

Feasibility of Home Jejunal Feeding Following Discharge after Major Gastrointestinal Surgery—A Randomised Controlled Trial

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Abstract

Purpose: Following major upper gastrointestinal surgeries, patients often struggle to eat after discharge from hospital. Home jejunal feeding is a potential nutrition support method, but few studies have explored such practice. The aim of this study is to quantitatively and qualitatively assess the feasibility of home jejunal feeding. **Methods:** Thirteen people having had major upper gastrointestinal surgeries were recruited and randomised into one of two isocaloric nutrition support interventions; oral supplement (OS) or jejunal feeding (JF), for one month post-discharge at home. Anthropometric, patient-generated subjective global assessment, food intake and quality of life surveys were collected at baseline, one month and three months post-discharge. Qualitative interviews were conducted with 6 participants after the three month review. **Results:** No statistically significant baseline differences were found between the two groups. At one month post-discharge, median weight loss was found to be significantly greater in OS group compared to JF group, 7.7% (inter-quartile range (IQR) = 7.3) and 0.5% (IQR = 3.5) respectively ($p = 0.035$). No significant differences were found in other parameters. Qualitative interviews showed positive feelings towards JF, while OS was deemed as not very helpful. **Conclusions:** This preliminary research shows the use of home JF is feasible when compared to oral nutrition support. This parallels with the limited existing literature, which indicate that JF is clinically beneficial. Larger studies are required to validate clinical and quality of life outcomes.

Keywords

Jejunal Feeding, Gastrectomy, Oesophagectomy, Nutritional Support, Qualitative Research

*On behalf of the Jejunal Feeding Study Group.

1. Introduction

Patients who have undergone upper gastrointestinal tract surgery face many nutrition-related problems. In particular, anatomical structure of the gut can cause problems such as lack of appetite, reduced functional capacity to eat, reflux, nausea, vomiting and malabsorption [1] [2], leading to malnutrition [3] [4].

Reduced oral intake, malnutrition and malabsorption can be catastrophic to patient recovery and quality of life [5], especially when lost weight is not regained post-surgery [2]. Previous studies have reported that patients experienced over 10% weight loss 3 - 6 months post-oesophagectomy where weight loss was associated with loss of appetite [6] [7]. Similarly, total gastrectomy surgery results in 10% - 15% weight loss within the first year of discharge, in which weight loss was related to reduced intake and was not regained [8] [9] [10] [11].

Early enteral feeding post-surgery has been associated with reduced length of hospital stay and improved clinical outcomes in patients undergoing major upper gastrointestinal surgical resection [12]. The benefits are believed to include the preservation of gut mucosa integrity and improved immunological functioning [13]. However, little is known about nutrition support beyond the first few days post-surgery. After discharge, eating difficulties emerge, making oral nutrition support problematic. The anatomical changes in the gut promote symptoms such as early satiety [7], nausea, vomiting and bloating [14]. These symptoms mean patients are only able to eat small amounts of food [2] [8], cannot meet their full nutritional requirements, and thus experience a decline in nutrition status [4]. This may also impact the tolerance of any further treatments if required [3]. Limited oral intake also means that oral nutrition support may be insufficient in helping patients to recover from upper gastrointestinal surgeries.

Home Jejunal Feeding (JF) could be a promising solution to overcome the challenges that oral feeding poses. Currently there is limited literature looking at the feasibility of home JF in upper gastrointestinal surgical patients. Some studies have found improvements in nutrient status, quality of life and reduced weight loss with the use of home JF compared to oral diet [15] [16] [17], while others have not [18] [19]. Although complications of JF have been reported in previous research [11] [20] [21], qualitative studies have reported positive feelings towards home JF [22] although there are consequences, such as disturbed sleeping pattern and stoma site-related problems.

There has not been any quantitative or qualitative exploration of the feasibility of JF compared to oral nutrition support, where calories, protein and fluid intake are matched. A mixed methods randomised controlled feasibility trial was therefore undertaken within the Australian population to compare the outcomes and experiences of patients receiving JF versus Oral Supplement (OS) support for one month post-discharge from hospital following major upper gastrointestinal surgery, where caloric content and the volume of the feeds were matched in both groups. The aim of this study is to quantitatively and qualitatively explore the feasibility of home JF compared to OS in this patient group.

2. Methods

2.1. Study Design

This was a multi-centre prospective randomised controlled feasibility trial, with additional qualitative analysis. The two arms of the study were 4 weeks of home JF or OS, along with oral eating. The caloric content of the supplemental feeds were matched. The participants and the researchers were not blinded to the randomisation due to the nature of the intervention.

2.2. Participant Selection

Patients who have had total gastrectomy or oesophagectomy were included in this study. Consecutive patients from 4 tertiary hospitals that routinely place jejunal feeding tubes for post-operative feeding in upper gastrointestinal patients were invited to participate. Patients who had non-curative surgery, those who were discharged to facilities other than home, or those with limited English or mental capacity to provide written consent were excluded from the study. The time period for recruitment was from August 2015 to December 2017. All participants received immediate post-operative JF during their inpatient admission. Before hospital discharge, consented participants were randomised to either the OS group or the JF group. Block randomisation were used, stratified for type of surgery and patient-generated subjective global assessment (PG-SGA). Participants were given their assigned nutrition support and were taught how to use the equipment. All the equipment required for JF and OS were supplied for one month free of charge. The JF group received Nutrition Energy™ ± Multifibre™ at 60 mL/hour for 10 hours overnight, and the OS group received three 200 mL serves of Fortisip™ ± Multifibre™ per day. The calorie, protein and volume were matched for the two groups, who received 900 calories, 36 g protein and 600 mL of total volume per day. The enteral and oral supplementation aimed to meet half of the daily energy requirements for an average adult. All participants also received dietary education on a high calorie and high protein oral diet, and were encouraged to have small, frequent meals. Participants remained on the assigned feeding regimen for the duration of one month post-discharge. At one month the dietitian made a clinical decision to continue or cease the intervention based on the individual patient's clinical condition.

2.3. Outcome Measures and Data Collection

2.3.1. Clinical Outcomes

The main clinical outcome measure was weight change between baseline and one month. Other measures included reported symptoms, nutritional status, oral food intake and quality of life. Baseline data was collected while the participant was still an inpatient just prior to discharge. Weekly follow-up phone reviews were conducted at one, two, and three weeks after participants were discharged from the hospital. Phone interviews consisted of a standardised checklist including undertaking a diet history, presence or absence of symptoms, bowel

habits, and intervention tolerance; and advice on jejunostomy care and symptom management. One month and three month follow-up reviews were conducted either by phone or face-to-face. The baseline, one-month and three-month data collection comprised PG-SGA, calorie and protein intake via a diet history, quality of life measure, presence or absence of symptoms checklist and patient-reported compliance with the allocated intervention. Calorie and protein intake was assessed by analysing diet histories (not including oral or enteral supplementation) using Foodworks 2007 (Xyris Software Pty Ltd, Brisbane, Australia).

2.3.2. Quality of Life Measure

Quality of life was assessed using the European Organisation for the Research and Treatment of Cancer version 3.0 (EORTC QLQ-C30) questionnaire [23]. The questionnaire consists of 30 questions and is validated in an oncology setting. There are 3 main measures: global quality of life, functional and symptom measures, and the result is scaled from the responses to questions according to the scoring manual [24]. Higher scores on each measure reflects increased quality of life, except for the symptom scale, which is inverse, where a high score indicates lower quality of life.

2.3.3. Qualitative Interviews

At the end of the three month follow-up, participants were asked whether they would be interested in participating in a qualitative phone interview. Participants were contacted by telephone if they had answered “Yes” to this question. Participants’ carers were invited to attend the interviews as well. The time period for the recruitment for the qualitative interview was from March 2018 to April 2018. Semi-structured interviews were conducted by telephone and designed to explore patients’ physical and emotional experiences while they were receiving OS or JF.

2.4. Data Analysis

2.4.1. Clinical and Quality of Life Analysis

Statistical Package for Social Science version 24 (SPSS Inc, Chicago, IL, USA) was used to perform statistical analyses. Due to the skewed nature of the data, non-parametric statistical analysis was undertaken, and all data is presented as median and inter-quartile range (IQR). Differences between groups were assessed using Chi-square, Mann-Whitney U and Kruskal-Wallis tests. A two-tailed *p*-value of less than 0.05 was considered as statistically significant.

In order to gain clinical significance, a power calculation was performed prior to the start of the trial, indicated that two groups of 30 patients ($n = 60$) would give a power of 80% for detecting an effect size of 0.5 (representing a 2 kg difference between groups). As recruitment was much slower than expected the study was stopped after 2.5 years and hence clinical outcomes were not powered for significance. All data was analysed on an intention-to-treat basis.

2.4.2. Qualitative Analysis

Semi-structured interviews were transcribed and coded using NVivo (10th edition) qualitative computer software program (QRS International 2012), noting patient and carer responses. Inductive thematic data analysis [25] was used to explore themes within the interviews. The transcripts were first coded into broader themes, and further refined to elicit main themes. To enhance the reliability and validity [26], a semi-structured interview format was used. The interviews were reviewed by 2 researchers; interpretations and findings of the interview transcripts were discussed between the 2 researchers.

2.5. Ethics

This study was approved by the coordinating hospital's ethics committee and site specific approval obtained for each hospital that participated in the study.

3. Results

3.1. Participant Characteristics

Thirteen people were recruited to this study. Participant recruitment and progress can be seen in **Figure 1**. Participant demographic and baseline characteristics can be seen in **Table 1**, where no significant differences were observed between the two groups. Participants were recruited from 4 major hospitals within Sydney, Australia. One participant opted out of the study after one month data collection, the response rate at three month data collection was 75%.

3.2. Clinical Outcomes

A significant weight change between the OS and JF group was observed between baseline and one month follow-up (**Figure 2**), where a greater weight loss was observed in the OS group compared to the JF group, 7.7% (IQR = 7.3) and 0.5% (IQR = 3.5) respectively ($p = 0.035$). A similar trend can be observed at three months but the difference was not statistically significant.

At one month follow-up ($n = 12$), dumping syndrome was the most reported complication, which was experienced in 4 out of 5 participants in the OS group, compared to 1 out of 7 participants in the JF group. Diarrhoea was experienced in 2 participants from each group; vomiting and reflux were both experienced in 1 participant from the OS group, and 3 participants from the JF group. There was one reported case of jejunostomy site infection from JF and none from OS. One of the JF group had a blocked tube, which was successfully unblocked and the intervention resumed. One of the JF group had the JF tube fall out after one month. Intervention compliance for the JF group was 100%, compared to 36% in the OS group. Some participants remained on OS or JF after the one month intervention period, and one participant from OS group required JF after the intervention period.

Changes in quality of life scores, nutritional status and oral intake are summarised in **Table 2**. Quality of life measures were not correlated with weight loss,

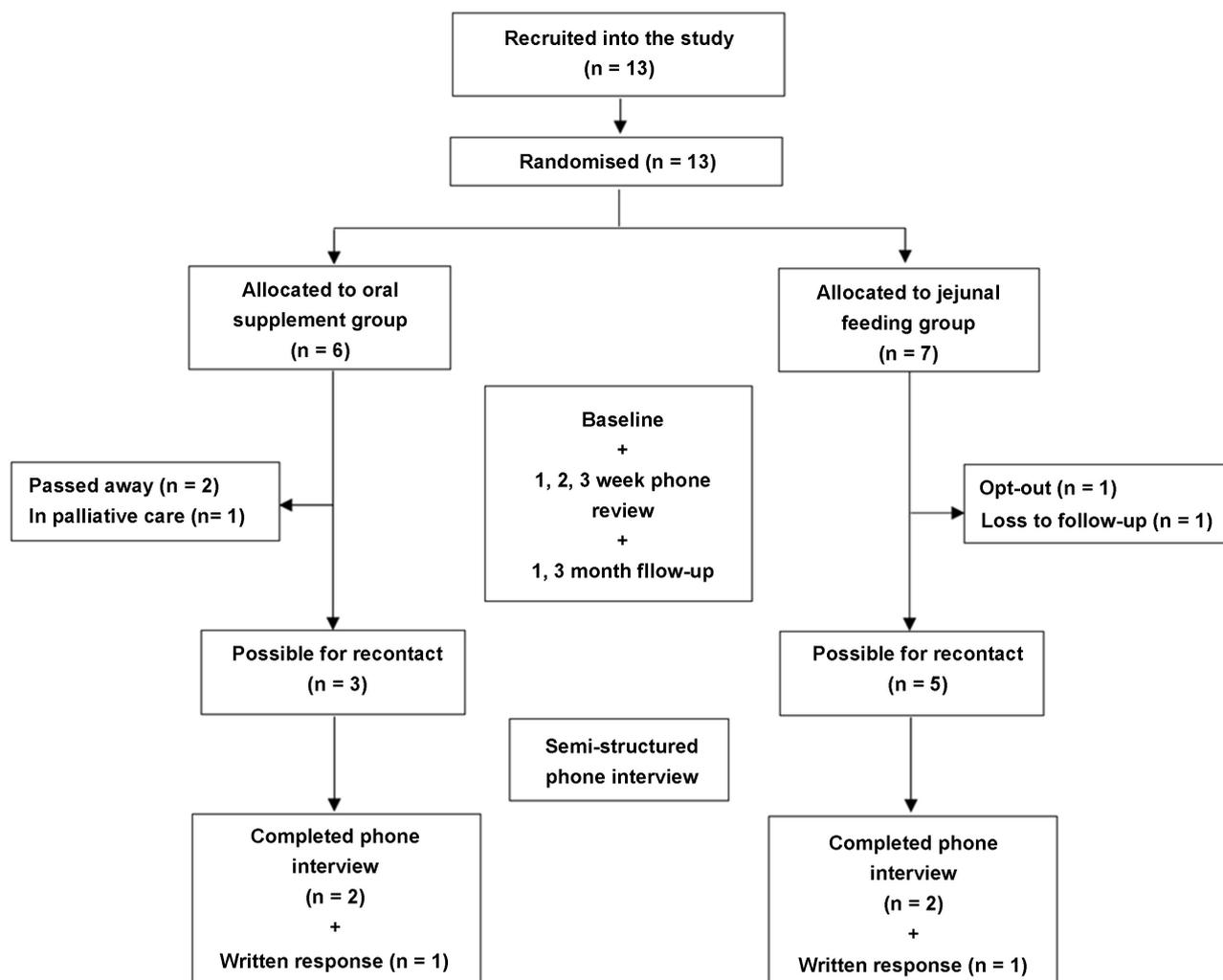


Figure 1. Participant disposition, recruitment and progress diagram.

Table 1. Participant demographics and nutrition profile.

	Oral (n = 6)	Jejunal (n = 7)	Total (n = 13)
Sex (Male:Female), n	5:1	6:1	11:2
Age (years), median (IQR)	67 (11)	63 (11)	63 (12)
Type of surgery, n			
Total gastrectomy	2	2	4
Oesophagectomy	4	5	9
Pre-operative weight loss (%), median (IQR)	1.0 (3.1)	1.2 (3.5)	1.2 (3.1)
Baseline body mass index (kg/m ²), median (IQR)	27.8 (8.7)	32.9 (7.3)	29.1 (8.5)

IQR: Inter-quartile range. No significant differences were found between groups.

change in Body Mass Index (BMI) or time since surgery. No difference in quality of life was observed between OS and JF at any time point.

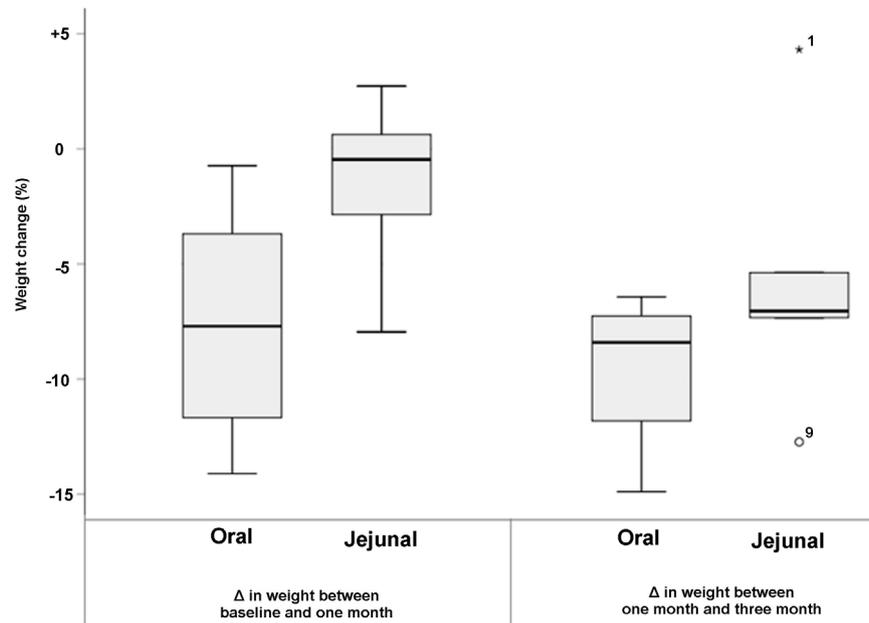


Figure 2. Weight change over time post-hospital discharge. Oral supplement group loss significantly more weight than the jejunal feeding group at one month ($p = 0.035$).

Table 2. Change in weight, nutritional status, intake and quality of life scores at baseline, 1 and 3 months (median and interquartile range).

	Baseline		One month		Three month	
	Oral (n = 6)	Jejunal (n = 7)	Oral (n = 6)	Jejunal (n = 6)	Oral (n = 5)	Jejunal (n = 4)
Weight (kilograms)	97.1 (27.8)	86.0 (24.5)				
Patient-generated subjective global assessment (A:B:C)	2:3:1	3:4:0	0:5:1	1:5:0	1:4:0	1:3:0
Oral Calorie Intake (kilojoules)	5101 (2976)	4228 (3462)	4682 (5987)	3984 (7371)	8140 (9979)	4760 (5034)
Oral Protein Intake (grams)	48.5 (51)	45 (52)	57 (46)	45 (74)	81 (165)	54 (64)
Global QoL	29.2 (27.1)	41.7 (33.3)	50.0 (25.0)	50.0 (16.7)	66.7 (39.6)	66.7 (25.0)
Functional Scales	45.4 (21.7)	62.6 (30.5)	61.1 (12.2)	70.7 (28.3)	80.7 (23.6)	82.3 (9.4)
Symptom Scales	37.7 (30.7)	38.2 (18.8)	39.5 (19.8)	33.3 (21.6)	22.2 (17.1)	18.5 (17.9)

QoL: Quality of life. No significant difference between groups at any time.

3.3. Qualitative Outcomes

Two JF and 2 OS participants agreed to the follow-up qualitative interview, with 3 carers also attending the interview. Interviews lasted from 11 to 32 minutes. Additionally, one JF and one OS participant also provided written responses to the semi-structured interview at the end of the intervention period. Three main themes emerged from the total 6 interviews.

Struggling with eating after surgery. All participants expressed difficulty with being able to judge the correct amount of food they could tolerate to avoid symptoms such as reflux and dumping “mainly pain, because a lot of times you might eat something too big and you have trouble passing it through the small

intestine joining up to your oesophagus, ...you eat too much and you do a fair bit of dumping, ...like diarrhoea.” Participant 7

Tolerance of Invention: When asked how achievable it was to consume OS, participants overwhelmingly felt the OS were not tolerable.

“I always tried it, you know, like, every time the dietician give it to me, I always tried to drink it ...it just didn’t happen, no, just didn’t agree with me ...just made me too sick [diarrhoea, nausea and vomiting], on top of being sick anyway.” Participant 7 (OS)

This was in comparison to the JF group that expressed relief and gratitude to have supplemental feeding.

“I was probably glad I was on that thing [JF] because otherwise I wouldn’t have been able to eat ... being able to take it home was a good thing.” Participant 9 (JF)

Practicality of Intervention: In the JF group, it was clear that the benefits of the intervention outweighed the practical inconvenience. While there were issues with learning to use the pump, caring for the jejunal tube site and so on, these were seen as minor. Participant 4 (JF) mentioned the noise of the pump but weighing the benefit of it made him “had a love-hate relationship with the pump”. Alternatively participants in the OS felt the oral nutrition supplements contributed to their symptoms.

4. Discussion

This study aimed to explore the feasibility of home JF compared to OS on patients who have undergone major upper gastrointestinal surgeries. Participants were randomly allocated to one of the two intervention groups, OS or overnight JF. Despite low participation numbers, baseline participant characteristics were homogeneous. Although the study was not powered for significance, weight change was found to be significantly different between the two groups.

As previous studies have found, eating after major upper gastrointestinal surgery is very challenging [14]. The data from this study indicates that oral intake is not different between people who have JF or OS, in that both groups struggle to manage food after surgery. Previous research looking at providing nutrition support through dietary education and oral nutrition support has shown that oral support alone is not sufficient in preventing significant weight loss [14]. Hence the use of JF needs to be considered. Our study supports previous studies [15] [16] [17] [22] showing JF is feasible and does not negatively impact food intake.

A smaller weight loss in the JF group suggests JF is a good alternative to oral supplements after discharge. Of interest was the weight loss that JF patients experienced once the month of JF finished. This would indicate that JF for 2 - 3 months may be more beneficial to prevent weight loss experienced by this patient group. A study by Gavazzi C *et al.* (2016) found that in 79 patients undergoing surgery for upper gastrointestinal cancer, patients randomised to receive JF at home maintained their weight over a 2 month period, while patients who

received nutrition counselling lost 3.6 kg. Furthermore patients on home JF had a higher chance to complete chemotherapy as planned (48% versus 34%), and there were no differences in QoL reported between groups [27].

The reduced rate of weight loss in patients receiving 6 weeks of home JF following oesophageal-gastric resection have been observed to continue for up to 6 months post-surgery. Bowrey *et al.* (2015) reported that patients who received treatment as usual lost an average 3.9 kg more compared with patients on home JF (95% CI—1.6 - 6.2). The difference in weight loss continued to be observed at 3 months (mean difference 2.5 kg, 95% CI—0.5 - 5.6) and 6 months (mean difference 2.5 kg, 95% CI—1.2 - 6.1) [28].

While this study did not show, and was not powered to show significant differences in quality of life scores with weight loss, other research has shown a correlation between reduced quality of life and weight loss [2]. Hence the positive experience of reduced weight loss may not have been fully realised in this study. An adequately powered study with longer term JF would help to elucidate this and more definitively guide clinical practice.

Qualitative interviews confirm findings from previous research that patients struggle to eat in the initial months after surgery [22]. Analysis of participants' calorie and protein intakes support this. Since eating is already compromised, having OS was not helpful when the participants are not finding eating pleasurable in the first place. Similar to previous studies, participants from this study viewed the benefits of JF as valuable, and the technical problems that arose were easily managed [22]. As participants from both groups showed positive feelings towards JF, we can therefore suggest that JF is a feasible option for post-discharge nutrition intervention.

There are some limitations in this study. Firstly, the number of participants was low, reducing generalisability and increasing the skew of the data. Small numbers make it difficult to find significant differences between or within groups. Secondly, the time frame for qualitative data collection was not controlled. The qualitative interviews were conducted at some time after the intervention period, and were not the same for all participants. This meant that some participants had undergone other surgeries or operations, or had developed other conditions, prior to the interviews. This may have resulted in poor recall of their experiences during the intervention period. Lastly, due to the nature of aging and cancer survivorship, only 50% of the initial participants were able to participate in the follow-up qualitative interview, and this may have influenced the findings.

Nonetheless, our study is the first Australian study to establish the feasibility of home JF for upper gastrointestinal surgery patients, and the first study to control the caloric content between the two interventions that were prescribed. Actual nutrition delivery differed between groups because not all participants in the OS group consumed all oral supplements, and thus we are unable to show a definitive benefit of JF over OS. However if we consider the OS group as usual care, it can certainly be inferred that JF is a safe and beneficial route in which to

support patients' nutritional status post-surgery, and better recovery post-discharge. This research supports further studies into the use of JF within this patient group, with larger sample sizes.

5. Conclusion

In conclusion, this research is a preliminary study looking into the potential of home JF for patients who have undergone major upper gastrointestinal surgery, compared to oral nutrition support. Findings indicate that home JF is a safe and feasible method to deliver valuable nutrition support without causing patients undue stress.

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Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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