Oral Oncology 72 (2017) 17–25

Contents lists available at ScienceDirect

Oral Oncology

journal homepage: www.elsevier.com/locate/oraloncology

Impact of early prophylactic feeding on long term tube dependency outcomes in patients with head and neck cancer

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ARTICLE INFO

Article history:
Received 8 May 2017
Accepted 24 June 2017
Available online 5 July 2017

Keywords:
Gastrostomy
Enteral feeding
Head and neck cancer
Chemoradiotherapy
Dysphagia
Tube dependency
Post treatment
Oral cancer

ABSTRACT

Objectives: Prophylactic gastrostomy tube (PGT) is frequently used in patients with head and neck cancer (HNSCC). There are concerns this leads to tube dependency but this phenomena is not well defined. This study aimed to determine whether early feeding via PGT impacted on longer term tube feeding outcomes.
Materials and methods: Patients with HNSCC with PGT were observed monthly post-treatment regarding tube use and time to removal up to twelve months. Patients were from a randomised controlled trial comparing an early feeding intervention via the PGT (n = 57) versus usual care which commenced feeding when clinically indicated (n = 67).
Results: Patient characteristics; male (88%), mean age 60 ± 10.1 years, oropharyngeal tumours (76%), receiving chemoradiotherapy (82%). Tubes were used by 87% (108/124) on completion of treatment and 66% (83/124) one month post. No differences in tube use between groups at any time point or tube removal rates over 12 months (p = 0.181). In patients free of disease (n = 99), the intervention had higher tube use at 4 months (p = 0.003) and slower removal rates (p = 0.047). Overall ten patients had their tube in-situ at 12 months (8%) but five were awaiting removal (4% true dependency rate). Of the five patients legitimately using the tube, only one (<1%) was from severe dysphagia post definitive chemoradiotherapy.
Conclusion: PGT use is high in the acute phase post-treatment. Encouraging early use may prolong time to tube removal but it does not increase long term dependency rates beyond four months post treatment. Monitoring tube use is important to prevent over-estimation of dependency rates.
Clinical trial registration: This trial has been registered in the Australian New Zealand Clinical Trials registry as ACTRN12612000579897. Available at http://www.anzctr.org.au.

Introduction

Prophylactic gastrostomy tube (PGT) placement is a common method of nutrition support in patients with mucosal head and neck cancer (HNSCC), however there are concerns this leads to dysphagia and long term tube dependency [1–4]. Some studies have reported nil impact on swallowing function [5,6], and the most recent systematic review on this topic remains inconclusive [7]. As there is no agreed definition of the term gastrostomy dependency, its use can therefore be misunderstood [8]. Although many investigators are now reporting rates of gastrostomy retention it is unclear if patients are legitimately so because of dysphagia, other nutrition impact symptoms or poor nutritional status, or if patients elect to continue gastrostomy use despite no physical barriers to oral nutrition.

Several studies document the predictive factors for long term tube feeding, or gastrostomy dependency, such as tumour sites [9,10], tumour stage [11–15], treatment modality [12,13,16], radiotherapy treatment fields and dose [9,15,17,18], smoking [18], age [12,14,16], and pre-treatment weight loss or low body mass index (BMI) [16,19]. These types of clinical factors are often

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http://dx.doi.org/10.1016/j.oraloncology.2017.06.025
1368-8375/

considered for the prediction of patients who may benefit from PGT placement [20–22], as they are anticipated to require a feeding tube for longer than four weeks and thus a gastrostomy is the most suitable long term feeding device [23]. It is therefore little surprise that these characteristics are also associated with prolonged use.

However prolonged feeding tube use can also be influenced by psychosocial factors [24] as well as ongoing nutrition impact symptoms which continue to effect the patient's nutritional status and intake [25]. Many studies which report on gastrostomy dependency outcomes fail to report adequate information on the patient's nutritional status [26,27] which may be the key reason for prolonged tube feeding. Another limitation of historical studies is the lack of information on the level of allied health input they have received both during and post-treatment for swallowing and nutritional rehabilitation. Maintenance of oral intake during treatment has been shown to reduce the duration of feeding tube use [28]. The role of the dietitian has been identified as important in assisting patients wean from their feeding tube [29] and the prophylactic swallowing exercises prescribed by the speech pathologist are also important to maintain or improve long term swallow outcomes [30,31].

Likewise there is also insufficient detail on the criteria used for decision making regarding gastrostomy removal. Whilst some guidelines advocate a multidisciplinary team decision [20], there is still minimal information in the literature on when it is appropriate to remove a gastrostomy. One study addressed predictors of gastrostomy removal and reported patients with localised HNSCC and those under 65 years old were independent predictors, however this was in a mixed population of HNSCC, other malignancies and neurological indications [32]. Further limitations of this study were that oral intake resumption was used as the reason for gastrostomy removal however there was no additional information on the adequacy of the oral intake or the patients' nutritional status at the time of removal. The lack of evidence in this area means that evidence based guidelines [33,34] are unable to provide clear recommendations to guide clinical practice on gastrostomy removal indications and report the patient should be able to maintain their nutritional status with safe swallowing prior to tube removal [34].

A recent randomised controlled trial comparing an early feeding intervention versus standard care in patients with HNSCC and a PGT prior to treatment has been completed to determine the effectiveness of this early intervention on minimising weight loss [35] with the main outcomes reported elsewhere [36]. This current study is a planned secondary analysis from this trial to determine whether this early feeding intervention had any impact on longer term tube feeding outcomes. In addition, patterns of tube use post treatment and their role in providing nutrition support will be described.

Patients and methods

Participants and study setting

Adult patients with HNSCC were recruited from a tertiary hospital in Queensland, Australia from September 2012 to June 2015 if referred for a PGT prior to treatment based on a validated protocol [37]. Patients identified as high risk from this protocol and recommended a PGT typically received definitive or adjuvant chemoradiotherapy. Other patients may be considered for a PGT based on a consultant decision.

Radiotherapy was delivered using helical-intensity modulated radiotherapy at a standard 2 Gy per fraction, five fractions per week, to a total maximal dose of 60–66 Gy for adjuvant treatment (to the surgical bed) and 70 Gy (to the gross disease) for definitive treatment. Elective nodal irradiation was delivered to bilateral neck using the same technique. Cervical lymph node levels at risk of harbouring subclinical disease were electively irradiated simultaneously to a total dose of 52–54 Gy in 33–35 fractions delivered at 5 fractions per week. Concurrent chemotherapy was prescribed at the discretion of the medical oncologist and usually consisted of high dose cisplatin, weekly cisplatin or cetuximab.

Patients were excluded from the study if: planned for non-curative intent treatment; or were severely malnourished; or were moderately malnourished with significant dysphagia requiring a liquid or puree texture modified diet.

The study was approved by the Royal Brisbane and Women's Hospital Human and The University of Queensland Medical Research Ethics Committees. All patients provided written informed consent to participate. This trial is listed in the Australian New Zealand Clinical Trials registry (ACTRN12612000579897) and the protocol is published for further information [35].

Randomisation

Patients were stratified according to baseline nutritional status and randomly assigned to either the intervention or standard care (allocation ratio 1:1). Simple randomisation procedures were followed with a computer-generated randomisation sequence concealed to the researcher enrolling participants.

Interventions

All patients were seen by the dietitian during overnight admission for PGT placement and then reviewed weekly by the dietitian and speech pathologist in a joint clinic as part of routine care. All patients were encouraged to maintain some level of oral intake during treatment as long as it remained safe to do so.

Patients in the standard care group were commenced on enteral nutrition following assessment by the dietitian during treatment. Patients in the intervention group were commenced on supplemental enteral nutrition immediately following PGT placement prior to commencement of treatment in addition to their current oral intake. The prophylactic enteral nutrition consisted of 2×200 ml bolus feeds (1.5 kcal/ml polymeric formula with fibre) per day and was continued until completion of treatment, increasing as necessary during treatment. Indicators for commencing or increasing enteral nutrition in both groups followed local protocol recommendations [37].

On completion of treatment all patients were referred to their local health service district dietitian and speech pathology service either at the tertiary centre itself or a regional cancer centre in Queensland, Australia. The research dietitian maintained monthly telephone contact with the patient to determine degree of tube use for up to six months post-treatment or until the tube was removed. If the tube was still in situ at six months, then follow up was repeated at 12 months post-treatment.

Outcomes

The primary outcome for this sub-study was the day of tube removal in relation to the day of completion of treatment. The null hypothesis being no difference in time to tube removal between the two groups. The use of the tube at each month was assessed as either: tube removed; tube in situ but not using; tube in situ and using for either 25% or 50% or 75% of nutrition requirements (Supplementary nutrition); or tube in situ and using for 100% of nutrition requirements (with either oral intake as tolerated or nil by mouth due to aspiration risk). Diet texture, classified as either full, soft, minced, puree, or liquids, was recorded at baseline and at three months post treatment.