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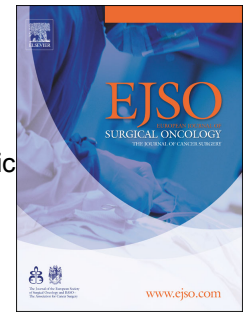

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Health-related quality of life and survival in the two years after surgery for gastric cancer

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Abstract

Background: This prospective study examined health-related quality of life (HRQL) and survival in patients with potentially curable gastric cancer.

Methods: Consecutive patients (n=58) selected for curative surgery completed a validated questionnaire (EORTC QLQ-C30) and site-specific module (QLQ-STO22) before surgery and regularly for two years afterwards. Changes of 10 or more points on a 0 to 100 scale were considered clinically significant.

Results: Some 30 patients were alive after two years (52%). In the first three months after surgery, HRQL was significantly reduced across all dimensions except emotional and cognitive functioning (mean reduction of 10 or more points). Functional aspects of HRQL recovered by six months in patients who subsequently were alive at two years, although at least a third of patients experienced specific symptoms, even six months after surgery, especially diarrhoea. For those dying within two years, some post-operative functional HRQL recovery occurred, but many symptoms were common.

Conclusions: Potentially curative gastrectomy for cancer has a detrimental impact on HRQL that mostly recovers in patients surviving some two years. Patients who die within two years may experience limited post-operative recovery. It is recommended that patients receive HRQL information about the outcomes of surgery for gastric cancer.

Keywords: gastrectomy, quality of life, decision making, informed consent

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Introduction

Gastric carcinoma is the fifth most common malignancy in the world and a leading cause of cancer death[1]. Surgical resection of the primary tumour and regional lymph nodes is the mainstay of cure and surgery may be combined with peri-operative chemotherapy or chemoradiation to improve long-term survival[2-4]. Gastrectomy is, however, associated with significant morbidity and median survival in the western world remains less than 24 months. Understanding the impact of radical gastrectomy on patient reported outcomes such as health-related quality of life (HRQL) is important. This information about HRQL outcomes can then form an important component of fully informed consent before surgery[5].

Current guidance in the UK states that in the process of obtaining consent, the patient should be informed of what they may experience as a result of an intervention, including any life style changes that may result[6,7]. Evaluating surgery with robust HRQL assessments is therefore critical. There is currently a lack of well-designed prospective studies with robust HRQL outcomes evaluating surgery for gastric cancer. The aim of this study was to document the short and long-term HRQL outcomes of potentially curative gastrectomy for cancer and to describe the HRQL trajectory of patients surviving or not surviving two or more post-operative years.

Methods

Patient details

Between November 2000 and November 2004 consecutive patients with adenocarcinoma of the stomach were considered for this study. Patients with potentially curable tumours without a previous or concurrent malignancy, who could understand the language of the HRQL questionnaire and who could provide written informed consent were included. Excluded were patients undergoing emergency surgery, planned palliative gastrectomy or a bypass, patients undergoing peri-operative chemotherapy

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and surgery or patients undergoing non-operative palliative treatment for gastric cancer. Ethical committee permission and written informed consent were obtained.

Treatment details

The upper gastrointestinal cancer multi-disciplinary team of the Avon, Somerset and Wiltshire Cancer Network makes treatment decisions for all new patients with gastric cancer (population approximately 1.5 million). Potentially curative surgery was offered to fit patients without evidence of haematogenous or peritoneal metastasis and no perceived lymph node involvement outside the proposed surgical field. Diagnosis and staging involved upper gastrointestinal endoscopic biopsies, computerized tomography of the chest and abdomen and staging laparoscopy with peritoneal cytology. Patients with tumours of the proximal stomach also underwent endoluminal ultrasonography. All gastrectomies were performed in the cancer centre (United Bristol Healthcare Trust) by a team of four consultant surgeons or trainees under consultant supervision. Depending upon the location of the tumour, the surgeon performed either total or subtotal gastrectomy. Reconstruction of the gastrointestinal tract was performed using the Roux en Y technique. After total gastrectomy all patients had a feeding jejunostomy inserted but not additional parenteral feeding was used. D2 lymphadenectomy was standard procedure, except where preoperative staging classified the tumours as T1N0M0, where D1 lymphadenectomy was performed. All surgeons had visited the Gastric Surgery Division of the National Cancer Centre Hospital, Tokyo. Clinical details and outcomes were recorded from hospital records, coding major complications as a second operation or readmission to the intensive care unit and all other complications as minor (infections, cardiorespiratory or gastrointestinal). In-hospital mortality was also recorded.

Health related quality of life questionnaires

Health-related quality of life was assessed with the validated European Organisation for Research and Treatment of Cancer (EORTC) core questionnaire, EORTC QLQ-C30 (version 3.0), and the site-

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specific module for gastric cancer, EORTC QLQ-STO22[8-10]. The core instrument assesses key functional aspects of HRQL and global quality of life and has symptom scales and individual items assessing symptoms that commonly occur in patients with cancer. The gastric module has five symptom scales (dysphagia/odynophagia, pain/discomfort, dietary restrictions, upper gastro-intestinal symptoms, emotional problems) and four single items. All QLQ-C30 and QLQ-STO22 responses were linearly transformed to scores from 0 to 100 according to the authors' guidelines. In multi-item function scales, higher scores can be interpreted as higher levels of functioning but, in symptoms scales/single-items, they reflect more symptoms[11]. A change in any scale of at least 10 points is considered to be clinically relevant[12].

Timing of questionnaire assessments

Patients were asked to complete questionnaires within a three- week period before surgery. Further HRQL assessments were performed six weeks after surgery, every three months in the first post-operative year, and at 18 and 24 months. Time windows of +/- two weeks were applied for each post-operative assessment. Questionnaires were distributed by post and completed by patients themselves. After questionnaires were returned they were scrutinized for missing individual items and patients telephoned for these responses. If questionnaires were not returned at all, one phone call and one postal reminder were made. Where patients died or were too ill to complete a questionnaire, the HRQL assessment was classified as ineligible. HRQL assessments were classified as missing if this was due to patient refusal, patient non-response (not returned for unknown reasons) or administrative error (questionnaire not sent out or not requested within the correct time window).

Data analyses and statistical methods

Comparisons were made between patients surviving for two years and those dying within this time. Mean scores and confidence intervals were calculated for HRQL functional scores at baseline and at

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six months for both groups of patients. Given the skewed nature of the data the non-parametric bootstrap bias corrected and accelerated method, based on 5000 iterations, was used to calculate 95% confidence intervals. These results were compared with standard means and confidence intervals and because they were similar, standard scores are presented. Given the heavily skewed symptom scores; the percentage of symptomatic patients at each time point was calculated. Symptomatic patients were defined as patients responding, 'a little', 'quite a bit' or 'very much' to symptom items and scales, whereas patients reporting 'not at all' were classified as asymptomatic. Percentage of symptomatic patients at baseline and 6 months post surgery are presented with 95% Wilson confidence intervals.

Graphs were plotted to show HRQL changes over time, but only where there were more than 10 available patients at a particular time point. Kaplan Meier survival analysis was performed. All analyses and graphs were performed using the Stata/IC 10.2 statistical software version (Stata Corporation, College Station, Texas, USA, 2005).

Results

Clinical outcomes

During the study period, 131 patients with gastric cancer were discussed at the multi-disciplinary team meeting and 58 selected for potentially curative gastrectomy. Four patients died in hospital after surgery. Of the 58 patients, 30 were alive two years after surgery and 28 had died. Table 1 and Figure 1 shows the baseline details, clinical outcomes and survival of patients undergoing surgery and living or dying within two years.

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Questionnaire compliance and missing data

Before treatment, 97% of patients returned HRQL questionnaires. Overall compliance during follow up exceeded 80%.

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HRQL in patients surviving 2 years

Before surgery, most functional aspects of HRQL were higher (better) and most symptom scores were lower (less common) for patients surviving two or more years than in patients who subsequently died within two years (Tables 2 and 3). At the first post-operative assessment (6 weeks), functional aspects of HRQL deteriorated by at least 10 points, except for emotional, social and cognitive function. The proportions of symptomatic patients, including those experiencing appetite loss, diarrhoea and eating restrictions, increased except for dysphagia scores. Recovery of physical, role and social function was seen to begin within three months and mean scores reached within 6 points of baseline mean scores by six months (Table 2). Six months after surgery, however, over 50% of patients still reported some degree of nausea and vomiting, diarrhoea, pain, reflux, dry mouth and sleep difficulties and over 70% reported fatigue and eating problems (Table 3). Mean physical function scores in the two years after surgery are shown in Figure 2. Results for social function and global quality of life scores show a similar pattern to Figure 2. Both cognitive and emotional function scores did not change before or after surgery (data not shown).

HRQL in patients dying within 2 years

At least half of the patients in this group died before the six month follow up. In patients living for six months but dying within two post-operative years, functional aspects of HRQL did generally recover briefly before deterioration (Figure 2). Symptom scores showed a mixed pattern with relief of dysphagia reported after surgery but persistent problems with appetite loss, diarrhoea and eating restrictions before death (data not shown).

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Discussion

Summary of the main findings

This prospective study examined HRQL and survival in patients selected for potentially curative gastric cancer surgery. Patients surviving two years generally recovered most aspects of HRQL within six months of surgery and thereafter only reported problems with a few specific symptoms. In the patients with a poor survival after surgery (dying within two years), however, although a brief post-operative recovery was observed at six months, 20% of patients died within six months of surgery during which HRQL recovery was not achieved. Surgery for gastric cancer, therefore, has a major impact on most aspects of HRQL and, even if this is only temporary, it is suggested that the information is given to patients before surgery during the process of shared treatment decision-making.

Previous research

Since the time of this study, the vast majority of Western patients with gastric cancer now receive neoadjuvant or adjuvant treatment with surgery and it is possible that this influences post-operative HRQL [2,3]. In this study the numbers receiving adjuvant chemotherapy or palliative radiotherapy were too small to draw meaningful conclusions. At present there is a lack of studies evaluating this, but prospective research into the impact of neoadjuvant chemotherapy before oesophagectomy on post-operative HRQL shows that pre-operative treatment has little effect on HRQL recovery[13,14]. It is likely, however, that post-operative chemotherapy significantly delays HRQL recovery, as is testified by the proportions of patients who did not complete the post-operative course of chemotherapy in the UK randomised trial[2]. This issue is currently being addressed in the new trial of peri-operative chemotherapy with or without a bevacizumab, which includes a comprehensive HRQL assessment[15]. ***Patients with gastric cancer may also be severely malnourishedand/or immunosuppressed and this may influence HRQL. These issues were not specifically assessed in this study but should be addressed in future work.*** The few studies assessing HRQL in patients undergoing gastrectomy alone

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show similar results to those reported in the present paper in patients experiencing a survival benefit of surgery[16, 17]. Other studies, however, have excluded patients with recurrent disease, and many focus upon younger patients. The present study provides additional evidence about the impact of surgery for gastric cancer on HRQL, when cure is attempted but not achieved and it is relevant to every day clinical practice because it included all age patients. All these studies lack evaluation with a disease-specific measure and it is recommended that this is used to obtain a detailed symptom profile after surgery[18].

Implications of the findings

One purpose of describing the impact of surgery for cancer on HRQL is to provide evidence for information provision for future patients. It is well known that patients want information about treatment outcomes, including data about the impact of treatment on lifestyle factors and expected recovery[19]. Robust documentation of the effects of surgical treatment for cancer on HRQL, therefore, is essential to meet these information needs. Documenting HRQL outcomes after surgery may also contribute to core information required for disclosure during the process of informed consent for surgery. This may be particularly important in jurisdictions that use a “reasonable patient”[20] legal standard of disclosure. Indeed, the UK General Medical Council consent guidelines mandate that surgeons share all the information patients want to reach a substantial understanding of surgery[21]. Only then can patients autonomously give authorisation for a procedure to take place[22]. The best methods for communicating HRQL information, however, in clinical practice need to be determined but this study does provide some information that can be useful to inform patients [23].

Study limitations

Although the present study was prospective and longitudinal with high compliance rates using validated multi-dimensional disease-specific questionnaires, the sample size was small. This precluded

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formal significance testing between groups and it did not allow a separate analysis of the HRQL in patients undergoing total or subtotal gastrectomy. A larger study is needed to explore the differences in post-operative HRQL between total and sub-total gastrectomy. It is likely that HRQL differences in the types of resection and reconstruction in survivors of surgery will be mostly related to symptom profiles, which diarrhoea and eating restrictions predominating after total gastrectomy. Another potential impact on post-operative recovery of quality of life may be the use of fast track and minimal access surgery. A randomised trial has reported better HRQL after laparoscopic surgery for gastric cancer but quality of life assessments were completed by an observer, introducing possible bias, and more work is needed in this area [25].

Conclusions

In summary, gastrectomy for cancer has a temporary negative impact on most aspects of HRQL that typically recovers within the first post-operative year in patients surviving at least two years. Patients not experiencing survival beyond six months after surgery never recovery post-operative HRQL and every effort to identify these patients before surgery is needed. ***At present there is insufficient evidence to selectively deny patients with locally advanced cancers gastric surgery because of the risk of both poor survival and poor HRQL, however, larger and better-designed studies should be performed to further explore this issue.*** Until patient selection improves, it is recommended that these findings be used to inform patients about what to expect after surgery and to guide timely supportive post-operative interventions. Methods to inform patients of the likely HRQL impact of surgery currently do not exist. Future studies that develop aids to communicate HRQL results to patients and clinicians within a clinical context are warranted.

Conflict of Interest

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None.

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Figure 1 Kaplan-Meier survival estimates for patients undergoing potentially curative gastrectomy (n=58)

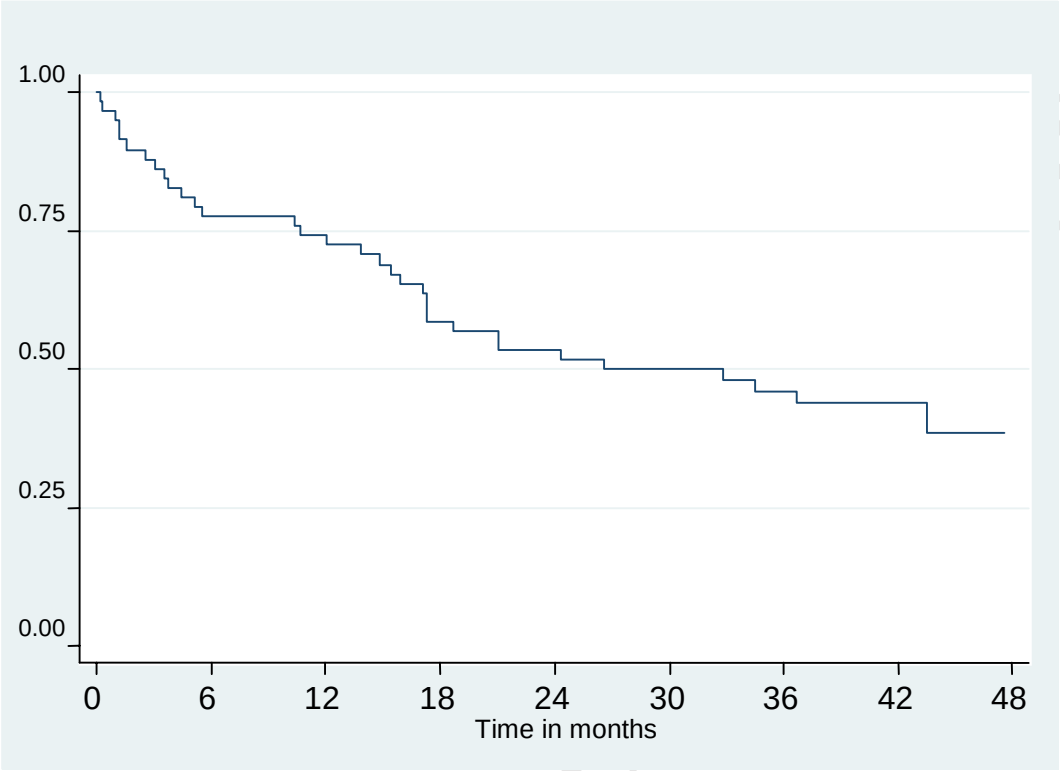

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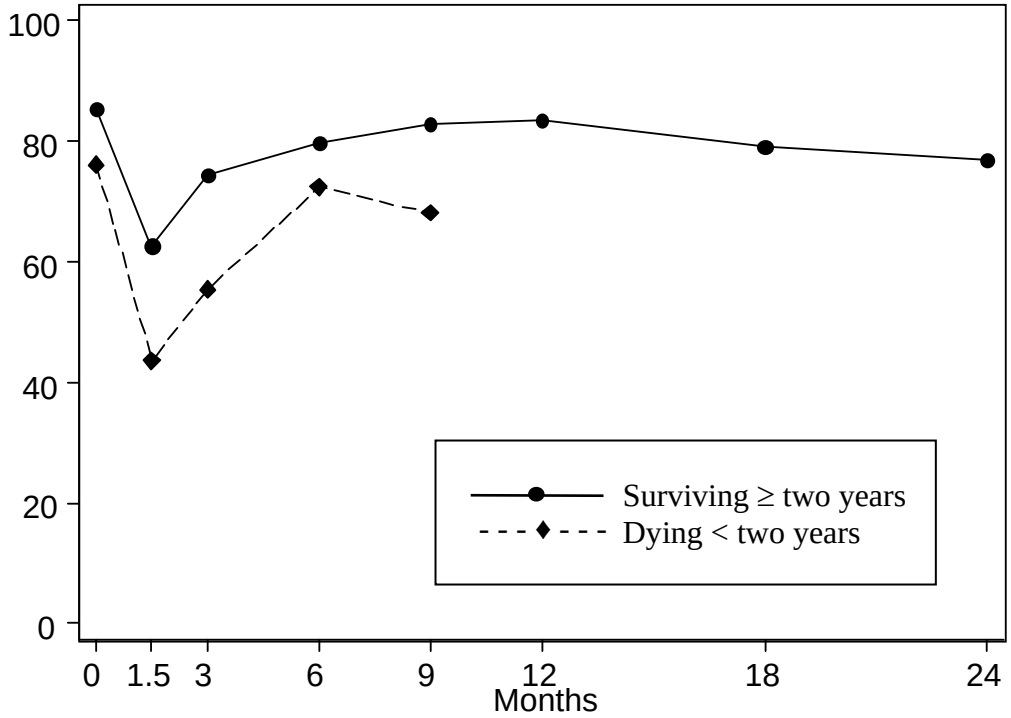
Figure 2 Mean physical function scores in the two years after surgery for gastric cancer (a high score indicates better function)



≥ 2 years n =	28	25	25	26	26	27	26	24
< 2 years n =	28	20	16	14	13			

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Table 1 Baseline details and clinical outcomes of patients selected for potentially curative gastrectomy (n=58)

	Patients surviving ≥ two years, n=30	**Patients dying < two years, n=28**	**P value**
Mean age years at time of surgery (range)	70 (52 - 84)	72 (47 - 87)	n.s[a]
Gender, male	19	23	n.s[b]
Median Karnofsky performance score (range)	90 (50-100)	80 (60-100)	0.03[c]
Cohabitation status			
Living alone	7	8	n.s[b]
Living with family/other adults	23	18	
Unknown	0	2	
Education			
Less than compulsory school	2	1	n.s[b]
Compulsory school	23	19	
Post compulsory school & university	5	7	
Other/unknown	0	1	
Employment status			
Employed	12	4	n.s[b]
Unemployed	0	1	
Retired	16	21	
Other/unknown	2	2	
Type of operation			-
Total D2 gastrectomy	15	19	
Total D1 gastrectomy	1	0	
Subtotal D2 gastrectomy	11	3	
Subtotal D1 gastrectomy	3	0	
Laparotomy alone (unsuspected M1 disease)	0	6	
Pathological stage[24]			-
Ia	6	0	
Ib	5	3	
II	13	5	
IIIa	6	9	
IIIb	0	4	
IV	0	7	
ASA grade			-
I & II	26	22	
III	4	6	
Lymph node status (SD)			-
Mean number of nodes in specimen	30 (14)	33 (16)	
Mean number of positive nodes	2 (4)	6 (8)	
Body Mass Index[d] (range)	25 (17-33)	25 (16-34)[e]	-

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Mean number of days in hospital, (range)	16 (6-56)	16 (3-47)[f]	-
Number reporting one or more complications	11	11[f]	-
Minor complications*	11	10	-
Patient returned to theatre	2	2	-
Patient returned to intensive treatment unit	2	3	-
Adjuvant chemotherapy	3	5	-
Palliative radiotherapy	0	2	-

SD = standard deviation, ASA= American Society of Anesthesia, n.s=non significant

[a] Student's t-test, [b] Chi-squared test, [c] Mann Whitney test, [d]weight(kg)/height^2(m^2), [e]data missing for 1 patient, [f]excluding 4 patients who died in hospital, *minor complications included other complications except

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Table 2 Baseline and six month mean EORTC QLQ-C30 function scores and 95% confidence intervals in patients surviving or not surviving two years after planned curative gastrectomy

	Patients surviving ≥ two years		**Patients dying < two years**	
Function[a]	**Baseline (n=28)**	**Six months (n=28)**	**Baseline (n=28)**	**Six months (n=13)**
Physical	85 (77 - 94)	80 (72 - 87)	76 (67 - 85)	72 (56 - 89)
Role	70 (57 - 83)	76 (66 - 87)	54 (39 - 70)	62 (42 - 82)
Social	72 (61 - 83)	71 (61 - 81)	69 (58 - 80)	74 (57 - 91)
Emotional	71 (60 - 82)	73 (63 - 83)	71 (62 - 80)	80 (65 - 95)
Cognitive	85 (76 - 94)	82 (75 - 89)	76 (66 - 87)	74 (56 - 92)
Global QL	68 (58 - 77)	69 (60 - 78)	61 (50 - 72)	67 (56 - 78)

[a] A high score indicates better HRQL

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Table 3 Percentages of patients (95% confidence intervals[a]) at baseline and six months after surgery reporting symp-ms (two-year survivors *versus* patients dying within two years)

	Patients surviving ≥ two years		**Patients dying < two years**	
Symp-ms QLQ-C30[b]	**Baseline (n=28)**	**Six months (n=28)**	**Baseline (n=28)**	**Six months (n=13)**
Nausea and vomiting	36% (21 - 54)	54% (35 - 71)	39% (24 - 58)	71% (45 - 88)
Pain	39% (24 - 58)	69% (50 - 83)	57% (39 - 73)	57% (33 - 79)
Fatigue	68% (49 - 82)	81% (62 - 91)	86% (69 - 94)	100% (78 - 100)
Appetite loss	50% (33 - 67)	38% (22 - 57)	50% (33 - 67)	71% (45 - 88)
Diarrhoea	14% (6 - 31)	54% (35 - 71)	11% (4 - 27)	43% (21 - 67)
Sleep difficulties	39% (24 - 58)	54% (35 - 71)	43% (27 - 61)	46% (23 - 71)
Symp-ms QLQ-S-22[b]				
Dysphagia	44% (28 - 63)	36% (20 - 55)	50% (33 - 67)	57% (33 - 79)
Eating restrictions	59% (41 - 75)	76% (57 - 89)	75% (57 - 87)	71% (45 - 88)
Reflux	67% (48 - 81)	68% (48 - 83)	61% (42 - 76)	64% (39 - 84)
Dry mouth	56% (37 - 72)	60% (41 - 77)	39% (24 - 58)	29% (12 - 55)

[a] Wilson Confidence Interval, [b] A high score indicates more symptoms or worse problems

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