PRIMARY VERSUS SECONDARY REPAIR OF CLEFT PALATE USING INTRAVELAR VELOPLASTY APPROACH

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ABSTRACT

INTRODUCTION: Cleft palate is a common congenital anomaly of the craniofacial region. Intravelar veloplasty is a procedure for correcting cleft palate depends on dissection and retro-positioning of levator palati muscle from the posterior line of hard palate. Velopharyngeal insufficiency requires palatal re-repair procedure. The present study aimed to evaluate the microscopic surgical repair of CP with IVVP on clinical and radiological basis.

METHODS: The study was conducted using a comparative quasi- experimental study design on 35 patients; 21 patients underwent primary IVVP repair and 14 patients underwent palatal re-repair. Postoperative outcomes were assessed immediately after surgery and after 6 months. Clinical assessment included cleft types and complications, while the radiological assessment was through lateral video-fluoroscopy and nasopharyngoscopy.

RESULTS: Primary cleft palate repair was done for 21 patients of which 57.1% were females, while cleft palate re-repair was done for 14 patients of which 50% were females. There was a significant difference between primary and re-repaired cases in regard to residence, weight, height and type of cleft, while the complications showed insignificant difference. Primary and re-repaired cases showed insignificant difference in the parameters at nasopharyngoscopy except for closure ratio change and lateral video fluoroscopy except for resting and contracting gaps changes.

CONCLUSION AND RECOMMENDATIONS: Only small rate of oronasal fistula following IVVP was found with significant improvement in velopharyngeal function and complete correction of velopharyngeal incompetence of secondary cleft palate repair following different operational techniques. IVVP is a minimally invasive procedure for correcting cleft palate both for primary or secondary repair.

KEYWORDS: Microscopic surgical repair, cleft palate, intravelar veloplasty, lateral video fluoroscopy.

RUNNING TITLE: Repair of cleft palate with intravelar veloplasty

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INTRODUCTION

Orofacial clefts (OFCs) are common congenital anomalies that occur solitary or in combination with other anomalies or syndromes (1). OFCs include anomalies of lips and both hard or soft palate. They also include structures surrounding the oral cavity which can stretch out onto the facial tissues causing oral, facial and craniofacial distortion (2, 3).Worldwide, the incidence of OFCs is estimated to be between 1-2/1000 (1.42/1000) live births. This incidence shows wide variation between different regions as a result of different distribution of the risk factors (4, 5). The incidence of isolated CP is estimated to be 1 in 2000 live births. The percentages of different types of OFCs are 15% for cleft lip alone, 45% cleft lip with CP and 40% isolated CP (5). In Egypt, a study conducted by Alswairki and his colleagues (2019) in four different governorates among more than 200,000 children found the prevalence of OFCs 0.4/1000 births (6). A retrospective study conducted in Sohag University (2017) found that over fifteen years 1318 patients with OFCs were admitted to the hospital and underwent more than 1900 surgical operations. Within these patients, 43.1% had combined CL and CP, 34.1% had CL alone and 22.6% had CP alone (7).

For the repair of the soft and/or hard palate, many techniques have been described. The aim of palatoplasty is not limited to simple closure of the soft and hard palate but also improvement in speech and avoidance of abnormal maxillofacial growth after repair (8, 9).

Intravelar veloplasty was modified by Sommerlad to be a more physiological technique aiming to preserve the anatomy of the velum. It provides a radical retro-positioning of velar muscles in combination with minimal dissection of hard palate, the tensor tenotomy and repair of levator sling. This modified technique showed promising results in reduction of velopharyngeal incompetence and associated resonance complications (10, 11). Velopharyngeal dysfunction after primary CP repair might need secondary surgery with reported rates of 5% - 38%. Velopharyngeal incompetence causes the nasal air to escape during speech. Hypernasality can lead to development of compensatory speech errors (eg, glottal stops) and speech quality problems (12, 13). Palate re-repair is a physiologic surgical technique for velopharyngeal incompetence aiming to complete dissection and repositioning of the abnormally oriented velar muscles into a more horizontal and posterior functional position which leading to increased functional length of the velum and better excursion. The procedure was promoted by Sommerlad et al., who portrayed clear surgical details for velopharyngeal incompetence. After re-repair, around 66% of cases will have their velopharyngeal incompetence resolved without causing obstructive sleep apnea because of its dynamic nature (14-16).

The present work aimed to assess the clinical and radiological outcomes of primary and re-repair cleft palate using the intravelar veloplasty technique.

Null hypothesis of this study assumed there will be no difference between primary and secondary repair of cleft palate using intravelar veloplasty approach, otherwise the opposite would be approved.

METHODS

This study was approved by the Research Ethics Committee, Faculty of Dentistry, Alexandria University. The study complied with the International Guidelines for Research Ethics. All participants were informed that their participation was voluntary and informed consent was obtained before undergoing the operation to ensure and confirm their understanding of the outcome of the operation and the risks they might be subjected to during the intervention. A comparative quasi-experimental study was conducted on 35 cleft palate patients; 21 patients underwent cleft palate primary repair, and 14 patients underwent cleft palate re-repair in the period from August 2019 till December 2020 in Maxillofacial and Plastic Surgery Department, Faculty of Dentistry, Alexandria University. Inclusion criteria included patients having isolated CP including submucous CP and having velopharyngeal incompetence for palatal re-repair. Exclusion criteria included medically unfit patients, syndromic patients with cleft lip and palate, cleft palate associated with multiple congenital anomalies and patients with neurological disorders.

Surgical technique:

The surgical procedure of this study was performed by single surgeon (A.S). The surgery was performed under general anesthesia using surgical loupes or surgical microscope ZEISS model S88 (Germany) applying the Sommerlad palatoplasty technique: (17, 18)

1. Cleft secondary palate (Figure 1A): the incision was placed along the cleft and the reconstruction of the uvula was maintained in respect to patient’s requirements. Injection of 200,000 adrenaline normal saline was done to minimize the bleeding in the operative area.
2. A triangular flap was prepared in front of the cleft to comprise new epithelial tissue to help closing the nasal mucosa.
3. The triangular flap was prepared and turned joining the nasal mucosa to close it. (Figure 1B) By using a single hook, the oral palatal mucosa and the minor salivary glands were separated from the muscle layer to keep it intact dissecting the greater palatine nerve-vessel bundle and revealing the white bone around the root of the bundle.
4. The periosteum was cut releasing the palatal flap and dissection of the greater palatine nerve vessel bundle depended on the width of the cleft, however, this dissection was not too thorough in narrowed cleft cases.
5. The anterior flap was raised by a curved periosteal elevator for easing suturing the cleft using a stent suturing on both sides. At the same time, the nasal mucosa and muscle were exposed for preparing their closure.
6. Dissection of levator palati muscle sling started from the posterior rim of muscle and 5 mm from midline with the incision been made from back to front (far to near). The LVP muscle was freely going to the cleft rim in front of the middle part of soft palate and not attached to the hard palate.
7. A separation of LVP up to the Eustachian tube and marking the position of LVP on the nasal mucosa on both sides was done. The apparent palatine aponeurosis that attached to the posterior boundary was also separated.

8. After complete dissection of the mucosa, the nasal mucosa was visualized with the relaxed LVP. The LVP on both sides was shown using a forceps.
9. Suturing the LVP and palatopharyngeal muscles was done using 4.0 or 5.0 non absorbable nylon (Figure 1C) to keep it for long time and kept the knot on the nasal side to reduce the discomfort or exposure.
10. Closure of oral mucosa with simple mattress sutures (Figure 1D).

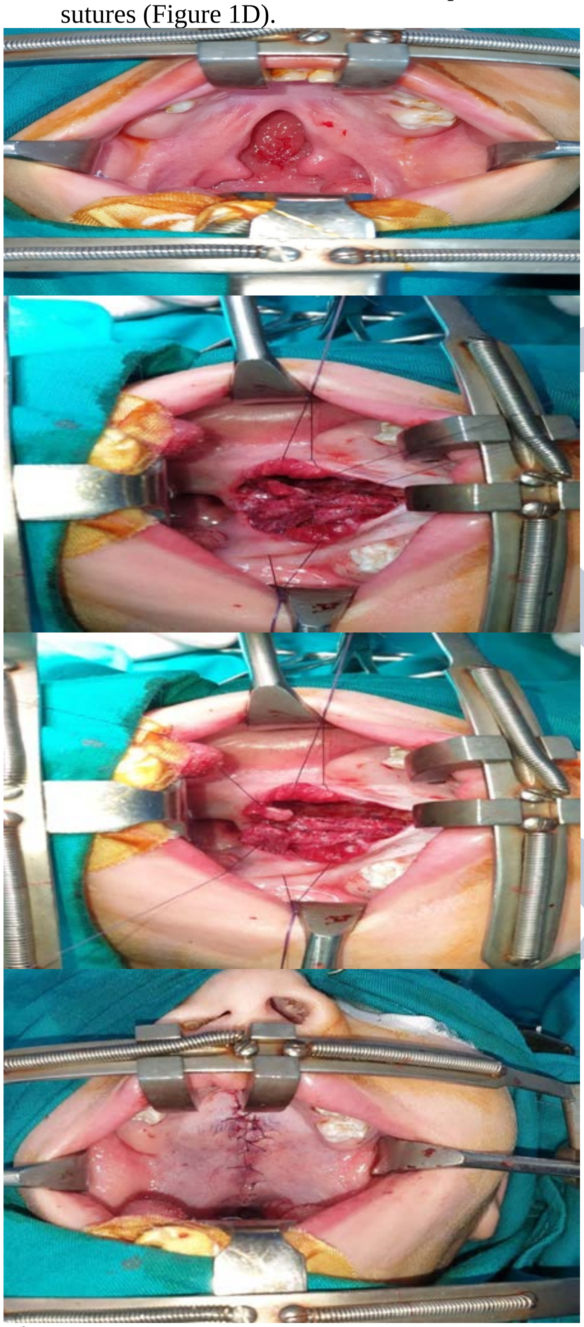

Figure 1: Microscopic IVVP in a six-year-two-month-old male child presented by cleft secondary palate. A: Cleft secondary palate. B: Complete nasal layer closure. C: Posterior retro positioning of velar muscles with plication of levator palati muscle slings and suturing them in transverse direction. D: Complete tension free closure of oral layer without the need of lateral releasing incisions.

Data collection methods and tools:

Lateral video fluoroscopy (Figure 2) was performed preoperatively and after 6 months postoperatively using the modified technique of Sommerlad et al (16) for objective evaluation. The ratio of soft to hard palate length was used as a reference for calibration depending on the fixed hard palate length of the patients. The measurements included; resting velar length, velar length during contraction, functional velar length, resting velopharyngeal gap, contracting velopharyngeal gap, resting and contracting velar thicknesses, closure ratio (gap size at contraction – gap size at rest/ gap size at rest x 100) and extensibility (total palatal length at contraction – total palatal length at rest/ palatal length at rest x 100). Fiberoptic Naso-endoscopy using kay pentax TM RLS 9100 B model* was used to evaluate the velar closure patterns, velopharyngeal valve competence, lateral pharyngeal wall and velar movements preoperatively and 6 months postoperatively. The measurements were palatal convexity (0; notched, 1; flat palate and 2; palatal hump), overall closure (0; none to 4; complete closure), degree of velar and lateral pharyngeal wall movements (ranged from 0; no movement, 1; weak, 2; fair, 3; good and 4; normal movement) and closure ratio (velopharyngeal gap at contraction – velopharyngeal gap at rest / the gap during rest and x 100). (19)

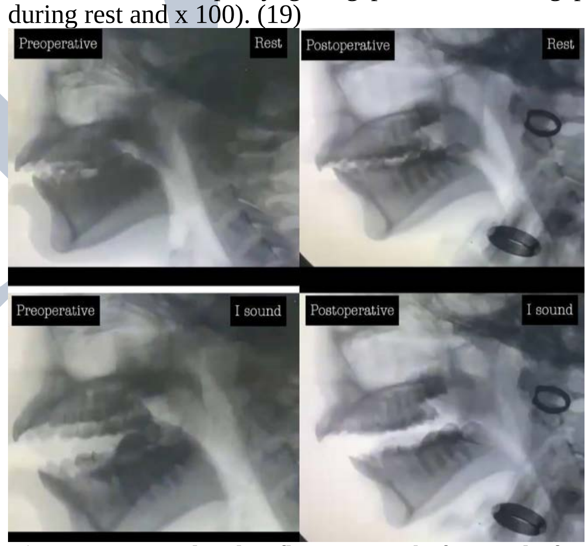

Figure 2: Lateral video-fluoroscopy before and after 6 months of secondary microscopic Re-IVVP procedure. A: Preoperative resting velar length and resting gap. B: Post-operative resting velar length and gap C: Preoperative contracting (during production of I sound) velar length and gap D: Post-operative contracting (during production of I sound) velar length and gap.

Statistical analysis:

The collected data were revised, coded, tabulated and analyzed using SPSS version 25 (IBM, USA). Qualitative variables were expressed as frequency and percentage and quantitative variables were expressed as median and range. Categorical variables were analyzed using chi-square, whenever chi square was not valid**,** Monte Carlo and Fisher exact probabilities were used for RxC tables. Quantitative variables were analyzed using Mann-Whitney test. Differences at p value < 0.05 were considered to be statistically significant.

RESULTS

As shown in table 1, the present work included 35 patients; 21 patients needed primary CP repair (Group 1) and 14 patients needed CP re-repair (Group 2) matched in age and sex. Group 1 cases aged mainly below 5 years (61.9%), while 50% of group 2 aged between 5 and 10 years, females were accounted for 57.1% and 50.0% of both primary and re-repaired cases, respectively. Most cases were from Behira governorates (76.2% primary and 35.7% re-repaired). Weight and height showed a significant difference between primary and re-repaired cases (p= 0.004 and 0.012, respectively).*

Table 1: Characteristics of the patients with primary and re-repaired cleft palate

	Primary cases (n= 21)	**Re-repaired cases (n= 14)**	**p**
Age (years) n (%)			
<5	13 (61.9)	5 (35.7)	0.426
5 – 10	6 (28.6)	7 (50.0)	
>10	2 (9.5)	2 (14.3)	
Gender n (%)			
Male	9 (42.9)	7 (50.0)	0.678
Female	12 (57.1)	7 (50.0)	
Residence n (%)			
Alexandria	4 (19.0)	4 (28.6)	0.022*
Behira	16 (76.2)	5 (35.7)	
Other	1 (4.8)	5 (35.7)	
Weight (Kg) median (range)	15 (9 – 65)	31.5 (13 – 70)	0.004*
Height (cm) median (range)	95 (67 – 170)	123.5 (65 – 170)	0.012*
Type of CP n (%)			
Complete CP	1 (4.8)	9 (64.3)	<0.001*
Incomplete CP	16 (76.2)	5 (35.7)	
Submucous CP	4 (19.0)	0 (0.0)	
Complications n (%)	4 (19.0)	1 (7.1)	0.0627
Fistula n (%)	4 (19.0)	0 (0.0)	0.133
Infection n (%)	4 (19.0)	0 (0.0)	0.133
Hemorrhage n (%)	0 (0.0)	1 (7.1)	0.4

As regards the type of CP, most of primary cases had incomplete CP (76.2), while the majority of re-repaired cases had complete CP (64.3%) with a significant difference (p<0.001). Complications of primary cases were mainly postoperative fistula and infection (19.0% each) and complications of re-repaired cases were only hemorrhage (7.1%).

Both primary and re-repaired cases showed a significant change in fluoroscopic and nasoscopic parameters postoperatively. The change of parameters of lateral video fluoroscopy did not show a significant difference between primary and re-repaired cases except for resting gap change (p= 0.024) and contracting gap change (p= 0.001), and the only parameter that showed a significant difference in the nasopharyngoscopy was the closure ratio change (p= 0.005), Table 2.

Table 2: The change of fluoroscopic and nasoscopic between primary and re-repaired cases

	Primary cases (n= 21)	Re-repaired cases (n= 14)	p
Lateral video fluoroscopy:			
Velar resting length change	0.25 (0.09 - 0.47)	0.25 (0.11 - 0.40)	0.51
Velar contractile length change	0.62 (0.50 - 0.84)	0.65 (0.51 - 0.79)	0.5
Resting gap change	-0.16 (-0.27 - -0.1)	-0.2 (-0.29 - -0.12)	0.024*
Contractile gap change	-0.16 (-0.23 - -0.07)	-0.23 (-0.26 - -0.11)	0.001*
Contracting velar thickness change	0.20 (0.10 - 0.43)	0.36 (0.15 - 0.45)	0.257
Resting velar thickness change	0.10 (0.05 - 0.32)	0.21 (0.06 - 0.30)	0.085
Closure ratio change	0.3 (0.1 - 0.52)	0.38 (0.19 - 0.46)	0.056
Extensibility change	-2.0 (-6.0 - -1.0)	-2.0 (-5.0 - -1.0)	0.875
Functional velar length change	0.22 (0.14 - 0.37)	0.20 (0.13 - 0.32)	0.52
Nasopharyngoscopy:			
Palatal convexity change	1.0 (1.0 - 2.0)	1.0 (1.0 - 2.0)	0.641
Overall closure change	2.0 (2.0 - 3.0)	2.0 (1.0 - 3.0)	0.453
Degree of velar movement change	2.0 (1.0 - 4.0)	2.0 (2.0 - 3.0)	0.872
Lateral pharyngeal wall movement change	2.0 (1.0 - 3.0)	2.0 (1.0 - 3.0)	0.598
Closure ratio change	15.53 (5.78 - 40.1)	32.0 (2.98 - 50.48)	0.005*

DISCUSSION

Cleft palate repair aims to correct the abnormal passage that connects the nasal and oral cavities. It enhances the development of normal speech and subsequently it improves the quality of life and improve the health of patients and their families (20, 21). Failure to achieve these goals might causes oronasal fistula and velopharyngeal incompetence which require secondary surgical repair (21, 22). The current study conducted on 35 patients: of which 40% were secondary repair of the cleft palate for various causes. In United States, the estimated secondary CP repair accounts for nearly 37% of all CP procedures (21). Another study conducted by Sitzman et al found that 27.5% of children who underwent primary CP repair needed a secondary CP repair. The risk of secondary repair was associated with age of the child; children underwent repair before age of 9 months were 4 times more likely to require secondary repair compared to children aged 16-24 months (22).

Sommerlad intravelar veloplasty correcting the levator muscle has the advantage of reducing the hypernasality and fistula rate (23). Another advantage is the use of microscope which has high quality, various magnification powers and good illumination that made it providing a direct reliable image during surgical procedure. The use of microscope also allows the change of angle view of the binocular camera to easiness the surgery (24). Moreover, the palate repair using intravelar veloplasty does not require muco-periosteal flap elevation of incision laterally which help in reduction the occurrence of oronasal fistula and scars and subsequently leads to improvement of the movement of the palate and speech (15).

The rate of fistula was observed among primary cases in 19.0%. Oronasal fistula is a well-known consequence of CP repair. Fistula had a negative impact on normal speech (25, 26). Mapar et al (27) found a rate of fistula of 7.5% after Sommerlad intravelar veloplasty which mainly was associated with Veau III and IV. Occurrence of fistula usually is associated with the surgical correction before the age of 18 months. The rate of fistula in literature ranged from zero up to sixty percent which might be related to the experience of the surgeon (28-32). Sommerlad stated that 15% suffer from postoperative oronasal fistula after intravelar veloplasty and this percentage could be reduced after exclusion of bilateral CP cases to 12% (15).

Both primary and secondary CP repair showed a significant change in lateral video fluoroscopic and nasoscopic parameters. Moreover, the difference between primary and secondary repair showed no significant difference which proves the success of the intravelar veloplasty in correction of CP. The difference in the velar length normally is higher in the secondary cases as the preoperative of secondary cases was lower than the primary cases so the change after operation was minimal in the secondary cases as compared to primary cases. Only the resting and contracting gap showed a difference between both primary and secondary cases as the gap in secondary cases normally is smaller as it was slightly corrected in the primary surgery. There are very limited studies comparing the velopharyngeal function between primary and secondary CP repair. Richard et al (33) excluded secondary repaired patients from speech and velopharyngeal function assessment as it was no longer possible for them to compare the results in relation to the primary surgery. As a result, they did not compare the velopharyngeal function of these patients to the function of primary cases.

Conclusion and recommendations:

The present clinical study found minimal rate of oronasal fistula following intravelr veloplasty with significant improvement in velopharyngeal function and complete correction of velopharyngeal incompetence of secondary cleft palate repair following different operational techniques. Intravelar veloplasty is a minimally invasive and good surgical option for correcting cleft palate whether primary or secondary repair.

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Conflict of interests:

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REFERENCES

1. Worley ML, Patel KG, Kilpatrick LA. Cleft lip and palate. Clin Perinatol. 2018;45:661-78.
2. Agbenorku P. Orofacial clefts: A worldwide review of the problem. ISRN Plastic Surgery. 2013;2013:348465.
3. Mossey P, Little J. Addressing the challenges of cleft lip and palate research in India. Indian J Plast Surg. 2009;42:S9-S18.
4. Malic CC, Lam M, Donelle J, Richard L, Vigod SN, Benchimol EI. Incidence, Risk factors, and mortality associated with orofacial cleft among children in Ontario, Canada. JAMA Network Open. 2020;3:e1921036-e.
5. Vyas T, Gupta P, Kumar S, Gupta R, Gupta T, Singh H. Cleft of lip and palate: A review. Fam. Med. Prim. Care Rev. 2020;9:2621-5.
6. Alswairki HJR, El-Sayed FAA, Fouda MY, Fahim FH, Haque S, Alam MK. Incidence of Egyptian live births of cleft lip and/or palate in

Cairo, Luxor, Aswan and New Valley Governorates: a survey study in 237,783 children. Pesqui Bras Odontopediatria Clin Integr. 2019;19.
7. Abulezz TA. Cleft lip and palate: An experience of a developing center in Egypt. J Craniofac Surg. 2017;28:e731-e4.
8. Shaw W, Semb G, Lohmander A, Persson C, Willadsen E, Clayton-Smith J, et al. Timing of primary surgery for cleft palate (TOPS): protocol for a randomised trial of palate surgery at 6 months versus 12 months of age. BMJ Open. 2019;9:e029780-e.
9. Nakamura N, Tezuka M. Surgical strategy of cleft palate repair and nasometric results. In: Almasri MA (editor). Designing strategies for cleft lip and palate care. 2017. p. 61.
10. Nguyen DC, Patel KB, Skolnick GB, Skladman R, Grames LM, Stahl MB, et al. Progressive tightening of the levator veli palatini muscle improves velopharyngeal dysfunction in early outcomes of primary palatoplasty. Plast. Reconstr. Surg. 2015;136:131-41.
11. Agrawal K. Cleft palate repair and variations. Indian J Plast Surg. 2009;42 Suppl(Suppl):S102-S9.
12. Fisher DM, Sommerlad BC. Cleft lip, cleft palate, and velopharyngeal insufficiency. Plast Reconstr Surg. 2011;128.
13. Woo AS. Velopharyngeal dysfunction. Semin Plast Surg. 2012;26:170-7.
14. Sommerlad B. Surgical management of cleft palate: a review. J R Soc Med. 1989;82:677-8.
15. Sommerlad BC. A Technique for cleft palate repair. Plast Reconstr Surg. 2003;112.
16. Sommerlad BC, Mehendale FV, Birch MJ, Sell D, Hattee C, Harland K. Palate re-repair revisited. Cleft Palate Craniofac J. 2002;39:295-307.
17. Shi B, Sommerlad BC. Cleft lip and palate primary repair: Springer; 2013.
18. Sommerlad BC, Li S. Sommerlad's technique of cleft palate repair. In: Shi B, Sommerlad BC, editors. Cleft lip and palate primary repair. Berlin, Heidelberg: Springer Berlin Heidelberg; 2013. p. 265-76.
19. Elsherbiny A, Gelany A, Mazeed AS, Mostafa E, Ahmed MA, Allam KA, et al. Buccinator re-repair (Bs + Re: IVVP): A combined procedure to maximize the palate form and function in difficult VPI cases. Cleft Palate Craniofac J: official publication of the American Cleft Palate-Craniofacial Association. 2020;57:543-51.
20. Mani M, Carlsson M, Marcusson A. Quality of Life Varies with Gender and Age among Adults Treated for Unilateral Cleft Lip and Palate. Cleft Palate Craniofac J. 2010;47:491-8.
21. Thompson JA, Heaton PC, Kelton CML, Sitzman TJ. National estimates of and risk factors for inpatient revision surgeries for orofacial clefts. Cleft Palate Craniofac J. 2017;54:60-9.
22. Sitzman TJ, Carle AC, Heaton PC, Helmrath MA, Britto MT. Five-fold variation among surgeons and hospitals in the use of secondary palate surgery. Cleft Palate Craniofac J. 2018;56:586-94.
23. Kummer A. Cleft palate and craniofacial anomalies: effects on speech and resonance USA: Thomson Delmar Learning. Inc; 2011.
24. Sommerlad BC. The use of the operating microscope for cleft palate repair and pharyngoplasty. Plast Reconstr Surg. 2003;112:1540-1.
25. Bykowski MR, Naran S, Winger DG, Losee JE. The rate of oronasal fistula following primary cleft palate surgery: A meta-analysis. Cleft Palate Craniofac J. 2015;52:81-7.
26. Bureau S, Penko M, McFadden L. Speech outcome after closure of oronasal fistulas with bone grafts. J. Oral Maxillofac. Surg. 2001;59:1408-13.
27. Mapar D, Khanlar F, Sadeghi S, Abdali H, Memarzadeh M, Davari HA, et al. The incidence of velopharyngeal insufficiency and oronasal fistula after primary palatal surgery with Sommerlad intravelar veloplasty: A retrospective study in Isfahan Cleft Care Team. Int. J. Pediatr. Otorhinolaryngol.. 2019;120:6-10.
28. Winters R, Carter JM, Givens V, St. Hilaire H. Persistent oro-nasal fistula after primary cleft palate repair: Minimizing the rate via a standardized protocol. Int. J. Pediatr. Otorhinolaryngol. 2014;78:132-4.
29. Phua YS, de Chalain T. Incidence of Oronasal Fistulae and Velopharyngeal Insufficiency after Cleft Palate Repair: An Audit of 211 Children Born between 1990 and 2004. Cleft Palate Craniofac J. 2008;45:172-8.
30. Jayarajan R, Natarajan A, Nagamuttu R. Intravelar veloplasty: A review. J Cleft Lip Palate Craniofac Anomal. 2018;5:68-73.
31. Emory Jr RE, Clay RP, Bite U, Jackson IT. Fistula formation and repair after palatal closure: an institutional perspective. Plastic Reconstr Surg. 1997;99:1535-8.
32. Shaw WC, Dahl E, Asher-Mcdade C, Brattström V, Mars M, McWilliam J, et al. A six-center international study of treatment outcome in patients with clefts of the lip and palate: Part 5. general discussion and conclusions. Cleft Palate Craniofac J. 1992;29:413-8.
33. Richard B, Russell J, McMahon S, Pigott R. Results of randomized controlled trial of soft palate first versus hard palate first repair in unilateral complete cleft lip and palate. Cleft Palate Craniofac J. 2006;43:329-38.