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Tube feeding during treatment for head and neck cancer – Adherence and patient reported barriers

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ABSTRACT

Objectives: The main aim was to investigate the incidence of patient adherence to nutritional tube feeding recommendations in patients with head and neck cancer and to determine patient barriers to meeting tube feeding prescription.
Materials and methods: This was an observational study from a randomised controlled trial in patients with head and neck cancer deemed at high nutritional risk with prophylactic gastrostomy (n = 125). Patients were randomised to receive early tube feeding prior to treatment (intervention group) or standard care. All patients in the intervention and standard care groups then commenced clinical tube feeding as required during treatment. Patients maintained a daily record of gastrostomy intake, main nutrition impact symptom necessitating gastrostomy use, and reasons for not meeting nutrition prescription. Adherence was defined as meeting ≥75% of total prescribed intake.
Results: Patients were predominantly male (89%), median age 60, with oropharyngeal tumours (78%), stage IV disease (87%) treated with chemoradiotherapy (87%). Primary reasons for gastrostomy use were poor appetite/dysgeusia (week 2–3) and odynophagia/mucositis (week 4–7). Early tube feeding adherence was 51%. Clinical tube feeding adherence was significantly higher in the intervention group (58% vs 38%, p = 0.037). Key barriers to both phases of tube feeding were; nausea, early satiety and treatment factors (related to hospital healthcare processes).
Conclusions: Early tube feeding can improve patient adherence to clinically indicated tube feeding during treatment. Low adherence overall is a likely explanation for clinically significant weight loss despite intensive nutrition interventions. Optimising symptom management and strategies to overcome other barriers are key to improving adherence.
Clinical trial registration: This trial has been registered in the Australian New Zealand Clinical Trials registry as ACTRN12612000579897.

Introduction

Treatment fidelity is important to assess in intervention research trials as it refers to the extent to which interventions are delivered as intended according to the study protocol [1]. It is particularly important for intervention research trials which encompass behavioural change, so that the efficacy of the intervention can be considered in the correct context and inappropriate rejection of potentially effective interventions can be minimised [2]. Treatment fidelity has been described as having at least four core components including: study design and protocol to outline how the intervention should be organised and delivered; training and supervision of those delivering the intervention to ensure consistency; monitoring of intervention delivery to determine whether the intervention was delivered as intended; and monitoring of intervention receipt to determine whether the intervention was received and understood [1,3]. A recent systematic review identified that monitoring of intervention delivery is currently the most widely reported component in the literature, with monitoring of intervention receipt having the least focus [1]. Assessment of intervention receipt can include considerations to

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patient comprehension, engagement and adherence to the intervention [2].

Patient adherence alone is a complex area of treatment fidelity affecting many aspects of healthcare. A number of studies have investigated patient adherence in different aspects of generic multidisciplinary cancer care and their impact on clinical outcomes such as; oral chemotherapy [4,5], analgesics [6,7], and anti-emetic medication [8]. Patient characteristics have been shown to influence adherence to clinical practice guidelines in the critical care setting [9]. It has been reported that patients with head and neck squamous cell carcinoma (HNSCC) have a high rate of mental health problems, substance use and social issues which increases psychologic distress and depression [10], which in this population, can predict malnutrition outcomes [11]. Depression has also been shown to reduce adherence to medical treatment recommendations [12] and so the characteristics of this patient population suggests that adherence may be particularly challenging. Indeed a recent systematic review on swallowing preservation exercises reported low adherence rates in all trials reporting on this outcome (n = 4) [13].

Adherence to dietary advice in patients with HNSCC has rarely been studied. One study defined adherence as patient acceptance of dietary counselling or tube feeding as part of their nutrition program, and found non-adherence resulted in more weight loss [14]. However this did not account for adherence to the dietary advice actually provided. This has been addressed more recently, where a study defined adherence to dietary counselling as consuming $\geq$75% of recommended energy and protein intake, and this confirmed favourable outcomes on body composition parameters with adherence [15].

Nutrition support and intervention is considered an integral component of HNSCC management and includes regular nutrition screening and assessment, dietary counselling and tube feeding interventions, including consideration to prophylactic gastrostomy placement [16]. However despite these intensive recommended nutrition interventions, significant weight loss still occurs [17,18]. A randomised controlled trial (RCT) was initiated to further intensify nutrition intervention through commencement of an early supplementary tube feeding phase via the prophylactic gastrostomy before there were any clinical indicators for tube feeding during treatment [19]. It was hypothesised that this "early tube feeding phase" would reduce fear and anxiety associated with the tube [20], assist patients to adapt to using the tube for when it was required during the "clinical tube feeding phase" to meet nutritional requirements [21], and thus result in less weight loss. There was no difference in the primary outcome of weight loss or secondary outcomes including quality of life, nutritional status, body composition, clinical outcomes and survival [22].

The primary aim of this sub study from the RCT described above was to report on patient adherence to nutritional tube feeding recommendations, as a measure of one component of treatment fidelity, and to determine if there were any differences in adherence following the early tube feeding intervention versus standard care. The second aim was to determine any patient barriers to meeting the prescribed level of tube feeding, during both the early and clinical phases of tube feeding. Once the clinical phase of tube feeding had commenced the final aim was to explore reasons why patients felt they needed the tube for nutrition support, to gain a greater understanding of their experience and perspective.

Patients and methods

Participants and study setting

Patients with HNSCC were recruited from the Royal Brisbane and Women's Hospital (RBWH), a tertiary/quaternary hospital in Queensland, Australia from September 2012 to June 2015. They were included if referred for a prophylactic gastrostomy prior to treatment based on a validated protocol [23]. Patients were randomly assigned using a computer generated concealed allocation sequence to either the early intervention or standard care (1:1). The full trial protocol has been published and describes the full eligibility criteria, randomisation procedures, primary outcome measures and sample size calculation in more detail [19]. The study had ethical approval by the RBWH Human Research Ethics Committee and The University of Queensland Medical Research Ethics Committee. All patients provided written informed consent to participate.

Interventions

Patients were reviewed weekly by the dietitian, speech pathologist, radiation oncologist and medical oncologist, and had access to nursing support and other allied health services as required. Radiotherapy was delivered using helical-intensity modulated radiotherapy at doses of 2 Gy per day to a total 60–70 Gy. Chemotherapy was prescribed at the discretion of the medical oncologist.

Patients in the intervention group had supplemental tube feeding commenced immediately following gastrostomy placement (prior to treatment/surgery) in addition to their current oral intake. The prescription consisted of two bolus feeds (1.5 kcal/ml polymeric formula with fibre) per day (total 400 ml) which continued as a minimum until completion of treatment. This was defined as the "early tube feeding phase" and was only prescribed in the intervention arm. Weekly supplies were provided to the patient and they were all encouraged to maintain oral intake as much as possible.

Once treatment commenced, patients were assessed weekly by the dietitian and in response to clinical criteria, were commenced on tube feeding (standard care) or had tube feeding increased (intervention). Indicators for commencing or increasing enteral nutrition in both groups were stated in the local protocol [23] and included factors such as reduced oral intake, weight loss and/or uncontrolled symptoms. This was defined as the "clinical tube feeding phase" and was possible in both groups. When this phase commenced the patient was given a script requiring copayment to obtain supplies through pharmacy or home delivery. The regimen was determined by the dietitian to suit the patients' individual requirements and adjusted weekly as required. If tolerance was a concern, alternative feed formulas and delivery methods were negotiated and trialled.

On commencement of either phase of tube feeding all patients were provided with weekly diary log books. Patients were asked to record the main reason necessitating gastrostomy use each week, which may have been for the study intervention itself. A checklist of nutrition impact symptoms was provided and included free text space for any other reasons. Patients were asked to complete this step to determine the underlying cause of the triggers for the recommendation to commence clinical tube feeding (i.e. the resultant weight loss or poor oral intake). This patient reported information would also prevent any bias from clinician interpretation of the reasons. Secondly patients were asked to maintain a daily record of gastrostomy intake with any reasons for not meeting nutrition prescription if applicable (free text space). The dietitian collected the diaries from the patients at each weekly review and if incomplete assisted with completion as able with information obtained from interview/assessment.

Outcomes

Daily percentage adherence to tube feeding was calculated from patient diaries based on prescribed versus actual recorded intake