



# Incidence of velopharyngeal insufficiency and oronasal fistulae after cleft palate repair: A retrospective study of children referred to Isfahan Cleft Care Team between 2005 and 2009



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## ABSTRACT

**Objective:** The purpose of this study is to determine the incidence of velopharyngeal insufficiency (VPI) and fistulae development in patients seen by the Isfahan Cleft Care Team and also determine the association of gender, age at repair, and cleft type with the incidence of each.

**Methods:** This retrospective study was completed using records of patients referred to Isfahan Cleft Care Team between 2005 and 2009. One hundred thirty-one patients with a history of cleft palate (with or without cleft lip) who had undergone primary palate repair and were at least 4 years of age at the time of the speech evaluation were included in this review. The main outcome of this study was the incidence of fistulae and hypernasality following palatoplasty. A secondary outcome was the association of gender, age at the time of repair, and cleft type on the incidence of fistulae and hypernasality.

**Results:** A post-surgical fistula was present in 23.7% of the patients studied. Fistula rates were significantly higher in patients who had undergone repair of bilateral clefts of the lip and palate (40.9%) than for those patients who had undergone repair of a unilateral cleft lip and palate (16.9%) ( $p = 0.02$ ). Presence of a fistula was not associated with gender ( $p = 0.99$ ) or age at time of primary surgical repair ( $p = 0.71$ ). Mild hypernasality was noted in 15.3% of patients. Moderate or severe hypernasality was present in 66.5% of the patients and the remaining cases presented with normal resonance. Severe hypernasality was significantly higher in patients with a Veau IV type cleft as compared to patients with Veau III cleft types ( $p = 0.04$ ). There was a significantly higher incidence of hypernasality in boys than in girls ( $p < 0.001$ ). The association of age at the time of palatal repair and incidence of hypernasality was not significant ( $r = 0.13$ ,  $p = 0.07$ ).

**Conclusions:** Overall, post-surgical complications were high in this cohort of patients who had undergone cleft palate repair by Isfahan Cleft Care Team during the study time frame. Therefore, there is a high priority need for increased training of best practices for the surgeons.

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## 1. Introduction

The aim of a cleft palate repair is to create an intact palate to allow for normal speech production and feeding. Surgery should result in

competent velopharyngeal function while ensuring minimal disruption of maxillary growth. Post-surgical development of a fistula and/or velopharyngeal insufficiency is an undesirable complication. Reported results of cleft palate repair vary widely and criteria for successful outcomes are not standardized [1,2].

### 1.1. Rates of VPI

The most commonly reported outcome measure for success of an initial palatal repair is whether there is a need for secondary

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surgery [3]. However, secondary VPI surgery rates depend on many factors [4] including the speech severity threshold for the cleft team and/or surgeon to consider surgical intervention (e.g., some consider surgery for milder disorders than others); the patient's and parent's wishes; the impact of comorbidities (i.e., oral-motor speech disorders, obstructive sleep apnea, other structural anomalies, cognitive levels, etc.); and adherence to returning for follow-up appointments [4].

Velopharyngeal insufficiency occurs in approximately 20–30% of patients following primary cleft palate repair [5–8]. Variable outcomes might reflect a number of different factors, such as severity and type of the cleft, surgical technique, and age at the time of palatoplasty all affect the success of the cleft palate repair [9]. In general, children who have clefts of the lip and palate have comparatively higher rates of secondary cleft palate procedures than those children who only have a cleft of palate [6,7,9–11]. However, the effect of cleft type on VPI outcomes according to Veau classification is still debated as there are other studies that refute the theory that cleft type affects speech outcomes [12–14]. In addition, these studies that show a difference in the rate of VPI by cleft type may be influenced by the presence of unknown syndromes in subjects with cleft palate only, the anatomical differences of the subjects in these studies, and even by the number of cases studied [14].

There are numerous studies indicating that the greater the delay in the initial repair of the cleft, the more likely that the child will demonstrate hypernasality and an abnormal articulation pattern, including compensatory errors [10,11,15]. It has also been suggested that gender can be a determinant factor influencing the rate of VPI in favor of males rather than females [3]. Alternatively, there are studies that challenge the findings of gender-based VPI outcomes [16–18].

## 1.2. Fistula rate

A palatal fistula is an opening between the oral and nasal cavity that occurs along the suture line(s) after surgery [19]. This post-surgical complication can have an adverse effect on speech, and can cause nasal regurgitation of fluids. The occurrence of fistulae, as noted in published reports, varies widely, ranging from 3.4% to 15% [4,18]. Several predisposing factors may affect fistula development, including age at the time of the palatoplasty [15], cleft type [7,20,21], surgical technique [22–24] and the experience of surgeon [14,20,22], although findings from other studies do not support the aforementioned effect of age of palatoplasty [25,26] and cleft type [22] respectively. Studies show that there is no effect of gender on fistula development [20,26].

The Iranian based Isfahan Cleft Care Team was established in 2005 for the purpose of providing interdisciplinary management of patients with cleft lip and palate. The key members of the Isfahan Cleft Care Team include a pediatric surgeon, plastic surgeons, maxillofacial surgeon, orthodontist, speech-language pathologist, and ENT. The primary purpose of this investigation was to examine the outcomes of patients seen by the team in order to determine the incidence of velopharyngeal insufficiency and fistula development after primary surgery in this patient cohort. This is the first study done in Iran that has examined the results of primary cleft palate surgeries. An additional purpose was to assess the association of cleft type, age at the time of surgery, and gender on the incidence of velopharyngeal insufficiency in this cohort of patients. This study was undertaken in an effort to inform and improve future care as well as add knowledge regarding the relationship of key factors to surgical outcomes.

## 2. Methods

The clinical records of 260 patients with cleft palate (with or without cleft lip) who had undergone primary cleft palate repair at

the hospitals affiliated to Isfahan University of Medical Sciences between 2005 and 2009 were reviewed. Most of the primary surgeries were done using either the Veau–Wardill–Kilner or (V) von Langenbeck techniques. The most frequent muscle repairs were to the tensor veli palatini and levator muscles. Only those patients whose speech had been evaluated by the Isfahan Cleft Care Team at the age of 4 years or older were included in this study. Because the current study was a retrospective review, it required an equivalent regulatory approval instead of institutional review approval. The following data were collected for each patient: presence of a post-surgical fistula, presence of VPI (as indicated by moderate or severe hypernasality), gender, cleft type, age at the time of primary repair, and the surgeon. In cases where the timing of soft and hard palatal surgical closure was different, the time of soft palate surgery was used. Assessment of resonance was done using an informal Persian Speech Screening Test. This test consists of a list of pressure-sensitive words and sentences that the patient repeats. All evaluations were done by the speech-language pathologist who is a specialist in cleft palate speech (the corresponding author: F.D.). Auditory perceptual ratings of hypernasality were done using a four-point Likert scale as follows: none (0), mild (1), moderate (2), and severe (3). Data regarding phonological errors, developmental articulation errors, or compensatory articulation errors were not used as outcome measures for this study. Presence of an oronasal fistulae of the primary or secondary palate were identified via intraoral examination performed by the physician.

Cleft type was assigned according to the Veau classification: I – soft cleft palate (SCP), II – hard/soft cleft palate (HSCP), III – unilateral cleft lip/palate (UCLP), and IV – bilateral cleft lip/palate (BCLP) (Veau, 1990). A subgroup of patients with submucous cleft was considered separately.

## 2.1. Data analysis

All data were summarized and analyzed using the Statistical Package for Social Sciences (SPSS) version 17.0. The comparisons between the groups of patients were made using: Chi-square, Mann–Whitney and Kruskal–Wallis tests. As appropriate, non-parametric Spearman correlation was used for the establishment of age groups and hypernasality depending on whether the results of the Kolmogorov–Smirnov test revealed a normal range or not. None of the data showed a normal distribution; therefore this correlation coefficient was used. The differences were judged as statistically significant when  $p < 0.05$ .

## 3. Results

Following record review, 131 of the 260 patients met all inclusion criteria. The median patient age for primary palate repair was 12 months with a range from 2 months to 132 months (mean  $18.49 \pm 1.77$  months). There were 76 males and 55 females in the study. The characteristics of the 129 patients who did not meet the inclusion criteria are shown in Table 1. Demographic and clinical characteristics of the review population are also shown in Table 2.

### 3.1. Rates of VPI

There was a higher incidence of severe hypernasality in boys (65.8%) compared to girls (25.5%). There was a statistically significant difference in the degrees of hypernasality with respect to gender (Mann–Whitney test,  $p < 0.001$ ). The incidence of normal velopharyngeal function was higher in girls (27.3%) in comparison with boys (11.8%) (see Fig. 1).

Speech outcomes were poorer in Veau IV and Veau II clefts compared with other Veau categories (Table 3). Out of 59 patients,

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