Quality of life after oesophageal stenting in patients with palliative oesophageal cancer

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ABSTRACT

BACKGROUND AND AIM: Patients with incurable oesophageal cancer have poor outcomes, with disabling symptoms and a poor quality of life (QOL), which may be improved by oesophageal stenting. We aimed to measure change in symptoms related specifically to oesophageal cancer and overall QOL before and 30 days after stent insertion, to measure adverse effects and to define any patient factors that may be significant in predicting patients who may benefit most.

METHODS: We prospectively enrolled patients in an observational study at Middlemore Hospital, New Zealand, and administered validated QOL- and symptomatology-based questionnaires before and 30 days after stent insertion. Additional patient-related demographics, procedural characteristics, adverse events and outcomes were collected.

RESULTS: Between 31 March 2014 and 3 July 2020, 57 patients were initially recruited. Four patients withdrew from the study, and 13 patients died before 30 days. Forty patients (29 males; mean±SD age, 72±12 years) completed the study. A significant improvement was noted at one-month post stent insertion in the overall global QOL score (mean 35 to 46, p=0.01). The most significant score improvements were seen in dysphagia, trouble eating, trouble swallowing saliva and dry mouth (p<0.001). Physical, emotional, cognitive and social functioning did not change. Post-procedural adverse events occurred in 17 patients (43%). A poorer initial level of functioning was associated with reduced improvement in global QOL (p≤0.04). Patients followed-up died a mean of 2.8 months after insertion.

CONCLUSION: In patients surviving longer than 30 days, there is significant improvement of overall QOL and dysphagia one-month post oesophageal stent insertion for malignant, palliative dysphagia. Multiple psychosocial facets were unchanged with this intervention. Stent-related adverse events were common.

Oesophageal carcinoma remains a leading cause of cancer death worldwide, with over 500,000 cases diagnosed in 2018.[1] It is increasing in incidence, with reports of an annual increase of 4.2% per year in Australia.[2–4] In New Zealand in 1950, the age-standardised registration rate was 2.2/100,000 with 46 cases diagnosed, which increased to 4.3/100,000 with 364 cases diagnosed by 2000.[5] Despite advances in diagnosis and screening being available in some countries, over 50% of patients have either unresectable lesions or metastasis at diagnosis.[6] Outcomes are poor for these patients, with an overall five-year survival of less than 5%.[7] In addition, there is a disproportionate incidence in ethnic minorities with poorer global outcomes.[8,9] Averaged over time, excess mortality is 68% greater for Māori oesophageal cancer patients, and patients in the lowest income quintile experience 10% greater excess mortality compared to patients in the highest income quintile.[10]

Quality of life in these patients may be poor. Pain, malnutrition and significant dysphagia are thought to be the most debilitating symptoms.[11] Various endoluminal palliative treatments for dysphagia have been trialled, including dilatation,

photodynamic therapy, laser therapy and brachytherapy.[12] However, oesophageal self-expanding metal stent (SEMS) insertion has become the most widely accepted treatment and is thought to improve quality of palliation.[11,13–17] Nonetheless, there are conflicting data, with some trials utilising specific comprehensive disease-specific questionnaires, wherein stenting is shown to even worsen overall quality of life with inferior outcomes compared to brachytherapy or thermal tumour ablation.[18,19] No studies have been conducted to corroborate findings in Australasia, where health systems may differ not only in delivery of supportive care, but also in personal financial cost. This publicly funded healthcare may reduce financial distress, which is known to lead to maladaptive coping and poor subsequent health and non-health outcomes in palliative cohorts.[20] In addition, the additive effect of palliative care involvement has not been measured.

SEMS insertion also has a known significant adverse event rate, including complication during insertion, requirement for admission post endoscopic procedure, bleeding, pain, reflux, migration, perforation and stent failure.[21] Given the alternative options, possible adverse events, limited life-expectancy and cost, further analysis of demographic or tumour-related factors that may assist in patient selection to help decide which patients may benefit most is currently limited.

The primary aim of our study was to assess change in symptoms related specifically to oesophageal cancer and overall quality of life both before and 30 days after stent insertion. We wanted to secondarily assess procedural adverse effects and perform an analysis to define any factors which may be significant in improving symptoms.

Materials and methods

We completed a prospective, observational study at Middlemore Hospital, Auckland, New Zealand, from 31 March 2014 to 3 July 2020. This is a tertiary centre servicing a population of 550,000.

Patients were included if they had a confirmed diagnosis of oesophageal cancer and were deemed to be for palliative care due to either metastatic extension or co-morbid conditions by a local multidisciplinary team. Patients complaining of dysphagia to liquids (grade 3) or complete dysphagia (grade 4)[22] were considered for stenting. Patients were excluded if they did not consent to enter the study; if they changed their mind and did not wish to complete the final questionnaire; or if they had passed away within 30 days of stent insertion. Demographic and disease details were abstracted from clinical notes, and if the details were unclear, they confirmed at time of initial interview. Additional palliative care services were offered to all patients. Its uptake and length of involvement was also included.

The study received institutional ethics approval by the Counties Manukau District Health Board research review committee, with all patients enrolled with written informed consent. All authors had access to the study data and reviewed and approved the final manuscript.

Questionnaire

Patients were assessed with two sets of questionnaires before the procedure in a one-on-one interview and then via phone call 30 days post procedure.[23] We administered the European Organisation for Research and Treatment of Cancer (EORTC) questionnaire for patients with oesophageal cancer (OES-18) consisting of 18 disease specific questions [24] and the 30-item overall quality of life (EORTC QLQ-C30) questionnaire. The scoring was completed using the EORTC QLQ-C30 scoring manual (third edition).[25] These validated questionnaires include measurement of emotional and social performance indices in addition to physical performance.

Endoscopic procedure

Patients referred by a clinician as either inpatients or outpatients were considered for stenting by three main gastroenterologists (AS, DL, RO) experienced in performing endoluminal stents. All procedures were performed under conscious sedation with xylocaine throat spray and intravenous midazolam and fentanyl. Three main types of stents were used in this study: Niti-S fully covered single layer, Niti-S double-layered stent[26] (Taewoong Medical, Seoul, Korea) and EndoMAXX (Merit Medical). Technique

of insertion and type of stent insertion was left to the discretion of the user. Following insertion, all patients were provided with a detailed post-stent dietary and pain management guide.

Statistical analysis

Sample size calculations were conducted using NCSS PASS 12 (Utah, USA), with dysphagia score as the designated outcome, and showed that a minimum of 36 participants was required to detect a change in 15 points before and after stent insertion with 80% power (β=0.2) and a two-sided statistical significance level of 5% (α=0.05). The standard deviation of normal values was estimated to be approximately 20 to 25 points.

Statistical analysis was performed using IBM SPSS Statistics version 26.0 (New York, USA) and GraphPad Prism version 8.2.0 (California, USA). Data are presented as mean±SD, median (IQR) or number of participants (% of participants), unless otherwise stated. All tests were two-tailed, and $p<0.05$ was considered statistically significant. Comparisons between baseline and post-treatment symptomology scores were performed using the paired t-test. Preliminary univariate linear regression analysis was used to identify potential predictors for the change in symptomology scores. Multivariable linear regression analysis was then conducted incorporating relevant variables with a univariate association threshold of $p<0.15$.

Results

Between 31 March 2014 and 3 July 2020, 57 patients were initially recruited. Four patients withdrew from the study, and 13 patients died before 30 days. Therefore, a total of 40 patients (29 males, 11 females; mean±SD age, 72±12 years) completed the study. Twenty-three patients (58%) had co-existing hypertension and 23% had coronary artery disease and diabetes mellitus. Histological subtypes included 27 (68%) with adenocarcinoma, 11 (28%) with squamous cell carcinoma and 2 (5.0%) patients with other subtypes (Table 1). The mean stricture length was 5cm, with 63% of lesions located in the lower third of the oesophagus. Six patients (15%) received additional chemotherapy, and 15 (38%) received additional radiotherapy. Most patients (80%) accepted and received palliative care input, and 20 of these patients had their initial consultation while in hospital. Their average length of involvement was 2.4 months.

A significant improvement was noted at one-month post stent insertion in the overall global quality of life (QOL) score (mean 35 to 46, $p=0.01$). The most significant score improvements were seen in dysphagia, trouble eating, trouble swallowing saliva and dry mouth ($p<0.001$) (Table 2, Figure 1). Furthermore, there were significant reductions in nausea and vomiting, appetite loss, oesophageal pain and choking (all $p\leq0.03$). Other measured parameters did not significantly alter, such as physical, emotional, cognitive or social functioning. Stenting did not improve fatigue, insomnia or constipation, which remained substantial issues.

Post-procedural adverse events occurred in 17 patients (43%), including pain in seven (18%), reflux in four (10%), bleeding in two (5.0%) and stent migration in four (10%). A total of 16 patients (40%) required further gastroscopy following stent insertion.

Unadjusted univariate and multivariable-adjusted linear regression analysis of predictors of change in global QOL and dysphagia scores are presented in Appendix Table 1. Multivariable regression analysis demonstrated that poorer ASA (American Society of Anaesthesiologists) physical status classification grading[27] and coronary artery disease were associated with reduced improvement in global QOL scores (both $p\leq0.04$), and additional chemotherapy treatment was associated with greater reduction in dysphagia scores ($p=0.02$).

Stents were inserted a mean of 1.5 months after initial diagnosis of cancer, and patients followed-up died a mean of 2.8 months after its insertion (Figure 2).

Discussion

This research demonstrates stenting of advanced, incurable oesophageal cancer results in a substantial 30-day improvement of dysphagia and overall quality of life in patients surviving to this time. However, there is little effect on individual psychosocial outcomes. Secondarily, many patients reported adverse events requiring

Table 1: Baseline and procedural characteristics of patients. Data are presented as mean±SD, median (IQR) or number of participants (% of participants).

Parameter	Value
Demographics	
Age (years)	71.6±12.1
Male sex	29 (72.5%)
Ethnicity	
New Zealand European	22 (55.0%)
Māori	9 (22.5%)
Other ethnicity	9 (22.5%)
Co-morbidities	
American Society of Anaesthesiologists (ASA) physical status classification	
ASA II	21 (52.5%)
ASA III	15 (37.5%)
ASA IV	4 (10.0%)
Body mass index (kg/m^2)	24.6±5.8
Coronary artery disease	9 (22.5%)
Chronic obstructive respiratory disease	5 (12.5%)
Diabetes mellitus	9 (22.5%)
Hypertension	23 (57.5%)
Current smoker	8 (20.0%)
Clinical characteristics	
Previous gastroscopy prior to diagnosis	6 (15.0%)
Anti-reflux medication dose	
None	9 (22.5%)
20mg	1 (2.5%)
40mg	14 (35.0%)
60mg	2 (5.0%)
80mg	14 (35.0%)
Histology	
Adenocarcinoma	27 (67.5%)
Sqamous cell carcinoma	11 (27.5%)
Other histology type	2 (5.0%)
Additional treatments	
Chemotherapy	6 (15.0%)
Radiotherapy	15 (37.5%)
Length of palliative care involvement (months)	2.4 (0.8–6.2)

Table 1: Baseline and procedural characteristics of patients. Data are presented as mean±SD, median (IQR) or number of participants (% of participants) (continued).

Parameter	Value
Procedural characteristics	
Conscious sedation	40 (100.0%)
Image intensifier use	24 (60.0%)
Stent crossing gastro-oesophageal junction	22 (55.0%)
Tumour location	
Middle third	15 (37.5%)
Lower third	25 (62.5%)
Stricture length (cm)	5.4±2.2
Stent type	
EndoMAXX	22 (55.0%)
Niti-S covered	18 (45.0%)
Stent length	
100mm	17 (42.5%)
120mm	16 (40.0%)
150mm	7 (17.5%)
Stent diameter	
18mm	31 (77.5%)
24mm	9 (22.5%)
Outcome	
Length of hospital admission following stent insertion (days)	1 (0–2)
Complications	17 (42.5%)
Pain	7 (17.5%)
Reflux	4 (10.0%)
Bleeding	2 (5.0%)
Stent migration	4 (10.0%)
Further gastroscopy performed following stent insertion	16 (40.0%)
Time from diagnosis to stent insertion (months)	1.5 (0.5–7.6)
Time from diagnosis to death (months)	7.8 (3.3–13.3)
Time from stent insertion to death (months)	2.8 (1.5–6.3)

Table 2: Baseline and one-month post-treatment symptomology and quality of life (QOL) scores. Data are presented as mean±SD.

Parameter	Baseline	Post-treatment	Change	*P* value
EORTC QLQ-C30				
Global health status				
Quality of life	34.6±22.6	45.5±26.9	+10.9±27.4	0.01
Functional scales				
Physical functioning	56.8±28.9	55.8±29.9	-1.0±28.9	0.83
Role functioning	49.2±35.8	49.2±34.8	+0.0±31.4	>0.99
Emotional functioning	64.8±26.0	66.9±29.9	+2.1±28.4	0.51
Cognitive functioning	64.2±32.8	66.3±29.6	+2.1±26.7	0.63
Social functioning	50.4±35.7	54.6±36.8	+4.2±40.3	0.51
Symptom scales and items				
Fatigue	66.7±27.3	61.4±31.7	-5.3±19.5	0.09
Nausea and vomiting	42.5±28.0	29.2±31.3	-13.3±31.8	0.01
Pain	37.9±32.5	37.1±33.0	-0.8±28.2	0.85
Dyspnoea	30.8±33.2	32.5±32.0	+1.6±35.0	0.64
Insomnia	47.5±36.9	40.8±38.1	-6.7±36.4	0.24
Appetite loss	72.5±34.5	56.7±40.1	-15.8±44.6	0.03
Constipation	47.0±35.6	40.4±38.9	-6.7±37.4	0.31
Diarrhoea	12.5±25.8	6.8±19.0	-5.7±30.1	0.20
Financial difficulties	32.5±35.8	26.5±32.6	-6.0±32.2	0.34
EORTC QLQ-OES 18				
Symptom scales and items				
Dysphagia	65.8±27.6	31.1±18.5	-34.7±34.8	<0.001
Trouble eating	68.3±23.8	39.5±25.9	-28.8±27.5	<0.001
Reflux	36.3±37.0	34.6±27.6	-1.7±32.2	0.70
Oesophageal pain	33.1±30.1	24.2±20.4	-8.9±25.6	0.03
Trouble swallowing saliva	47.0±36.4	19.2±31.9	-27.8±48.5	<0.001
Choking	34.2±37.1	12.8±22.4	-21.4±37.5	<0.001
Dry mouth	50.4±38.9	25.6±28.1	-24.8±37.7	<0.001
Altered taste	35.8±38.8	32.5±35.4	-3.4±40.8	0.76
Cough	35.8±37.3	28.2±32.0	-7.6±41.2	0.19
Trouble talking	21.7±31.6	13.7±22.6	-8.0±38.3	0.16

Figure 1: Baseline and one-month post-treatment global quality of life and dysphagia scores. Each point represents the score of an individual patient. Bars represent the mean score, and error bars represent the standard deviation.

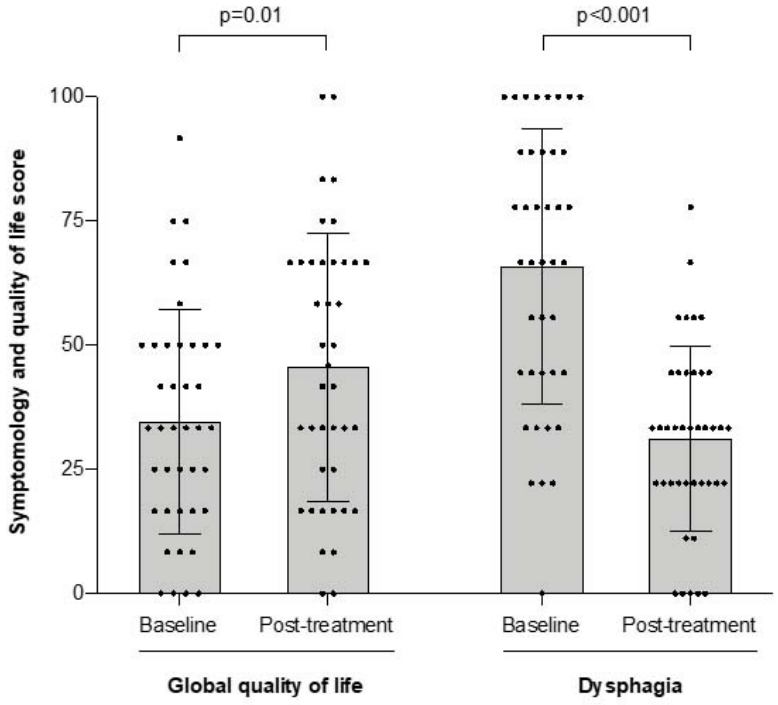
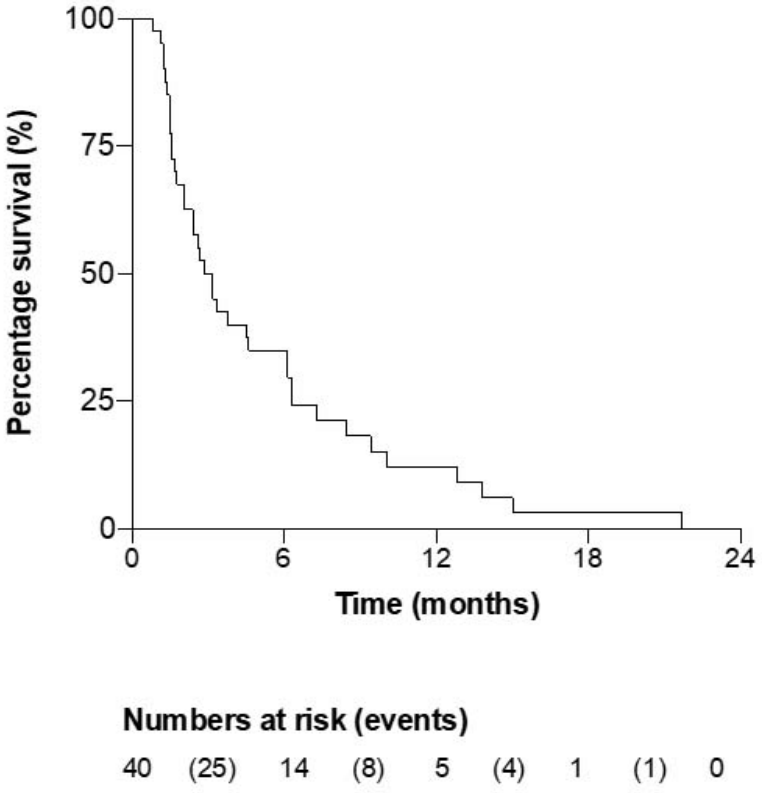


Figure 2: Kaplan–Meier survival curve following initial diagnosis of oesophageal cancer (excludes death prior to 30 days).



further medicalisation. Other than initial poorer overall physical status, there are no predictive features to indicate which patients may benefit the most from stenting.

A similar paper from an Indian cohort using a different brand of SEMS noted similar findings, but the paper also recorded significant improvements in fatigue, insomnia, constipation and financial strain[15] The latter may be in part explained by the New Zealand medical system, whereby patients are covered by fully subsidised national healthcare and are therefore not financially impacted by having to pay for endoscopy, stenting and supplementary medical care. Of note, stenting is thought to be cost effective.[17]

Another prospective study in malignant but not palliative dysphagia from America that only included patients requiring stenting of the distal third of the oesophagus or the gastroesophageal junction (GOJ) also noted improvements in dysphagia and overall quality of life.[28] They noted significant reflux in the first two weeks and improvements thereafter, which was also our experience in the 55% of patients in our cohort in whom the stent crossed the GOJ. Four patients in our study had very severe reflux and had a repeat endoscopy for this reason. In the American cohort, patients had neoadjuvant chemotherapy, with a subsequent 63% stent migration rate, which corresponded to a pathological response in 85% of these patients.[28] Two out of the four cases of stent migration in our cohort also occurred in patients receiving chemotherapy or radiotherapy, highlighting the likelihood of this occurrence in these clinical situations.

Similar rates of adverse events were also noted in other studies, including a 21–39% reintervention rate for stent blockage, overgrowth or migration.[15,17,29] A cohort from the Netherlands using through-the-scope (TTS) placement noted adverse events in 63%.[30] Although we did note a similarly high rate of adverse events, there were no instances of aspiration, haemorrhage or perforation, as noted in 6/32 patients (19%) in the Dutch study. Unlike in our study, many of these studies performed pre-stent dilation,[15,18] which, in a malignant stricture, poses large risks in itself.[31] This study included use of stents containing nitinol, known for improved conformability and a smaller profile compared to earlier woven stainless steel stents described in some of the previous studies.[13,29] Without appropriately designed research, we cannot draw conclusions about whether this may have improved safety with less serious adverse events. Of the 13 deaths prior to one month, one patient died suddenly after 14 days of haematemesis, but it was not clear that this was stent related, and no post-mortem was undertaken; the other 12 were not thought to be stent related. Our overall adverse event rate of 43% is in keeping with other series[32–34] and should be used to both educate and consent patients to help manage expectations for this procedure.

This study illustrates the importance of patency of swallow on overall quality of life. Dysphagia is known to be an incredibly disabling symptom, and improvement of dysphagia (>50% improvement on EORTC QLQ-OES 18 scale) led to an overall improvement in quality of life, despite limited improvement in other important parameters. Interestingly, although there was no improvement in overall pain, there was a small and statistically significant improvement in oesophageal-specific pain (-9 points, p=0.03). Madhusudhan and colleagues noted initial worsening of pain post stent, with a gradual reduction to baseline levels, but similarly no overall improvement in scores.[15] This should remind clinicians of the limits of our endoscopic intervention, with the incredible multifactorial burden and stress of this diagnosis seen in these patients with ongoing high levels of not only physical pain, but also emotional, cognitive and social distress, which we must aim to address with additional supportive care measures.

The mean survival of only 2.8 months after stent insertion shown in this study suggests that any additional treatment needs to be given without delay. Waiting the estimated 4–6 weeks required for improvement in dysphagia with primary palliative radiotherapy[35] is wholly unsatisfactory. This poor prognosis is in keeping with other large series.[18,29,36] With a meaningful and rapid improvement in quality of life and short estimated life expectancy, it could be appropriate to argued for prompter referrals for palliative stenting. We were able to place all

the stents under conscious sedation, with 16 patients (40%) discharged as day-cases, suggesting expeditious referrals could feasibly be performed quickly. Furthermore, this study was the first to measure the additive palliative care involvement, which was accepted by 80% of patients for an average of 2.4 months. There was no significant impact on any quality-of-life factors with regard to its uptake or length of involvement.

Poorer overall ASA physical status classification, and coronary artery disease specifically, were associated with reduced quality of life scores, reflecting a poorer outcome in a cohort that (as could be expected) are co-morbid, physically frail and diminished. Standard palliative intent platinum-based chemotherapy may prolong overall survival by less than one month, with some additional improvement in quality of life, including dysphagia. These changes in quality of life may take some time to come into effect, and patients may opt to forgo this option given the known higher treatment-related toxicity.[37] In our study, only additional chemotherapy treatment was associated with reduction in dysphagia scores, whereas concomitant radiotherapy was not, confirming that the routine additive effect of radiation is minimal once a stent is sited.[38] We feel that very frail and co-morbid patients with a high ASA score in particular should be carefully discussed, informed and consented of the likelihood of adverse events that may also require repeat endoscopy, in the context of possible very short life expectancy and a lesser improvement of overall quality of life.

Strengths of this paper include use of detailed validated questionnaires including the disease-specific oesophageal cancer (OES-18) score. The prospective nature allowed for complete and accurate data collection.

The results of this paper must be interpreted in the context of some important limitations. Final analysis of these data excludes 13 patients who died prior to 30-day follow-up, which may lead to possible bias.

Most notably, potential factors that may confound emotional and psychosocial outcomes, such as social support networks, health literacy, access to healthcare and financial reserves, were not collected. Additional therapies, such as brachytherapy, are not widely available in our centre and therefore additive effects of these interventions that may be beneficial were not able to be assessed.[18,39] It was difficult to discern causality with some of the adverse events noted, which may have been related to disease progression as opposed to the stent intervention.

In conclusion, despite a considerable proportion of patients developing stent-related adverse events, there is significant improvement of overall quality of life and dysphagia in patients who survive to one-month post oesophageal stent insertion for malignant, palliative dysphagia. Multiple psychosocial facets are not improved with this intervention.

This manuscript was originally published as clinical correspondence. It was republished as an original article on 16 November 2021.

Appendix

Appendix Table 1: Linear regression analysis of predictors of change in global quality of life and dysphagia scores.

	Univariate linear regression		Multiple linear regression	
	Standardised coefficient	***P* value**	**Standardised coefficient**	***P* value**
Change in global quality of life score				
Age (years)	-0.131	0.42	-	-
Male sex	-0.079	0.63	-	-
Ethnicity				
New Zealand European	-0.014	0.93	-	-
Māori	-0.107	0.51	-	-
Other ethnicity	0.124	0.45	-	-
ASA physical status classification grade	-0.320	0.04	-0.381	0.002
Body mass index (kg/m^2)	0.180	0.27	-	-
Coronary artery disease	-0.247	0.12	-0.311	0.04
Chronic obstructive respiratory disease	-0.153	0.35	-	-
Diabetes mellitus	-0.015	0.93	-	-
Hypertension	-0.143	0.38	-	-
Current smoker	-0.067	0.68	-	-
Previous gastroscopy prior to diagnosis	-0.084	0.61	-	-
Anti-reflux medication dose (mg)	-0.201	0.22	-	-
Adenocarcinoma versus squamous cell carcinoma histology type	0.128	0.44	-	-
Additional chemotherapy	0.048	0.77	-	-
Additional radiotherapy	-0.146	0.37	-	-
Middle versus lower third tumour location	0.005	0.24	-	-
Stricture length (cm)	-0.030	0.88	-	-
EndoMAXX versus Niti-S covered stent type	-0.052	0.75	-	-
Length of palliative care involvement (months)	-0.136	0.42	-	-

Appendix Table 1: Linear regression analysis of predictors of change in global quality of life and dysphagia scores (continued).

	Univariate linear regression		Multiple linear regression	
	Standardised coefficient	***P* value**	**Standardised coefficient**	***P* value**
Change in dysphagia score				
Age (years)	0.095	0.56	-	-
Male sex	0.120	0.46	-	-
Ethnicity				
New Zealand European	0.078	0.63	-	-
Māori	0.094	0.56	-	-
Other ethnicity	-0.188	0.25	-	-
ASA physical status classification grade	0.267	0.10	0.199	0.18
Body mass index (kg/m^2)	-0.140	0.39	-	-
Coronary artery disease	0.039	0.81	-	-
Chronic obstructive respiratory disease	-0.140	0.39	-	-
Diabetes mellitus	0.057	0.73	-	-
Hypertension	0.174	0.28	-	-
Current smoker	-0.032	0.85	-	-
Previous gastroscopy prior to diagnosis	-0.027	0.87	-	-
Anti-reflux medication dose (mg)	-0.125	0.44	-	-
Adenocarcinoma versus squamous cell carcinoma histology type	-0.234	0.16	-	-
Additional chemotherapy	-0.429	0.006	-0.368	0.02
Additional radiotherapy	0.125	0.44	-	-
Middle versus lower third tumour location	0.251	0.14	0.121	0.43
Stricture length (cm)	0.236	0.15	-	-
EndoMAXX versus Niti-S covered stent type	0.109	0.52	-	-
Length of palliative care involvement (months)	-0.0234	0.89	-	-

Competing interests:
Nil.
Acknowledgements:
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