Fistula after primary palatoplasty: consensus among plastic surgery and Speech-Language Pathology

Fístula após palatoplastia primária: consenso entre profissionais da cirurgia plástica e da fonoaudiologia

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Introduction: The identification of complications of primary palatoplasty may vary among professionals from different areas of health due to the lack of standardization of the fistula classification. This study aimed to verify the consensus among professionals of plastic surgery (PC) and Speech-Language Pathology (SLP), regarding the occurrence of fistula, according to what was reported in the same craniofacial service. Methods: Analysis of the chart’s records of the areas of the PC and SLP of 466 patients with cleft lip and palate was performed about the presence and location of fistulas, as reported in 466 medical records of patients with a history of unilateral cleft lip and palate. To compare the findings between both areas, a gold standard classification for the occurrence of fistula (GSF) was established by an experienced plastic surgeon. Results: The PC area reported that 25% of the 466 patients had a fistula compared to the 37% reported by the SLP, while the GSF indicated fistula in 35% of the cases. The Kappa statistic reveals regular agreement between GSF and PC (r = 0.32) and substantial agreement between GSF and SLP (r = 0.63). Conclusion: There was a discrepancy between the areas of Speech-Language Pathology and plastic surgery regarding the occurrence and location of the fistula after primary palatoplasty in the same craniofacial center. The data indicates the need to create and implement a standardized fistula classification system. In this way, craniofacial teams can use it effectively, taking advantage of the scientific evidence that emerges from the results of cleft lip and palate treatment.

ABSTRACT

Keywords: Cleft palate; Oral fistula; Medical records; Plastic surgery; Speech Therapy.
INTRODUCTION

Among the complications after primary palatoplasty, one of the most discussed in the literature, is the formation of oronasal fistulas. In the literature, it is observed that the occurrence of palate fistula is widely variable, ranging from authors who report the absence of these complications (0%) to those that indicate a 78% occurrence of palate fistula after primary palatoplasty. The wide variation in the occurrence of fistula reflects the diversity of protocols for primary surgical correction of the cleft lip and palate. However, it can also be related to the lack of consensus regarding terminology and the classification of fistula according to what is reported by professionals from different areas of health.

The terminology found in the literature to classify fistula is quite varied. Studies report that fistulas located on the primary palate (anterior to the incisive foramen), for example, can be called palate fistula, anterior palate fistula, labial alveolar fistula, lingual alveolar fistula and also vestibular fistula. Fistulas located on the secondary palate (or posterior to the incisive foramen), in turn, can also be called palate fistulas, observing variation in terminology according to the affected region (hard palate fistula, transition fistula between the hard palate and soft palate, soft palate fistula).

Fistula classification systems involving a systematic approach to document the occurrence and location of the fistula have been described in the international literature. An acceptable level of agreement between evaluators in identifying fistula, however, can be challenging to achieve even when a standardized protocol is implemented. Characterizing aspects where there is a lack of consensus among evaluators during fistula identification is essential for the development of a standardized classification protocol, and that it can be implemented in Brazilian craniofacial services in order to provide a systematic documentation of the results of primary palatoplasty.

OBJECTIVE

This study aimed to verify the consensus among plastic surgery (PC) and Speech-Language Pathology (SLP) professionals regarding the occurrence of fistula in the same craniofacial service.
METHODS

The study was approved by the institution’s Human Research Ethics Committee under number 1,337,917. This study involved an analysis of the presence and location of fistulas in data in the medical records of 466 patients. The medical records studied belonged to patients with unilateral cleft lip and palate, without syndromes or associated malformations, of both sexes, who underwent primary palatoplasty in a single stage by the surgical techniques of von Langenbeck or Furlow. The primary palatoplasties of the studied group were performed between 1996 and 2004. The reports of the occurrence of fistula of interest for this study were obtained during the clinical evaluation and recorded in the post-surgical evaluation protocols in the patients’ medical records, as is routinely performed at the research institution in the areas of PC and SLP. For this study, records of fistula up to three years after primary palatoplasty were included. (by the PC area, by the SLP area or by both areas).

In this work, dehiscence records (partial or total) were treated as a fistula. The survey of data contained in the post-surgical evaluation forms of plastic surgery gave rise to the registration of the occurrence of fistula by the PC area. However, the survey of the data contained in the speech therapy assessment protocol gave rise to the registration of the occurrence of fistula by the area of the SLP.

Clinical record of fistula by plastic surgery

The post-surgical evaluation protocol in the area of plastic surgery, in force during the period studied, was applied by the plastic surgeon who performed a face-to-face assessment based on an oral inspection of the areas of the hard and soft palate after primary palatoplasty. The oral inspection was performed with the use of a flashlight to illuminate the evaluated area and a spatula to lower the tongue and allow visualization of the entire soft palate. When observing on the palate a region suggestive of false fistula (false-bottom) or hidden fistula, the diagnostic tests performed by the professional included: a) lighting with the flashlight to check the projection of the light in the nasal area; b) palpation/manipulation of the irregular area of the palate, seeking to verify false-bottom in recesses of tissue; c) use of air injection in the area (using dental equipment) to check the passage of air to the nostrils through the patient’s report or observation of bubble.

Data were recorded in person by the plastic surgeon in the post-surgical evaluation protocol for plastic surgery, including the following observations: registration of the method for closing the anterior palate and the soft palate (relaxing incisions; vomerian flap, pharyngeal flap, others); transoperative complications (flap fraying, suture under tension; review of hemostasis and others) and postoperative complications (fistula or dehiscence; infection and others). In cases of fistula, the evaluation protocol also requested an indication of the affected area and the drawing of the occurrence in a diagram of the palate (as shown in the evaluation form). From the post-surgical evaluation protocol for the PC area, therefore, the presence and location of the fistula in the palate for the present study are identified.

Clinical record of fistula by Speech-Language Pathology

The speech therapy evaluation protocol, in effect during the period studied, was applied by a speech therapist on the same day that the post-surgical PC evaluation protocol was applied. For inclusion in the study, therefore, all patients had their PC and SLP assessments performed in person on the same day, independently for each area.

During the evaluation, the speech therapist performed an inspection of the areas of the hard and soft palate using a flashlight to illuminate the evaluated area and a spatula to lower the tongue in order to visualize the entire soft palate, including the uvula. In cases of identification of an area suggestive of a false or hidden fistula, the Speech-Language Pathologist referred the patient for diagnostic testing of lighting, palpation, and/or air injection by the plastic surgeon.

The data were recorded in person by the Speech-Language Pathologist. The evaluation protocol included the following information regarding the fistula: absent; vestibular on the right; vestibular on the left; on the hard palate; on the soft palate; in the transition region from the hard palate to the soft palate. In the SLP area assessment protocol; therefore, the registration of the presence and location of the fistula was identified for the present study.

Gold standard classification for the occurrence of fistula (GSF)

Once the data of the protocols of the areas of the PC and the SLP were collected, there was a divergence in the records between the areas, and it was decided to apply a gold standard assessment of the occurrence of fistula (GSF). For the GSF assessment, a fistula was defined as a failure of healing or a rupture of the suture, observed after primary repair of the palate. That is, after an attempt to repair the tissues in the area of the cleft palate, the unwanted opening of the sutures occurred.

The GSF evaluation was performed by a single professional in the field of plastic surgery, with over
30 years of clinical experience in surgical correction of the palate and in the post-palatoplasty evaluation. The GSF was not performed in person and was based on the analysis of all records documented in the medical records about fistula and also on the analysis of photographic images of the fistula, when existing. It should be noted, however, that at the time of the post-surgical evaluation of the studied cases, the photographic records of the fistulas, although indicated, were not made in a standardized way and were not obtained for all cases. The photographs in the institutional collection were taken by the institution’s photographer and not by professionals from the areas of PC and SLP, and these images were used in a complementary way to the survey of fistula records in the medical record.

In the medical record, all existing documentary protocols were consulted where the occurrence of fistula could be registered. That is, in addition to the consultation carried out in the PC and SLP protocols (objects of this work), documentation from other areas (nursing, pediatrics and dentistry) was analyzed. For the analysis of the photographs, the plastic surgery professional who performed the GSF evaluation used the incisive foramen (IF) as an anatomical landmark and grouped the fistulas according to their location concerning the IF, indicating, therefore, if the occurrences were before or after the IF.

The findings obtained from the analysis of all documentary records in the medical record plus the findings from the analysis of existing photographs were combined to establish the gold standard assessment of the occurrence of fistula (GSF). GSF was the tool used as a reference for interpreting the findings recorded individually in the protocols of the areas of PC and SLP, allowing researchers to corroborate and compare the findings of this study. According to the GSF, 466 patients were grouped into four categories regarding the existence and location of a fistula after primary palatoplasty, including Group 1: patients who did not present a fistula (N = 302; 65%); Group 2: patients with fistulas located in the area anterior to the incisive foramen (N = 91, 20%); Group 3: patients with fistulas located in the area posterior to the incisive foramen (N = 43; 9%); Group 4: patients with fistulas covering the area before and after the incisive foramen (N = 30; 6%). That is, while the majority of patients did not have a fistula (65%), a total of 164 (35%) patients had some type of fistula on the palate, as indicated in the GSF. Of the 164 fistulas identified in the GSF assessment, 78 (17%) occurred in patients who received the Furlow procedure, and 86 (18%) occurred in patients who received the von Langenbeck procedure. However, it should be noted that data on the transversal amplitude of the fissure, on the surgical technique, and the surgeon in primary palatoplasty was not the object of this study.

The data presented below include the percentages of occurrence of fistula reported by the areas of PC, ST, and GSF. The concordance between the findings was verified with Kappa statistics.

RESULTS

When analyzing the data obtained in the records of the PC area, it was observed that the surgeons reported that 275 patients (59%) did not present fistulas, 117 patients (25%) presented some type of fistula and 74 patients (16%) did not present records about the presence or absence of fistula (no data). Of the 117 patients who had fistula reported by the PC, 48 patients (10%) did not indicate the location (incomplete data), 31 patients (7%) had fistulas in the region before the IF, 32 patients (8%) had a fistula in the region after IF and six patients (1%) presented fistulas involving both regions, before and after IF.

The same analysis was done for the records in the area of the SLP, observing that the speech therapists reported 295 patients (63%) without fistulas and 171 patients (37%) with some type of fistula. Of the 171 patients who presented a fistula, 69 patients (15%) did not indicate the location (incomplete data), 73 patients (15.6%) were fistulas in the region before the IF, 27 patients (6%) were fistulas in the posterior region at IF, and two patients (0.4%) were fistulas involving the two regions, anterior and posterior to IF.

As shown in Table 1, the gold standard assessment of the occurrence of fistula (GSF) identified fistula in 164 patients (35% of the cases studied), differing from the area of speech therapy and plastic surgery, which reported 171 (37%) and 117 (25%) cases with fistula, respectively. That is, when the findings reported in the specific protocol for plastic surgery were considered, the occurrence of fistula was 10% less than the occurrence observed in GSF. Furthermore, when considering the findings reported in the specific speech therapy protocol, the occurrence of fistula was 2% higher than the occurrence observed in GSF.

It was also observed that the indication of the location of the fistula (before or after the IF) was not possible for 48 cases evaluated by the PC due to incomplete data. That is, 10% of the fistulas identified by the PC did not indicate the place of occurrence (incomplete data). Also, analyzing the findings of PC, it was found that 74 patients (16%) had no record regarding the absence or presence of fistula (no data). The data collected in the SLP protocols, in turn, did not allow the identification of the location of the fistula for 69 (15%) cases due to incomplete data. There was no
The data in the present study reflect disagreement between the areas of plastic surgery and speech therapy, in the same craniofacial center, when reporting the occurrence and location of a fistula after primary palatoplasty. The difficulty in interpreting data from medical records and the lack of information regarding the occurrence or location of a fistula justified these findings and was mentioned in other studies 4,5,10,11,13,15,16.

Comparing the findings about the occurrence of fistula observed in this study with the findings reported in the literature is a complex task, since, according to the area of PC, a total of 25% of the 466 patients had a fistula, and according to the area of the SLP a total of 37% had a fistula. The GSF evaluation, in turn, suggested that a total of 35% of the cases had a fistula. This disagreement can be explained both by the lack of data and by the incomplete data aggravated by the disagreement as to the terminology to indicate the location of the fistula.

Since these are patients with transforamenal cleft, it was expected that the highest incidence of fistula would occur in the pre-foramen incisor region, which was documented in this study by the SLP area and the GSF assessment. The area of PC, in turn, had 59.7% agreement with the GSF assessment, while the SLP area had 79.6% agreement. According to the Kappa statistic, there was a regular agreement between the GSF and the reports in the PC area (r = 0.32) and a substantial agreement between the GSF and the reports in the SLP area (r = 0.63).

It is noted that the highest percentage of agreement between professionals in the areas of PC and SLP with GSF was for cases where there was no fistula, with 77.2% for the PC area and 94.4% for the SLP area. The highest percentage of disagreement with the GSF was for the group of fistulas that involved both the anterior and posterior areas of the IF, 83.3% for the PC area, and 96.6% for the SLP area.

**DISCUSSION**

The data in the present study reflect disagreement between the areas of plastic surgery and speech therapy, in the same craniofacial center, when reporting the occurrence and location of a fistula after primary palatoplasty. The difficulty in interpreting data from medical records and the lack of information regarding the occurrence or location of a fistula justified these findings and was mentioned in other studies 4,5,10,11,13,15,16.

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does not always consider the pre-foramen fistula to be a surgical complication, since the “intentional fistula” may be the result of a clinical decision taken at the time of surgery depending on the width of the cleft palate and the surgical procedure performed, which justifies, in part, the absence of data for 74 patients observed in the protocols completed by the PC area. It should be noted, even when the pre-foramen fistula affects only the vestibular region, the inspection exam and intraoral photographs may not be sufficient for the correct identification of this type of fistula. A standardized, systematic, and consecutive documentation of the results of the surgeries, therefore, must be established by the interdisciplinary team, as it is essential and necessary for the identification of surgical complications.

The task force known as “Task Force Beyond Eurocleft”[17], reports the importance of multicentric studies (national and international) to document the results of the management of cleft lip and palate, so that scientific evidence can be established to substantiate the use of treatment protocols with acceptable results worldwide. The absence of a standardized and validated protocol for documenting complications after primary surgeries in cleft lip and palate in Brazil, in some way, justifies the existence of conflicting reports. Also, it makes the performance of comparative studies between different craniofacial centers a complicated task.

The gold standard assessment of the occurrence of fistula used as a tool to compare the findings of this study should be considered with caution, since, in addition to not being an assessment performed in person, it considered data from various areas of the medical record (in addition to the PC and ST) combined with the photo analysis findings. It should also be noted that intraoral photographs were not obtained for all cases (with a fistula and also without a fistula). That is, all 466 cases should have intraoral photographic images obtained using a standardized protocol and with quality control. The lack of a single terminology and a standardized post-surgical evaluation protocol and used in consensus by the areas of PC and ST, therefore, justifies the divergence found in this study.

In addition to the methodological limitations concerning photographic images that were not obtained for all 466 cases and the fact that the GSF assessment was not performed in person, it is also noted that information on the transversal width of the fissure and the surgeon in the primary palatoplasty was not the subject of this study.

Regardless of the limitations existing in the methodology implemented in the present study, the present data showed the lack of consensus regarding the reports of fistula, suggesting that a systematic and adequate documentation of the results of the primary palatoplasty will only be possible based on a reliable record of the clinical findings registered interprofessionally, in person and also with photographic images registration. It is suggested, therefore, the need to establish and validate a fistula classification protocol, which can be applied both during the face-to-face oral inspection and from the analysis of intraoral photographs (which must be obtained for all cases: with and without fistula).

**CONCLUSION**

In this study, there was a discrepancy between the areas of speech therapy and plastic surgery regarding the occurrence and location of the fistula after primary palatoplasty in the same craniofacial center. The data point to the need for adjustments in the evaluation protocols that take into account the terminology and location of the fistula.

It is suggested to be essential to create and implement a standardized fistula classification system, which can be used effectively, consecutively and systematically, by craniofacial teams, in order to provide multicenter studies that can establish scientific evidence of the results of the treatment of the cleft lip and palate.

**COLLABORATIONS**

**MFJ**  Analysis and/or data interpretation, conception and design study, data curation, final manuscript approval, formal analysis, methodology, project administration, writing - original draft preparation, writing - review & editing.

**GAP**  Analysis and/or data interpretation, data curation, final manuscript approval, writing - original draft preparation, writing - review & editing.

**TVSB**  Analysis and/or data interpretation, data curation, final manuscript approval, writing - original draft preparation, writing - review & editing.

**HLAS**  Analysis and/or data interpretation, data curation, final manuscript approval, methodology, writing - review & editing.

**JCRD**  Analysis and/or data interpretation, conception and design study, final manuscript approval, formal analysis, project administration, supervision, writing - original draft preparation, writing - review & editing.
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