ABSTRACT

**Background:** Pharyngocutaneous fistula is a serious complication after total laryngectomy. The reported incidence varies from 1% to 50%. There is still no agreement regarding when to begin oral feeding after total laryngectomy. The aim of this study was to demonstrate the safety of early oral feeding after total laryngectomy.

**Materials and Methods:** In a prospective study, patients who underwent total laryngectomy were randomly divided into either the oral feeding or the nasogastric tube (NGT) groups. For patients in the oral feeding group, feeding was initiated orally with a clear liquid diet on the third postoperative day, whereas patients in the nasogastric tube group were fed through NGT and received nothing orally until the seventh postoperative day.

**Results:** Between September 2002 and October 2006, 25 patients were studied in this trial. There were 13 patients (52%) in the oral feeding group and 12 patients (48%) in the NGT group. Their ages ranged from 49 to 77 years (mean 66.07 ± 7.22 and 63.83 ± 7.58 years in oral feeding and NGT groups, respectively). Mann-Whitney U and Chi-square tests showed that differences between the two groups were not statistically significant with regard to age, tumor location and tumor stage. One case of fistula occurred in each group.

**Conclusion:** Our results indicate that in a selected group of patients, it is possible to initiate oral feeding much earlier in the postoperative period than what was formerly thought. *(Tanaffos 2008; 7(2): 64-70)*

**Key words:** Laryngectomy, Nasogastric tube, Oral feeding, Pharyngocutaneous fistula

INTRODUCTION

Pharyngocutaneous fistula (PCF) is a serious and common complication after total laryngectomy (1). The reported incidence varies from 1% to 50% (2-6). Despite the large number of studies in this regard, there is still a disagreement on factors predisposing to this complication. Numerous contributing factors have been implicated in fistula formation. Preoperative radiotherapy especially high dose, short interval between radiotherapy and operation, prior tracheotomy, tumor localization and size, advanced tumor stage, tumor differentiation, presence of positive tumor margins, extensive surgery, type of pharyngeal closure, concurrent radical neck dissection, suture material, low serum albumin (<3.5 g/dL), low level of serum proteins (<6.5 g/dL), poor preoperative nutritional and medical status such as uncontrolled diabetes, liver diseases, low postoperative hemoglobin level, gastroesophageal
reflux, alcohol consumption, fever in the immediate postoperative period, significant post-operative vomiting, technical errors and early oral feeding have been implicated as potential risk factors contributing to fistula formation (7-13). This complication must be avoided not only for medical but also for economic reasons. Adequate nutrition is an important aspect of postoperative management but it is widely accepted that early oral feeding may facilitate the development of PCF. However, there is no international agreement on when to begin oral feeding after total laryngectomy. Many head and neck surgeons prefer to use a nasogastric tube to delay oral feeding up to 7 to 10 days after surgery to prevent fistula (14). But, the nasogastric tube (NGT) itself has several complications such as permanent nasal alar deformity, acute sinusitis, pneumothorax, aspiration pneumonia, gastroesophageal reflux and persistent dysphagia (15,16). Some surgeons believe that movement of NGT may cause additional stress on the suture line in the postoperative period and contribute to PCF development (7,18); therefore, some studies do not recommend NGT (17-19). The purpose of the present study was to examine the influence of early oral feeding on fistula formation.

MATERIALS AND METHODS

This prospective, randomized controlled study was performed in the "Otorhinolaryngology Clinic of Loghman Training and Research Hospital" and was approved by the ethics committee. Informed consent was obtained from all patients. Patients who underwent total laryngectomy for a malignant tumor of the larynx were included in the study and those who had previously been operated and patients who had been laryngectomized for intractable aspiration, locally invasive thyroid carcinomas, posttricoïd or cervical esophageal cancers, and those who had received preoperative irradiation were excluded from the study. Patients undergoing partial laryngectomy were also excluded from this study. Initial evaluation included head and neck examination and necessary hematologic and biochemical tests were obtained. Radiographs of chest and neck with use of computed tomography or magnetic resonance imaging studies were performed when needed. Direct laryngoscopies with biopsy of the lesion were performed under general anesthesia. Patients’ age, sex, location of primary tumor, histological findings and prior treatment (radiotherapy) were recorded. All surgical procedures were carried out or supervised by the same surgeon. A transverse collar incision was used approximately two finger breadths above the sternal notch, extending superiorly and laterally on both sides. In all patients, standard total laryngectomy was performed, including the hyoid bone, isthmus, and lobe of the thyroid gland on the affected side. Unilateral or bilateral neck dissection (RND) was carried out as indicated, mostly standard radical neck dissections on the affected side. The pharyngeal mucosal defect was repaired meticulously with 3-0 Vicryl sutures (Eticon, USA). The closure was T-shaped, without tension. After surgery, patients were randomly divided into either the oral feeding group or the nasogastric tube (NGT) group. Intravenous fluid replacement to support the patient’s metabolic status was continued until postoperative intake was considered adequate. Suction drains were used and the amount and appearance of fluid collected in the hemovac system was carefully monitored until the drains were removed, usually on the fourth postoperative day, when the amount of wound drainage was less than 50 mL in 24 hours. All patients were given perioperative antibiotic intravenously until the suction drains were removed. Furthermore, they were also given intravenous infusion of Lipovenoes 10% PLR 500 ml (Ferseius kabi), and amino acids (Aminoplasmal-5% E, B.Braun) 500 ml, vitamin A 50,000 U (Osvehpharma
Co.), and vitamin C 500 mg (Daroupakhsh Co.) once daily; Ranitidine (Chemidarou Co.) 50 mg twice daily, bromhexin (Toliddaru Co.) 4 mg and methoclopramide (Osvehpharma Co.) 10 mg 3 times/day, for three days. On the 3rd postoperative day, all patients in the oral feeding group were started on small sips of water. During the feeding a physician observed the drains to detect any entrance of swallowed material into the suction system that would indicate fistula development. In the absence of any sign of fistula, clear liquids and then milk were added to the diet, usually on the 4th postoperative day. Soft foods were started on the 6th and 7th days. Patients in the NGT group were fed through NGT and received nothing orally until the 7th postoperative day; then they were fed orally if fistula had not occurred. Intravenous fluids were stopped once the patient’s oral intake was considered adequate. Standard criteria for discharge were used for all patients. The diagnosis of PCF was made by direct inspection of the neck wounds and the detection of saliva or any entrance of swallowed material into the suction system or through the neck wounds. No radiographic assessment was performed to assess the size of the fistula. If a pharyngocutaneous fistula was diagnosed, an NGT tube was inserted to maintain alimentation and pressure dressings were applied and changed twice a day. Parenteral antibiotic treatment was started to clear any local infection. Weekly follow-up for the first month and monthly follow-up for the next three months were advised. The patients were instructed to contact the surgeons immediately, if they had any problems. The Chi-square and Fisher exact tests were used to analyze the data. Results were considered significant at p-values of less than 0.05.

RESULTS

Between September 2002 and October 2006, 28 patients were enrolled in this trial, and complete data were available for 25 patients (13 patients, 52% in the oral feeding group and 12 patients, 48% in the NGT group). Their ages ranged from 49 to 77 years, (mean 66.07 ±7.22 and 63.83 ± 7.58 years in oral feeding and NGT groups respectively). Mann-Whitney U test determined that differences of age between the two groups were not statistically significant (mean rank of oral feeding and NGT groups were 14 and 11.9 respectively). Chi-square test showed the differences between the two groups were not statistically significant according to tumor location and tumor stage. Table 1 summarizes the characteristics of patients. The final surgical pathological finding was squamous cell carcinoma for all patients, and all margins of resection were negative on pathological analysis. One case of fistula occurred in each group. Fisher exact test showed the differences between the two groups for fistula formation were not statistically significant. Our study showed that with Fisher exact test the differences regarding the rate of fistula formation between patients who underwent RND compared with those who did not, were not statistically significant. Grade and stage of the disease, were not statistically significant between the two groups. All fistulas closed spontaneously with wound care without surgical intervention.

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<th>Table 1. Patient characteristics.</th>
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DISCUSSION

PCF is generally considered to be a serious problem for the patients in terms of delayed oral feeding, prolonged hospitalization, possible additional surgery and additional psychological problems. Currently, the most common practice among head and neck surgeons is to withhold oral feeding for a 7 to 10-day period after total laryngectomy (16-20). The use of NGT for feeding after total laryngectomy is a routine practice. This concept developed from concern that early initiation of oral feeding might stress the suture line and result in PCF (16). It is well known that a skin incision heals in a watertight fashion within 24 to 48 hours after surgery. It seems reasonable to assume that the pharyngeal mucosa could do the same in a similar period. Under normal conditions, saliva is swallowed constantly at a rate of 1500 mL/24 h. Saliva is potentially and mechanically as harmful as other swallowed liquids or soft foods. The concept of early oral feeding after laryngectomy stemmed from the realization that most laryngectomy patients begin swallowing their saliva 24 to 48 hours after surgery (20). Furthermore, some authors have thought that the NGT itself is probably more irritating to the suture line than swallowing (6,16). Boyce and Meyers considered that the time of oral feeding has little to do with the development of fistula and the motion of the NG tube is probably more irritating than oral feeding three times a day (17). With both methods, patients swallow their saliva which never lets the pharynx rest totally (17,18). Akyol also believes that oral feeding does not give significant additional stress to the suture line which may cause fistula formation (18). It is also clear that, carrying an NG tube for approximately two weeks is uncomfortable and a major stress factor for the patient in addition to having its own complications. It has been shown that it can also be an ascending path to infect the wound (21). The reported incidence of PCF varies from 1% to 50% (2-6). Horgan and Dedo suggested that the wide variability in the rate of fistulization could be extensively explained by variation in patient selection and surgical technique (22). Hosal et al. also reported a successful series of cases more than a decade ago where postoperative oral feeding without using an NG tube was practiced (23). Aprigliano reported a fistula rate of 9% in a series of 625 patients without using the feeding tube and suggests that the nasogastric tube is not necessary after total laryngectomy (19). However, there is little evidence to support the view that the timing of oral feeding influences fistula formation following laryngectomy, and in most cases, PCF developed before the patients received any oral feeding. Most authors did not delay oral feeding up to the 7th postoperative day unless fever, wound erythema, swelling, or continuous elevated drainage (which raise the suspicion of an impending fistula) were present (6,17,24,25). In our study, one case of fistula occurred in each group with no statistically significant differences between the two groups. This is within the lower range of reported rates. Preoperative radiotherapy is reported as a significant risk factor in the development of pharyngocutaneous fistula (11,26,27). Some authors emphasize that after high dose radiotherapy, not only does the incidence of fistula increase but also hospitalization period is considerably prolonged and surgical treatment is often required to close the defect (28). But some feel that this is not statistically significant (27,29). In our study preoperative radiotherapy was an excluding criteria. We also reviewed some other risk factors for fistula formation including concomitant RND, positive surgical margins, extended hypopharyngeal mucosal resection and tumor stage. According to Horgan and Dedo, RND tends to increase the diameter of the fistula (22). Cavalot et al. stated that the risk of fistula formation in their cases was slightly higher in patients who underwent RND than...
in those who did not (11). Briant, on the other hand, claimed that the role of RND is not important unless the patient has undergone previous irradiation (30). In our cases the differences regarding the rate of fistula formation between patients who underwent RND and those who did not were not statistically significant.

Sarkar reported that involvement of resection margins by the tumor has not been found to influence the complication rates (31). None of our patients had positive surgical margins. The type of surgery is one of the less controversial predisposing factors for fistula development in the literature, but extended laryngectomy invariably carries a higher incidence of fistulization (31-33). Resection of a large amount of pharyngeal mucosa leads to more tension during closure. These wounds are more prone to break down and formation of PCF is anticipated (12). Qureshi et al. reported that the pyriform sinuses disease appeared significantly associated with PCF (34). None of our patients had extended hypopharyngeal mucosal excision.

Tomkinson et al. demonstrated an association between post-operative vomiting and the occurrence of fistula. It is possible that the vomiting was induced either by the developing fistulae itself, before its appearance on the skin surface, or by a metabolic or physiological disturbance that led to both the vomiting and the fistula (13). However, we used antivomiting drugs (methoclopramide, IM) for the first three days after surgery then orally if needed. Prevention of vomiting in the early post-operative period may decrease the incidence of fistula development. Various studies have been conducted to predict fistula as early as possible. The relevance of wound amylase concentration for early detection of PCF has been shown in many studies. An increase in the wound amylase concentration can be a useful marker in the early detection of PCF, thus leading to early rehabilitation (35-37). We routinely do not employ any of the above techniques to detect or diagnose fistulas. Our diagnosis of a fistula is clinical based on factors such as skin flap edema, neck erythema, salivary leak, etc. Most fistulas close spontaneously, but some require multiple surgical procedures. If left untreated it can lead to fatal complications such as carotid artery rupture. In our study all fistulas closed spontaneously with local wound care without surgical intervention except for one case in which gastrostomy was needed for feeding.

CONCLUSION
We may assume that in a selected group of patients, it is possible to initiate oral feeding much earlier in the postoperative period than what was formerly thought.

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