



## Original article

## Long term nutritional status and quality of life following major upper gastrointestinal surgery – A cross-sectional study

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## SUMMARY

**Background & aims:** Major upper gastrointestinal surgery results in permanent alterations to the gastrointestinal tract, and previously been shown to impair nutritional status. The aim of this study was to assess long term nutritional status and quality of life in people having had major upper gastrointestinal surgery, and the relationship between the two measures.

**Methods:** People having had major upper gastrointestinal surgery greater than 6 months ago were recruited. Nutrition assessment included weight, anthropometry, Subjective Global Assessment, dietary intake and assessment of gastrointestinal symptoms; quality of life was assessed using the EORTC QLQ-C30 questionnaire. Associations between nutritional status, type of surgery and quality of life were analysed.

**Results:** Thirty people were recruited with fourteen people showing a degree of malnutrition according to subjective global assessment. Total gastrectomy and oesophagectomy surgery resulted in significantly higher percent weight loss than those having undergone pancreaticoduodenectomy ( $p = 0.01$ ). Subjective global assessment correlated with quality of life ( $p = 0.003$ ). Subjective global assessment and gastrointestinal symptoms were both significant variables in explaining quality of life ( $p < 0.001$ ).

**Conclusions:** Nutritional status in this group was significantly compromised, and impacted on quality of life. Individualised nutrition intervention to address malnutrition and gastrointestinal symptoms should be integrated into post surgery management.

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### 1. Introduction

Historically the nutritional consequences of gastrectomy surgery have been documented since the late 1940's. A seminal paper by Visick in 1948 outlined symptoms among 500 patients who had undergone gastrectomy between 1936 and 1947. Symptoms at follow up including pain, fullness, vomiting and weakness (dumping) syndrome were reported. Although these symptoms would invariably result in some nutritional consequences, the author stated that "the degree of disability caused is slight".<sup>1</sup>

Today cancer is the primary reason to undertake major upper gastrointestinal surgeries, such as oesophagectomy, gastrectomy or pancreaticoduodenectomy (Whipples) procedures and survival rates post surgery are relatively modest and are directly related to local or metastatic disease. Further to the risk of recurrence there is significant change in anatomical structure from such surgeries, the nutritional consequences of which impact patient outcomes.<sup>2</sup>

Previous research has demonstrated that patients having undergone total gastrectomy will lose 7–15% of their body weight, usually within the first year of surgery, and will not regain this weight nor return to a pre-operative weight.<sup>3–5</sup> Body composition changes have been reported, with some researchers finding large losses in fat mass, with only small losses in muscle<sup>5</sup> while others report significant losses in both muscle and fat.<sup>3</sup> There appears to

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be no one reason for this weight loss, and it has been associated with malabsorption,<sup>4–6</sup> lower caloric intake,<sup>3–6</sup> higher resting energy expenditure<sup>7</sup> and presence of symptoms.<sup>4</sup>

Published data on the nutritional status of patients having had oesophagectomy and pancreaticoduodenectomy (Whipples) surgery is scarce, and of limited value. In oesophagectomy patients, Martin et al. (2009) reports an average one year post-surgical weight loss of 10%.<sup>8</sup> Another reports weight stabilisation six months post-operatively.<sup>9</sup> Both studies report gastrointestinal symptoms, including odynophagia as possible reasons for the weight loss in post-oesophagectomy patients. In pancreaticoduodenectomy (Whipples) patients there is conflicting research showing an average one year post-surgical weight loss of approximately seven percent with a third of patients having significant fat malabsorption,<sup>10</sup> while others report no weight loss and only mild symptoms of malabsorption in this group.<sup>11,12</sup>

Nutritional status has been linked to quality of life in many disease states, including the oncology population.<sup>13</sup> Although a number of researchers have assessed quality of life in long term survivors of upper gastrointestinal surgery,<sup>14</sup> very few have specifically looked at the link with nutritional status. In this patient group where five-year survival rates are low, quality of life should be considered a key measure.

The nutritional status of this group is still difficult to ascertain, as many studies are outdated, with much improved surgical technique, hospital management and a much different patient group in the past two decades. Previous studies have used a variety of nutrition assessment methods and may only collect data on limited nutrition-related parameters rather than being a comprehensive nutrition assessment. An additional limitation of these studies is that patients are assessed at different stages after surgery, many short term follow-up studies. The aim of the current study was to assess the long term (greater than 6 months after surgery) nutritional status of people who have had major upper gastrointestinal surgery, as defined by either an oesophagectomy, partial or total gastrectomy or pancreaticoduodenectomy (Whipples) procedure. An additional aim was to investigate associations between nutritional status and quality of life.

## 2. Subjects and methods

### 2.1. Study design

Consecutive patients having had major upper gastrointestinal surgery with roux-en-y reconstructive surgery greater than six months ago attending three upper gastrointestinal surgeons clinics were invited to participate in this study. The surgeon's clinics covered surgery from three major hospitals in the Sydney region of New South Wales, Australia. Initial interest for study participation was made by the consulting surgeon before then being contacted by the research Dietitian. Patients with known recurrence of disease, pyloric preserving surgery, inability to consent, or living greater than 2 h from the centre were excluded from the study. Time period for recruitment included from August 2009 to December 2009 from Royal Prince Alfred Hospital, and from May 2010 to August 2010 from Bankstown and Concord Repatriation General Hospital. Two additional people were recruited from an educational evening for people who had been treated for upper gastrointestinal cancer. This study was approved by the Royal Prince Alfred ethics committee, Concord Repatriation General Hospital ethics committee and Sydney South West Area Health Service (Western Zone) ethics committee and ratified by the University of Sydney human ethics committee.

### 2.2. Study measures

#### 2.2.1. Nutritional status

Nutritional Status was assessed:

- (i) Weight was measured using calibrated Seca<sup>®</sup> (Seca 770, Hamburg, Germany) stand-on scales determining weight in kilograms to the nearest 0.1 kg (minimum load 2 kg and maximum load 200 kg). People were in light day clothing. Height and weight at time of surgery were taken from pre-operative medical records. Where these data was not available patient recall was used. Body Mass Index (BMI) was calculated using the standard formula weight (kg)/height (m<sup>2</sup>), and malnutrition deemed  $\leq 20$  kg/m<sup>2</sup> for people aged less than 65, and  $\leq 22$  kg/m<sup>2</sup> for people 65 years of age and over.<sup>15</sup> Percentage weight change was calculated using the formula weight at time of surgery (kg) minus current weight (kg)/weight at time of surgery (kg).
- (ii) Anthropometric measures included tricep skinfold, mid-arm circumference, mid-arm muscle mass and hand grip strength. All anthropometry was performed on the non-dominant arm. Equipment included calibrated Holtain<sup>®</sup> calipers (Holtain LTD, Crymych, UK) and a calibrated Jamar<sup>®</sup> dynamometer (Sammons Preston Rolyan, Bolingbrook, Illinois) and technique in alliance with recommended practice. Triceps skinfold and mid-arm muscle mass were compared to standard percentile ranges for sex and age.<sup>16</sup> Where people were older than 74 years of age, the percentile related to age 64–74 was used. Percentage of normal grip strength was calculated using standard formula as previously documented.<sup>17</sup>
- (iii) Subjective Global Assessment (SGA), a validated nutritional assessment tool<sup>18</sup> using a range of medical factors including weight, weight change, dietary intake and change, gastrointestinal symptoms and functionality; along with a physical examination of sites related to subcutaneous fat and muscle mass. Assessment results in one of three categories being 'well nourished (A)', 'mild-moderate malnutrition (B)' and 'severe malnutrition (C)'.

#### 2.2.2. Dietary intake and requirements

Nutritional intake was assessed using a 3-day food diary, using household measures of weights and fluids. People were asked to record all food, fluid and snacks consumed for 3 consecutive days including details of food preparation methods and any plate wastage. This method of estimating dietary intake has been described in detail elsewhere.<sup>19</sup> Participants were asked to record two weekday and one weekend day, and standard instructions were sent to subjects to facilitate accurate recordings. Food Diaries were analysed using the computerised nutrition package Foodworks 2007 (Xyris Software Pty Ltd., Brisbane, Australia). If people had limited written English skills, a detailed diet history was obtained by the research dietitian instead. Nutritional requirements for energy were calculated using the Schofield equation for estimating energy requirements,<sup>20</sup> where basal requirements were multiplied by 1.5–1.8 activity factor,<sup>21</sup> dependent on reported level of activity. Protein requirements were based on standard requirements for free living individuals, with a range of 0.8–1.0 g/kg per day. Energy and protein requirements were calculated for maintenance of current weight and weights were adjusted for those people with a BMI  $\geq 30$  kg/m<sup>2</sup>, in which an adjusted weight half way between ideal and actual weight<sup>22,23</sup> was used to calculate requirements. Energy requirements were reported in kilocalories; while protein was recorded in grams.

### 2.2.3. Gastrointestinal symptoms

A 15 question Gastrointestinal Symptom Rating Scale (GSRS) was used to assess gastrointestinal symptoms. The GSRS was selected as it has been validated in other gastrointestinal illness<sup>24</sup> and previously used in this surgical population.<sup>25</sup> This self-administered questionnaire addresses total severity of symptoms and also 5 subcategories including abdominal symptoms, reflux, diarrhoea, indigestion and constipation. The higher the score, the greater the degree of symptoms reported. The Visick scale<sup>1</sup> has historically been used in this patient population to record degree of gastrointestinal dumping, and is a four point scale. The four point scale ranges from zero indicating no signs of dumping syndrome up to a score of four, indicating debilitating dumping. It has never been officially validated, but was also scored in this study.

### 2.2.4. Quality of life measure

Measurement of quality of life was assessed using the European Organisation for the Research and Treatment of Cancer version 3.0 (EORTC QLQ-C30) questionnaire.<sup>26</sup> This is a self-administered 30-item questionnaire specifically validated in an oncology setting. It comprises global quality of life, functional and symptom measures. The functional scale takes into consideration physical, role, cognitive, social and emotional measures; while the symptom scale takes into consideration fatigue, nausea and vomiting, pain, dyspnoea, insomnia, appetite loss, constipation, diarrhoea and financial difficulties. Higher scores on the global quality of life and functional scales indicate higher quality of life; while lower scores on the symptom scale indicate lower reporting of symptoms. While this study does not aim to specifically observe people having had surgery due to cancer, this is the leading reason for having major upper gastrointestinal surgery, and so was deemed an appropriate tool for this population.

### 2.3. Statistical analysis

Data was collected on a pre-designed data collection form, de-identified, entered into and analysed using the Statistical Package for Social Sciences version 18 (SPSS Inc., Chicago, IL). Descriptive statistics were expressed as mean and standard deviation. Differences between surgical treatments, measurements of nutritional status, quality of life scores and category of SGA were assessed with ANOVA, using Tukey's post hoc analysis. Pearson's correlation coefficient, partial correlation and multiple linear regression were computed, adjusting for age, to determine associations between the nutrition measures, time since surgery and quality of life. Data for non-participants was collected from medical records including demographics, weight and height; and compared to that of participants using Chi-square and unpaired *t*-tests, to ensure no selection bias. Statistical significance of  $p < 0.05$  was assumed.

## 3. Results

Thirty people (20 males, 10 females) were recruited for this study, with a participation rate of 83%. Differences between participants and non-participants can be seen in Table 1, with no significant differences between the two groups. Basic demographics of those people that participated in the study can also be seen in Table 1. The mean age of the group was 67.9 ( $\pm 13.3$ ) years and mean time since having surgery was 32.2 ( $\pm 26.0$ ) months. All participants with the exception of one had surgery due to neoplasm. The other participant had surgery for severe achalasia. No people received pre-operative nutrition assessment or a standardised nutrition care pathway post-operatively. Five people reported readmission post surgery for nutrition support; three receiving enteral and two receiving parenteral nutrition. At the

**Table 1**  
Comparison between participants and non-participants.

	Participants ( <i>n</i> = 30)	Non-participants ( <i>n</i> = 6)
Male:Female Ratio	20:10	4:2
Age (years)	67.9 ( $\pm 13.3$ )	72.2 ( $\pm 7.3$ )
Body Mass Index (kg/m <sup>2</sup> )	24.3 ( $\pm 4.9$ )	Missing
Percent weight change (%)	-9.8 ( $\pm 10.5$ )	Missing
Type of Operation		
Oesophagectomy	8	1
Total Gastrectomy	5	2
Whipples	9	2
Partial/Subtotal Gastrectomy	8	1
Time since surgery (months)	32.2 ( $\pm 26.0$ )	28.0 ( $\pm 13.3$ )

time of data collection only one participant was having regular monitoring by a Dietitian.

### 3.1. Overall nutritional status

Overall nutritional status can be seen in Table 2. Fourteen people displayed some degree of malnutrition on SGA scores. Mean weight change was -9.8 ( $\pm 10.5$ ) kilograms, and people under the age of 65 had a mean BMI of 27.1 ( $\pm 5.1$ ), while those 65 years of age and over had a mean BMI of 22.8 ( $\pm 4.3$ ); at the lower end of normal. Mean triceps skinfold and mid-arm muscle circumference fell between the 25th and 50th percentile compared to the normal population, and grip strength was 79% of expected. Caloric and protein intake as a percent of estimated requirements was 79.0  $\pm$  20.6 and 118.2  $\pm$  32.9%, respectively. Total GSRS scores showed reporting of mild symptoms (9.1  $\pm$  3.9) with no significant differences between the five symptom categories. The mean score on the Visick dumping scale was 1.4 ( $\pm 0.8$ ).

### 3.2. Time since surgery

Nutritional status, in terms of SGA, BMI, percent weight change, anthropometry, dietary intake and reported symptoms was not correlated with the time since having surgery. Global and symptom quality of life scores were also not correlated, while functional quality of life was negatively correlated with time since surgery ( $r = -0.413$ ;  $p = 0.023$ ). Therefore as time passes since having surgery, functional quality of life deteriorates.

### 3.3. Quality of life

Univariate analysis (ANOVA) was used to examine the relationship between SGA and quality of life, assessed by the EORTC QLQ-C30 as shown in Table 3. In general those with malnutrition had poorer quality of life and more symptoms. Global quality of life was correlated with BMI ( $r = 0.524$ ;  $p = 0.004$ ) and percent weight change ( $r = 0.494$ ;  $p = 0.006$ ) after adjustment for age. Quality of life was not significantly correlated with triceps skin folds, mid-arm muscle circumference, grip strength, or dietary intake.

A stepwise backward linear regression model was used to assess which measures might explain global quality of life for this patient population. All measures of nutritional status including SGA, BMI, percent weight loss, muscle and fat mass, grip strength, and caloric and protein intake were included; along with gastrointestinal symptoms as scored by the GSRS were included in the model. In the final model, only SGA and GSRS were significant in explaining 50.3% of variance in global quality of life, ( $F = 13.646$ ;  $p < 0.001$ ). Both measures recorded high beta values of beta = -0.458 ( $p = 0.003$ ) and beta = -0.441 ( $p = 0.004$ ) respectively.

**Table 2**  
Nutritional measures across surgical groups.

	Oesophagectomy n = 8	Total Gastrectomy n = 5	Whipples n = 9	Partial/subtotal gastrectomy n = 8	Total n = 30
SGA (ratio A:B:C) <sup>a</sup>	4:2:2	1:2:2	8:1:0	3:5:0	16:10:4
Body Mass Index (kg/m <sup>2</sup> )	23.7 (5.2)	20.5 (4.5)	26.7 (4.5)	24.5 (4.4)	24.3 (4.9)
Percent weight change (%) <sup>a,b</sup>	-13.7 (9.7)	-18.6 (12.3)	-1.6 (8.6)	-9.9 (6.2)	-9.8 (10.5)
Tricep Skin Fold (mm)	13.4 (5.2)	13.3 (5.7)	18.3 (10.8)	11.8 (3.8)	14.4 (7.3)
Mid-Arm Muscle Mass (cm)	23.9 (4.1)	21.4 (6.1)	25.6 (4.7)	24.4 (3.8)	24.1 (4.6)
Grip Strength (KG)	33.0 (12.9)	17.8 (7.2)	26.0 (16.0)	29.3 (8.2)	27.4 (12.7)
Nutritional Intake:					
Total Calories (kcal)	1806.2 (372.7)	1285.2 (530.1)	1978.9 (653.0)	1726.4 (238.7)	1749.9 (508.1)
Total Protein (g) <sup>a</sup>	73.8 (15.4)	53.8 (25.5)	88.6 (28.4)	71.5 (10.1)	74.3 (23.1)

<sup>a</sup> significant difference between total gastrectomy and whipples surgery.

<sup>b</sup> significant difference between oesophagectomy and whipples surgery.

### 3.4. Type of surgery

Univariate analysis (ANOVA) was used to assess differences in nutritional status (Table 2), reported symptoms and quality of life across the different surgeries. Statistical differences were seen between people having had total gastrectomy and pancreaticoduodenectomy (Whipples) procedures for SGA ( $F = 3.24$ ;  $p = 0.038$ ), percent weight change ( $F = 4.487$ ;  $p = 0.011$ ) and protein intake ( $F = 3.044$ ;  $p = 0.047$ ). Oesophagectomy surgery also resulted in significantly greater weight loss than pancreaticoduodenectomy (Whipples) surgery ( $F = 4.487$ ,  $p = 0.011$ ). Trends indicate that total gastrectomy surgery results in the greatest nutritional impairment, while pancreaticoduodenectomy (Whipples) surgery had the least impact on nutrition. No significant differences were seen between the surgical groups for GSRs, global quality of life and functional quality of life scores. Symptom quality of life scores, and specifically nausea and vomiting scores were significantly different between total gastrectomy surgery and pancreaticoduodenectomy (Whipples) surgery ( $F = 3.752$ ;  $p = 0.023$  and  $F = 3.357$ ;  $p = 0.034$  respectively). While total gastrectomy surgery has a greater impact on the above quality of life measures; people having had pancreaticoduodenectomy (Whipples) surgery still reported a similar presence of gastrointestinal symptoms on the GSRs ( $9.4 \pm 2.2$  and  $9.5 \pm 4.3$  respectively). Eight of the nine people having undergone pancreaticoduodenectomy (Whipples) surgery had been prescribed pancreatic enzyme replacement therapy.

**Table 3**  
Self reported QOL scores across nutritional groups as defined by SGA.

	SGA = A n = 16	SGA = B n = 10	SGA = C n = 4	Total n = 30
Global QOL <sup>a,b</sup>	78.6 (15.5)	69.16 (16.22)	43.75 (20.8)	70.8 (19.7)
Functional Scale <sup>a</sup>	88.4 (13.8)	84.6 (15.3)	65.6 (20.7)	84.1 (16.5)
Physical <sup>a</sup>	90.4 (21.4)	78.0 (17.2)	63.3 (19.2)	82.7 (21.4)
Role <sup>a,b</sup>	94.8 (11.7)	83.3 (24.9)	50.0 (23.6)	85.0 (23.3)
Emotional	84.9 (24.0)	88.3 (13.2)	72.9 (33.6)	84.4 (22.2)
Social	87.5 (19.7)	88.3 (31.5)	70.8 (28.5)	82.8 (22.5)
Cognitive	84.4 (23.9)	85.0 (14.6)	70.8 (34.4)	85.6 (25.0)
Symptoms Scale <sup>a,b</sup>	12.1 (10.5)	10.4 (6.8)	36.9 (19.9)	14.8 (13.8)
Fatigue <sup>a,b</sup>	21.5 (18.8)	22.1 (15.7)	61.0 (45.0)	26.9 (25.6)
Pain	7.3 (14.6)	11.7 (27.3)	31.3 (29.2)	11.9 (22.2)
Nausea & vomiting <sup>a,b</sup>	10.9 (14.5)	8.9 (12.3)	39.6 (4.2)	14.1 (16.2)
Dyspnoea <sup>a</sup>	4.2 (11.4)	16.7 (17.6)	41.7 (50.0)	13.3 (24.1)
Sleep Disturbance <sup>a</sup>	12.5 (20.6)	16.7 (23.6)	50.0 (43.0)	18.9 (27.2)
Appetite <sup>a</sup>	18.8 (27.1)	10.0 (16.1)	75.0 (31.9)	23.3 (31.7)
Constipation	8.3 (14.9)	6.7 (21.1)	33.3 (27.2)	11.1 (20.2)
Diarrhoea	16.7 (24.3)	0.0 (0.0)	16.7 (33.3)	11.1 (22.0)
Finance	8.3 (19.3)	3.3 (10.5)	8.3 (16.7)	6.7 (16.1)

<sup>a</sup> significant difference between SGA A and C.

<sup>b</sup> significant difference between SGA B and C.

### 4. Discussion

This study aimed to investigate the impact of major upper gastrointestinal surgery on nutritional status and quality of life, excluding the impact of disease. The overall nutritional status of people who have had major upper gastrointestinal surgery was certainly compromised, with significant weight loss following surgery, lower muscle mass, muscle strength and lower fat mass when compared to percentile ranges for age and sex. Forty-seven percent of this study group had some degree of malnutrition as assessed by SGA. Overall BMI was within the healthy weight range, but when comparing the older population to revised BMI standards for people 65 years of age and over, this group was at the lower end of their healthy weight range. Ten percent weight loss, the average weight loss for this group, classifies people at severe nutritional risk according to international terminology.<sup>27</sup>

Dietary analysis indicates that this population is only meeting 80% of their energy requirements, but 120% of protein requirements. However, when considering the possible under reporting involved in using food dairies as a form of diet analysis<sup>28,29</sup> it would appear that caloric intake was adequate to maintain current weight, but not adequate to promote weight gain.

Not only is this reduced nutritional status associated with quality of life, but has also been shown to impact on tolerance of further treatments should they be required.<sup>30–32</sup> This is an important factor considering the high degree of reoccurrence or metastatic disease in this population.

When assessing the impact of specific surgeries on nutritional status, there were significant differences between those people having undergone a pancreaticoduodenectomy (whipples) procedure, compared to that of a total gastrectomy. There were no statistically significant differences between the nutritional status of the other groups. Previous research has also compared the nutritional differences after partial versus total gastrectomy, with overall results indicating no difference in weight loss between the two surgeries.<sup>5–7</sup> However, this study shows strong trends to indicate that those people having undergone total gastrectomy are nutritionally compromised and those undergoing oesophagectomy and partial/subtotal gastrectomy still have considerable nutrition impairment.

The current findings indicate that those people having undergone a pancreaticoduodenectomy (Whipples) procedure have a nutritional status similar to that of the general population, which supports previous findings.<sup>10,11</sup> However, reporting of gastrointestinal symptoms is still similar to that of the other surgical groups. While this study did not measure faecal fat losses, eight of the nine people were prescribed some dosing of pancreatic enzyme replacement therapy which would suggest that there is significant fat malabsorption associated with such surgery, yet if managed does not impact on nutritional status.

In assessing nutritional status over time, the current findings support previous research that this population group rapidly lose weight after surgery, and never regain this weight, even years afterwards.<sup>3–5</sup> This is also the case with reporting of gastrointestinal symptoms. Nutrition support in this population group may be delayed or overlooked with the assumption that their condition will improve with time, but this is not the case. Nutrition support in the initial post hospital months may be vital in preventing nutritional deterioration, including loss of muscle mass and function. Ongoing diet counselling should focus on maintaining nutritional status and managing symptoms.

Quality of life scores were highly correlated with nutritional status when looking at global, functional and symptom scales compared to SGA, BMI and percent weight change. This finding has been supported in other disease states<sup>33</sup> but had not been fully explored in this population previously. Previous research had shown quality of life to be associated with meal size<sup>34</sup> and reporting of symptoms.<sup>35,36</sup> Reduced quality of life in this population appears to be multifactorial, with deleterious nutritional status and gastrointestinal symptoms strong influences. This would support the notion that having individualised nutrition support for this population would be highly beneficial, as both nutritional status and symptom management can be addressed in this setting. While there are no randomised controlled trials to assess the benefits of such a model in this population group, other patient groups have shown improved outcomes when randomised to individualised nutrition support.<sup>37,38</sup>

While it is acknowledged that the results of this study are based on a small sample size, such significant results support a larger, multicentre study to determine whether deficits are substantiated for partial gastrectomy in addition to total gastrectomy and oesophagectomy. The above findings also support further research into the role of long term individualised nutrition support in the post hospital period to prevent nutritional deterioration and improve symptom management, ultimately improving quality of life.

While only a small number of people are suitable for major upper gastrointestinal surgery, and prognosis due to underlying disease is poor, this is a group that is greatly compromised. It is clear that major alterations to the gastrointestinal tract are not without consequences to the nutritional status of the patient, and the degree of symptoms they experience. This significantly impacts on the quality of life of this population group. Future intervention studies are needed to determine best practice models and improve quality of life.

#### Statement of authorship

All authors have contributed to the paper. S Carey designed the research, collected the data, analysed the results and drafted the manuscript. D Storey, A Biankin and D Martin assisted with recruitment of patients, and manuscript review. M Allman-Farinelli and J Young were involved in the design of the research, analysis and interpretation of results and manuscript preparation.

#### Conflict of interest statement

There was no conflict of interest from the authors related to this paper. There was no external funding or sponsorship associated with this project.

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