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Quality of life after palliative treatment for oesophageal carcinoma – a prospective comparison between stent placement and single dose brachytherapy

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Abstract

Metal stent placement and single dose brachytherapy are commonly used treatment modalities for the palliation of inoperable oesophageal carcinoma. We investigated generic and disease-specific health-related quality of life (HRQoL) after these palliative treatments. Patients with dysphagia from inoperable oesophageal carcinoma were randomised to placement of a covered Ultraflex stent ($n = 108$) or single dose (12 Gy) brachytherapy ($n = 101$). We obtained longitudinal data on disease-specific (dysphagia score, European Organisation for Reasearch and Treament of Cancer (EORTC) OES-23, visual analogue pain scale) and generic (EORTC Quality of Life-Core 30 Questionnarie (QLQ-C30), Euroqol (EQ)-5D) HRQoL at monthly home visits by a specially-trained research nurse. We compared HRQoL between the two treatments and analysed changes in HRQoL during follow-up. Dysphagia improved more rapidly after stent placement than after brachytherapy, but long-term relief of dysphagia was better after brachytherapy. For generic HRQoL, there was an overall significant difference in favour of brachytherapy on four out of five functional scales of the EORTC QLQ-C30 (role, emotional, cognitive and social) ($P < 0.05$). Generic HRQoL deteriorated over time on all functional scales of the EORTC QLQ C-30 and EQ-5D, in particular physical and role functioning (on average −23 and −24 on a 100 points scale during 0.5 years of follow-up). This decline was more pronounced in the stent group. Major improvements were seen on the dysphagia and eating scales of the EORTC OES-23, in contrast to other scales of this disease-specific measure, which remained almost stable during follow-up. Reported levels of chest or abdominal pain remained stable during follow-up in both treatment groups, general pain levels increased to a minor extent. The effects of single dose brachytherapy on HRQoL compared favourably to those of stent placement for the palliation of oesophageal cancer. Future studies on palliative care for oesophageal cancer should at least include generic HRQoL scales, since these were more responsive in measuring patients' functioning and well-being during follow-up than disease-specific HRQoL scales.

Keywords: Oesophageal cancer; Quality of life; Stent placement; Brachytherapy; Palliation

1. Introduction

Oesophageal cancer is associated with a poor prognosis with a 5-year survival rate of around 10% [1,2]. More than 50% of patients with oesophageal cancer have inoperable disease at presentation and most of these patients develop progressive dysphagia [3]. Palliative treatments aim to relieve dysphagia with minimal morbidity and mortality. Two widely used treatment modalities for palliation of malignant dysphagia include self-expanding metal stent placement [4–7] and single dose brachytherapy [8–11].

The preservation of health-related quality of life (HRQoL) is an important goal of palliative treatment,

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and therefore HRQoL should be an outcome measure in trials comparing palliative treatment modalities [12]. In most studies, relief of dysphagia is the only aspect of HRQoL being measured, although physical, mental and social functioning and other oesophageal cancer-specific aspects of HRQoL are additional important outcome measures. HRQoL is commonly assessed by combining generic and disease-specific measures. Various validated measures are available to assess generic HRQoL after cancer treatment [13,14]. In addition, measures for the assessment of disease-specific HRQoL have been developed, and these have been suggested to be more specific for measuring differences in outcome between various treatment modalities for oesophageal cancer [15].

We conducted a randomised trial comparing metal stent placement with single dose brachytherapy for the palliation of oesophageal cancer. Longitudinal data on HRQoL before treatment and during follow-up were obtained. We compared these two treatment modalities with respect to generic and disease-specific HRQoL. In addition, we determined the changes of HRQoL in patients with oesophageal carcinoma during follow-up.

2. Patients and methods

2.1. Study population

Between December 1999 and July 2002, 209 patients with inoperable cancer of the oesophagus or oesophagogastric junction due to metastatic disease and/or a poor medical condition with progressive dysphagia were randomised to metal stent placement ($n = 108$) or single dose brachytherapy ($n = 101$). Patients were treated with a covered Ultraflex stent (Boston Scientific, Natick, MA, USA) or a single dose of 12 Gy brachytherapy (intraluminal radiotherapy). Patients were included and treated in three university hospitals and six general hospitals in the Netherlands. The study was approved by the Central Committee on Research Involving Human Subjects in The Netherlands. The results of this study in terms of clinical outcome [16] and costs [17] were reported previously.

2.2. Health-related quality of life assessment

Disease-specific quality of life was assessed with the dysphagia score [18], the oesophageal cancer-specific European Organisation for Research and Treatment of Cancer (EORTC) OES-23 measure [15] and a visual analogue pain scale. Dysphagia was scored as follows: score 0, ability to eat a normal diet; score 1, ability to eat some solid food; score 2, ability to eat some semi-solids only; score 3, ability to swallow liquids only; score 4, complete obstruction [18]. The EORTC OES-23 measure determines disease-specific HRQoL which is relevant to patients with oesophageal carcinoma. It incorporates six multi-item scales (dysphagia, deglutition, eating, indigestion, chest/abdominal pain and emotional) and four single symptoms (having a dry mouth, troublesome taste, troublesome coughing and troublesome talking). The original measure has one extra symptom (hair loss). This item was removed because it was not applicable to the treatments under investigation. Before the start of the study, a Dutch translation was validated according to EORTC guidelines. Answer categories of the questions ranged from 'not at all' (scored as 1) to 'very much' (scored as 4). We used a visual analogue pain scale consisting of a horizontal line of 10 cm in length on which patients were asked to score the severity of pain that they experienced, from 'no pain' to 'the most severe pain they could imagine'.

Generic HRQoL was assessed using the oncology-specific EORTC Quality of Life-Core 30 Questionnaire (QLQ-C30) measure [14], and the Euroqol (EQ)-5D [13] including an index score and a visual analogue scale (EQ-VAS) for self-rated health. The EORTC QLQ-C30 covers aspects of generic quality of life specific for cancer patients. The EORTC QLQ-C30 incorporates nine multi-item scales: five functional scales (physical, role, cognitive, emotional and social), three symptom scales (fatigue, pain and nausea and vomiting), and a global health/quality of life scale. Various single symptoms are included as well. The scoring system is equivalent to the scoring system of the EORTC OES-23; answer categories on the questions ranged from 'not at all' (scored as 1) to 'very much' (scored as 4). Scores on the items for the global health/quality of life scale ranged from 1 ('very poor') to 7 ('excellent'). The EQ-5D assesses 5 dimensions including mobility, self-care, usual activities, pain/discomfort and anxiety/depression. For each dimension, patients mark one of three levels of severity (level 1 = no problems, level 2 = some/moderate problems, level 3 = severe/extreme problems), which subsequently can be classified into one of 243 (3^5) possible health status profiles. Each profile can be linked to an index score based on empirical preferences for health status from an English general population sample [19]. The EQ-VAS is a 20 cm vertical visual analogue scale on which patients are asked to rate their overall health between 0 ('worse imaginable health state') and 100 ('best imaginable health state').

Patients were prospectively followed by home visits of specially trained research nurses at 14 days, 1 month and then monthly until one year after treatment. After one year of follow-up, patients were visited every 3 months, and/or telephone calls to the patient and the patients' practitioner were made until death. The EORTC OES-23, EQ-VAS and visual analogue pain scale were filled out before treatment and during each home visit; the EORTC QLQ-C30 and EQ-5D were filled out before treatment, and 1, 3, 6, 9 and 12 months after treatment. The baseline HRQoL questionnaires were completed

Table 1
Clinical characteristics of 209 patients randomised to brachytherapy or stent placement for palliation of dysphagia due to inoperable carcinoma of the oesophagus or oesophagogastric junction

	Brachytherapy ($N = 101$)	Stent placement ($N = 108$)
Age (mean ± SD)	69 ± 13	69 ± 11
Male/female	76/25	86/22
Tumour histology		
Squamous cell carcinoma	29 (29%)	29 (27%)
Adenocarcinoma	69 (68%)	75 (69%)
Other	3 (3%)	4 (4%)
Dysphagia score before treatment (mean ± SD)	2.8 ± 0.9	2.8 ± 0.7

SD, standard deviation.

with help from one of the physicians or the principal investigator, whereas questionnaires during follow-up were completed with help from the research nurses. Clinical baseline and follow-up data were obtained from all patients. The response of the quality of life measures was almost 95% during the entire follow-up period (in total 681/724 (94%) questionnaires were collected in the brachytherapy group and 717/752 (95%) in the stent group).

3. Statistics

Analyses were performed on an intention-to-treat basis. The occurrence of clinical endpoints was analysed with Kaplan–Meier curves and log rank tests [16]. The dysphagia scores at different time points between treatment groups were compared with a linear regression model that included the baseline dysphagia score to adjust for any pre-treatment differences between the groups. Time was included as a restricted cubic spline function, which was chosen because of its flexibility and smoothness [20]. The interaction between time and treatment group was also included to allow for the presence of different time courses in the two groups.

The HRQoL measures were scored according to standard scoring algorithms to obtain scores for the various multi-item scales for the EORTC OES-23 [15] and EORTC QLQ-C30 [14] and the index and VAS scores for the EQ-5D [19]. For the EORTC OES-23 and EORTC QLQ-C30, the crude scores for the individual items within a scale were first summed, and then divided by the number of items within the scale. Then, these scores were linearly transformed such that all scales ranged from 0 to 100 with a higher scale score representing a higher level of functioning. For the symptom scales and single symptoms of both measures, higher scores are equivalent to a higher level of symptoms. For the EQ-5D index score and the EQ-VAS, higher scores represent a better health status. We compared quality of life scores of both treatments with analysis of repeated measurements [21]. For each scale, a model was fitted that included day and treatment group as fixed factors, and the baseline measure and interaction between day and treatment group as covariates. A simple compound symmetric covariance structure was assumed to hold for all scales.

For the analysis of the changes of HRQoL during follow-up, a model was fitted for each scale with time as a linear factor. In case of interaction between both treatment modalities (with a P-value of <0.10), this model was fitted separately for each treatment, otherwise one model was fitted for the whole group. For the dysphagia and eating scale of the EORTC OES-23, two phases were described: an acute phase (<30 days after randomisation) and a chronic phase (>30 days after treatment), as these scores did not follow a reasonable linear pattern in time. For each phase, a separate line was fitted. Calculations were performed with the stastical package for the social sciences (SPSS) 10.1 (SPSS Inc., Chicago, IL, USA) and SAS 8.2 (SAS Institute Inc., Cary, NC, USA).

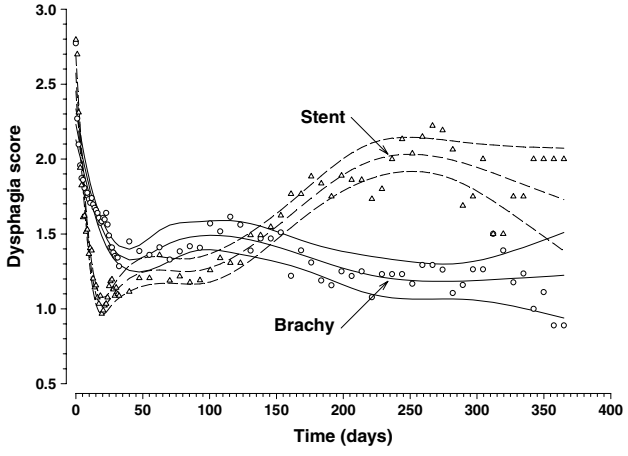

Fig. 1. Dysphagia scores (scored on a scale from 0 (normal) to 4 (complete dysphagia)) in patients randomised to brachytherapy ($n = 101$) or stent placement ($n = 108$) for dysphagia due to inoperable carcinoma of the oesophagus or oesophagogastric junction. The symbols △ and ○ represent mean dysphagia scores, the lines are spline functions with 95% Confidence Intervals.

4. Results

4.1. Clinical outcomes

The two patient groups were comparable with respect to their clinical characteristics (Table 1). Major complications during follow-up occurred more frequently after stent placement than after brachytherapy (28 in 27 patients (25%) vs 14 in 13 patients (13%); $P = 0.02$). Complications mainly consisted of bleeding (stent: 14 vs brachytherapy: 5), perforation (2 vs 2), fistula formation (6 vs 3) and severe pain (3 vs 1). Patients often needed additional treatment during follow-up for persistent or recurrent dysphagia. However, the number of patients needing re-treatment was not different between the 2 groups (stent: 52 in 43 patients (40%) vs brachytherapy: 53 in 43 patients (43%); $P > 0.20$). Reasons for re-treatment after stent placement were mainly tumour recurrence ($n = 16$), stent migration ($n = 18$) and food bolus obstruction ($n = 16$), and after brachytherapy tumour persistence ($n = 18$) or tumour recurrence ($n = 26$). Median survival was 155 (95% Confidence Interval (CI), 127–183) days after brachytherapy and 145 (95% CI, 103–187) days after stent placement ($P > 0.20$).

4.2. Disease-specific health-related quality of life

The dysphagia score [18] improved more rapidly after stent placement than after brachytherapy. however, at 30 days after treatment the dysphagia score was not significantly different between stent placement and brachytherapy, and in the long-term, the dysphagia score was better after brachytherapy (Fig. 1).

The disease-specific EORTC OES-23 scale scores showed overall significant differences in favour of brachytherapy on the dysphagia ($P = 0.009$) and eating scales ($P = 0.003$), both with similar patterns (Fig. 2). The other scales (deglutition, indigestion, retrosternal pain and emotional) did not show major differences between stent placement and brachytherapy, nor did the single symptoms of the EORTC OES-23. The visual analogue pain scale showed a trend towards less pain in the brachytherapy group (overall score, $P = 0.07$) (Fig. 3).

Scores on the dysphagia and eating scales of the EORTC OES-23 improved after both treatments during the first month of follow-up. After 1 month, scores on both

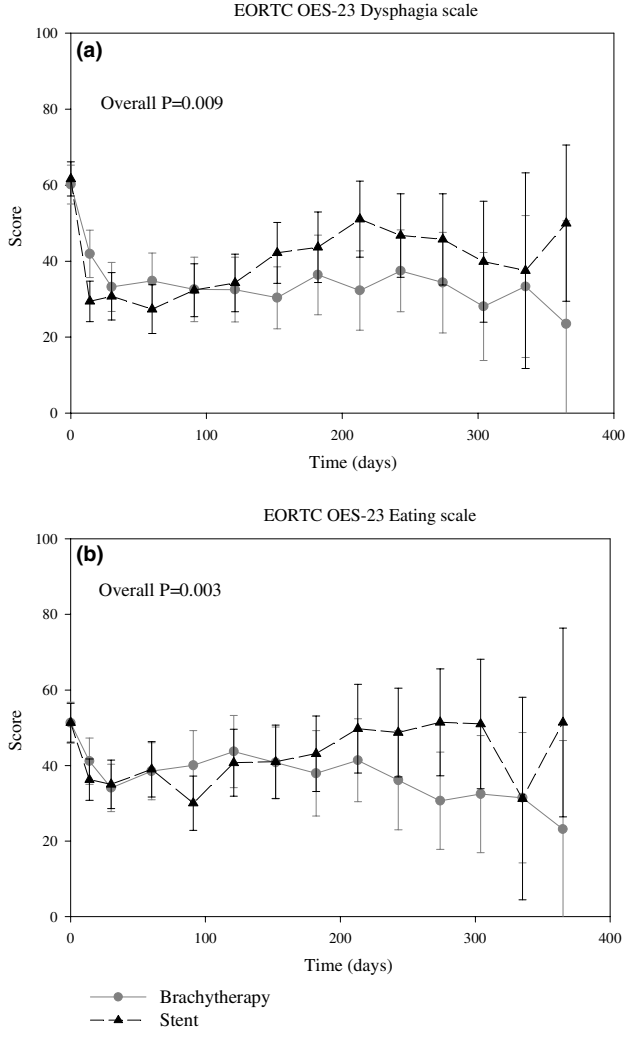

Fig. 2. Dysphagia scale (a) and eating scale (b) of the disease-specific EORTC OES-23 measure after treatment with brachytherapy ($n = 101$) or stent placement ($n = 108$) for dysphagia due to inoperable carcinoma of the oesophagus or oesophagogastric junction. Graphs show the mean scores with 95% Confidence Intervals of the scales during follow-up. Higher scores represent more dysphagia or problems with eating.

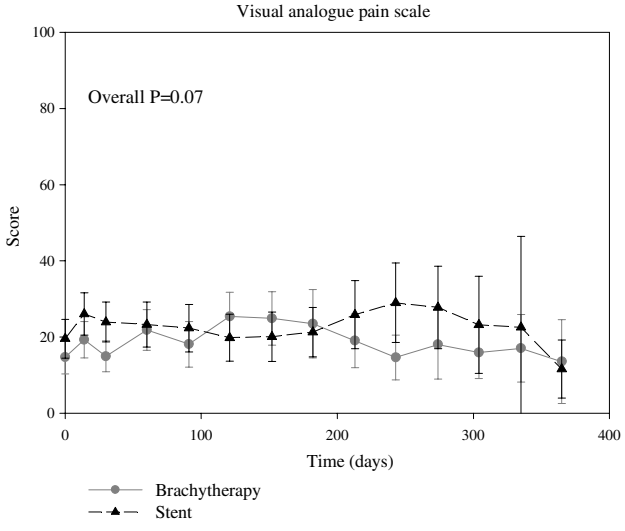

Fig. 3. Self-reported pain level on the visual analogue pain scale after treatment with brachytherapy ($n = 101$) or stent placement ($n = 108$) for dysphagia due to inoperable carcinoma of the oesophagus or oesophagogastric junction. Graphs show the mean scores with 95% Confidence Intervals of the scales during follow-up. Higher scores represent a higher level of pain.

scales deteriorated slowly during follow-up (Table 2, Fig. 2). The scores on the deglutition, indigestion and pain scales of the EORTC OES-23 remained stable during follow-up in both treatment groups. Scores on the emotional scale (10 points on a 100 points scale during 0.5 years of follow-up in both treatment groups) and the different single symptoms (8 points, on average, during 0.5 years of follow-up in the brachytherapy group vs. 13 points in the stent group) deteriorated to a moderate degree during follow-up. Experienced pain on the visual analogue pain scales increased only slightly during follow-up (+6 points during 0.5 years of follow-up in both groups; Table 2, Fig. 3).

4.3. Generic health-related quality of life

There was an overall benefit for brachytherapy on the generic HRQoL measures over time. The EORTC QLQ-C30 scale scores showed an overall significant difference in favour of brachytherapy on four out of five functional scales including role functioning ($P = 0.05$), emotional functioning ($P = 0.04$), cognitive functioning ($P = 0.006$), and social functioning ($p = 0.03$) (Fig. 4). This difference was most predominant at 6 months or later after randomisation. Patients randomised to brachytherapy scored overall better on the single item dyspnoea ($P = 0.003$), and there was a trend towards fewer symptoms of fatigue and pain after brachytherapy (both $P = 0.07$). The scores on the EQ-5D index and visual analogue scale for overall self-rated health were not significantly different for both treatments (Fig. 5).

The generic HRQoL of our patient group with inoperable oesophageal cancer was already lower before treatment compared with the general population (Table 2). Their generic HRQoL deteriorated further during follow-up on all functional scales of the EORTC QLQ-C30, in particular physical and role functioning (Table 2). This decline was more pronounced in the stent group than in the brachytherapy group (brachytherapy: −18 and −19 on a 100 points scale during 0.5 years of

Table 2
Average changes in health-related quality of life (HRQoL) during follow-up after brachytherapy (B) or stent placement (S) for palliation of dysphagia due to inoperable carcinoma of the oesophagus or oesophagogastric junction

Scale	General population scores[a]	Mean baseline value	Changes in HRQoL during follow-up (per 0.5 year of follow-up) (95% CI)[b]	
			Total group of patients	Brachytherapy group (B), Stent group (S)
EORTC OES-23				
Dysphagia scale (0 = best)				
<30 days		58	−27 (−31 to −23)[c]	
>30 days				B: 12 (8 to 16) S: 21 (16 to 25)
Deglutition scale (0 = best)		12	2 (0.2 to 4)	
Eating scale (0 = best)				
<30 days		49	−13 (−17 to −9)[c]	
>30 days				B: 11 (7 to 16) S: 21 (16 to 26)
Indigestion scale (0 = best)		18	0.8 (−1 to 3)	
Pain scale (0 = best)		21	2 (0.02 to 4)	
Emotional scale (100 = best)		44	−10 (−12 to −8)	
EORTC QLQ-C30				
Physical functioning (100 = best)	87	64		B: −18 (−23 to −12) S: −28 (−34 to −23)
Role functioning (100 = best)	85	62		B: −19 (−25 to −12) S: −30 (−37 to −23)
Emotional functioning (100 = best)	81	74	−6 (−9 to −2)	
Cognitive functioning (100 = best)	88	83		B: −6 (−11 to −2) S: −16 (−20 to −11)
Social functioning (100 = best)	87	76	−14 (−18 to −10)	
Global health/quality of life (100 = best)	66	59		B: −7 (−12 to −3) S: −13 (−18 to −9)
Pain (0 = best)	20	25	12 (9 to 16)	
Euroqol				
EQ-5D (100 = best)	76	63	−21 (−27 to −16)	
Euroqol visual analogue scale (100 = best)		59		B: −12 (−15 to −10) S: −16 (−19 to −14)
Visual analogue pain scale (0 = best)		18	6 (4 to 8)	

[a] For the EORTC QLQ-C30 scores of a general German population ($n = 390$) of men between 60 and 69 years are given [28]. For the EQ-5D, scores of a general Swedish population ($n = 1321$) of men and women between 60 and 69 years are given [29]. Norm scores were not available for the EORTC OES-23 and visual analogue pain scale.

[b] In case of interaction between treatment and time ($P < 0.10$), we fitted a model for each treatment, in case of no interaction, the model was fitted for the total group of patients. A change of −10 means that HRQoL deteriorates with 10 points on a 100 point-scale during 0.5 years of follow-up.

[c] Change in HRQoL for 30 days of follow-up.

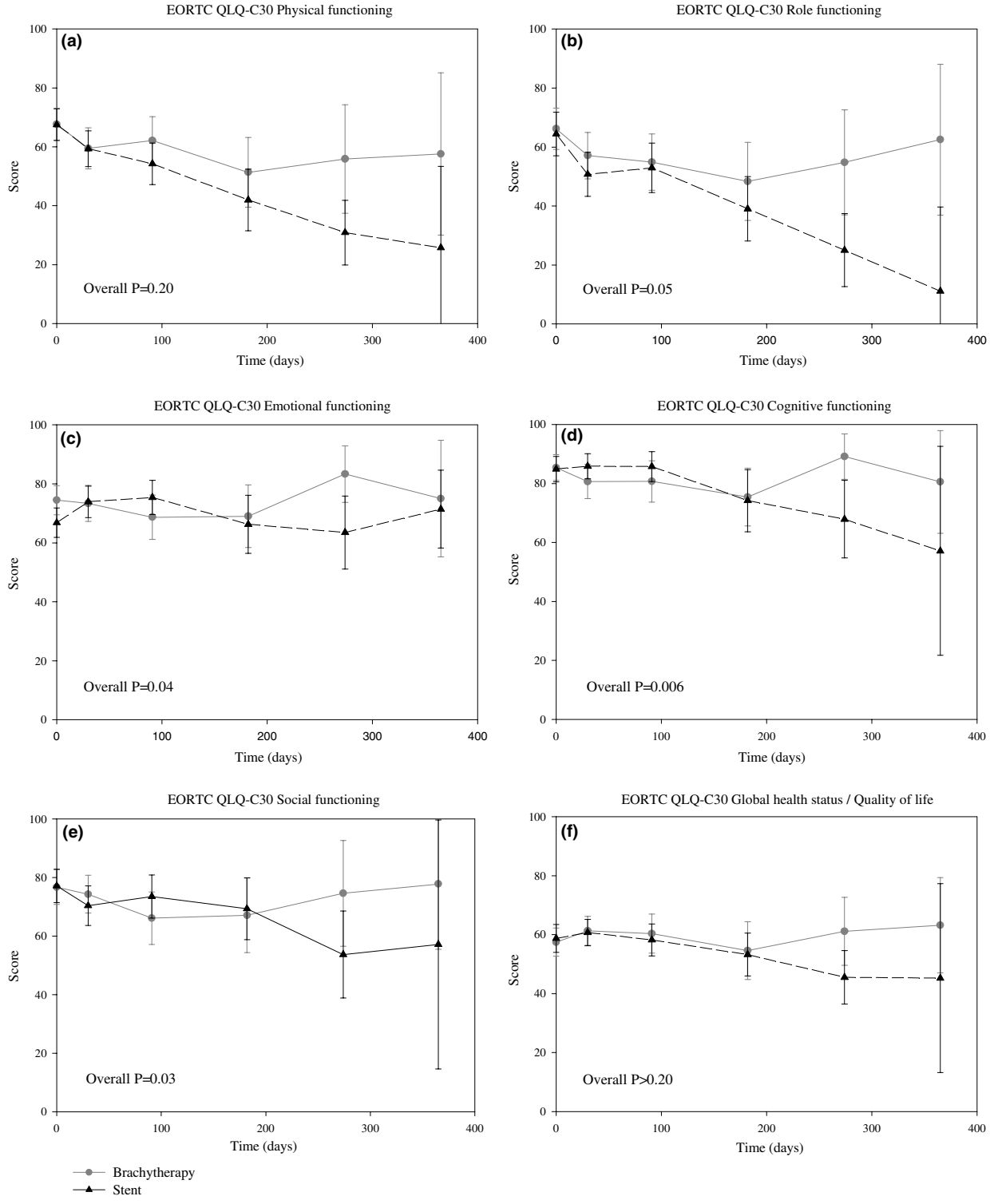

Fig. 4. Functional scales of the EORTC QLQ-C30 measure after treatment with brachytherapy ($n = 101$) or stent placement ($n = 108$) for dysphagia due to inoperable carcinoma of the oesophagus or oesophagogastric junction. Graphs show the mean scores with 95% Confidence Intervals of the scales during follow-up. Higher scores represent a higher level of functioning.

follow-up vs stent: −28 and −30 points for physical and role functioning, respectively). In addition, the scores on the symptom scales and most single symptoms increased during follow-up (indicating a higher level of symptoms), in particular fatigue, dyspnoea and appetite loss. Pain level on the EORTC QLQ-C30 increased during follow-up (+12 points during 0.5 years of follow-up in both groups; Table 2). We found no change in the

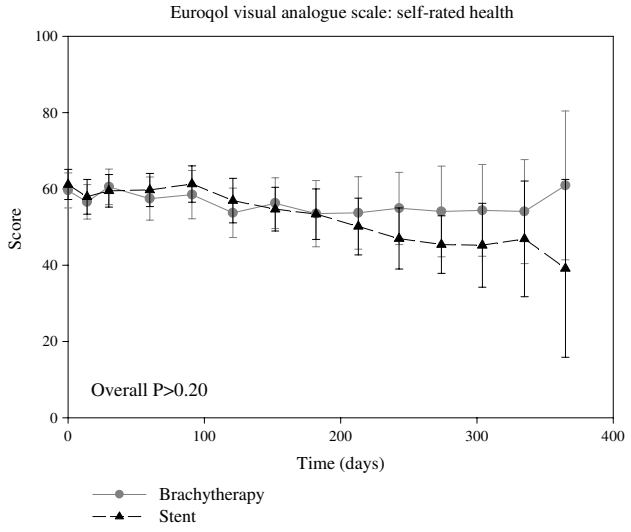

Fig. 5. Euroqol visual analogue scale (EQ-VAS) for self-rated health after treatment with brachytherapy ($n = 101$) or stent placement ($n = 108$) for dysphagia due to inoperable carcinoma of the oesophagus or oesophagogastric junction. Graphs show the mean scores with 95% Confidence Intervals of the scales during follow-up. Higher scores represent a better self-rated health status.

symptom constipation/diarrhoea and in financial difficulties during follow-up. Scores on the EQ-5D index and Euroqol visual analogue scale also declined during follow-up (Table 2).

5. Discussion

This study provides a longitudinal prospective comparison of generic and disease-specific HRQoL between two commonly used palliative treatments for oesophageal cancer, i.e. single dose brachytherapy and stent placement. Although both treatments were effective in relieving dysphagia, treatment with single dose brachytherapy gave better overall scores on HRQoL scales compared with stent placement for the palliation of oesophageal cancer. Most aspects of HRQoL deteriorated during follow-up in both treatment groups. However, the decline was more pronounced in the stent group.

Only a few studies have been published on HRQoL after palliative treatment for oesophageal carcinoma [22–26]. Palliative therapy in these studies included placement of a plastic [23,25,26] or a metal stent [23,24], laser therapy [22,24,25], external beam radiation [26] and chemoradiation [23]. No studies have been published assessing HRQoL after single dose brachytherapy for the palliation of malignant dysphagia. An overview of the results of these studies is shown in Table 3. From these studies, it can be concluded that although dysphagia scores improved after most of these palliative treatments, other aspects of HRQoL remained stable or deteriorated during follow-up. However, none of these studies made a comparison between two palliative treatments with respect to HRQoL, and patient numbers were small. Moreover, our study provides detailed longitudinal data with monthly assessments of HRQoL.

A variety of measures has been used in the reported studies to assess HRQoL after palliative treatment for oesophageal carcinoma [22–26] (Table 3). In our study, we assessed disease-specific HRQoL, as well as generic HRQoL, after brachytherapy and stent placement. We expected that the disease-specific HRQoL measure (the EORTC OES-23) would have been the one that was most responsive to differences between the two treatments and changes in HRQoL during follow-up. The separately scored dysphagia scores [18] and the dysphagia scale of the EORTC OES-23 followed a similar pattern over time, consisting of a rapid improvement after treatment and a slow deterioration of dysphagia scores during follow-up. In line with this, the eating scale showed a similar pattern. However, all other scales of the EORTC OES-23 did not reveal differences between the two treatments. In addition, most of these scales remained stable during follow-up. In contrast, several aspects of generic HRQoL differed between the two treatments, becoming even more evident after 6 months of follow-up. Generic HRQoL deteriorated during follow-up, and this decline was more pronounced after stent placement. Therefore, we consider the generic HRQoL measures (in particular the EORTC QLQ-C30) more responsive in measuring patients' functioning and well-being during follow-up than the disease-specific EORTC OES-23.

Recently, the EORTC OES-23 has been revised to a measure with 18 questions. This revised EORTC OES-23 was recently validated in a large cohort of patients [27]. In this revised measure, the emotional scale and the single item 'hair loss' were removed, whereas the indigestion scale now consists of two instead of three items. The authors recommended the new EORTC OES-18 as a valuable addition to the EORTC QLQ-C30 for patients with oesophageal cancer. However, since only the dysphagia and eating scales showed differences in the EORTC OES-23 and these items can effectively be measured with the separate dysphagia score, we consider it sufficient to use the EORTC QLQ-C30 in combination with the separate dysphagia score to obtain complete HRQoL data in patients with inoperable oesophageal carcinoma.

In our study, we also used the EQ-5D for generic HRQoL. This measure provides a single index value, which is easy to use for cost-effectiveness calculations, and is therefore advisable in case a cost-effectiveness analysis will be performed. A detailed cost calculation of our study was reported previously [17].

For the interpretation of the HRQoL in our patient group and the differences during follow-up, it is

Table 3
Overview of studies investigation health-related quality of life (HRQoL) after palliative treatment for oesophageal cancer

Author [Ref.]	*N*	Treatment	HRQoL measures	Follow-up measurements	Major conclusions
Barr and colleagues [22]	40	Laser	Dysphagia score Linear analogue self-assessment (LASA) Physician's assessment using a quality of life index (QLI)	Monthly until death	Dysphagia score improved LASA and QLI were improved at some time after laser therapy
Loizou and colleagues [25]	38	Laser $n = 15$ Plastic tube $n = 23$	Dysphagia score Linear analogue self-assessment (LASA) Physician's assessment using a quality of life index (QLI)	Various times (not further specified) until death	Dysphagia score improved LASA + QLI scores improved aftertreatment, but deteriorated during follow-up
O'Hanlon and colleagues [26]	43	Plastic tube Radiotherapy	Dysphagia score Rotterdam symptom checklist Measure on activities on daily living	6 and 16 weeks	Dysphagia improved Other HRQoL parameters remained stable or deteriorated
Blazeby and colleagues [23]	37	Plastic/metal stent $n = 30$ Chemoradiotherapy $n = 7$	EORTC QLQ-C30 EORTC OES-24 (only dysphagia scale)	Monthly until death	Most aspects of HRQoL remained stable during follow-up
Dallal and colleagues [24]	65	Laser $n = 34$ Metal stent $n = 31$	Dysphagia score Hospital anxiety and depression questionnaire Short Form 36 EORTC QLQ-C30 EORTC OES-24	1 month	Dysphagia scores were not improved after both treatments Laser group: other HRQoL scores remained stable Stent group: other HRQoL scores had deteriorated at 1 month after treatment
Present series	209	Brachytherapy $n = 101$ Metal stent $n = 108$	Dysphagia score EORTC QLQ-C30 EORTC OES-23 EQ-5D Visual analogue pain scale	14 days, then monthly until death	Dysphagia scores improved after both treatments Scores on the EORTC QLQ-C30 and EQ-5D deteriorated in both groups, but more so in the stent group Scores on the EORTC OES-23 improved or remained stable

interesting to compare HRQoL in our patient group with inoperable oesophageal cancer with HRQoL in the general population. Norm scores of the general population were available for the EORTC QLQ-C30 [28] and the EQ-5D [29]. We are not aware of norm scores of the EORTC OES-23 and the visual analogue pain scale. As expected, the scores on all scales of our study population at baseline were lower compared with the available scores of the general population [28,29] (Table 2). In particular, substantial differences were noted for physical and role functioning, as well as for the EQ-5D. This stresses the importance of preserving the already diminished HRQoL in patients with oesophageal cancer needing palliative treatment.

Pain is an important issue of HRQoL after palliation. In our study, pain was assessed using various pain scales, i.e., the pain scale of the EORTC OES-23, which measures pain while eating, chest pain and abdominal pain, the pain scale of the EORTC QLQ-C30, which measures pain in general, and a visual analogue pain scale on which patients could rate their experienced level of general pain. Pain level on the EORTC OES-23 (both chest and abdominal pain) remained stable during follow-up in contrast to general pain, which increased moderately on both the EORTC QLQ-C30 and the visual analogue pain scale (Table 2). The three pain scales had similar baseline scores of, on average, 20 points on a 100-points scale, which has also been reported previously [23]. Chest or abdominal pain might well be the result of the palliative treatment itself. In our experience, this pain usually diminishes or disappears a few days to a week after the procedure. Although the pain scale of the EORTC OES-23 is not a measure for acute post-treatment pain (the first follow-up visit was at 14 days after treatment), the scores indicate that chest or abdominal pain was not a problem during follow-up. During follow-up, more than 50% of our patients needed narcotic analgesics. In most patients, this is probably due to progression of their disease rather than as a result of the palliative treatment. The reported pain levels on the EORTC QLQ-C30 and the visual analogue pain scale only moderately increased during follow-up. This indicates that pain management was adequate during follow-up.

In conclusion, treatment with single dose brachytherapy gave better overall scores on HRQoL scales compared with stent placement for the palliation of oesophageal cancer. Major improvements were seen on the dysphagia and eating scales of the disease-specific EORTC OES-23, in contrast to other scales of this disease-specific measure, which remained almost stable during follow-up. In addition, pain levels remained stable or slightly increased during follow-up, indicating that adequate pain management during follow-up is important. Future studies on palliative care for oesophageal cancer should at least include generic HRQoL scales, since these were more responsive in measuring patients' functioning and well-being during follow-up than disease-specific HRQoL scales.

Conflict of interest statement

None declared.

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Appendix A

The Dutch SIREC study group consisted of:

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References

1. Pisani P, Parkin DM, Bray F, *et al*. Estimates of the worldwide mortality from 25 cancers in 1990. *Int J Cancer* 1999, **83**, 18–29.
2. Sundelof M, Ye W, Dickman PW, *et al*. Improved survival in both histologic types of oesophageal cancer in Sweden. *Int J Cancer* 2002, **99**, 751–754.
3. Sagar PM, Gauperaa T, Sue-Ling H, *et al*. An audit of the treatment of cancer of the oesophagus. *Gut* 1994, **35**, 941–945.
4. Siersema PD, Hop WC, van Blankenstein M, *et al*. A comparison of 3 types of covered metal stents for the palliation of patients with dysphagia caused by esophagogastric carcinoma: a prospective, randomized study. *Gastrointest Endosc* 2001, **54**, 145–153.
5. Raijman I, Siddique I, Ajani J, *et al*. Palliation of malignant dysphagia and fistulae with coated expandable metal stents: experience with 101 patients. *Gastrointest Endosc* 1998, **48**, 172–179.
6. Kozarek RA, Raltz S, Brugge WR, *et al*. Prospective multicenter trial of oesophageal Z-stent placement for malignant dysphagia and tracheoesophageal fistula. *Gastrointest Endosc* 1996, **44**, 562–567.
7. Bartelsman JF, Bruno MJ, Jensema AJ, *et al*. Palliation of patients with esophagogastric neoplasms by insertion of a covered expandable modified Gianturco-Z endoprosthesis: experiences in 153 patients. *Gastrointest Endosc* 2000, **51**, 134–138.
8. Homs MY, Eijkenboom WM, Coen VL, *et al*. High dose rate brachytherapy for the palliation of malignant dysphagia. *Radiother Oncol* 2003, **66**, 327–332.
9. Gaspar LE, Nag S, Herskovic A, *et al*. American Brachytherapy Society (ABS) consensus guidelines for brachytherapy of esophageal cancer. Clinical Research Committee, American Brachytherapy Society, Philadelphia, PA. *Int J Radiat Oncol Biol Phys* 1997, **38**, 127–132.
10. Brewster AE, Davidson SE, Makin WP, *et al*. Intraluminal brachytherapy using the high dose rate microselectron in the palliation of carcinoma of the oesophagus. *Clin Oncol (R Coll Radiol)* 1995, **7**, 102–105.
11. Sur RK, Levin CV, Donde B, *et al*. Prospective randomized trial of HDR brachytherapy as a sole modality in palliation of advanced esophageal carcinoma – an International Atomic Energy Agency study. *Int J Radiat Oncol Biol Phys* 2002, **53**, 127–133.
12. Blazeby JM. Measurement of outcome. *Surg Oncol* 2001, **10**, 127–133.
13. Brooks R. EuroQol: the current state of play. *Health Policy* 1996, **37**, 53–72.
14. Aaronson NK, Ahmedzai S, Bergman B, *et al*. The European Organization for Research and Treatment of Cancer QLQ-C30: a quality-of-life instrument for use in international clinical trials in oncology. *J Natl Cancer Inst* 1993, **85**, 365–376.
15. Blazeby JM, Alderson D, Winstone K, *et al*. Development of an EORTC questionnaire module to be used in quality of life assessment for patients with oesophageal cancer. The EORTC Quality of Life Study Group. *Eur J Cancer* 1996, **32A**, 1912–1917.
16. Homs MY, Steyerberg EW, Eijkenboom WM, *et al*. For the Dutch SIREC study group. Single dose brachytherapy versus metal stent placement for the palliation of dysphagia from oesophageal cancer [submitted].
17. Polinder S, Homs MY, Siersema PD, *et al*. For the Dutch SIREC study group. Cost study of metal stent placement versus single dose brachytherapy in the palliative treatment of oesophageal cancer. *Brit J Cancer* 2004 [in press].
18. Ogilvie AL, Dronfield MW, Ferguson R, *et al*. Palliative intubation of oesophagogastric neoplasms at fibreoptic endoscopy. *Gut* 1982, **23**, 1060–1067.
19. Dolan P. Modeling valuations for EuroQol health states. *Med Care* 1997, **35**, 1095–1108.
20. Harrell Jr FE, Lee KL, Pollock BG. Regression models in clinical studies: determining relationships between predictors and response. *J Natl Cancer Inst* 1988, **80**, 1198–1202.
21. Fairclough DL. Design and analysis of quality of life studies in clinical trials. London, Chapman and Hall/CRC, 2002.
22. Barr H, Krasner N. Prospective quality-of-life analysis after palliative photoablation for the treatment of malignant dysphagia. *Cancer* 1991, **68**, 1660–1664.
23. Blazeby JM, Farndon JR, Donovan J, *et al*. A prospective longitudinal study examining the quality of life of patients with esophageal carcinoma. *Cancer* 2000, **88**, 1781–1787.
24. Dallal HJ, Smith GD, Grieve DC, *et al*. A randomized trial of thermal ablative therapy versus expandable metal stents in the palliative treatment of patients with esophageal carcinoma. *Gastrointest Endosc* 2001, **54**, 549–557.
25. Loizou LA, Rampton D, Bown SG. Treatment of malignant strictures of the cervical esophagus by endoscopic intubation using modified endoprostheses. *Gastrointest Endosc* 1992, **38**, 158–164.
26. O'Hanlon DM, Harkin M, Karat D, *et al*. Quality-of-life assessment in patients undergoing treatment for oesophageal carcinoma. *Brit J Surg* 1995, **82**, 1682–1685.
27. Blazeby JM, Conroy T, Hammerlid E, *et al*. Clinical and psychometric validation of an EORTC questionnaire module, the EORTC QLQ-OES18, to assess quality of life in patients with oesophageal cancer. *Eur J Cancer* 2003, **39**, 1384–1394.
28. Schwarz R, Hinz A. Reference data for the quality of life questionnaire EORTC QLQ-C30 in the general German population. *Eur J Cancer* 2001, **37**, 1345–1351.
29. Burstrom K, Johannesson M, Diderichsen F. Health-related quality of life by disease and socio-economic group in the general population in Sweden. *Health Policy* 2001, **55**, 51–69.