



Heterogeneous Acellular Dermal Matrix Combined with Infrahyoid Muscles Flap for Reconstruction of Laryngopharynx in Pyriform Sinus Carcinoma

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Abstract

Background: Many methods of laryngopharyngeal reconstruction after extended laryngopharyngectomy have been described, but the functional outcomes and morbidities have not been satisfactory. The objective of the study was to evaluate the outcomes of laryngopharyngeal reconstruction with Heterogeneous Acellular Dermal Matrix (H-ADM) combined with infrahyoid muscle reinforcement.

Methods: From 2014 to 2018, 7 patients with T2–T3 squamous cell carcinoma of the pyriform sinus were included in this retrospective study. Reconstruction of laryngopharyngeal defects was performed using H-ADM combined with infrahyoid muscle graft after tumor resection. The functional and oncological outcomes were evaluated at follow-up greater than 3 years.

Results: Resection of the pyriform sinus and infiltrated hemilarynx was performed in all patients. The diameter of the defect after laryngopharyngectomy was less than 6 cm. During 30 to 60 days after reconstruction, the H-ADM was covered with normal mucosa. One patient developed a pharyngeal fistula one-week post-operation, but recovered after dressing change about 2 months. No other severe postoperative complication occurred. Patients recovered normal swallowing function at a mean of 21.5 days after surgery. Laryngeal function was preserved in all patients, and decannulation was performed at a mean of 12.3 weeks after the surgery. The follow-up period ranged from 39 to 53 months, the overall 3-year survival rate was 71.4%, and the local-control rate was 57.1%.

Conclusion: H-ADM combined with infrahyoid muscles flap is a simple, safe and effective method of reconstruction after pyriform sinus resection. This technique offers a novel alternative for these patients with normal swallowing function, and a relatively acceptable survival duration.

Keywords: Biocompatible materials; Hypopharyngeal neoplasms/surgery; Surgical flaps; Heterogeneous acellular dermal matrix; Infrahyoid muscle; Reconstruction; Pyriform sinus carcinoma

Introduction

Pyriform sinus carcinoma is one type of hypopharyngeal carcinoma which makes up 2% of total head and neck cancer cases [1]. Due to the poor prognosis [2], the aim of the surgery is to prolong the survival time and to improve patients' quality of life. As is closely associated with the larynx in anatomic, surgical excision of T2–T3 pyriform sinus carcinoma frequently leads to massive laryngopharyngeal defects and thus affecting the function of the larynx. With the development of reconstructive techniques, various pedicled and free-tissue flaps including myocutaneous, gastric pull-up, jejunum, radial forearm, lateral arm, rectus abdominis, lateral thigh, and gastro-omental flaps have been used for hypopharyngeal reconstruction [3]. However, most of these techniques involve considerable donor-site morbidity, long operative times, risk of flap failure, and other severe postoperative complications [3,4].

We have been looking for a new artificial material to reconstruct the defects. Allogeneic acellular Dermal matrix (AlloDerm) was first described by Wainwright for the treatment of deep burns [5]. Owing to its properties of biologic inertness, low immunogenicity, vascular ingrowth facilitation, and rapid epithelialization, AlloDerm has been widely used as a dermal and mucosal substitute for various

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Received Date: 26 Sep 2022

Accepted Date: 14 Oct 2022

Published Date: 20 Oct 2022

Citation:

Chen M, Zhang C, Yao H, Li H, Zheng H, Zhu M. Heterogeneous Acellular Dermal Matrix Combined with Infrahyoid Muscles Flap for Reconstruction of Laryngopharynx in Pyriform Sinus Carcinoma. *Am J Otolaryngol Head Neck Surg.* 2022; 5(9): 1211.

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reconstructive procedures in head and neck surgery, including nasal soft-tissue, periorbital soft-tissue, and oral and pharyngeal mucosal reconstructions [6,7]. Although reconstruction with AlloDerm has yielded promising results, it does have some drawbacks, including the possibility of infectious spread, shortage of donor sources, and ethical issues. To overcome these problems, Heterogeneous Acellular Dermal Matrix (H-ADM), which is derived from mammals, was developed and has been applied in many reconstructive procedures. Compared to AlloDerm, H-ADM has similar biological properties, low cost, and more donor sources [8,9]. However, few studies have investigated the use of H-ADM for the reconstruction of large laryngopharyngeal defects caused by the resection of pyriform sinus carcinoma. In this study, we have applied H-ADM in combination with infrahyoid muscles flap to repair hypopharynx, and we have evaluated the procedure-related outcomes.

Patients and Methods

Patients

Seven patients with T2–T3 pyriform sinus carcinoma (AJCC, 2017) who underwent resection of hypopharynx were selected as main sample for this thesis. Those with esophageal invasion were excluded from the study. All involved patients were operated on between September 2014 and May 2018 in the Department of Otolaryngology Head and Neck Surgery, Changhai Hospital, Naval Medical University. In all patients, H-ADM (Haiao Biotechnology Co. Ltd., China) was used in combination with infrahyoid muscles flap to reconstruct the hypopharyngeal defect resulting from tumor resection. The study protocol was reviewed and approved by the local Ethics Committee.

Preoperative examination

Videolaryngoscopy, Computed Tomography (CT), or Magnetic Resonance Imaging (MRI) was conducted in all patients to localize the primary tumor (Figure 1). Clinical examination, gastroscopy, and barium meal examinations were routinely performed preoperatively for clinical staging and to detect secondary cancers in the upper gastrointestinal area. To exclude the presence of distant metastasis, chest radiography, radionuclide bone scintigraphy, or Positron-Emission Tomography Computed Tomography (PET-CT) was also performed before surgery. The diagnosis of hypopharyngeal carcinoma was confirmed by biopsy and histological examination (Figure 1).

Surgical procedure

All patients underwent cervical lymph node dissection followed by primary tumor resection, and the dissection was conducted bilaterally when the lesions crossed the midline. Partial hypopharyngectomy and laryngectomy were performed in all 7 patients. The laryngopharyngeal defect was assessed after excision of the primary lesion. The defect size ranged from 4 cm to 6 cm: Therefore, primary tension-free defect closure was not feasible (Figure 2A, 2B). Accordingly, an appropriate-sized H-ADM graft was selected based on the defect size. The graft was placed into the laryngopharyngeal defect with the basement membrane facing towards the pharyngeal lumen. A gastric tube was then placed through the pharynx into the stomach, and the laryngopharyngeal defect was reconstructed with the H-ADM graft combined with the infrahyoid muscles flap. Precise reconstruction was performed to obtain a watertight closure *via* anastomosis of the graft with the remaining pharyngeal mucosa with 3-0 absorbable sutures (Figure 2C, 2D). During the surgery, the



Figure 1: Computed tomography scan of the neck before surgery showing squamous cell carcinoma (stage T2) of the right hypopharynx (black arrow) and metastatic cervical lymphadenopathy (stage N2 *).

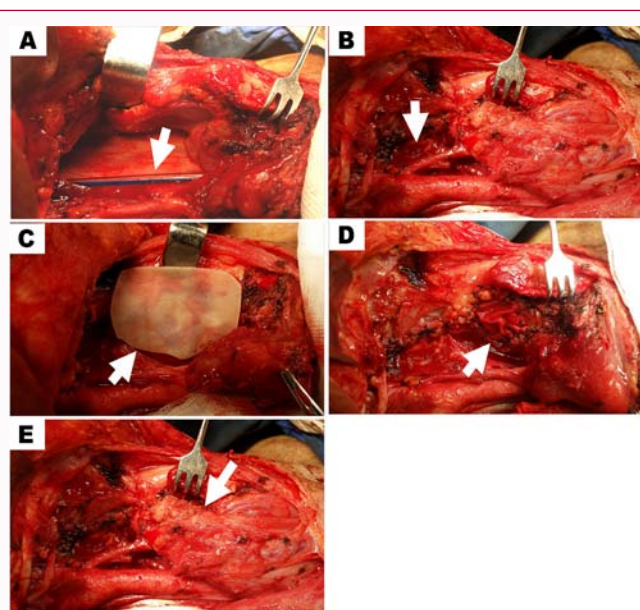


Figure 2: Reconstruction of hypopharyngeal defect: The defect (gastric tube (white arrow)) (A) is sutured by residual pharyngeal mucosa (B). H-ADM (white arrow) is used for defect reconstruction (C, D) with infrahyoid muscle (white arrow) reinforcement (E).

infrahyoid muscles were carefully preserved without compromising oncological principles. The upper ends of the infrahyoid muscles were carefully separated under the hyoid bone before resection of the primary tumor. After anastomosis of the H-ADM graft with the pharyngeal mucosa, the ipsilateral or contralateral infrahyoid muscles were placed over the graft and sutured to the external side of the H-ADM graft to reinforce the pharyngeal closure (Figure 2E). When the ipsilateral partial laryngectomy was performed for tumor invasion, the ipsilateral infrahyoid muscles were used to reconstruct the laryngeal defect, and the contralateral muscles were used to reinforce the H-ADM.

Post-operative care and treatment

After the surgery, all patients received nutritional support, anti-inflammatory treatment, anti-coagulation therapy, and regular dressings. Videolaryngoscopy was conducted every week to observe the condition of the anastomosis, biograft intake, and sloughing. Before the patients resumed oral intake, a barium swallow study

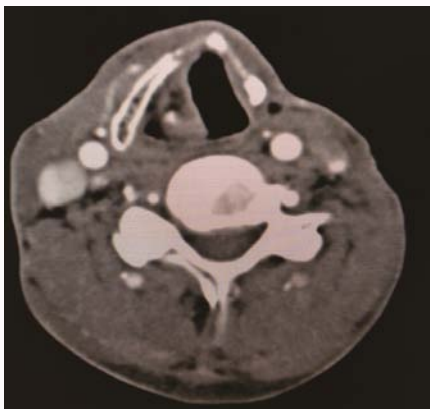


Figure 3: Computed tomography scan of the neck after surgery reveals that the reconstructed pharynx and larynx have healed well.

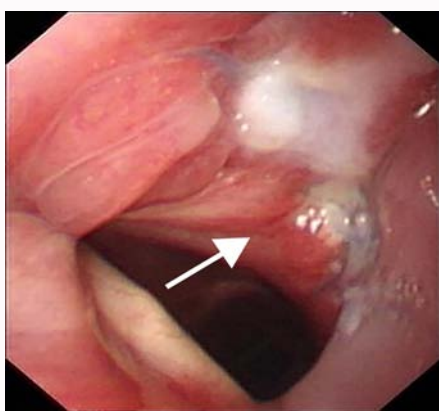


Figure 4: Laryngoscopy shows the reconstructed laryngopharynx. The H-ADM graft has good epithelialization (white arrow).

was performed to detect the presence of leakage and to assess the postoperative swallowing function. In the absence of fistulas or wound complications, the nasogastric tube was removed, and oral feeding was resumed.

Follow-up

Follow-up was performed at 3-month intervals during the first 2 years and at 6-month intervals after 2 years. Follow-up examinations included CT or MRI scans of the neck (Figure 3), chest radiography, abdominal and cervical ultrasonography. Additional examinations, such as PET-CT scanning, were conducted if necessary.

Survival data for the patients were obtained *via* letters, telephone calls, and outpatient follow-up visits. Follow-up was performed until October 2021, and patients were considered disease-free if an absence of disease was documented at the date of last visit.

Results

Patient characteristics

Characteristics of the patients are presented in Table 1. All patients were male, and their median age was 61 years (range 51 to 67 years). The main clinical manifestations included pharyngeal paraesthesia (5/7), pharyngalgia (4/7), hoarseness (4/7), dysphagia (7/7), and cervical masses (4/7). Most patients were 'ever drinkers' (those who had drunk at least one alcoholic beverage/week for at least 1 year during their lifetime) and 'ever-smokers' (those who had

smoked at least 100 cigarettes in their lifetime). All patients were initially diagnosed with SCC confirmed by histological examination of biopsy tissues. Before the surgery, three patients received induction chemotherapy, which elicited only a partial response and none had undergone surgery or preoperative radiotherapy. Videolaryngoscopy showed that the primary lesions were located in the pyriform sinus of the hypopharynx in all patients. CT or MRI examination indicated that all patients had laryngeal invasion, and all 7 patients had cervical lymph node metastases (level II–IV; Figure 1). Gastroscopy and barium meal examination excluded esophageal invasion. After comprehensive analysis of the results of the preoperative examinations, SCC of the pharynx was staged according to the AJCC TNM staging system (8th edition) as follows: T2, 6 patients; T3, 1 patient; N1, 6 patients; N2, 1 patient; stage 1 disease, 6 patients; and stage A disease, 1 patient. Resection of the pyriform sinus and infiltrated hemi larynx was performed in all patients. The diameter of the defect after laryngopharyngectomy was less than 6 cm.

Surgical outcomes and complications

After the surgery, patients were monitored intensively to detect early flap failure and other post-operative complications. The weekly endoscopic examinations showed mucosalization of the H-ADM graft at the reconstruction site (Figure 4). No appreciable sloughing was observed, and the intake rate of H-ADM was 100%. Among the seven patients, six had primary healing about 2 to 3 weeks after surgery. The H-ADM was covered with normal mucosa, during 30 to 60 days after reconstruction. One patient developed a pharyngeal fistula one-week post-operation, but recovered after dressing change about 2 months. No other severe postoperative complications were found.

Functional outcomes

After radical surgery and laryngopharyngeal reconstruction, endoscopy and post-operative barium meals was used to evaluate patients' swallowing function. No graft contracture or pharyngoesophageal stenosis was observed in the patient, and the gastric feeding tubes were removed after mucosalization of the graft. Apart from the patient with pharyngeal fistula, the mean swallowing function recovery time is 21.5 days (range =18–25 days) after the surgery. The patients with the pharyngeal fistula also resumed oral intake after fistula healing. Laryngeal function was preserved in all patients, and decannulation was performed at a mean of 12.3 weeks after the surgery. There were no complications influencing the capacity for phonation, and intelligible speech was gained in all patients.

Oncologic outcomes

After surgical treatment and recovery of normal swallowing function, all patients received postoperative treatments, including radiotherapy and chemotherapy. The last follow-up was performed in October 2021; thus, the follow-up period ranged from 39 to 53 months. Three of the seven patients developed contralateral cervical lymph node metastasis 13 to 26 months after the operation and underwent additional radical neck dissection. Two patients died between 26 and 31 months after the first operation for distant metastases. The remaining four patients were still alive and disease-free at the time of the last follow-up (Table 1). The overall 3-year survival rate was 71.4%, and the 3-year disease-free rate was 57.1%.

Discussion

The present study showed that the use of an H-ADM graft combined with the infrahyoid muscles for single-stage primary

Table 1: Clinical characteristics of the seven patients who underwent laryngopharyngeal reconstruction.

Case no.	Sex	Age (yr)	Induction chemotherapy	TMN stage	Clinical manifestations	Treatment after surgery	Local recurrence (mo)	Outcome (mo)
1	M	51	NO	T2N1M0	PP, PG, HS, DP	RT, CT	-	Survived (53)
2	M	57	NO	T2N1M0	PG, DP, CM	RT, CT	13	Died (26)
3	M	61	YES	T3N1M0	PP, HS, DP, CM	RT, CT	-	Survived (48)
4	M	62	YES	T2N2M0	PP, HS, DP, CM	RT, CT	26	Died (31)
5	M	67	YES	T2N1M0	PP, PG, HS, DP	RT, CT	-	Survived (42)
6	M	64	NO	T2N1M0	PG, DP, CM	RT, CT	22	Survived (39)
7	M	56	NO	T2N1M0	PP, DP	RT, CT	-	Survived (39)

PP: Pharyngeal Paraesthesia; PG: Pharyngalgia; HS: Hoarseness; DP: Dysphagia; CM: Cervical Mass; RT: Radiotherapy; CT: Chemotherapy

reconstruction of laryngopharyngeal defects resulting from the resection of pyriform sinus carcinoma yielded satisfactory functional and oncological outcomes. Moreover, there were no perioperative complications and no severe postoperative complications apart from pharyngeal fistula formation, which occurred in one of the seven patients. This suggests that this reconstruction technique is a potentially reliable and safe method to repair defects resulting from the radical resection of pyriform sinus carcinoma.

As is anatomical close to the larynx, pyriform sinus carcinoma is widely treated using total laryngopharyngectomy, which necessitates permanent tracheostomy resulting in voice loss and impaired deglutition [10]. To preserve laryngopharyngeal function after radical resection, a number of reconstructive techniques have been utilized. The optimal reconstructive procedure for such defects should maximally restore laryngeal and pharyngeal function in one stage, have a high success rate with low postoperative mortality and morbidity, and rapidly improve the patient's quality of life.

While local and regional flaps, such as the pedicled myocutaneous flap and vascularized free myocutaneous flap, as well as alimentary tract grafts have been used for reconstruction surgeries, they have disadvantages, such as lack of reliability, bulkiness, and high complication rates [11]. Recently, AlloDerm is widely used in head and neck surgery for both esthetic and reconstructive purposes [12]. AlloDerm is a natural extracellular matrix with a collagen lattice as the basic framework. It is produced *via* the de-epithelialization and decellularization of fresh skin, which leaves the extracellular matrix structure and basement membrane intact. AlloDerm is remarkably stable [13] and has yielded inspiring results in defect reconstruction; however, its application is associated with several deficiencies, such as a shortage of donor sources and ethical issues [9,14]. To overcome these problems, H-ADM grafts were developed. Compared to AlloDerm, H-ADM has similar biological properties, low cost, and abundant donor sources. Thus far, H-ADM grafts have been successfully used for the reconstruction of the breast, vocal cords, lacrimal duct, and pharynx [9,15,16].

H-ADM alone can be used to reconstruct superficial defects that can be easily monitored and managed. For deep defects, such as those in the pharynx and alimentary tract, it is necessary to combine H-ADM grafts with soft-tissue reinforcements to decrease the incidence of graft migration and anastomotic fistula, which may lead to severe postoperative complications and reconstruction failure. Yin et al. [9]. reported a series of five patients with advanced hypopharyngeal carcinoma, in which an H-ADM covered with a pectoralis major muscle flap was used for reconstruction. The authors reported that this technique was associated with minor peri- and post-operative

morbidity. Although the pectoralis major muscle flap can provide a robust blood supply and powerful support for defect reconstruction, it has some unavoidable disadvantages, such as donor-site morbidity, esthetic problems, and unsuitable thickness.

Compared to the pectoralis major muscle flap, the infrahyoid muscle has distinct advantages, including a suitable thickness for the reconstruction of pharyngeal and laryngeal defects, a satisfactory pliability, and lack of hair. Since the infrahyoid muscle flap was first described as a muscle transposition flap to eliminate "dead space" in 1977, it has been widely used clinically for the reconstruction of defects in the head and neck, including defects of the trachea, tongue, and pharynx [17-19]. Owing to its thinness and malleability, the infrahyoid muscle flap has been proven to be safe and reliable for the reconstruction of head-and-neck surgical defects and provides favorable cosmetic and functional outcomes [18]. Compared to other procedures using free or pedicled flaps, the operative time was much shorter, and had fewer complications [20]. However, the infrahyoid muscle is inappropriate for the reconstruction of the laryngopharyngeal defect and can only serve as a soft-tissue support for the H-ADM graft to facilitate rapid graft incorporation, due to the partial sacrifice of the blood supply caused by the surgery.

In our series, there was no donor-site morbidity, and watertight closure of the defect could be achieved. We consider that the pliability of H-ADM provides the feasibility to reconstruct complex defects in the laryngopharynx, and the optimal tissue thickness of infrahyoid muscles offers effective reinforcement and an esthetic appearance. In our study, mucosalization of the graft occurred within 4 to 8 weeks after the operation, and no sloughing was found during the weekly laryngoscopy examinations. The graft can degenerate and regenerate simultaneously, which maintains the structural integrity during the incorporation process, and continues to provide an effective barrier between the reconstructive area and the neck during the healing process. This reconstructive technique preserved laryngeal function well, and all patients achieved decannulation, normal swallowing function, and satisfactory voice without laryngopharyngeal stenosis. Although animal studies have shown that external-beam radiation, which is usually administered to patients with advanced pharyngeal carcinoma, may hinder early fibroblast ingrowth into the graft. Whereas the graft thickness and neovascularization of the AlloDerm dermal implant do not appear to be adversely affected by a field that has received external beam radiation [21]. Except for one patient who developed an anastomotic fistula, all other patients received postoperative radiotherapy and achieved primary healing without severe complications resulting from the surgery and radiation in our study. This indicates that the reconstructive procedure was a safe and

reliable choice for the reconstruction of defects resulting from the resection of T2-T3 pyriform sinus carcinoma with few postoperative complications, such as graft failure and donor-site morbidity.

Despite the advantages of this reconstructive technique, there are several key points that should be emphasized. It is important to support the graft with soft tissue for faster incorporation and a watertight seal. Furthermore, as the dimensions of the infrahyoid muscles is restricted, this technique is not adapted to defects wider than 6 cm after tumor resection or larger than 2 cm after suturing of the residual mucosa.

Larger defects should be reconstructed using other techniques, such as pectoralis major myocutaneous flap combined with ADM, and free flaps. In our study, pharyngeal fistula occurred in one patient possibly because the defect was too large, which prevented the infrahyoid muscle flap from adequately bracing the H-ADM. When the infrahyoid muscles have been infiltrated by the lesion, reconstruction should be performed with other pedicled or free flaps to meet the principles of oncological resection. Due to deficits in venous drainage and blood supply, patients with a history of cervical radiotherapy should be cautiously selected for this reconstructive technique to prevent postoperative pharyngeal fistula formation. Owing to the high incidence of submucosal infiltration in patients with hypopharyngeal carcinoma [2,22], it is important to perform radical resection of the tumor to decrease the risk of tumor recurrence, which also affects the reconstruction outcomes. Therefore, proper excision of the tumor margins must be performed to ensure sufficient oncological resection without tumor exposure.

Conclusion

In conclusion, the results of this retrospective analysis of 7 patients with T2-T3 pyriform sinus carcinoma suggest that the use of H-ADM combined with infrahyoid muscle flap reinforcement is a safe and reliable method of reconstruction after radical resection of pyriform sinus carcinoma in selected patients. The technique resulted in satisfactory surgical outcomes, few perioperative complications, satisfactory laryngeal and pharyngeal function, and acceptable quality of life. Future studies with a larger sample size and longer follow-up periods are needed to verify our findings.

Funding

This work was supported by a grant from the National Natural Science Foundation of China (81772881, 81970868).

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