Perioperative Management in Patients With Cleft Lip and Palate

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Abstract: In cleft care, perioperative treatment strategies like ear nose and throat (ENT) diagnostics as well as postoperative antibiotics, feeding, and duration of inpatient stay are nonstandardized procedures varying between different centers. Likewise, intraoperative choice of suture materials and time of suture removal are performed inconsistently. Therefore, we wanted to collect information on protocols focusing on these topics to summarize and subsume currently approved treatment strategies of centers around the world. We ask members of international cleft centers for their respective treatment strategies and performed descriptive statistics.

Absorbable suture material is used for reconstruction of the outer lip skin in 20 of 70 centers. Removal of skin sutures is conducted after 7.0 ± 1.5 days. Suturing of the orbicularis oris muscle, the enoral and nasal mucosa, as well as the palatal musculature is predominantly performed with absorbable suture materials. Intraoperative antibiotic prophylaxis is applied in 82.9% of the participating centers. In contrast, 31.9% of the departments do not apply any antibiotic postoperatively. Postoperative feeding is performed in 27 centers via a nasogastric tube for 4.6 ± 2.3 days on average. Mean length of postoperative inpatient stay is 4.1 ± 2.6 days in children after cleft lip surgery and 4.5 ± 2.7 days after cleft palate surgery. ENT consultation before surgery is routinely conducted in 52.8% of the centers and 82.9% of ENT colleagues investigate middle ear pathologies in the same operation in which cleft repair is performed.

Closure of the lip skin is predominantly performed with nonabsorbable suture material followed by a suture removal after 1 week. Intraoperative antibiotic prophylaxis as well as inpatient hospital stay of 4 to 5 days in combination with oral feeding and a preoperative consultation and intraoperative cooperation with the ENT department seems to be well-proven concepts in cleft lip palate patient care. However, this analysis illustrated the variations and differing approaches in perioperative care emphasizing the need to verify perioperative management concepts in cleft surgery—preferably in the context of multicenter studies.

Key Words: Cleft lip and palate, perioperative management

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Cleft lip palate (CLP) is the most frequent congenital facial malformation worldwide. Caused by unsuccessful embryonic facial fusion processes, the cleft can affect the lip, the alveolar crest, or the palate or all of these regions at once and can occur unilaterally or bilaterally. CLP treatment is usually performed in multidisciplinary teams, involving the expertise of pediatric and surgical physicians, speech pathologists, orthodontists, ear nose and throat (ENT) specialists and various other medical professions. It is a well-known problem of CLP care that treatment regimes are predominantly more eminence-orientated than evidence-based, which can be explained by the small number of caseloads per unit and the high variations of CLP. Therefore, chronology of therapeutic steps, techniques of cleft surgery, as well as perioperative CPL management differ from one centre to another.

Surgical repair of cleft lip and palate defects is frequently performed within the first 1 to 2 years of life. However, it can vary depending on the child's specific needs and conditions. Aiming at a natural appearance of the lip and nose with physiological function and minimal scarring as well as regular facial tissue development, the surgical procedures themselves basically depend on the surgeon's personal preferences and techniques.[1]

Diverse concepts and techniques of presurgical orthopedics have been introduced over decades.[2,3] The currently most used technique is nasoalveolar moulding (NAM), first described by Grayson in 1993, which aims to reduce the cleft width, align the cleft lip and alveolar segments, and correct the cleft-specific nasal deformity.[4] Despite various studies showing the effectiveness of NAM,[5–7] there remain controversies among experts about its overall benefit.[8,9]

Besides the differences in surgical techniques, there is an ongoing debate on suture materials in cleft surgery with special regards to wound-healing, scar formation, and the setting for suture removal.[10,11] Furthermore, postoperative wound infection is a serious and feared complication in cleft surgery possibly leading to further complications such as wound dehiscence, fistulas, secondary hemorrhage, or even systemic infection prolonging hospital stay and sometimes requiring additional interventions.[12,13] There are currently no evidence-based guidelines available referring to indications for antibiotic therapy and prophylaxis during or after surgical cleft lip and palate interventions in the literature. Likewise, protocols determining immediate postoperative nutrition and length of hospital stay in treated children with surgical wounds also vary between different departments, even within a single region or country.[14]

Considering the fact that randomized controlled trials are rare in CLP treatment and systemic reviews in the literature focusing on perioperative patient care have revealed only inconclusive

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and inconsistent treatment guidelines,[14–16] we wanted to collect information on protocols and perioperative regimes of numerous international hospitals and healthcare centers to summarize and subsume approved treatment strategies.

MATERIALS AND METHODS

We designed a questionnaire for an international data acquisition in September 2018 and contacted international craniofacial and plastic surgical departments treating cleft lip and palate patients. We asked the participating centers for treatment protocols regarding diagnostic participation and involvement of the ENT department, detailed information regarding the sewing materials including suture characteristics, suture label, and size (according to USP) with regard to dedicated steps during cleft lip and palate repair, time point and type of sedation during skin suture removal, postoperative feeding protocols, use of intra- and postoperative antibiotics, length of hospital stay, and use of presurgical NAM.

We collected the returned data of the participating departments until the beginning of December 2018 and conducted a descriptive, comprehensive analysis (SPSS 21.0 for Mac, IBM Inc., NY). As some respondents wrote down >1 suture label and size as the answer to the respective question, only the first answer was used for this analysis. In questions requiring a numerical answer, we chose the mean value if a range was noted.

RESULTS

In total 70 international plastic and maxillofacial departments (Europe: 56 centers, North America: 7 centers, Asia: 6 centers) participated (Supplemental Digital Content 1,Table S1, http://links.lww.com/SCS/A835).

Surgical Sewing Material

During cleft lip repair the reunion of the orbicularis oris muscle is performed with absorbable suture material in 98.6% of the participating centers. Regarding the suture label, most surgeons prefer Vicryl as suture material, predominantly in size 4–0 (Fig. 1A and B). However, 15 surgeons said they use different thread sizes for this procedure. Of those, size 5–0 is applied most often (10/15). Closure of the outer lip skin is performed with nonabsorbable suture material in 50 of 70 departments (71.4%) using a large variety of different suture labels (Fig. 1C). Suture size is predominantly 6–0 according to this analysis (Fig. 1D). For closure of the enoral mucosa in the upper lip and the oral vestibulum, most surgeons prefer an absorbable suture material (94.3%) with Vicryl again the most frequently used label (Fig. 1E). Comparable to the repair of the orbicularis oris muscle, 4–0 is most frequently used during this procedure (Fig. 1F). Again, 18 respondents mentioned the use of different thread sizes. Eleven of those choose size 5–0 for mucosal repair instead of using 4–0 or 6–0.

In cleft palate surgery, the closure of the nasal mucosa is performed with an absorbable suture by most surgeons (95.7%). In this situation, Vicryl is applied most frequently using predominantly size 4–0 or 5–0 (Fig. 1A and B). Comparable to that, adaptation and closure of the palatal musculature and the oral mucosa are performed with absorbable suture material in most centers using Vicryl as well. For palate repair and mucosal closure, 4–0 is used most frequently (Fig. 1D and F). Of those using an alternative thread size, 8 of 20 surgeons use 5–0 sutures during closure of the palatal mucosa (Fig. 2).

Regarding the time point for suture removal at the outer lip skin, in 55 departments, the material is removed on average after 7.0 ± 1.5 days. Interestingly, in 3 departments, suture material in the facial skin is removed, although absorbable material is applied

Cleft lip repair:

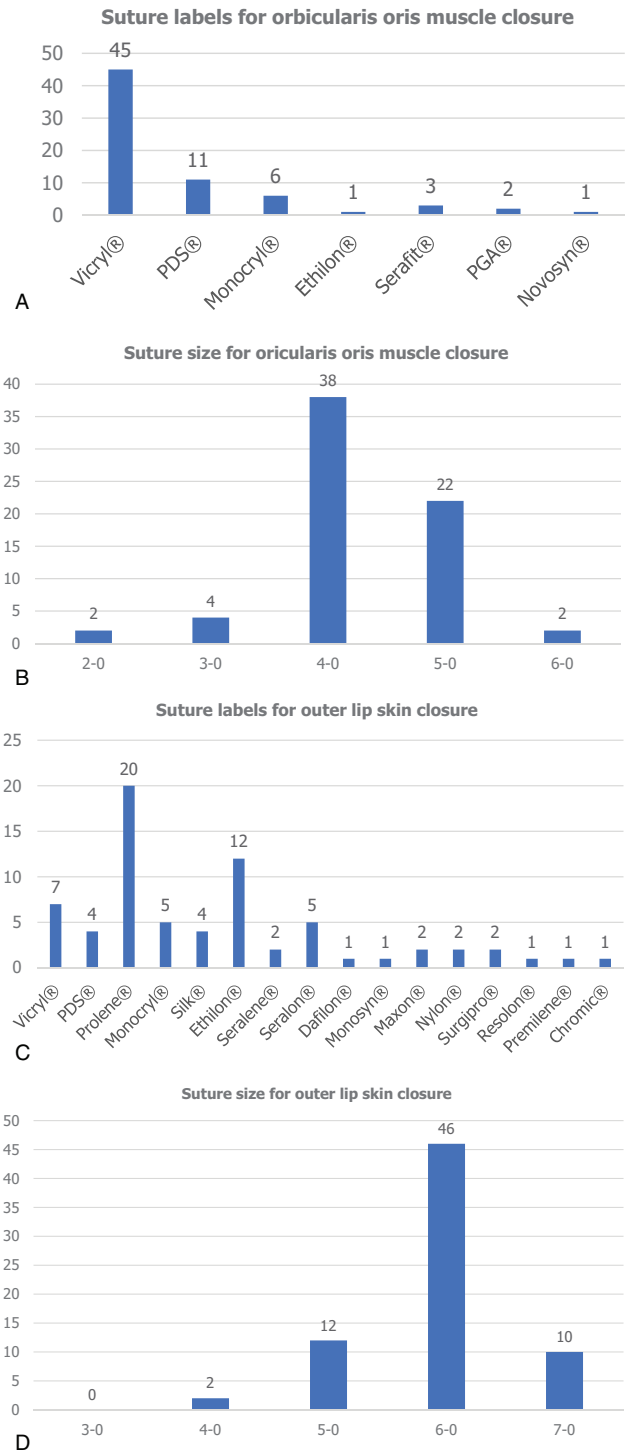

FIGURE 1. Surgical sewing material used during cleft lip repair. Closure of the orbicularis oris muscle is mainly performed with absorbable suture material (Vicryl) (A) at an applied suture size of 4-0 in most cases (B). Used suture labels during repair of the outer lip skin present the largest variety in this analysis, with Prolene and Ethilon being the most frequently used labels (C). Most surgeons prefer 6–0 during skin closure (D). The enoral mucosa is predominantly repaired with Vicryl suture (E) using 5–0 or 4–0 in most healthcare centers (F).

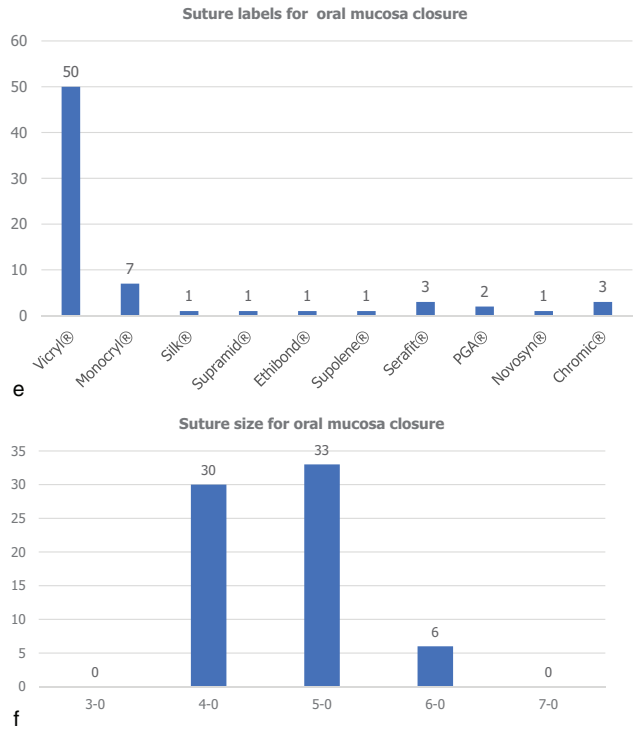

FIGURE 1. (Continued).

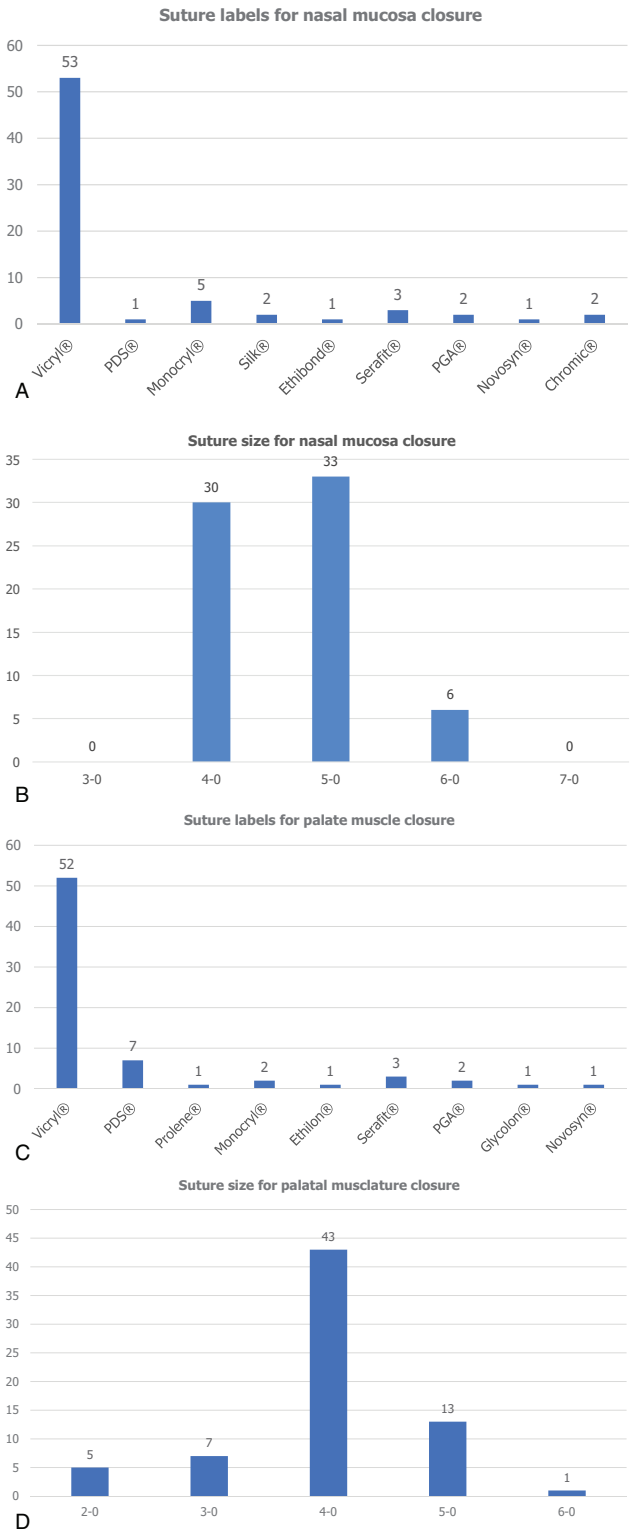

FIGURE 2. During cleft palate repair Vicryl as an absorbable suture material is predominantly used during repair of the nasal mucosa, palate musculature closure, and mucosal repair (A, C, E). Applied suture sizes are usually 4–0 or 5–0 (B, D, F).

intraoperatively. Regarding the type of anesthesia used during suture removal, general anesthesia is predominantly used in the participating healthcare centers (46.0%) (Fig. 3).

Perioperative Antibiotics

Fifty-eight of 70 participating centers (82.9%) routinely apply antibiotics intraoperatively. Fifty-four participants answered the question regarding the type of antibiotic drug class preferably used for patients without known allergies. Results show that penicillins are most frequently applied, followed by cephalosporins (Supplemental Digital Content 1, Table S2, http://links.lww.com/SCS/A835). When asked about the postoperative antibiotic treatment, 31.9% stated that they did not apply any antibiotic during this phase. In 29 departments (40.3%), a standardized postoperative concept for antibiotic treatment is followed, applying the drugs for another 3.4 ± 2.1 days on average (Fig. 4). In 2 centers, despite having a standard concept, duration of antibiotic use is adjusted individually according to the clinical situation.

Nutrition and Postoperative Inpatient Stay

Considering postoperative nutrition and feeding, in 27 centers (38.6%) children get a nasogastric tube for an average time span of 4.6 ± 2.3 days postoperatively. In departments where a nasogastric tube is used, it is applied in patients with cleft lip as well as cleft palate repair, except in one institution only using tube feeding after cleft lip closure. In centers not using tube feeding, postoperative nutrition is predominantly performed via liquids or mashed food (Fig. 5).

The average length of postoperative inpatient stay in the participating centers is shorter in children undergoing cleft lip closure compared to cleft palate closure (stay after cleft lip closure: 4.1 ± 2.6 days versus 4.5 ± 2.7 days after cleft palate repair) (Fig. 6) and depends primarily on standard protocols of the departments (Supplemental Digital Content 1, Table S3, http://links.lww.com/SCS/A835).

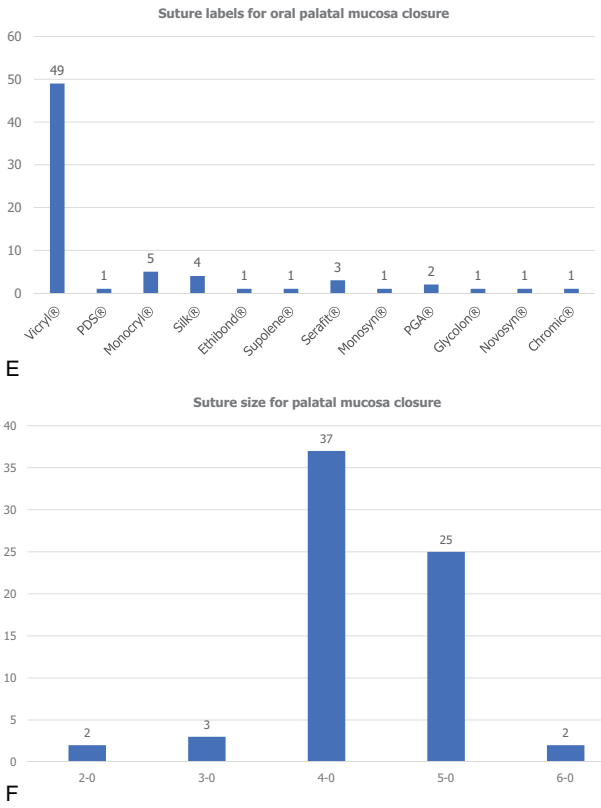

FIGURE 2. (Continued).

ENT Intervention

As the treatment of CLP patients relies on a multidisciplinary team, we asked the participants at what point in time ENT diagnostics and treatment via consultation of the ENT department, including phoniatrics and pedaudiology, are performed in their centers. In 52.8% of the treatment centers, consultation is conducted before the operation (Supplemental Digital Content 1, Table S4a, http://links.lww.com/SCS/A835). Two participants answered that they only send cleft palate patients to the ENT department but independently of the operative procedure. Intraoperative

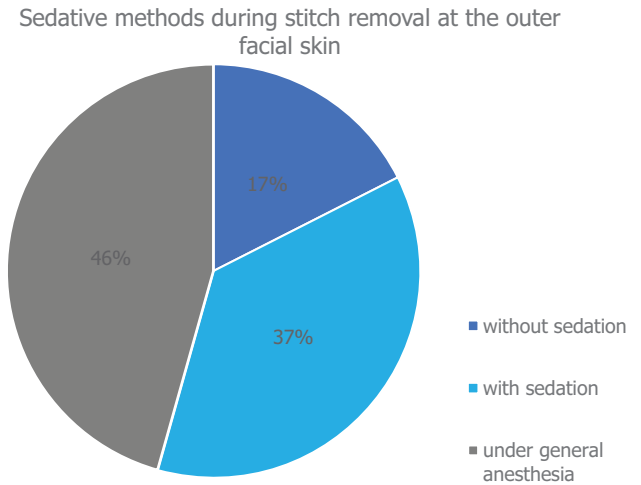

FIGURE 3. For suture removal at the facial lip skin after primary lip surgery, general anesthesia is most frequently performed by the participating centers.

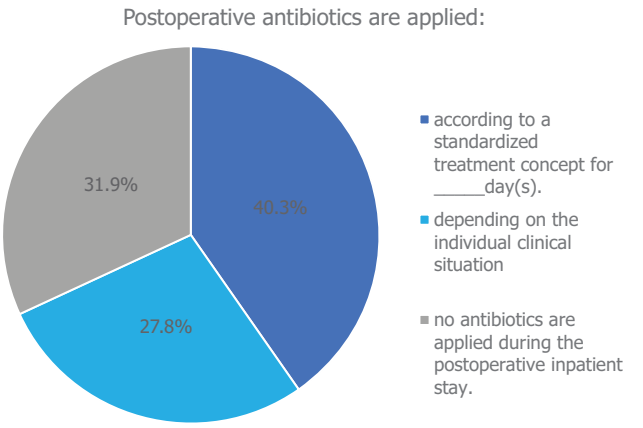

FIGURE 4. Postoperatively, the majority of surgeons apply antibiotics according to a standardized treatment concept. In almost one-third of the centers, antibiotics are not applied following cleft surgery.

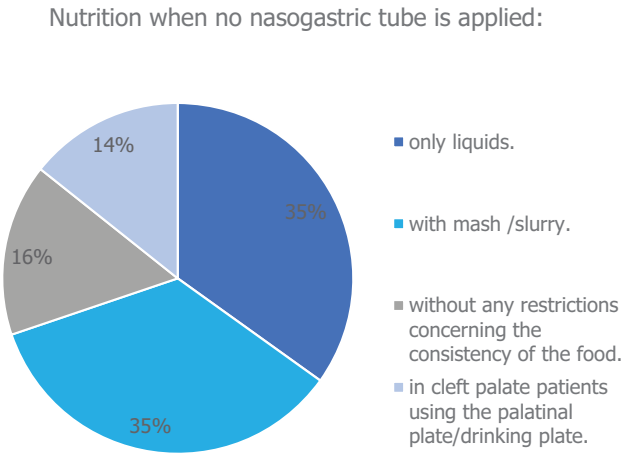

FIGURE 5. In 43 centers of 70, postoperative nutrition is performed without using nasogastric tubes. In these institutions feeding is performed predominantly via application of liquids or mashed food. In 10 centers nutrition is performed without any restriction regarding the consistency of the food.

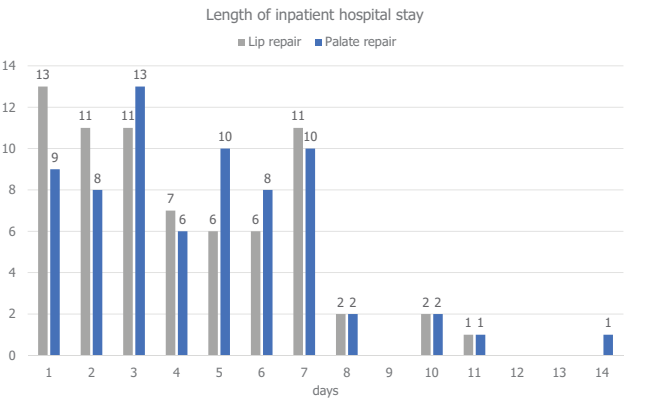

FIGURE 6. Postoperative inpatient stay varies between the participating departments, stretching from only 1 day up to 14 days (A). Numerous departments have a treatment concept regulating the length of the postoperative stay. Besides this, the respondents also stated that sufficient postoperative oral feeding is a decision criterion for determining the point of patient discharge (B).

diagnostics and treatments concerning the middle ear are conducted by a member of the ENT team during cleft repair interventions in 82.9% of departments (Supplemental Digital Content 1, Table S4b, http://links.lww.com/SCS/A835).

NAM

The concept of preoperative NAM is established and applied in 26 of 70 (37.1%) centers. The responding departments state they use this method on average on 45.9% ± 28.8% of the children. There were no additional questions concerning the indication, duration, and detailed technique of NAM in the centers.

DISCUSSION

CLP treatment concepts vary between different cleft centers as the level of evidence for surgical and perioperative procedures within this group of patients is based on a comparably low level. Considering randomized controlled trials (RCTs) as the criterion standard of medical investigations, even the realization of larger single-center trials on operative procedures is challenging in most institutions within an appropriate amount of time. The reasons for this unsatisfactory situation, just to mention a few, are presumably the small patient population with regard to a single healthcare center, the high diversity of cleft types, differences in surgeon skill, and technical learning curve as well as ethical challenges in a predominantly young group of patients.[16]

In craniofacial surgery >90% of the published RCTs were conducted at a single institution. Focusing on CLP repair, the majority of currently applied operative procedures are supported by only a few RCTs, which can be measured up to a standard of level II at best.[16] Furthermore, there is a need for standardized measurement tools of surgical outcomes to validate surgical results, as present analyses show substantial methodological and clinical heterogeneity. As a result, there are limitations to the pooling of the data for meta-analysis.

Owing to the variety of surgical techniques for cleft lip and cleft palate closure, the choice of suture material and suture removal are still under debate. This survey indicates the differences in applied suture material especially during closure of the outer lip skin. Not only do the fundamental surgical strategies of using an absorbable or nonabsorbable material seem to vary between the participating centers, but also the time point of suture removal. Interestingly, some surgeons also perform suture removal despite using an absorbable suture material. This might be because of the fact that complete disappearance of the absorbable suture material applied in this survey takes between 42 and 240 days according to the manufacturers' information (Supplemental Digital Content 1, Table S5, http://links.lww.com/SCS/A835).

As there are currently no guidelines about the use of intra- and postoperative antibiotics in CLP patients, the results show a wide disparity among the participating centers.[17,18] Owing to bacteremia during CLP surgery and the association of cardiac anomalies like atrial or ventricular septal defects in CLP children, an intraoperative antibiotic prophylaxis is reasonable and therefore applied in >80% of the participating centers.[19] Surgeons advocating its use during and especially after cleft repair primarily refer to the potential complications caused by wound infections and subsequent systemic morbidity. Microorganisms found in CLP children are predominantly *Klebsiella pneumoniae* and *Staphylococcus aureus* with resistances to ampicillin and amoxicillin in up to 30% of the cases.[20] The disadvantages of widespread antibiotic use are well known and emerging resistant strains of bacteria indicate the need for a considered application of these drugs. Comparable to other studies in the literature, the most frequently applied antibiotic agents are penicillins and cephalosporins.[18] Most surgeons prefer selective intraoperative prophylaxis, whereas postoperative prophylaxis is conducted in only 29 of the centers routinely according to a standardized protocol. During the last decade, ambulatory surgery increased because of increasing costs and advances in medical care, not only in CLP patients.[21] According to the literature, complication rates in outpatient primary surgery are similar to that of inpatient surgery. However, in the United States >70% of CLP children are still admitted to hospital for at least 1 night after surgical cleft repair.[21,22] Interestingly, besides varying durations for children after cleft lip and cleft palate repair, inpatient hospital stay ranged from 1 to 14 days, indicating highly heterogeneous treatment concepts among the participants. Some surgeons additionally commented on the questionnaires that only because of long distances from home were children supervised in hospital for >1 day. This indicates that a shorter inpatient stay would be possible according to the respondents' opinion and evaluations.

The survey confirmed that feeding methods immediately after the surgical procedure are still controversially discussed. Reviewing the current literature, breast and bottle feeding seem to be more beneficial and have not shown major complications after cleft lip repair compared to other feeding methods. However, systemic reviews are lacking.[23] After cleft palate repair, diverging results on tube-, bottle-, cup- and spoon-feeding methods indicate the need for more studies on this particular topic.[14]

Supposing that NAM is particularly popular only in the United States, it was surprising to find more than one-third of all centers using NAM, especially considering the large proportion of European cleft centers participating in this survey. As we only asked for the percentage of NAM-treated cleft patients (result: 45.9% ± 28.8%), there was no information obtained about the indication for or against NAM. In literature, NAM is predominantly used in unilateral and bilateral CLP patients to overcome the problems with wide clefts,[7,24] but further studies will have to investigate this issue in more detail.

Although the presented data originated from hospitals that presumably treat a wide range of cases each year, we did not ask the participating centers for the number of patients treated annually. Another limitation of this study is the missing link between the surgical techniques conducted primarily for lip and palate closure in the respective departments, as the choice of suture material might vary when using different surgical approaches. Additionally, it would be interesting to compare complication rates and scar formation in association with the applied intra- and postoperative treatment protocols between the different healthcare centers in further investigations.

CONCLUSION

This descriptive analysis illustrates the current heterogeneity and varieties in CLP patient treatment not only with regard to applied suture materials but also in terms of postoperative inpatient hospital stay, antibiotics, nutrition, preoperative diagnostics, and treatments. However, absorbable suture material seems to be efficient and successful in the closure of the orbicularis oris muscle, the enoral as well as the nasal mucosa and the palatal musculature at a suture size of 4–0 or 5–0. In contrast, the outer lip skin closure in CLP patients is predominantly performed with nonabsorbable suture material with 6–0 being the predominantly applied size. Intraoperative antibiotic prophylaxis as well as an inpatient hospital stay of 4 to 5 days in combination with a preoperative consultation and intraoperative cooperation with the ENT department also seem to be proven concepts in CLP patient care.

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