudoephedrine 30minuts before take-off and the third one received both medications.

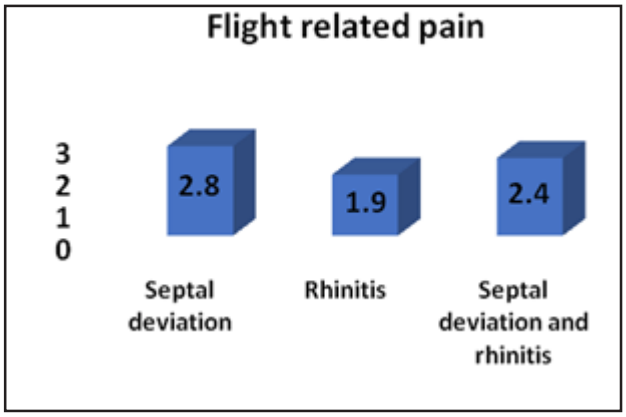

Fig. 9. Pain felt by patients using both medications

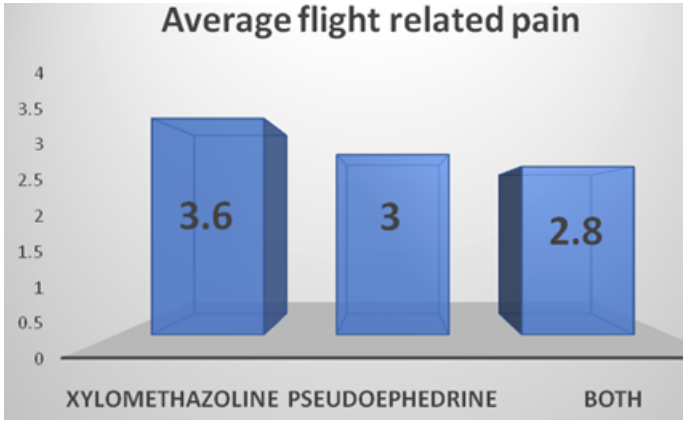

Fig. 10. Average flight related pain for each study group.

As seen in the diagrams above subjects with static nasal obstruction are less responsive to medication. On the other hand, patients suffering from a dynamic obstruction have been experiencing less pain due to the decongestant effect of both medications. The third group had received both medications and patients suffering from both causes of nasal obstruction had the best response.

Conclusions

Treatment with 60mg of pseudoephedrine 30minutes before flight departure decreases the chances to experience ear pain during flight better than xylometazoline nasal spray given alone but an association between pseudoephedrine and xylometazoline gave better clinical response than administrated separately. The results of this clinical study cannot be applied to the general population due to the small number of subjects. Further studies are required to establish specific guidelines for otic barotrauma prevention.

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Manuscript received: 14.03.2018