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# Tensor tenopexy: A clinical study to assess its effectiveness in improving Eustachian tube function and preventing hearing loss in patients with cleft palate

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## KEYWORDS

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Brainstem evoked response audiometry

**Summary** There is a consensus about the occurrence of otitis media in children with cleft palate before repair. However, controversy continues regarding the recovery of Eustachian tube function and level of hearing loss in the patients after cleft palate repair. Levator sling palatoplasty is an important component of the cleft repair. Most surgeons would routinely transect the tensor tendon (tensor tenotomy) during the course of palatoplasty. However, this procedure may pose a risk to Eustachian tube function. Some authorities feel that addition of tensor tenopexy during palatoplasty would maintain the Eustachian tube in an open conformation, thereby improving middle ear ventilation. The present study assesses the effectiveness of tensor tenopexy in improving Eustachian tube function and preventing hearing loss in cleft palate patients treated with palatoplasty. A prospective randomised controlled trial was conducted in the Department of Plastic Surgery at a tertiary care institute in India. A total of 17 children in the age group of 9–24 months were assigned to one of two groups: palatoplasty with either tensor tenotomy ( $n = 8$ ) or tensor tenotomy with tensor tenopexy ( $n = 9$ ). All patients were subjected to tympanometry, otoscopy and brainstem evoked response audiometry before surgery and at 3, 6, 9 and 12 months after surgery. Of these, 52.9% of patients already had hearing loss at the time of presentation. Hearing loss and middle ear effusion persisted even after palatoplasty. There was no significant difference in hearing loss and middle ear effusion between the two groups of patients. Thus, tensor tenopexy was not found to be

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helpful in maintaining Eustachian tube function or preventing hearing loss in cleft palate patients. However, further long-term studies are needed to confirm this study.

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Middle ear disease is common in childhood, with 71% of all children having at least one episode of otitis media by the age of 3 years.<sup>1</sup> By contrast, children with cleft palate have been reported to have a 97% incidence of otitis media with effusion at <24 months of age.<sup>2</sup> It has been found that the incidence of hearing problems in cleft lip alone (CP) patients is the same as in the controlled population. However, this increases sharply when there is associated submucous cleft palate in this group.<sup>3</sup>

Children born with a cleft palate have poor middle ear ventilation secondary to Eustachian tube dysfunction. The tensor veli palatine promotes ventilation of the middle ear by keeping the Eustachian tube open. This muscle originates partially from the cartilaginous border of the auditory tube, hooks around the pterygoid hamulus and inserts along the posterior border of the hard palate. In a cleft of the palate, the aponeurosis of the tensor veli palatini is instead inserted along the bony cleft edges. This abnormal insertion reduces its effectiveness as a Eustachian tube 'opener' and predisposes to middle ear effusion and infection.<sup>4</sup>

The association between hearing loss and a cleft palate is well established.<sup>2,4</sup> It is usually 'conductive type' and is related to scarring, adhesions and perforations of the tympanic membrane. It has been suggested that these symptoms are late sequelae of untreated or unresolved middle ear effusions.<sup>5</sup> Such patients typically have multiple episodes of otitis media with compromised hearing.<sup>6,7</sup> There is mild to moderate degree hearing loss<sup>8</sup> resulting in adverse effects on the child's perceptual learning and development.<sup>9</sup> Unfortunately the middle ear function may not improve with palatoplasty<sup>10</sup> alone and these children need to be followed up until adulthood. The major focus of cleft palate–craniofacial teams has been on the development of a competent velopharyngeal port<sup>11</sup> and normal facial development.<sup>12</sup> Unfortunately, this concern has diverted attention from a common complication of otitis media with effusion and hearing loss.<sup>4</sup>

Although there is a universal consensus on the occurrence of otitis media in unoperated children with cleft palate, controversy continues regarding the recovery of Eustachian tube function<sup>3</sup> and level of hearing loss in patients after cleft palate repair. Currently levator palatoplasty along with tensor transection (tenotomy) is the gold standard and has the lowest secondary pharyngeal flap rates.<sup>13,14</sup> However, the procedure may pose a risk to Eustachian tube function and this possibility has resulted in conflicting opinions regarding its use. Some surgeons advocate tensor tendon transection in order to reposition the levator veli palatini<sup>12</sup> and to facilitate a tension-free closure of the soft palate. Other experts condemn the tensor tendon transection procedure due to the possible

detrimental effect on middle ear ventilation. Cutting<sup>15</sup> advocated suturing the tensor tendon to the hamulus under tension prior to its division with the hope that it would maintain the Eustachian tube in open conformation. However, others feel that this tensor tenopexy is not warranted as the tensor tendon has fibrous attachments to the hamulus and so tensor transection will not have any detrimental effect on Eustachian tube opening.<sup>16</sup> Cutting concluded in a pilot study that the need for myringotomy tube insertion decreases if tensor tenopexy is combined with palatoplasty.<sup>17</sup>

Our study seeks to compare any improvement in Eustachian tube function and hearing profile in cleft palate patients treated with or without tenopexy during levator sling palatoplasty.

## Material and methods

The study was conducted in the departments of Plastic Surgery and Otolaryngology, PGIMER, Chandigarh, from 1 January 2010 to 31 December 2010. It included children between 9 and 24 months of age either with CP or with cleft lip and palate (CLP). The children with syndromic clefts, pre-existing diseases of the ears or any other medical condition or allergic condition were excluded from the study.

The selected patients were randomly allocated to either of the two operative groups, using block randomisation. Group A patients underwent two-flap palatoplasty with tensor transection (tenotomy) alone and group B patients underwent two-flap palatoplasty with tensor transection (tenotomy) and tensor tenopexy. The ethical guidelines set up by the Indian Council of Medical Research (1994) and the Helsinki Declaration (modified 2000) were adhered to in all patients enrolled in the study.

All the patients included in the study were subjected to tympanometry, otoscopy examination and brainstem evoked response audiometry (BERA) to document any pre-existing Eustachian tube dysfunction, otitis media with effusion and hearing loss (*vide infra*).

'Pneumatic otoscopy' was conducted by a specialist in the Ear Nose and Throat (ENT) department and it focussed on diagnosing middle ear effusion or any other disease condition of the ear. Observations were noted as normal, bulging tympanic membrane (indicating middle ear fluid) or retracted tympanic membrane (negative pressure in the middle ear). 'Tympanometry' was performed at the 226-Hz probe tone and the type of tympanogram, compliance of the middle ear and middle ear pressure were noted. The findings were interpreted as types A, B and C as described by Jerger in 1970.<sup>18</sup> Type A is classified as normal, type B is consistent with fluid in

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