

In-depth Survey of Demographic, Clinical, and Operative Measures in Cleft Lip and Palate Patients in Northwestern Turkey

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Abstract

Background: Orofacial clefts are the most common congenital craniofacial anomalies, globally. However, few reports describe cleft demographic, clinical, and surgical information in a Turkish population. **Aims and Objectives:** The aim of this study is to investigate the demographic, clinical, surgical information and outcomes of cleft lip and/or palate (CL/P) patients in Northwestern Turkey. **Materials and Methods:** We assessed demographic, clinical, operative characteristics, and postoperative complications data in this retrospective review of electronic medical records at a tertiary referral center from 2005 to 2015. **Results:** Our study included 150 CL/P patients (88 men, 62 women). Cleft lip and palate (CLP) was the most prevalent type of cleft (60%), followed by isolated cleft palate (31.3%) and isolated cleft lip (8.7%). The rates of maternal folic acid use, smoking, alcohol intake, and consanguinity were 83.3%, 5.3%, 1.3%, and 3.3%, respectively. Nasoalveolar molding was applied mostly in bilateral—not unilateral—CLP patients. The modified, extended Mohler technique was common for cleft lip repairs. Most cleft palate repairs used Bardach's two-flap palatoplasty combined with radical intravelar veloplasty. Most cases required grommet insertion. For cleft palate patients, myringotomy or paracentesis was performed in 12.8% of repairs, and acellular dermal matrix was used in 28.5% of repairs. **Conclusion:** Knowledge of CL/P characteristics is crucial for treatment planning and satisfactory health care. To our knowledge, this is the first study to assess CLP data in a Turkish population.

Keywords: Cleft lip and palate, cleft lip, cleft palate, demographic, Turkey

INTRODUCTION

Orofacial clefts, including cleft lip (CL), cleft palate (CP), and CL and palate (CLP), are the most common congenital craniofacial anomalies, occurring in 1 of 700 newborns worldwide.^[1] Genetic factors and maternal exposure to environmental factors including smoking, alcohol consumption, drug usage, and vitamin deficiencies comprise the etiology and pathogenesis of orofacial clefts.^[2] Cultural factors also seem pivotal. Therefore, the incidence of orofacial clefts can vary from one region to another within the same country.

CL/P can compromise respiration, swallowing, speech, feeding, hearing, and psychosocial reliability, requiring a multidisciplinary approach and early identification, given the increased mortality and morbidity risks for CL/P patients.

Rehabilitation, follow-up evaluation, and the provision of aesthetic and functionality are important for appropriate neuropsychomotor development in CL/P patients, who require careful study by a well-established cleft care team.

CL/P patients are managed by well-established cleft centers in developed countries that define standards and rates and describe

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successful results. An experienced cleft team, data collection, documentation, regular follow-up evaluations combined with orthodontic treatment, and speech intelligibility evaluations are the mainstays of proper orofacial cleft management. Cleft teams from developing countries have to face various challenges to fulfill these parameters for evaluation, treatment, and follow-up care.^[3-5]

Few studies in Turkey address CL/P patients. Reports describing the demographic variables, clinical characteristics, and surgical procedures are inadequate and provide insufficient detail.^[6-8] Therefore, this study aimed to investigate the demographic, clinical, operative characteristics, and outcomes of the CL/P patients in the Northwestern region of Turkey.

MATERIALS AND METHODS

We performed a retrospective review of electronic medical records of consecutive primary CL/P patients admitted to a tertiary referral center from 2005 to 2015. We reviewed the patient records for demographic, clinical, operative characteristics, and postoperative complications. Patients with a minimum follow-up of 9 months were included in the study. Records of patients referred after primary CL repair and those for patients older than 2 years were not included in this study.

We assessed demographic and clinical characteristics including gender, gestational age, birth weight, parental age, maternal drug or medication use, infection, alcohol and smoking status, pregnancy-related sickness (e.g. preeclampsia and diabetes), family history, prenatal diagnosis, type of birth, type and side of oral cleft, and the presence of other congenital anomalies. We also noted patients' feeding methods. For this study, we did not review early speech-language therapy records and follow-up evaluations.

As for operative variables, we documented cleft repair age, nasoalveolar molding (NAM) use, nostril retainer splint use, cleft repair techniques, acellular dermal matrix use (ADM; AlloDerm™, Allergan, Dublin, Ireland), and middle-ear status.

We also documented postoperative early complications, including infection, necrosis, fistula, and bleeding, along with late complications such as hypertrophic scarring.

A senior author of this study was the sole cleft surgeon operating with the same technique for a particular cleft type closure.

Standard mean statistical studies were done using Statistical Package for the Social Sciences version 13 (SPSS, Inc., Chicago, IL, USA). The results were presented as absolute numbers (*n*) and as frequency (%).

RESULTS

Patient demographics and clinical characteristics

A total of 150 orofacial cleft patients were included in this study; of those, 134 cases were nonsyndromic and 16 were syndromic. Eighty-eight (58.7%) patients were male and

62 (41.3%) were female. Gestational week of birth ranged from 32 weeks to 41 weeks with a mean 38 ± 1.8 weeks. Birth weight of cleft patients ranged from 1250 to 3560 g with a mean of 2868 ± 523 g. Maternal age ranged from 19 years to 37 years, with a mean age of 28 ± 5 years. Paternal age varied from 23 years to 44 years with a mean age of 32 ± 6 years [Table 1].

In 83.3% of the cases, maternal folic acid use was present from the first trimester with a dose of 0.4 mg/day. Smoking was present in 8 cases (5.3%). Maternal thyroid replacement therapy was noted in four cases (2.7%). In two cases, alcohol intake was present (defined as 10 standard units/week) in the first trimester (1.3%). The use of anticonvulsant containing levetiracetam was seen in one patient. We found no maternal illicit drug use, no reported exposure to irradiation, and no viral infection or parasitic infestation of any known causative factors [Table 1].

Two mothers developed gestational diabetes (1.3%). Preeclampsia was diagnosed in 2 cases [1.3%; Table 1]. These cases were regularly followed and properly managed. Progesterin was used in 3 cases (2%). We noted low molecular-weight heparin use in one case and acetylsalicylic acid use in another.

No families reported having a previous child with an orofacial cleft (per reported histories) or a second cleft child in the same family (per follow-up reviews). The rate of orofacial clefts

Table 1: Patient demographics and clinical characteristics

Data	Mean \pm SD (Min-Max)
Birth age (week), mean \pm SD (minimum-maximum)	38 \pm 1.8 (32-41)
Birth weight (g)	2868 \pm 523 (1250-3560)
Mother age (years)	28.3 \pm 5.74 (19-37)
Father age (years)	32.7 \pm 6.14 (23-44)
Gender, <i>n</i> (%)	
Male	88 (58.7)
Female	62 (41.3)
Medications used during pregnancy	
Thyroid replacement	4 (2.7)
Anticonvulsant	1 (0.6)
Folic acid	125 (83.3)
Infection	0 (0)
Exposure to irradiation	0 (0)
Maternal alcohol consumption	2 (1.3)
Maternal smoking	8 (5.3)
Pregnancy-related sickness	
Preeclampsia	2 (1.3)
Gestational diabetes	2 (1.3)
Type of birth	
Vaginal delivery	7 (4.7)
Cesarean section	143 (95.3)
Family history	
Cleft parent	3 (2)
Cleft in 3 generations	23 (15.3)
Consanguinity	5 (3.3)
Syndromic	16 (10.6)

SD: Standard deviation, SD: Standard deviation

reported in a family history was 17.3%. Three patients (2%) had a direct parent with an orofacial cleft and 23 patients (15.3%) reported a history of CL/P within three generations. We found 5 cleft patients (3.3%) whose parents reported being in consanguineous marriages [Table 1]. In those families, we noted no other affected sibling before and during the study follow-up. In one case, a newborn was syndromic [Table 1].

Prenatal diagnosis and type of birth

The rate of the prenatal ultrasonography (USG) diagnosis of CL/P was 28%. In the last third of the study period, this rate increased to 36%. Of the USG-diagnosed cleft fetus pregnancies, 4% were brought to the attention of a plastic surgeon or a cleft team member before birth, while 74% of the mothers did not apply to a cleft center before giving birth. The remaining USG-diagnosed pregnancies (22%) contacted a plastic surgeon via phone or email. All the deliveries occurred at municipality public hospitals or women’s and children’s hospitals with a pediatrician. The cesarean section (CS) rate for prenatally diagnosed cleft cases was 95.3%. The rate of spontaneous vaginal delivery was 4.7%.

Nine cases (6%) presented an airway problem at birth and recurrent aspiration pneumonia was noted in 12 cases (8%).

Cleft distribution

CLP was the most prevalent type of cleft (60%), followed by isolated CP (31.3%) and isolated cleft lip (8.7%). A distribution of clefts according to the type and side is presented in Table 2. Male patients were more frequent in all type of clefts compared with female patients; distribution of the clefts by gender is presented in Figure 1. The male-to-female ratio was 1.58 for unilateral CLP (UCLP), 1.33 for bilateral CLP (BCLP), and 1.35 for CP cases.

Sixteen cases were syndromic (10.6%). In most cases, cardiac findings via echocardiography were benign septal defects or patent foramen ovale. However, we found notable cardiovascular system involvement in 12 cases (8%) and 3 of these cases required cardiac surgery before cleft repairs. Pierre robin sequence was present in 4% of the CP cases. Micrognathia, glossoptosis, and mild respiratory obstruction findings were present in 5 cases (3.3%). None of these cases required surgical intervention.

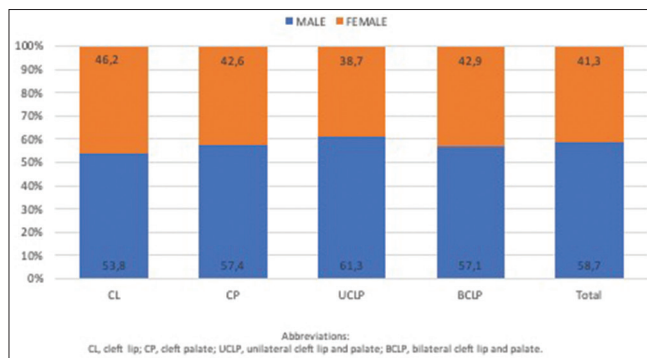


Figure 1: Graph of the distribution of clefts by gender

Feeding method

Breastfeeding was successful in 38 newborns (25.3%). Of these, 25 had CL or CLP and 13 were CP only. One hundred and twelve newborns were bottle-fed.

Feeding tube use

In two CL cases and ten CP cases, nasogastric or orogastric feeding tubes were used (overall feeding tube use, 8%). In 2% of the cases, feeding tube use was discontinued following NAM use.

Operative characteristics

NAM was applied in 52 of the 62 UCLP cases (83.9%; NAM was not indicated in 6 UCLP cases) and 27 of the 28 BCLP patients (96.4%). NAM follow-up compliance was 99%; one family discharged themselves due to socioeconomic reasons.

In 28 cases of CL (27.1%), a nostril retainer splint was applied to secure the nasal ala repair. CL repair age ranged from 10 weeks to 11 months, with a mean of 4.2 months.

In cheiloplasty, the extended Mohler modification of rotation-advancement technique was applied in all cases by the same surgeon [Figures 2a,b and 3a-d]. Primary rhinoplasty or septoplasty was performed at the time of CL repair for all patients.

Cleft palate repair

CP repair age ranged from 6 months to 16 months, with a mean age of 9.2 ± 2 months.

In all CP patients, external auditory examination combined with tympanography was regularly done at 6 months of age, and ear, nose, and throat surgeons routinely joined the

Table 2: Distribution of clefts by type and side

Type of cleft	Unilateral		Bilateral, n (%)	Total, n (%)
	Right, n (%)	Left, n (%)		
CL				
Microform or incomplete	4 (40.0)	6 (60.0)	0 (0)	10 (6.7)
Submucous	0 (0)	0 (0)	3 (100.0)	3 (2.0)
CP	0 (0)	0 (0)	47 (100.0)	47 (31.3)
CLP	26 (28.9)	36 (40.0)	28 (31.1)	90 (60.0)

CL: Cleft lip, CP: Cleft palate, CLP: Cleft lip and palate

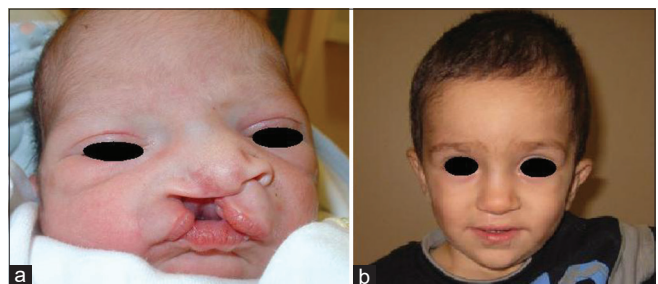


Figure 2: (a) Preoperative view of a male patient with a complete unilateral cleft lip and palate at birth. (b) Postoperative view at 3 years of age after cleft lip repaired with the modified, extended Mohler technique



Figure 3: Pre-and postoperative views of a male patient with complete unilateral cleft lip and palate repaired with the modified, extended Mohler technique. (a and b) Preoperative frontal and basal view at birth. (c and d) Postoperative frontal and basal view at 3 years of age

surgery for an examination via a microscope. Preoperative tympanography showing Type B response in 85% of the cases ($n = 119$) was managed operatively. In 72.2% of the cases, grommet insertion was performed, while in 12.8% of the cases, only myringotomy or paracentesis was performed. In those cases, three patients required grommet insertion in their follow-up examinations. Complications arose in the follow-up examinations for 14% of the cases with grommet insertion. In cases treated conservatively, the complication rate was $<1\%$.

In 67% of the CP cases, Bardach's two-flap palatoplasty was used in combination with radical intravelar veloplasty, as described by sommerlad.^[9] In 16.7% of the cases, the von Langenbeck technique was used. In 2% of the cases, Furlow double-opposing Z-plasty was used. In 11 patients (14.3%), the median incision-only technique was applied.

In 69% of the CP repairs, the vomer was used as a flap donor site for elevation to contribute to the nasal layer closure. Vomer flaps used for closure varied in pedicle, size, and shape. In 10% of the repairs, the vomer flap was added to the anterior nasal layer of the soft palate with a posteriorly based modification extending into the adenoid vegetations. The vomer use rate was 61.1% in BCLP cases, 56.7% in UCLP, and 15% in CP cases.

In 40 cases (28.5%), ADM was used to augment the closure. The mean CP width of these cases was 15 ± 4 mm. The ADM was laid between the oral and nasal mucosa layers, as described by Agir *et al.*^[10]

Postoperative complications

Early complications

In one CL case, an infection localized to the tip of the nose was successfully managed with topical and systemic antibiotic use. In two CP cases, oral infections were resolved with antibiotics. There were no dehiscence incidents. In one CP case, we observed partial necrosis of the palatal flap. The palatal fistula

rate was 3.2% inclusive of ADM-applied cases. The fistula rate was 1% in patients with ADM applied and 7.5% in patients without ADM application.

In one CP case, bleeding was reported in the ward, which was successfully ceased with topical tranexamic acid application.

Late complications

Hypertrophic scarring was present in three CL cases. In addition to topical silicone gel application in one case, one session of intralesional steroid (triamcinolone acetate) injection was needed, and the hypertrophic scar was resolved satisfactorily.

DISCUSSION

Few studies originate from Turkey, analyzing orofacial cleft data. In one study, only the sociodemographic data of the CLP patients living in the Southern Anatolian region were assessed.^[8] Isolated CP and CL patients were not assessed in that study. Altunhan *et al.* studied the incidence of congenital anomalies associated with CLP and isolated CP in neonates, not including the CL patients.^[6] Tomatır *et al.* investigated the registries of CLP patients, analyzing only the cleft types, gender, and ages of patients.^[7] In contrast, this study reviewed and analyzed the demographics, clinical and operative methods, and outcomes of oral cleft patients.

Our finding of a higher prevalence in orofacial clefts in male patients was compared with female patients aligns with the findings by Tomatır *et al.*^[7] and other reports across various ethnic groups.^[11,12] Other studies, including a report from the World Health Organization,^[13] reported a predominance of isolated CP in female patients.^[14,15]

Our mean birth weight (2868 g) was not significantly low compared with another study,^[11] but our finding was below the national average. Telatar *et al.* reported a mean birth weight of 3334 g among 3688 term neonates born in a state hospital in Turkey.^[16] Kianifar *et al.* found no association between low birth weight and oral clefts.^[11] In contrary to this study, Lei *et al.* showed a significant relationship between facial clefts and low birth weight (<1.5 kg) in Taiwan.^[17]

Our mean maternal age (28 years) and paternal age (32 years) was higher than those reported by Silva *et al.* (maternal, 26 years; paternal, 29 years).^[18] Silva *et al.* found no difference between the maternal ages of syndromic and nonsyndromic patients. Similarly, Kianifar *et al.* noted no significant differences in the maternal age of oral cleft patients.^[11]

In the Turkish population, smoking and alcohol consumption are not common during pregnancy due to high levels of teratogenic effect awareness. Our results and those reported by Altunhan *et al.* further support this claim.^[6] However, in the literature, significantly higher frequencies of smoking and alcohol use are reported compared with our findings.^[18,19] In Turkey, folic acid supplementation is very common due to pregnancy follow-up policies from gynecologists. Accordingly, we found

a significantly higher percentage of folic acid usage (83.3%) compared with Silva's reported findings (24.3%).^[18]

The incidence of oral clefts has a close association with consanguinity between parents,^[18,20] and a high rate of consanguineous marriage (53%) was reported in the middle region of Turkey.^[6] This study's consanguinity rate (3.3%) was significantly lower than the previously reported rates. Furthermore, even though our hospital is the only reference center in the region, the rate of syndromic oral clefts (10.6%) was significantly lower compared with previous reports (66%).^[6] The reason for this is that although our hospital is a referral center, all CLP patients who are born and operated in the region may not come to this center.

In this study, the rate of the prenatal diagnosis of oral cleft cases increased by the end of the study as a result of the development in perinatology, increased experience in ultrasound use, and more advanced ultrasound technology. A low percentage (4%) of expectant mothers applied to our center for this resource. While the reasons for this are not completely understood, Internet research, sociocultural position, and religious receptivity may be factors behind the lack of family contact with the center before birth, despite the parents being previously informed of the diagnosis.

The rate of CS for prenatally diagnosed cases was 95.3% in this study. In Turkey, the CS rate was 14.3% in 1993, increased to 51.9% in 2013, and was higher in women who were staying in the Western region of Turkey, which aligns with our results.^[21] In the middle region of Turkey, the CS rate was 67% in oral cleft patients, which is lower than our results.^[6] Due to the risk of trauma during spontaneous vaginal delivery and to avoid the risk of morbidity or mortality, gynecologists and expectant mothers may prefer CS to spontaneous vaginal delivery.

Our findings reflect a higher incidence of BCLP and isolated CP compared with previous studies.^[14,15,18] This elevated incidence of BCLP cases may be attributed to difficulties in managing these cases, and, thus, the referral incidence may be higher than for less difficult cases. Relatively mild cases of unilateral cleft palate (UCP) and partial cleft cases may be surgically repaired in either private practices or public hospitals. The greater prevalence of oral clefts on the left side observed in this study aligns with the findings of several previous reports.^[12,14,15]

As an early management option, NAM was applied mostly in bilateral CLP patients rather than UCLP patients in this study. In the literature, the pharyngeal airway volumes of patients with CLP who underwent NAM were compared with patients who did not undergo NAM. Astani *et al.* found that the pharyngeal airway volume enlargement was more apparent in BCLP patients than UCLP patients.^[22] In our study, all parents indicated that they would prefer NAM again and strongly advise other parents of cleft patients to consider NAM use. Furthermore, they reported that their anxiety levels decreased after observing the results of NAM therapy, a finding also reported by Nur *et al.*^[23]

The timing of lip and palate surgical repair is an important factor to consider in the treatment of oral cleft patients. The recommended age for the repair of CL is at least 3 months, preferably at 4 to 5 months, which aligns with our findings.^[24] As a result of the increased use of NAM, the mean age of surgical repair for CL patients was 4 months, and, in bilateral cleft patients, the mean age of surgical repair was closer to 5 months (especially in severe cases). Technically, in all CL patients, the modified, extended Mohler technique was used due to the satisfactory aesthetic and functional results in this study. Primary rhinoplasty or septoplasty was also performed at the time of CL repair to improve nose symmetry and reduce nasal deformity.

Ventilation tube (i.e. grommet) insertion may occur routinely at the time of palatoplasty or selectively on a separate occasion if symptomatic middle-ear disease develops. In our study, we did not routinely perform grommet insertion for all CP patients. The complication rate was high in those with grommet insertion compared to more conservatively treated cases. In accordance with our approach, Phua *et al.* recommended that a grommet should be inserted in patients with symptomatic infection or significant hearing loss.^[25]

For most of the CP repairs, Bardach's two-flap palatoplasty technique was used with radical intravelar veloplasty, as described by Sommerlad.^[9] The von Langenbeck and median incision-only techniques were also used, particularly for isolated CP cases. Double-opposing Z-plasty was not a popular technique in our unit, although it was applied successfully in some cases. In all the procedures, cleft in the whole palate was repaired in one session following the CL repair. Vomer flaps were used mostly in BCLP repairs, followed by CP repairs to obtain a tension-free closure on both nasal and oral sides.

ADM was used to augment and strengthen the repair and to reduce the fistula rate, scar tissue formation, and contracture. ADM use remarkably improved our results, particularly in wide clefts and/or in high-tension closure-prone cases. ADM reduced fistula rates in a previous study.^[10]

CONCLUSION

The knowledge of CL/P patients' characteristics is certainly important for plotting treatment plans and providing satisfactory health-care services. Orofacial clefts are more prevalent in male patients than female patients. NAM therapy (especially in BCLP cases) improves aesthetic results and parent satisfaction. ADM use remarkably improves the outcomes, particularly in wide clefts and/or high-tension closure-prone cases. Grommet use may increase complication rates compared to conservative treatment in CP patients. Therefore, grommet use is appropriate for the patient with symptomatic infection or significant hearing loss.

The data in this study do not represent all CL/P patients born in the region due to not all CL/P patients born in the region are referred to our clinic. These patients are also referred to

other referral centers located in the East and West of Turkey and to plastic surgeons worked in private clinics. Despite this limitation, to our knowledge, this is the first study to assess a variety of parameters of CL/P patients in Turkey.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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