Evaluating the Outcomes of a Two-stage Surgical Restoration of Newborn Cleft Palate at Hamedan Besat Hospital

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ABSTRACT
Infants born with cleft palate require long-term and group intervention by pediatric surgeons, ENT specialists, orthodontic specialists, and speech therapists. The aim of this study was to evaluate the results of a two-stage surgical repair of newborn cleft palate at Hamedan Besat Hospital during 2006 to 2014. This retrospective cohort study was conducted at Besat Hospital during the years 2006 to 2014. The medical documents of 35 infants diagnosed with cleft palate in large sizes [cleft palate over 13 mm] were examined, who had undergone cleft palate surgery. Data were collected and classified using a checklist, demographic information, incidence of fistula, cleft palate size before the first and 6 months after the second surgery, and, in case of unrecovered cleft palate, one year later. The lesion size was measured by a caliper. Data obtained were analyzed by SPSS software [Version 16] using Mann-Whitney test and t-test. The mean ages of male and female infants were 7 and 7.3 months, respectively, at the first surgical stage [p = 0.331]. The mean palate lesion during surgery was 13.57 mm in the whole subjects, which decreased to 7.57 mm after 6 months of the second surgical stage [p = 0.001]. A two-stage operation for the repair of cleft palate at the early stages of childhood is helpful in healing the cleft palate of such children.

Key words: Pediatric, cleft palate, restoration surgery.

INTRODUCTION
The most common forms of skull and facial malformations in newborns are oral gaps including a cleft lips with a cleft palate or cleft palate alone, which can be created associated with common abnormalities along with other malformations, or alone [1]. Recovery of infants born with cleft palate by oral and maxillofacial surgeon requires long-term and group intervention by pediatric surgeons, ENT specialists, orthodontic specialists, and speech therapists [2]. Specialist oral and maxillofacial surgeon surgeons believe that restoration of hard and soft cleft palate should be considered separately as the surgical goals are different for each one. In fact, the most important goal of soft palate healing is to provide the usual evolution of speech in such patients [3], and therapeutic goals for close fitting of a hard palate should include proper growth of the mandible and facial visage, suitable occlusion of the teeth, and closure of any fistula [4].

Nevertheless, realization of the above goals is not always possible in a single surgical operation. In some cases, more surgeries may be needed to achieve the best results. The average total number of surgeries required to achieve the best performance and beauty for patients born with a cleft palate is not defined being difficult to estimate according to the current information [5].
Moreover, the main advantage of a two-step cleft palate operation by oral and maxillofacial surgeon is to shrink the hard lesion and improve the maxillary growth curve [6]. In order for a proper speech to form, the palate should also function properly when the baby starts to speak [7]. Such patients require multiple surgeries from birth to adulthood. They experience many problems during the course of their growth, including severe disorders in speech and pronunciation, social-psychological problems, upper airway obstruction, mandibular and dental anomalies, pre- and post-surgical problems [e.g. bleeding], and so forth [8].

Many experts oral and maxillofacial surgeon believe that cleft palate should be fully and early recovered before the age of 2 years prior to the child’s achievement of speech ability. In addition, therapeutic interventions related to individual problems in this group of patients, including spoken, feeding, dental, and hearing problems, should be presented at appropriate ages in order to prevent future disorders and also gain the most therapeutic effects as delayed interventions occasionally lead to many negative and sometimes quite ineffective consequences [9]. Since cleft palate lesions account for a major dilemma for both family and society in different aspects, it is inevitable to identify the best method with an emphasis on avoiding repetitive surgeries in infants and control of both disease and child development [10]. The present study, therefore, aimed to evaluate the results of a two-step surgical repair of infant cleft palate at Hamedan Besat hospital from 2006 to 2015.

**MATERIAL AND METHODS**

The most common forms of skull and facial malformations in newborns are oral gaps including a cleft lips with a cleft palate or cleft palate alone, which can be created associated with common abnormalities along with other malformations, or alone [1]. Recovery of infants born with cleft palate by oral and maxillofacial surgeon requires long-term and group intervention by pediatric surgeons, ENT specialists, orthodontic specialists, and speech therapists [2]. Specialist oral and maxillofacial surgeon surgeons believe that restoration of hard and soft cleft palate should be considered separately as the surgical goals are different for each one. In fact, the most important goal of soft palate healing is to provide the usual evolution of speech in such patients [3], and therapeutic goals for close fitting of a hard palate should include proper growth of the mandible and facial visage, suitable occlusion of the teeth, and closure of any fistula [4].

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**RESULTS**

The numbers of male and female newborns participated in the study were 15 [42.9%] and 20
Table 1: Demographic and basic characteristics of patients with a defect one year after the intervention

<table>
<thead>
<tr>
<th>Gender</th>
<th>Age</th>
<th>Injury during surgery</th>
<th>Six months later</th>
<th>One year later</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>Six months</td>
<td>16 mm</td>
<td>11 mm</td>
<td>8 mm</td>
</tr>
<tr>
<td>Male</td>
<td>Seven months</td>
<td>17 mm</td>
<td>13 mm</td>
<td>9 mm</td>
</tr>
</tbody>
</table>

Table 2: Comparison of cleft palate lesions during surgery and 6 months after repair in subjects participated in the study using Wilcoxon test

<table>
<thead>
<tr>
<th>Cleft palate</th>
<th>Mean</th>
<th>SD</th>
<th>Min.</th>
<th>Max.</th>
<th>Median</th>
<th>P*</th>
</tr>
</thead>
<tbody>
<tr>
<td>During surgery</td>
<td>13.57</td>
<td>1.24</td>
<td>12</td>
<td>17</td>
<td>14</td>
<td>0.0001</td>
</tr>
<tr>
<td>Six months after surgery</td>
<td>7.57</td>
<td>1</td>
<td>5</td>
<td>13</td>
<td>7</td>
<td></td>
</tr>
</tbody>
</table>

[57.1%], respectively. The mean weights of the male and female infants before the cleft palate surgery were 7.02 kg and 7.04 kg, respectively.

The mean cleft palate during surgery was 13.77 mm in all subjects, which decreased to 57.7 mm 6 months after the surgery.

The results of Mann-Whitney test showed that mean palate gaps during the operation in the female and male infants were 13.65 mm and 13.66 mm, respectively, but this difference was not statistically significant [p = 0.551].

Infants [17 cases] with an initial lesion length of less than 13 mm exhibited reduced lesion length of 5.7 mm six months after repair. However, cleft palate length decreased by 6.3 mm after repair in infants [18 cases] with a lesion length of over 13 mm, but this decrease was not significant in both groups [P = 0.443]. Using Wilcoxon test in Comparison of cleft palate lesions during surgery and 6 months after repair in subjects participated show statistically significant difference [p = 0.0001].

DISCUSSION

The results of this study showed that a two-step surgery in patients with cleft palate has had beneficial outcomes, which is consistent with the studies by Friede [11], Landheer [12], and Liao et al [13]. The results of a study by Owman-Moll showed a better two-step surgical treatment of cleft palate in early childhood, which is in line with our observations [14]. However, there is a controversy among the specialists about choosing the time of second surgical procedure. Chait L et al implemented the first stage of surgery at the mean age of 10 months and the second stage at 22 months of age [15]. Various studies have shown that if a secondary surgery is not conducted or postponed by the adolescence or late childhood, the chance of success is considerably reduced [16-17].

The results of this study were in agreement with that of Muzaffar et al who showed that a two-stage cleft palate surgery is associated with minor complications suggesting a reduction in vascular damage in such patients [18]. Landhee et al demonstrated that unlike one-stage surgery, two-stage surgery results in lower incidence of fistula, however, they reported a 14% incidence of fistula in two-stage surgery, which is higher than that found in the present study [12]. Similar to our findings, Aslam et al detected a low incidence of fistula after a two-stage cleft palate surgery [19].

CONCLUSION

Based on the results of this study, a two-stage operation for the repair of cleft palate performed in early childhood is useful in the recovery of cleft palate in newborns. The incidence of fistula following a two-stage cleft palate surgery in early infancy is low in the affected infants. Apparently, a two-step repair of cleft palate draws the attention to the improvement and development of near-normal speech being also associated with lower negative impacts on the growth of bones and other facial tissues. As a result, a two-stage surgery increases the probability of success in full restoration consequently leading to reduced likelihood of a fistula incidence. It is recommended that other researcher follow-up our finding in a high crowded of these patients.

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Conflict of interests
There is no conflict of interests in this study.

REFERENCES