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HEAD AND NECK

Closing of large pharyngostomes with free flaps and proposal of a new classification

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Abstract

Purpose Large pharyngocutaneous fistulas or pharyngostomes are difficult complications to solve, which generate high morbidity and mortality, a poor quality of life and an increase in health costs. Its management must be comprehensive according to general, local and regional factors. We review our experience in treating these pharyngostomes with free flaps.

Methods Retrospective study analyzing the results of the reconstruction of 50 patients using free flaps during the period 1991–2019. We exclude patients who required free-flap reconstruction due to primary tumor or those who resolved in other ways. The different types of reconstruction were classified into three types.

Results The 86% (43) were men, and the mean age was 57 years (25–76). In 48% (24/50) the flaps performed were anterolateral thigh (ALT), in 24% (12/50) forearm, in 22% (11/50) parascapular, in 4% (2/50) jejunum and in 2% (1/50) ulnar. A salivary by-pass was placed in 74% (37/50) of the cases. Four cases (8%) presented flap necrosis and two patients died due to treatment. In 86% (43/50) there was some type of complication and 34% (17/50) required surgical revision. 94% (45/48) were able to reintroduce oral feeding.

Conclusion According to our experience, we proposed a regardless size classification: type 1 when only a mucous closure (pharynx) are required (6%), type 2 exclusively skin for cutaneous coverage (10%) and mixed type 3 (mucous and skin) (84%). The treatment of large pharyngostomes with free flaps, despite its complexity, is in our experience the best option for its management.

Keywords Pharyngocutaneous fistula · Pharyngostomes · Free flaps in head and neck · Pharyngolaryngectomy · Head and neck reconstruction

Introduction

Pharyngocutaneous fistulas or pharyngostomes are relatively frequent complications (15–30%) after pharynx and/or larynx surgery [1]. These complications occur especially in patients with advanced-stage tumors and poor general condition, mostly smokers/drinkers, with accompanying chronic lung, heart, vascular or liver diseases, and advanced TNM, among others [2].

In addition, there are other risk factors that favor the formation of fistulas in the postoperative period (local infection, anemia, etc.). The previous radiotherapy has been determined as an important factor triggered by the fistula in the postoperative period when leaving devitalized cervical tissues [2, 3].

Pharyngocutaneous fistulas significantly increase patient morbidity and mortality, hospital stay, change in the quality of life and determine a greater economic impact on health systems.

Preoperative measures such as good nutrition can reduce the risk of fistula [4], as well as intraoperative reinforcement techniques in the pharyngeal closure such as the use of regional flaps for well-vascularized tissue [5]. In the postoperatory, an early diagnosis and treatment allow a faster solution, with a shorter hospital stay. The primary treatment consists of local cures with compression bandages, placement of salivary bypass tubes [6], nasogastric tube feeding and systemic antibiotics. With this treatment, the cure of approximately 70% of the patients is obtained. In a more

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advanced situation, direct closures of the fistula, or with different types of local and regional flaps, serve to solve another percentage of cases.

However, despite proper handling, there are large fistulas, which are classified as major [3], and which will require a closure with free flaps.

There are several classifications based on the type and size of the defect to be reconstructed [7–9] that generally consider the size of the defect.

The objective of this article is to review the results obtained in the treatment of major pharyngostomes with free flaps in our department. In addition, based on our experience, a new classification is proposed. This classification, based on the type of defect, has been considered for the choice of the free flap in each of the patients.

Methods

We performed a retrospective study analyzing the results of the reconstruction of major pharyngostomes with microvascularized free flap during the period from 1991 to 2019. We excluded patients who required reconstruction with a free flap immediately during the treatment of the primary tumor or those that were solved in other ways such as direct closure or local or regional flaps.

Finally, we analyzed a total of 50 patients with pharyngostomes, 8 of whom also had severe pharyngeal stenosis. We collected the demographic data of the patients, previous tumors, previous treatments (both of the primary tumor and of the possible attempts of previous reconstruction including free flaps operated in other hospitals) (Table 1), characteristics of free flap reconstruction performed by us (Table 2), and the data of surgical follow-up (complications and type of feeding achieved) (Table 3). Survival was not considered due is an independent factor of the type of reconstruction.

With respect to the treatment of the primary tumor, we divide the total laryngectomies into simple total (LT) or extended LT when, according to the sites infiltrated by the tumor, the surgical margin is extended to the pharynx or adjacent tissues, including the skin.

Regarding complications, we define as short-term those that occurred in the first month after surgery and long-term complications those that occurred at least 30 days after reconstruction.

Within the short-term complications, we consider medical complications related to the procedure, and those inherent to the surgical technique: infection, bleeding, dehiscence, fistula and necrosis at the surgical site (neck and donor area) and viability of the flap.

As long-term complications, we include pharyngeal or esophageal stenosis and pharyngeal cutaneous fistulas due to both results in impaired swallowing.

Table 1 Clinical characteristics of the 50 patients

Characteristic	No. of patients (%)
Sex	
Woman	7 (14)
Man	43 (86)
Toxic habits	
Total	48 (96)
Tobacco	15 (31)
Tobacco + alcohol	33 (69)
Primary tumor location	
Larynx	30 (60)
Supraglottic	5 (10)
Glottic	25 (50)
Pharynx	20 (40)
Oropharynx	9 (18)
Hypopharynx	11 (22)
Previous treatment	
Surgical	49 (98)
Supraglottic laryngectomy	2 (4)
Total laryngectomy	21 (42)
Extended total laryngectomy	22 (44)
Pharyngectomy	4 (8)
RT radical	1 (2)
Complementary radiotherapy	
No	12 (24)
RT	27 (54)
QRT	11 (22)
Cervical emptying	
Total neck dissections	36 (72)
Functional	34 (68)
Radical	2 (4)
Unilateral	9 (18)
Bilateral	27 (54)
Previous flap	
Total	29 (58)
> 1 flap	10 (20)
Regional	
Pectoralis major	20 (69)
Deltopectoral	9 (31)
Supraclavicular	1 (4)
Free flap	
Radial forearm	3 (11)
Anterolateral thigh	3 (11)

The length of hospital stay was calculated as the time in days from the day of the intervention until the date of discharge. The follow-up was calculated as the time in months from the operation until the last visit or death of the patient.

Table 2 Characteristics of free flap reconstruction

Characteristic	No patients (%)
Type of defect and free flap used	
Mixed defect	42 (84)
Anterolateral thigh	21 (50)
Radial forearm	10 (24)
Parascapular	9 (21)
Jejunum	1 (2)
Ulnar	1 (2)
Mucous defect	3 (6)
Radial forearm	1 (33)
Parascapular	1 (33)
Jejunum	1 (33)
Skin defect	5 (10)
Anterolateral thigh	3 (60)
Radial forearm	1 (20)
Parascapular	1 (20)
Arterial pedicle	
Transverse cervical	18 (36)
Facial	9 (18)
Surface temporary	7 (16)
External carotid	8 (16)
Upper thyroid	3 (6)
Lingual	3 (6)
Occipital	1 (2)
Laryngeal	1 (2)
Venous pedicle	
Double	23 (46)
External jugular	16 (32)
Temporary	9 (18)
Facial	7 (14)
Thyrolinguofacial trunk	6 (12)
Internal jugular	7 (14)
Transverse cervical	3 (6)
Middle thyroid	3 (6)
Upper thyroid	3 (6)
Salivary bypass tube	
Yes	37 (74)
No	13 (26)

Results

We performed a total of 50 surgeries using a microvascular free flap for the reconstruction of large pharyngostomes, of which 8 were associated with severe pharyngeal stenosis.

The majority, 86% (43/50), were male, and the average age was 57 years (25–76 years). The 96% had a history of toxic habits: 31% only smoking and 69% smoking and alcohol. Except for one patient who had received exclusive radical RT, all patients had prior head and neck neoplasms previously treated by surgery. The location of the primary tumors and the interventions to which they had undergone are shown in Table 1. The 54% (27/50) had received complementary radiotherapy and 22% (11/50) chemoradiotherapy (CRT) (Table 1).

The 66% (33/50) of the patients were derived from other centers. In 58% (29/50) of the cases, previous reconstruction had been attempted by at least one flap and up to 20% (10/50) with more than one. The majority of these were regional flaps, being the most frequent the pectoralis major in 69% (20/29) and deltopectoral in 31% (9/29) (Table 1).

According to the type of defect to be reconstructed, the majority (84%, 42/50) had a mucous and skin defect; 10% (5/50) only skin, and 6% (3/50) only mucosa. The main surgeon was in all cases the same (JL^{1}). For mixed defects the most frequently used flap was anterolateral thigh (ALT), in 50% (21/42), followed by the forearm in 24% (10/42), parascapular in 21% (9/42), and only ulnar or jejunum in 2% respectively (1/42). In the exclusive skin defects (five cases) the ALT flap was used in three cases, in one a parascapular, and in another a forearm, chosen according to the size of the defect to be covered. In exclusively mucous defects (three cases) a parascapular, a jejunum and a forearm were used. Seven flaps were designed with double skin paddle: four parascapular and three ALT. All were used to cover defects that required mucosa and skin. The vascular pedicles used are summarized in Table 2. A Montgomery salivary bypass tube was placed in 74% (37/50) of cases.

With variations in time, all patients were treated after surgery with intravenous Clavulanic Amoxicillin 1 g/8 h except those with allergy or intolerance that were with intravenous Clindamycin 600 mg + Gentamicin 80 mg/24 h, a minimum of 7 days.

The 86% (43/50) of the patients had some complication, 72% (36/50) short term, 6% (3/50) long term and 8% (4/50) short and long term.

All patients with a medical complication also had a surgical complication. Medical complications were rare (12%, 6/50) being pneumonia and sepsis the most frequent (Table 3). Complications in the donor area occurred in 18% (9/50) being the only complication in two patients. The most frequent complication in the donor area was partial cutaneous necrosis and infection in three cases (6%) respectively (Table 3).

Among the cervical surgical complications in the short term, the most frequent was the pharyngocutaneous fistula, in 50% (25/50), which we consider as a late closure of the surgical wound that conditioned a longer hospital stay. Others were infection of the surgical wound in 24% (12/50) or bleeding in 16% (8/50).

The 34% (17/50) required surgical review for these surgical complications. In five of them, the direct closure of the fistula was attempted (suture, refreshing edges…), which was not completed upon discharge in any of the cases.

The viability of the flap was achieved in 92% of the patients (46/50). Therefore, total necrosis occurred in four patients, of which two were ALT flaps, one parascapular and one forearm. All of these had received prior CRT and two of them had prior bilateral functional dissection. One of them died due to sepsis as a result of the infection of the necrotized flap and in the other a new reconstruction was rejected given the poor state of the tissues and the vascularization of the patient. In the remaining two cases, rescue reconstruction was successfully performed using a regional flap, pectoralis major and latissimus dorsi.

In 56% of cases (27/48), the complete pharyngeal closure was confirmed before discharge simply observing the neck after the introduction of oral feeding. The rest of the patients were discharged with small fistulas with expected closure during outpatient follow-up, finally closing in 94% (45/48) of the cases (3 patients could not recover oral feeding). Here we did not include the two patients who died in the postoperative period because we could not assess the results beyond the postoperative period.

The average stay was 33 days (6–159), being 132 days among those who survived and presented flap necrosis.

The onset of oral tolerance was on average at 21 days after surgery, except in the 21 patients in whom there was no early pharyngeal closure, which was discharged with nasogastric tube or gastrostomy nutrition until the final closure. Finally, all patients with the closure of the defect (94%) were able to reintroduce oral feeding. Among the long-term complications, with a mean follow-up of 17 months, we included pharyngeal or esophageal stenosis, with difficulty feeding, which required periodic dilations in three patients, the infection that occurred in two patients and the late onset of a non-tumoral pharyngocutaneous fistula that occurred in two patients.

Table 3 Short and long-term complications are described

Short-term complications	No
Total patients	40
Total short-term complications	67
Medical	
Total patients	6
Total complications	6
Pneumonia	2
Sepsis	1
Esophageal perforation	1
Cerebral embolism	1
Oral bleeding	1
Surgical	
Donor zone	
Total patients	9
Total complications	11
Partial necrosis	3
Infection	3
Dehiscence	2
Bleeding	2
Seroma	1
Cervical	
Total patients	38
Total complications	56
Pharyngocutaneous fistula	25
Infection	12
Bleeding	8
Partial necrosis	5
Total necrosis	4
Dehiscence	2
Long-term complications	**No**
Total patients	7
Total long-term complications	7
Stricture	3
Infection	2
Fistula	2

Discussion

The existence of a pharyngostome supposes an important alteration in the quality of life of the patients who cannot have a correct oral intake, discomfort due to the saliva dropping to the neck or the tracheostoma and the need for almost constant care as aspiration or cures. The recommendations of this article are based on the experience of this series of 50 pharyngostomes with free flaps, but also on a many pharyngostome closures that did not require free flaps of tumors that required a pharyngolaryngectomy and that have not been included in this series.

We do not find in the literature extensive studies of the type of pharyngostome closure with free flaps. However, there are numerous publications in its use for reconstruction of primary pharyngolaryngectomies or in short and/or heterogeneous series of pharyngostome closure. In the pharyngolaryngectomies the situation is not the same as in the closure of pharyngostomes because we are systematically facing a local territory already damaged by surgery/s and/or previous radiotherapy and in general with high-risk patients. In pharyngolaryngectomies a common method in many centers is closure with a jejunum-free flap. However, in pharyngostomes its use is limited by the poor versatility of its vascular pedicle (without resorting to venous grafts) and the need for additional skin coverage if it does not exist.

At first, one of the solutions that partially mitigates the mentioned drawbacks of the salivary fistula is the placement of a salivary bypass tube, either under local or general

anesthesia [6], (Fig. 1a). This usually reduces saliva drainage and reduces the number of cures and discomforts that the pharyngostome causes, while we consider an optimal time for a definitive reconstruction. However, the inconvenience of the tube, the non-tightness or the mobility of the tube leads to it being only a palliative and transitory solution. Therefore, we should try to recover the pharyngeal transit and swallowing as soon as possible with a definitive reconstruction.

To decide the timing of the intervention, we should ideally recover nutritionally the patient in the preoperative period as much as possible, since there is strong evidence that good nutrition leads to better healing [10]. Sometimes this is not possible, and we must look for the best option, many times far from being the optimal one. It is also necessary to wait for the stabilization of the pharyngostome, especially in cases of prior radiotherapy/radionecrosis, without granulation tissue in the edges (Fig. 1a). A precipitated reconstruction will suture the flap in a non-viable tissue with the consequent detachment of the flap [11] (Fig. 1b). Waiting for a correct stabilization, sometimes despite the pressure of the situation, is crucial. Likewise, the realization of a PET-CT scan helps us to rule out the existence of recurrences or metastases that could change the general approach and management of the patient.

The sequence in surgery is usually: conservative conditioning of the pharyngostome, dissection of the cervical vessels, harvested of the free flap, suture of the flap in the neck closing the defect and microvascular anastomosis. It is important to make a resection of all granulation tissue that will prevent proper healing and exposure and regularization of the defect as conservatively as possible (Fig. 1c, d). A wide dissection leads to even more ischemia in already poorly irrigated necks.

The next decision is the type of reconstruction, which we must already have previously studied and decided, with its possible alternatives or unexpected variants according to intraoperative findings suggest or demand us. Of particular importance is the vascular assessment of the neck by choosing vessels away from the pharyngostome and also taking into account the length of the pedicle of the necessary free flap (Fig. 2a). The intraoperative search and dissection of the vessels will allow us to assess the suitability of using one or the other considering atherothrombotic phenomena (frequent in the facial or thyroid artery) or of low caliber (transverse cervical artery). Sometimes it may be necessary to perform

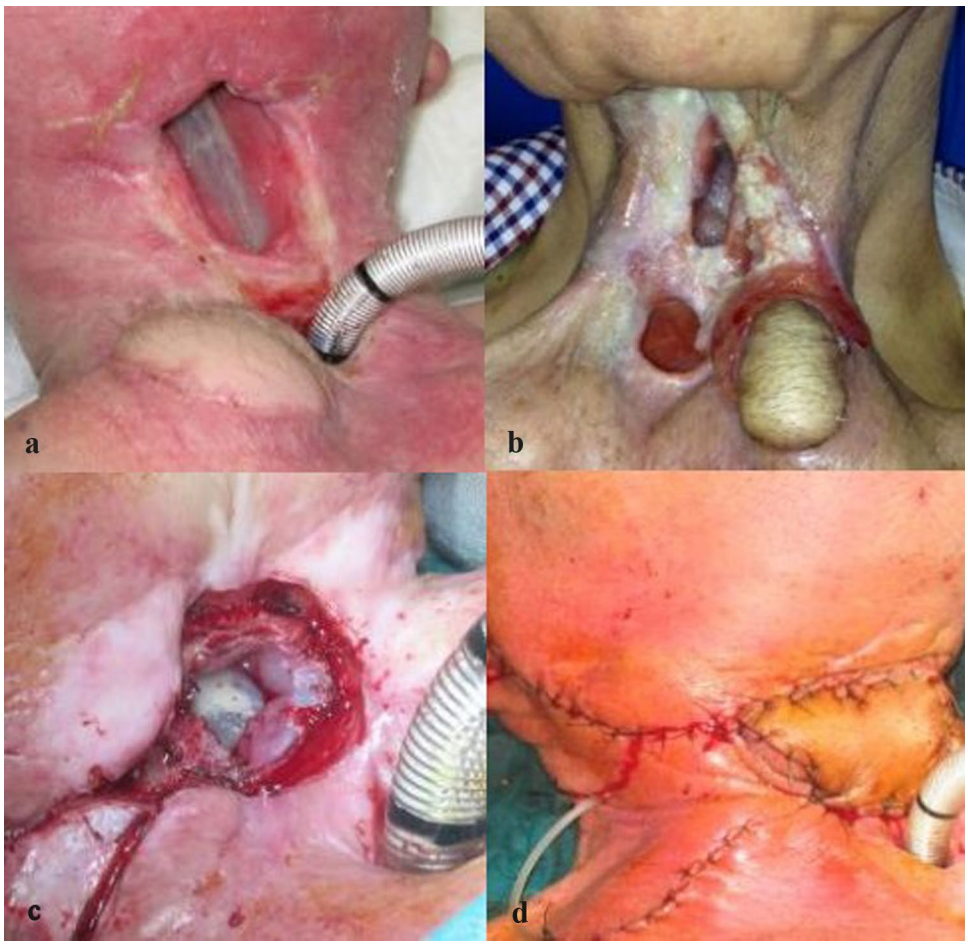

Fig. 1 **a** Wide stabilized pharyngostome in which the previous major pectoral stump is seen but displaced downwards. The placed salivary bypass tube prevents massive saliva leakage to the neck. **b** Patient with large pharyngostome, without salivary bypass tube, even with granulation tissue at the edges and with the previous pectoral equally detached. **c** Conservative dissection of pharyngostome to avoid ischemia. Cutaneous defect but enough mucosa for closure on a salivary bypass tube (Type 2). **d** Closure with free radial forearm flap of the same patient for skin coverage

a prior CT scan with contrast to assess the status of residual cervical circulation. There are necks whose vascularization after surgery and radiotherapy is very precarious and difficult to ensure.

The two great possibilities to choose are the closure with regional flaps (especially the pectoralis major) and the free flaps. However, at this point it is crucial to mention that the number of variables of the defect and neck, of the donor area and of the comorbidities of the patient make it essential to individualize each case. Sometimes ingenious and peculiar solutions must be taken into account in any step of the procedure.

It remains in debate whether to choose a regional or free flap as the first way of reconstruction. The regional flap is easier to harvested and takes less surgical time. However, their rates of partial or total necrosis approximately 30% are worse than those of free flaps (10% in large series and 8% in our series), although it depends on the series and experience of surgeons. The weight of the pectoralis major (Fig. 1a, b), a worse versatility and worse functional results, according to our experience and others [8], relegate it to an alternative in the case of the failure of a free flap. Other options such as deltopectoral or supraclavicular have indications in case of primary reconstructions or small pharyngostomes, but much less in large ones. Of course, this sequence can be reversed, especially considering the experience and availability of the different ENT services. In our series, 8% necrosis of the free flap is within acceptable parameters, similar to the percentage of global necrosis of all reconstructions with free flaps on head and neck performed by us [12].

Based on our experience, we propose a simple classification of the cervical pharyngeal cutaneous defect, regardless of its size, which guides our surgical choice.

The mucous defect (type 1) would include those patients in whom we do not need cervical skin coverage but who must reconstruct the pharynx totally or partially (Fig. 2a). The pharynx should be reconstructed when the remaining mucosa does not allow an easy closure on the shape of a salivary bypass tube (diameter 14 or 16 mm) [13]. For practical purposes, the designed flap should be about 6 cm wide (7.5 cm on average in our series) to allow a free closure with the remaining mucosa, in tubular form or on the prevertebral plane. The vertical size will depend on the height of the pharyngostome. If there are redundancies of the flap, they should be resected on demand, preserving its vascularization with a suture without tension, but without excesses. A slightly tense suture is usually ideal considering also that the patient is usually in a hyperextended position. A mucous strip remnant may favor a more anatomical closure and less tendency to stenosis. But a large inverted U-suture on the prevertebral plane (with a salivary bypass tube) is usually a good solution preventing healing, fibrosis and concentric stenosis (Fig. 2b). In this study, four patients required U-suture

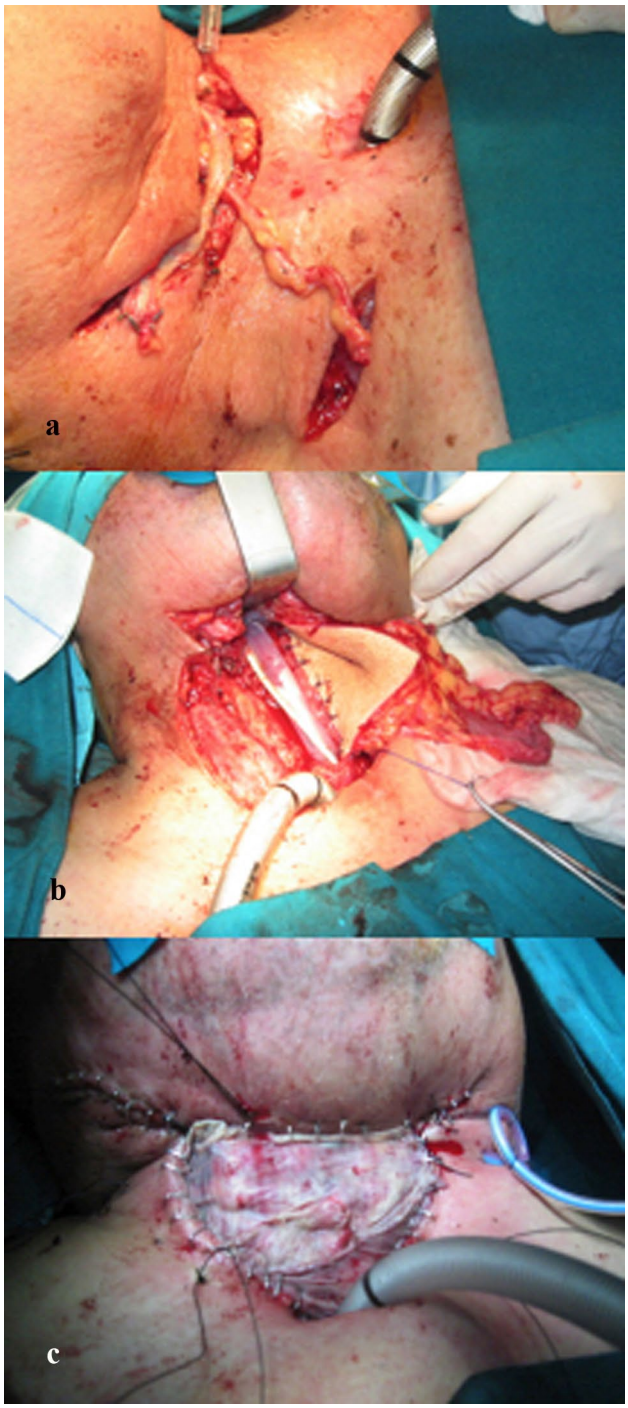

Fig. 2 **a** Detail of a patient whose pharynx was reconstructed with a radial forearm flap and does not require skin coverage (Type 1). The vascular pedicle of the flap can be seen on the skin of the neck that was then tunneled and sutured with the transverse cervical artery and the external jugular vein. **b** Closing the pharynx (type 3 defect) with a free ALT flap sutured in an U-inverted fashion, with a mucous remnant. The skin was placed inward, with the salivary bypass tube. **c** ALT free flap used to reconstruct the pharynx with the skin inward and a free skin graft covering the flap

at the prevertebral plane and we have not noticed differences between one method or another. The preservation of the mucosa should never be at the expense of cancer doubts. The free flap should be sutured with the skin towards the pharynx and quite lateral on both sides of the prevertebral plane, being careful not to injure the internal carotid with a stitch, since sometimes it is very close. It is also important to fix the posterior wall of the esophagus with two or three stitches to the prevertebral plane to avoid retroesophageal leaks into the mediastinum. The distal suture usually has a certain degree of stenosis and adequate dissection and suture (in flute peak …) should avoid this problem. In our experience, it is not necessary to place skin-free grafts on the prevertebral plane. In this type 1, because of its thin size, the radial forearm flap is especially useful. In thin patients, the ALT flap, the parascapular or even the jejunum are also an excellent option and therefore we find different choices in our series (33% forearm, 33% parascapular and 33% jejunum).

We have proposed as type 2 those defects in which we have enough pharynx for a direct closure on a salivary bypass tube. The extension will depend on the defect to be covered and in these cases the skin is left out. Sometimes because the skin does not adapt well, it may be necessary to de-epithelize part of the flap and once conditioned, place a skin-free graft in the denuded areas. The results are usually excellent (Fig. 1c, d). In these cases, the most used flap is the ALT (60%) because it has greater volume and minimum morbidity in the donor area. The parascapular is a good option, but more difficult to harvested, and the radial forearm is usually of small thickness or size.

Finally, the cases included in type 3 are usually major pharyngostomes and require closure of the pharyngeal mucosa and skin. In the past, we used in these cases a free flap (radial forearm or jejunum) to close the pharynx and covering the skin with a regional flap, pectoralis major and in some cases deltopectoral (not included in this series). Nor does it seem essential to perform double skin paddles [13]. Of the patients reconstructed in this series free microvascular flaps with double skin paddles, 43% had fistula (3/7) without significant differences with respect to reconstructions with a single paddle flap (45%; 18/40). Nor did we find differences in the rest of the clinical characteristics. Therefore, time has shown us that a safe closure can be made only with a single paddle flap. In these type 3 patients, the flap of choice is ALT (50%) because of its size, and which allows to be harvested skin in one side and the fascia lata on the other. In general, we use the skin for the reconstruction of the pharynx to adapt it to the pharyngeal defect. The outward part corresponds to the fascia lata, which we usually cover with a skin-free graft (Fig. 2c), with caution because the pedicle runs subfascial and some stitch of the suture could be inadvertently damaged it. We have also sutured in some cases (not included in this series for being during the removal of a primary tumor) the flap with the fascia lata towards the pharynx and the skin outward. We have always had a good result, but the pedicle is less protected from a possible saliva lesion or eventual fistula. The same indications of the ALT are for the paraescapular, with the limitation of its greater discomfort and difficulty in its harvested, although it is even more versatile in the design options. The radial forearm is usually scarce in these cases. It is important to give extra superior sutures to the flap to avoid its detachment because of gravity, especially in large and heavy flaps.

Postoperative care is as important as the rest of the procedure. As we have seen, postoperative complications are frequent (86%) and their early detection is important to avoid surgical failure. In our series, the 34% (17/50) required surgical review for these complications. Adequate antibiotic coverage is imperative, although optimal dosing regimen is a topic still under revision [14]. Relative bed rest can decrease the weight of the flap and allow time for its integration. In any case, precautions should be taken to avoid thromboembolic phenomena with adequate medication for this purpose with anticoagulants or antiplatelet agents.

Once the pharyngostome is closed, oral tolerance is tested with liquids (milk, colored water …). Another possible option is to perform a pharyngoesophagogram. If no obvious leaks are observed, the salivary bypass tube is removed and gradually started with oral feeding (liquids, soft diet …). In the end, 94% of the patients achieved oral feeding similar to the best results in pharyngolaryngeal reconstruction [15].

In conclusion, the treatment of large pharyngostomes with free flaps in a surgical time, despite the important local and general problems that these patients present, is in our experience the best way to manage them taking into account the results achieved. Our classification of the cervical pharyngeal cutaneous defect will help to choose the free flap to use in the reconstruction of pharyngostomas.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval This article does not contain any studies with human participants or animals performed by any of the authors.

Informed consent Additional informed consent was obtained from all individual participants for whom identifying information is included in this article.

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