

# Quality of life measures in dysplastic Barrett's oesophagus are comparable to patients with non-dysplastic Barrett's oesophagus and do not improve after endoscopic therapy

Elizabeth Ratcliffe ,<sup>1,2</sup> James Britton,<sup>3</sup> Calvin Heal,<sup>4</sup> Richard Keld,<sup>1</sup> Mark Murgatroyd,<sup>5</sup> Robert Willert,<sup>6</sup> John McLaughlin ,<sup>2,3</sup> Shaheen Hamdy ,<sup>2,3</sup> Yeng Ang<sup>2,3</sup>

**To cite:** Ratcliffe E, Britton J, Heal C, *et al.* Quality of life measures in dysplastic Barrett's oesophagus are comparable to patients with non-dysplastic Barrett's oesophagus and do not improve after endoscopic therapy. *BMJ Open Gastro* 2023;**10**:e001091. doi:10.1136/bmjgast-2022-001091

► Additional supplemental material is published online only. To view, please visit the journal online (<http://dx.doi.org/10.1136/bmjgast-2022-001091>).

Received 9 December 2022  
Accepted 27 February 2023



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For numbered affiliations see end of article.

## Correspondence to

Dr Elizabeth Ratcliffe;  
[elizabeth.ratcliffe@wvl.nhs.uk](mailto:elizabeth.ratcliffe@wvl.nhs.uk)

## ABSTRACT

**Objective** Barrett's oesophagus (BO) is a precursor lesion, via dysplastic phases, to oesophageal adenocarcinoma. Although overall risk from BO is low, it has been shown to adversely affect health-related quality of life (HRQOL). The aim was to compare dysplastic BO patients' HRQOL pre-endoscopic therapy (pre-ET) and post-ET. The pre-ET BO group was also compared with other cohorts: non-dysplastic BO (NDBO), those with colonic polyps, gastro-oesophageal reflux disease (GORD) and healthy volunteers.

**Design** Participants in the pre-ET cohort were recruited prior to their endotherapy and HRQOL questionnaires provided pre-ET and post-ET. Wilcoxon rank test was used to compare the pre-ET and post-ET findings. The Pre-ET group was compared to the other cohorts' HRQOL results using multiple linear regression analysis.

**Results** Pre-ET group of 69 participants returned the questionnaires prior to and 42 post-ET. Both the pre-ET and post-ET group showed similar levels of cancer worry, despite the treatment. No statistical significance was found for symptoms scores, anxiety and depression or general health measures with the Short Form-36 (SF-36) Score. Education for the BO patients was overall lacking with many of the pre-ET group still reporting unanswered questions about their disease.

The Pre-ET group was compared with NDBO group (N=379), GORD (N=132), colonic polyp patients (N=152) and healthy volunteers (N=48). Cancer worry was similar between the NDBO group and the Pre-ET group, despite their lower risk of progression. GORD patients had worse symptom scores from a reflux and heartburn perspective. Only the healthy group has significantly better scores in the SF-36 and improved hospital anxiety and depression scores.

**Conclusion** These findings suggest that there is a need to improve HRQOL for patients with BO. This should include improved education and devising-specific patient-reported outcome measures for BO to capture relevant areas of HRQOL in future studies.

## WHAT IS ALREADY KNOWN ON THIS TOPIC

- ⇒ Patients with Barrett's oesophagus have been found to have high rates of cancer worry and adversely impacted health-related quality of life (HRQOL), despite the low risk from their condition.
- ⇒ Studies have shown non-dysplastic Barrett's patients carry similar cancer worry to those who were previously treated for dysplasia.
- ⇒ Barrett's patients report poor disease-specific knowledge, and not enough emphasis is placed on patient education and support in routine care.
- ⇒ Alongside this, patients are expected to undergo invasive surveillance impacting HRQOL, and studies have shown poor control of symptoms can worsen worry and burden of their disease.

## INTRODUCTION

Barrett's oesophagus (BO) is a common condition with a pooled prevalence of histologically confirmed BO of 7.2% in patients with gastro-oesophageal reflux symptoms worldwide.<sup>1</sup> Patients with Barrett's have an overall per annum risk of progression to oesophageal adenocarcinoma (OAC) in the order of 0.33%.<sup>2,3</sup> OAC still carries a poor 10-year survival despite excellent advances in endoscopic therapy (ET) for preinvasive disease.<sup>4</sup> BO progresses through stages of non-dysplastic BO (NDBO) to low-grade dysplasia (LGD), high-grade dysplasia (HGD), intra-mucosal cancer to invasive OAC. National and international guidelines advise endoscopic surveillance to detect dysplasia and neoplasia amenable to ET such as endoscopic resection (ER) or radiofrequency ablation (RFA).<sup>5-8</sup> Most patients with BO will never progress to dysplasia or OAC; factors influencing this include genetic predisposition,

**WHAT THIS STUDY ADDS**

- ⇒ This large multicentre comparative cohort study shows patients undergoing treatment for dysplasia and early cancer had similar rates of worry of cancer pre and post endoscopic treatment.
- ⇒ Despite their intervention, there was no change in HRQOL across generic and gastrointestinal scores.
- ⇒ Non-dysplastic Barrett's patients showed similar cancer worry and HRQOL scores to the pretreatment cohort with dysplasia, while those with colonic polyps, gastroesophageal reflux disease and healthy volunteers had lower cancer worry scores than the pretreatment group.
- ⇒ Patients with Barrett's reported ongoing unanswered questions about their disease even when treated and satisfaction with follow-up services was mixed.

**HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY**

- ⇒ The provision of disease-specific knowledge around Barrett's needs to be optimised, and practice around follow-up and education of Barrett's patients could be studied to look for the best ways to deliver information.
- ⇒ Key aspects of symptom burden and cancer worry need particular attention in clinics and around endoscopic therapy to help reduce the HRQOL burden these patients' experience.
- ⇒ The design and validation of a specific Barrett's patient-reported outcome measure, which can be used to measure HRQOL in clinical interventions and research may be of value for this patient group.

smoking history, obesity, use of antacid medication and the length of their BO segment.<sup>9</sup> Despite this overall minimal risk, which is equivalent to a first degree relative of someone with a breast cancer gene associated breast malignancy,<sup>10</sup> patients are often given the impression of a greater risk of cancer and can be burdened with a 'precancer' label.<sup>11</sup> Patient-reported outcome measures (PROMs) have become a key part of how healthcare interventions are judged for efficacy, patient understanding and acceptability.<sup>12</sup> Health-related quality of life (HRQOL) has become a key domain in assessment of burden of disease. Qualitative and quantitative data show BO patients have a burden of anxiety about their risk of cancer, about the symptoms they experience and around their endoscopic surveillance tests.<sup>13–15</sup> Patients report their education around this condition has varied in its quality with many patients feeling their disease-specific knowledge is lacking.<sup>15</sup> The situation is compounded by misleading or alarming information on the internet or from other sources.

Studies looking at interventions for dysplastic BO (DBO) have shown improved HRQOL with RFA versus sham procedures<sup>16</sup> and for ET versus oesophagectomy for HGD or OAC.<sup>17</sup> Few studies have been undertaken in UK populations; one pilot study comparing RFA to argon plasma coagulation for post endotherapy BO eradication therapy used HRQOL measures as end points at 6 and 12 months of follow-up.<sup>18</sup> They showed minimal differences between HRQOL outcomes for both groups; however, they did not perform baseline

HRQOL measures so comparing pre and post therapy was not possible. Our study builds on the prior work of this group<sup>19</sup> using a collection of validated HRQOL measures in a UK prospective multicentre, multicohort study of HRQOL, focusing on a DBO cohort pre and post their ET. Currently, there is no disease-specific Barrett's PROM and studies so far have relied on using a combination of tools to cover different disease aspects.<sup>13 20 21</sup> This study may help to define key areas of need for BO patients, to support development of a Barrett's-specific PROM.

**Aims and objectives**

- ▶ To assess HRQOL in patients with BO and dysplasia or early OAC pre and post their ET.
- ▶ To compare the pretreatment DBO group's HRQOL with other comparator cohorts namely an NDBO group, those with gastro-oesophageal reflux disease (GORD), those with colonic polyps, healthy volunteers and a purely retrospective group who had received prior treatment for DBO.

**METHODS**

This study formed part of a concurrent mixed methods study exploring quantitative and qualitative aspects of BO HRQOL (quality of life measures in BO care pathways—CPMS ID 34114). Participants were recruited from four centres: two tertiary referral centres where BO ET is performed and two teaching hospitals in the Northwest of England.

Data from a questionnaire booklet consisting of a series of validated tools (outlined below) were obtained from a group of participants prior to their ET for DBO (pre-ET DBO group), the same patients were then invited to complete the questionnaire again (post-ET DBO group) >6 weeks to <6 months after completion of their ER or RFA 360 if this was the primary therapy or following a final surveillance not requiring further RFA 90 if this was their primary therapy.

Simultaneous data were collected from other groups for comparison to the pretreatment DBO group. These groups were:

- ▶ Non-dysplastic Barrett's cohort.
- ▶ Retrospective only cohort—patients with DBO recruited following treatment.
- ▶ GORD cohort—to determine the link with symptoms.
- ▶ Colonic polyps—chosen as also a premalignant condition requiring surveillance to explore differences with lower gastrointestinal (GI) endoscopy surveillance versus upper GI.
- ▶ Healthy individuals with no prior comorbidities—as a control group.

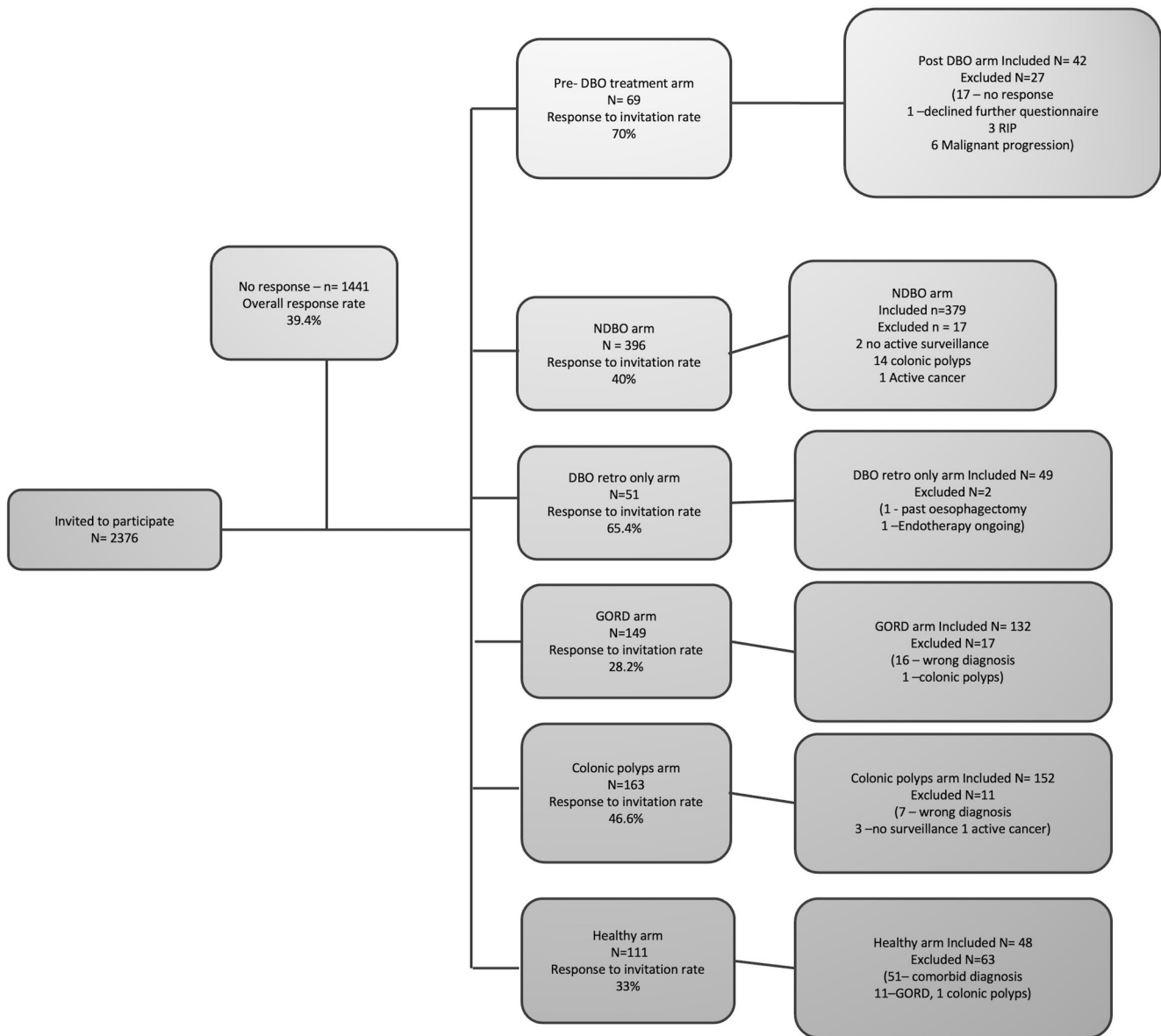
**Recruitment technique and inclusion criteria**

All participants recruited to the study were over 18 years of age and had capacity to consent for the study, detail of inclusion criteria for each cohort is provided in online supplemental appendix 1.

**Table 1** Summary of responder demographics and characteristics for all groups

	Pre-DBO N=69	Post DBO N=42	NDBO N=379	Retro DBO N=49	GORD N=132	Colonic N=152	Healthy N=48
Response rate %	70%	61%	40%	65%	28%	47%	33%
Age	Mean 70.7 Range 33–92	Mean 71.0 Range 55–84	Mean 65.1 Range 26–87	Mean 71.0 Range 55–84	Mean 60.9 Range 30–90	Mean 68.6 Range 48–89	Mean 50.3 Range 20–80
Sex	Male 60 Female 9 %Male 87%	Male 261 Female 132 %Male 66.2%	Male 261 Female 132 %Male 66.2%	Male 44 Female 5 %Male 89.8%	Male 72 Female 60 %Male 60.9%	Male 100 Female 52 %Male 65.8%	Male 24 Female 23 %Male 51.1%
Employment status	Employed 20.3% Unemployed 2.9% Retired 75.4%	Employed 31.2% Unemployed 7.1% Retired 58.6%	Employed 31.2% Unemployed 7.1% Retired 58.6%	Employed 8.2% Unemployed 0.0% Retired 91.8%	Employed 35.9% Unemployed 10.9% Retired 53.1%	Employed 17.3% Unemployed 2.7% Retired 80.0%	Employed 85.1% Unemployed 4.3% Retired 10.6%
Family history	Cancer 18.8% Disease- specific cancer 8.7% Chronic disease 26.1%	Cancer 20.3% Disease- specific cancer 7.4% Chronic disease 18.5%	Cancer 20.3% Disease- specific cancer 7.4% Chronic disease 18.5%	Cancer 24.5% Disease- specific cancer 2% (OAC) Chronic disease 16.3%	Cancer 27.8% Disease- specific cancer 5.4% (OAC) Chronic disease 21.5%	Cancer 16.9% Disease- specific cancer 22.5% (CRC) Chronic disease 13.9%	Cancer 50.0% Disease- specific cancer NA Chronic disease 33.3%
Carer	Yes 8.7% No	Yes 7.4% No	Yes 7.4% No	Yes 14% No	Yes 13.2% No	Yes 11.3% No	Yes 2.1% No
Smoking	Never 27.5% Current 2.9% Ex-smoker 69.6%	Never 42.9% Current 9.9% Ex-smoker 46.9%	Never 42.9% Current 9.9% Ex-smoker 46.9%	Never 26.5% Current 4.1% Ex-smoker 69.4%	Never 49.6% Current 11.6% Ex-smoker 38.8%	Never 39.7% Current 10.6% Ex-smoker 49.7%	Never 70.8% Current 8.3% Ex-smoker 20.8%
PPI use	Yes 92.8% No 7.2%	Yes 94.9% No 5.1%	Yes 94.9% No 5.1%	Yes 100% No 0%	Yes 84.6% No 15.4%	Yes 45.7% No 54.3%	Yes 0.0% No 100%
Antidepressant use	Yes 7.2% No	Yes 8.9% No	Yes 8.9% No	Yes 10.2% No	Yes 18.3% No	Yes 10.6% No	Yes 0.0% No
Prague M classification	Mean 6.2 Range 1–18	Mean 3.7 Range 1–18	Mean 3.7 Range 1–18	Mean 3.9 Range 1–18	Mean N/A Range N/A	Mean N/A Range N/A	Mean N/A Range N/A
Comorbidity prevalence	None 14.4% 1–2 42% 3–4 28.9% >4 14.4%	None 17% 1–2 48.7% 3–4 25.9% >4 8.4%	None 17% 1–2 48.7% 3–4 25.9% >4 8.4%	None 14.3% 1–2 59.2% 3–4 4.1% >4 14.3%	None 25.0% 1–2 55.3% 3–4 2.3% >4 17.4%	None 21.7% 1–2 57.9% 3–4 3.3% >4 17.1%	None 100.0% 1–2 0% 3–4 0% >4 0%

CRC, colorectal cancer; DBO, dysplastic Barrett's oesophagus; GORD, gastro-oesophageal reflux disease; NA, not applicable; NDBO, non-dysplastic Barrett's oesophagus; OAC, oesophageal adenocarcinoma; PPI, proton pump inhibitor.



**Figure 1** A flow chart depicting the responses for each cohort and reasons for non-response or exclusion. DBO, dysplastic Barrett's oesophagus; NDBO, non-dysplastic Barrett's oesophagus; GORD, gastro-oesophageal reflux disease; RIP, deceased.

Participants were approached by post or in-person at endoscopy lists or clinic appointments and deemed recruited when they had returned the completed questionnaire booklet. When provided in-person, participants were encouraged to complete the questionnaire >4 weeks after their intervention or clinic appointment.

## Data collected

### All participants

- ▶ Demographics; age, sex, family history, carer status, employment status, smoking status, proton pump inhibitor usage, antidepressant usage.
- ▶ Comorbidities (see questionnaire pack in online supplemental material).

Additional group-specific information was obtained and is outlined in online supplemental appendix 2.

## HRQOL tools

Prior literature review regarding HRQOL and BO was used as the basis to choose the tools for this study<sup>22</sup> as there is currently no specific BO PROM.

The tools used were:

- ▶ Gastrointestinal Symptom Rating Scale (GSRS) (15 items, 5 domains, 4-point Likert scale).<sup>23</sup>
- ▶ Hospital Anxiety and Depression Score (HDAS) (2 domains, 14 items, 4-point Likert scale).<sup>24</sup>
- ▶ Cancer Worry Scale (CWS) (6 domains, 4-point Likert Scale).<sup>25</sup>
- ▶ Short Form-36<sup>26</sup> (SF-36).

The questionnaire booklet is available on request.

## Statistical analysis

The impact of each disease state was assessed with the HRQOL tools, initially focusing on the pretreatment

**Table 2** Cancer worry and perception of cancer risk

HRQOL tool/item	Pre DBO	Post DBO	P value
<b>Cancer Worry Score—mean (range)</b>	<b>13 (0–20)</b>	<b>14 (6–21)</b>	<b>P=0.808</b>
Proportion CWS			
<10	15/66 (22.7%)	6/40 (15%)	
10–11	7/66 (10.6%)	4/40 (10%)	
≥12	44/66 (66.7%)	30/40 (75%)	
Perceived cancer risk	Median=3	Median=4	
1=very small	10/62 (14.5%)	5/39 (12.8%)	
2=small	10/62 (14.5%)	7/39 (17.9%)	
3=quite small	15/62 (21.7%)	7/39 (17.9%)	
4=neither small or large	17/62 (24.6%)	10/39 (25.6%)	
5=quite large	9/62 (13%)	8/39 (20.5%)	
6=large	0/62 (0%)	2/39 (5.1%)	
7=very large	1/62 (1.4%)	0/39 (0%)	
Perceived oesophageal cancer risk someone with BO	Median=4	Median=4	
1 in 1000	14/60 (23.3%)	5/39 (12.8%)	
1 in 500	9/60 (15%)	6/39 (15.4%)	
1 in 250	4/60 (6.7%)	8/39 (20.5%)	
1 in 100	8/60 (13.3%)	4/39 (10.3%)	
1 in 50	10/60 (16.7%)	8/39 (20.5%)	
1 in 25	5/60 (8.3%)	7/39 (17.9%)	
1 in 10	10/60 (16.7%)	1/39 (2.6%)	
Perceived oesophageal cancer risk you	Median=4	Median=4	
1 in 1000	13/59 (22%)	7/38 (18.4%)	
1 in 500	9/59 (15.3%)	7/38 (18.4%)	
1 in 250	6/59 (10%)	3/38 (7.9%)	
1 in 100	9/59 (15%)	5/38 (13.2%)	
1 in 50	10/59 (17%)	6/38 (15.8%)	
1 in 25	3/59 (5%)	6/38 (15.8%)	
1 in 10	9/59 (15.3%) (79.7% underestimate)	4/38 (10.5%) (57.9% underestimate)	
Horizontal VAS Score mean (range)	25 (10–50)	24.5 (10–41.5)	P=0.259

This table outlines the results of the Cancer Worry Score and questions regarding their perceived cancer risk for the pretreatment and post-treatment groups.  
BO, Barrett's oesophagus; CWS, Cancer Worry Score; DBO, Dysplastic Barrett's Oesophagus; HRQOL, Health Related Quality of Life; VAS, Visual Analogue Scale.

DBO group (N=69) and the comparison with their post-treatment responses (N=42) performed using Wilcoxon rank test. Comparisons using multiple linear regression analysis were performed comparing the pre-treatment group with the following groups: non-DBO (N=390), gastro-oesophageal reflux (GORD) (N=128), colonic polyps (N=146), healthy participants (N=45) and a purely retrospective post therapy DBO group (N=56) adjusted for a set of prespecified confounders from 4 hospital sites. These confounders were age, smoking history, sex, comorbidities and history of anxiety or depression. Independent t-test was used to compare BO groups' mean CWS pre and post January 2020 to assess the impact of the COVID-19 pandemic. Significance was determined with a p value<0.05, using Stata V.14 software.

## RESULTS

### Data quality

Greater than 90% completion of questions was deemed satisfactory—in this study 812/894 (90.8%) of the participants completed>90% of the questionnaire. A response consistency index (RCI) score of 0 means no contradictory

responses and is calculated on the SF-36 software. Ideally a study should achieve>90% of respondents with an RCI of 0, this study achieved 89% with an RCI of 0. Cronbach alpha is a measure of scale reliability—all the tools used in this study had greater than satisfactory scores for their Cronbach alpha (SF-36>0.85, HDAS 0.83, CWS 0.89, GSRS 0.6–0.85).

### Response rates and demographics

The response rate overall for all groups was 39.4%; this reflected the use of postal recruitment used for some of the cohorts. Demographics of the responders have been outlined in [table 1](#). Responder versus non-responder characteristics for the pre-DRO group have been outlined in the online supplemental appendix 3.

### Pre and post endotherapy DBO groups

A total of 69 pretreatment DBO cases were obtained (response rate 70%), of which 42/69 (60%) completed the follow-up questionnaire post treatment. Participants of the pre and post cohort and their outcomes are outlined in the flow chart [figure 1](#).



**Table 3** Cancer Worry Score and perception of risk for pretreatment dysplastic Barrett's oesophagus compared with the other cohorts.

	Cancer Worry Score				VAS	
	Total mean (SD)	Category % Normal (<10)	Category % Borderline (10-11)	Category % Positive (>12)	Pretreatment DBO versus p value	Pretreatment DBO versus other domains for VAS scoring p values
					Coefficient (95% CI)	
Pretreatment DBO	12.55 (4.85)	22.7% N=15	10.1% N=7	67.2% N=44	-	-
NDBO	12.19 (4.57)	31.8% (121)	15.8% (66)	50.9% (194)	-0.99 (-2.12 to 0.13)	0.713
Retro DBO	12.67 (4.95)	33.3% (16)	16.7% (8)	50.0% (24)	0.59 (-0.94 to 2.12)	0.967
GORD	10.88 (4.98)	45.7% (59)	10.9% (14)	43.4% (56)	-3.30 (-4.61 to -1.98)	0.003*
Colonic polyps	11.58 (3.93)	36.2% (54)	12.8% (19)	51.0% (76)	-1.29 (-2.53 to -0.46)	0.438
Healthy	10.02 (3.31)	47.9% (23)	22.9% (11)	29.2% (14)	-4.26 (-6.00 to -2.53)	0.773

\* ; Denotes statistical significance; DBO, dysplastic Barrett's oesophagus; GORD, gastroesophageal reflux disease; NDBO, non-dysplastic Barrett's oesophagus; VAS, Visual Analogue Scale.

### Cancer worry

Comparing the pretreatment and post-treatment group overall for cancer worry there was no significant difference in total CWS pre or post treatment (pre median 13 (range 10–16.5) post 13.5 (10.5–17),  $p=0.808$ ). In other studies, a cut-off was given of <10 for normal result, a score of 10–12 was a borderline result and >12 for significant cancer worry, the proportion of each group has been outlined in [table 2](#). Overall, 66.7% of individuals pre treatment had a significant CWS and 75% thereafter. When assessing their own risk of OAC, 79.7% underestimated their risk prior to endotherapy compared with 57.9% after treatment ([table 2](#)).

### GSRS

There was no significant pre versus post differences in GSRS total scores (median pre=4 (IQR 2–10) post=5 (3–10),  $p=0.567$ ). When broken down to disease-specific scores, the reflux scores were similar pre and post therapy.

### Short Form-36

The global assessment of QOL through the SF-36 showed there was also no significant differences between the pre and post endotherapy group with no significant difference between the overall norm-based scores (pre : 53.8 (41.6 to 55.6) post 51.5 (40.4. to 55.6),  $p=0.48$ ).

### Hospital Anxiety and Depression Score

Total HDAS showed no significant difference (pre treatment=7 (3–12) and post treatment 8.5 (6–15),  $p=0.516$ ).

### Pretreatment DBO versus other groups

#### Cancer worry

Cancer worry was lower in colonic polyps (-1.29, 95% CI -2.53 to -0.05,  $p=0.042$ ) GORD (-3.30, 95% CI -4.61 to -1.98,  $p<0.001$ ) and healthy volunteers (-4.26, 95% CI -6 to -2.52,  $p\leq 0.001$ ), compared with the pretreatment DBO group ([table 3](#)). Despite a much lower real terms risk of cancer progression, the NDBO group had no significant difference in cancer worry compared with the pretreatment DBO cohort ([table 3](#)).

#### Gastrointestinal Symptom Rating Scale

GSRS overall scores were higher in the GORD group (1.88 95% CI 0.22 to 3.54,  $p=0.027$ ) and lower in the healthy group (-5.93 95% CI -8.14 to -3.72,  $p<0.001$ ), compared with the pretreatment DBO group ([table 4](#)).

### Short Form-36

Only the healthy group showed a difference in SF-36 scores demonstrating a higher (better) score than the other cohorts and significantly higher than the pretreatment DBO group (OR 5.76, 95% CI 2.04 to 16.24,  $p=0.001$ ).

### Hospital Anxiety and Depression Score

Comparing pretreatment DBO, only the healthy volunteers had a significantly lower HADS scores (-5.04, 95% CI -7.53 to -2.55,  $p\leq 0.001$ ).



**Table 4** Breakdown of gastro-oesophageal symptom rating scale (GSRS) scores overall and for reflux symptoms alone for the pretreatment group versus the other cohort groups

	Total GSRS Mean (SD)	Reflux score Mean (SD)	Coefficient (95% CI)	Pretreatment DBO versus p value
Pretreatment DBO	5.96 (5.4) 0–23	0.9 (1.3) 0–6	n/a	n/a
NDBO	6.95 (6.1) Range 0–29	0.95 (1.33) Range 0–6	–0.92 (–1.52 to 1.33)	0.900
Retro DBO	6.43 (5.73) 0–22	0.7 (0.9) 0–3	0.77 (–1.19 to 2.73)	0.441
GORD	10.42 (7.41) 0–35	1.81 (1.75) 0–6	1.88 (0.22 to 3.54)	0.027*
Colonic polyps	5.29 (5.4) 0–25	0.49 (0.96) 0–5	–1.47 (–3.04 to 0.11)	0.068
Healthy	1.96 (2.48) 0–12	0.25 (0.53) 0–2	–5.93 (–8.14 to –3.72)	<0.001*

\*, Denotes statistical significance; DBO, dysplastic Barrett's oesophagus; GORD, gastroesophageal reflux disease; GSRS, Gastro-oesophageal Symptom Rating Scale; NDBO, non-dysplastic Barrett's oesophagus.

### COVID-19 impact

The SARS-COVID-19 pandemic spread across the globe from December 2019 and caused disruption to endoscopy services. The time from pretreatment recruitment to ET prior to December 2019 was median 62 days (range 13–243) excluding one case who declined treatment multiple times and waited 999 days. Time to ET post December 2019 was median 114 days (range 54–383). However, despite delay for the pre-ET DBO cohort, there was no significant difference in total CWS using independent t-test pre Jan 2020 versus post Jan 2020 (–1.606, 95% CI –4.323 to 1.11,  $p=0.242$ ) and again for the post DBO cohort (–0.381, 95% CI –3.179 to 2.417  $p=0.784$ ). For the NDBO cohort: –1.861 (95% CI –4.327 to 0.120,  $p=0.64$ ). All other cohorts were recruited prior to January 2020.

### Follow-up care and patient education

A crucial factor in patient HRQOL is disease-specific knowledge and education, in this questionnaire patient participants with BO were asked about their experience receiving information regarding BO (summary table in online supplemental appendix 4). Most information was acquired by patients from the medical team via face-to-face appointments or when they came for a procedure, with fewer gaining online information. Written information was provided to the majority of patients, with around 1/3 in each group seeking out self-taught information. Overall satisfaction with follow-up care and information was higher among patients who were going to or had received ET, with NDBO ratings being less satisfied. Overall, 73.2% of the NDBO participants reported being satisfied or very satisfied versus 90%–100% in those who have had or will have therapy. The overall satisfaction was

good despite 10%–30% of respondents still reporting they have unanswered questions.

### DISCUSSION

BO carries overall a low risk of cancer, but those with known dysplasia or neoplasia would be expected to have greater worry of cancer given they have a localised early cancer already or are at greater risk given their dysplasia. Those who have received ET are still at higher risk of developing cancer but we aimed to see if there was any change pre and post treatment. Though we are unable to attribute this to the treatment given the cohort design, there was no significant change in the mean scores or proportions of those with higher cancer worry. Overall, both the pre and post groups had high CWS suggesting background concern about this, appropriate for their increased risk of progression compared with the NDBO. However, this was not significantly higher than the NDBO, again confirming that this non-dysplastic group still has a high cancer worry despite overall low risk of progression. Other studies confirm this and have shown that anxiety and depression appear to be associated with greater cancer worry; likewise, a high symptom burden is seen in those with high cancer worry.<sup>13 19</sup> Despite their high CWS, a large proportion of the pretreatment and post-treatment groups underestimate their risk (79.7% pre and 57.9% post therapy); this may be reflective of patients finding the understanding of numerical estimates of risk difficult to interpret.<sup>27</sup>

Pre and post groups overall showed no significant differences between their HRQOL scores, particularly their CWS. One factor at play here may be that for DBO treatment it can be unclear to patients when their treatment



has concluded, their surveillance frequency might increase and they may require repeated treatments especially for RFA. In a study by Shaheen *et al* of RFA versus sham procedure, the RFA group at 12 months post treatment showed a reduction in worry of cancer ( $p=0.003$ ), depression ( $p=0.02$ ), stress ( $p=0.03$ ), dissatisfaction with their oesophageal disease ( $p<0.001$ ) and reduced worry about esophagectomy ( $p=0.009$ ) compared with the sham arm participants.<sup>16</sup> This may reflect the timing of their post-treatment follow-up questionnaire—at 12 months rather than within 6 months. As part of the LGD RFA or surveillance only RCT performed by Rosmolen *et al* they assessed HRQOL in each of the study groups.<sup>28</sup> Questionnaires were given at baseline (before randomisation) and at 2, 9, 14, 26 and 38 months after randomisation. The Illness Perception Questionnaire (IPQ) showed that patients in their ablation group perceived their disease lasted for a shorter period ( $p<0.001$ ) and experienced fewer symptoms ( $p<0.001$ ). Over time, there were improved outcomes at each of the further time points in the ablation group significantly compared with the surveillance group. This may reflect the positive reinforcement of each RFA session showing improvement/reduction in the presence of glandular mucosa and hence participants felt their condition was not as threatening as the surveillance-only group. Future time points could be assessed in the current study cohort to see if HRQOL improves.

Comparing the pre-treatment DBO group with all cohorts, it is striking that NDBO have a similar worry of cancer. Education is an important factor in patient's understanding of BO. Shaheen *et al* attempted to evaluate this after the 12-month follow-up, when they had informed them of their current disease status, for example, dysplasia or intestinal metaplasia was eradicated, and asked participants to consider what they understood in their disease state.<sup>16</sup> Only 59% of participants could correctly identify their disease state, this echoes our findings that despite satisfaction with follow-up, many participants with NDBO or DBO had unanswered questions about their disease. In the UK, currently, BSG guidelines advise an initial clinic appointment to discuss the diagnosis, and thereafter patients receive limited contact other than at surveillance. Practical improvements could include improving the quality of the initial contact by focusing on the key areas of symptom management, burden of surveillance, cancer-worry and disease-specific knowledge. Then, as Barrett's patients will undergo years of surveillance, opportunities should be created for patients to flag concerns, perhaps via an email or telephone link and health professionals could detect patients in need of support using a Barrett's-specific PROM provided at intervals between surveillance.

### Limitations

As this was a cohort study, we were unable to attribute cause or effect to the treatment for the pre and post groups. There was an unfortunate loss of recruited

subjects between pre and post groups, this was in part due to the clinical picture changing but there was a considerable issue with COVID-19 causing delays to treatment and some patients were still awaiting their ET at completion of the study. A similar cohort study halted their recruitment during the initial phase of the pandemic<sup>13</sup>; however, as ET procedures were protected in the UK, we continued recruitment during this time. Nonetheless, fewer patients were seen face to face in clinic, front-line working was required of the clinical research staff and research nurses were redeployed. The COVID-19 pandemic may have impacted patients' support networks and usual activities, which may have affected generic aspects of HRQOL.

Response rates overall were good and comparable to other survey studies; however, there is always an element of self-selection bias with questionnaires, though clinic recruitment improved rates of return. The tools used for this study, though all validated, were not specific to BO. In a systematic review, Van der Ende-van Loon *et al* assimilated the key areas of importance in HRQOL in BO according to patients from four qualitative works.<sup>29</sup> They outlined that individually the tools used in prior QOL work in BO did not address a full range of these issues, which could be true of the tools used in this study. To overcome this, we used multiple tools to address different aspects of HRQOL; however, this may have resulted in a burden to patients given the length of the questionnaire pack, though missing data proportions were low. A more streamlined tool designed specifically for BO patients and validated in this patient group would be beneficial for future studies.

### CONCLUSIONS

To the authors knowledge, this is the largest UK multi-cohort, multicentre study of DBO patients comparing to other disease states, and the first to explore the pre-post DBO experience prospectively. Our study shows high burdens of cancer worry across all stages of BO, and a need for improved education, reassurance and follow-up care for these patients.

#### Author affiliations

<sup>1</sup>Gastroenterology Department, Wrightington, Wigan and Leigh NHS Foundation Trust, Wigan, UK

<sup>2</sup>Division of Diabetes, Endocrinology and Gastroenterology, Faculty of Medical and Human Sciences, The University of Manchester, Manchester, UK

<sup>3</sup>Department of Gastroenterology, Northern Care Alliance NHS Foundation Trust, Salford, UK

<sup>4</sup>School of Health Sciences, Division of Population Health, Health Services Research & Primary Care, The University of Manchester, Manchester, UK

<sup>5</sup>Gastroenterology Department, Bolton NHS Foundation Trust, Bolton, UK

<sup>6</sup>Gastroenterology Department, Manchester University NHS Foundation Trust, Manchester, UK

Twitter Elizabeth Ratcliffe @lil\_ratcliffe

**Acknowledgements** We thank the research teams for their assistance posting and collecting questionnaires at all the sites involved. Special thanks to Professor Maria Horne for her support for the qualitative element of the wider project and to the volunteers and patients for completing the surveys.



**Contributors** All authors contributed significantly to this work. ER, YA, JM, SH and JB devised and designed the study. ER, JB, RK, MM, RW and YA were responsible for driving recruitment at each site. ER and JB performed the data collection and data analysis was undertaken by ER and CH. ER wrote the initial manuscript, all authors reviewed and revised the final manuscript. ER and YA are guarantors for the study and overall content of this manuscript.

**Funding** This study forms part of a larger research project, which has received unrestricted external funding support from Medtronic (previously Covidien). Medtronic have not influenced the design of this study, writing of the manuscript or decision to submit for publication (Medtronic, Grant/Award Number: ISR-2016-10773).

**Competing interests** ER and YA have research funding from Medtronic, YA has research funding from Cancer Research UK. ER has received honoraria for a podcast recording with Janssen and for a focus group with Takeda. SH is the director and chief scientific officer for Phagenesis and holds founder shares, he holds a patent for Anisys Go and Lyft device, and received honoraria for ESSD meeting Brussels and Chinese Dysphagia research forum.

**Patient consent for publication** Not applicable.

**Ethics approval** Prior ethical approval was obtained for the study from the Health Research Authority Yorkshire and Humber ethics committee (REC reference number 16/YH/0035). All participants received a participant information sheet alongside the questionnaire pack, written consent was not required as completion and return of the questionnaire pack implied consent and no changes were made to the individual's care. This is in accordance with the UK Health Research Authority guidance.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data availability statement** Data are available upon reasonable request.

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#### ORCID iDs

Elizabeth Ratcliffe <http://orcid.org/0000-0001-6521-2133>

John McLaughlin <http://orcid.org/0000-0001-6158-5135>

Shaheen Hamdy <http://orcid.org/0000-0001-9640-7427>

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## Supplementary Appendices

**Appendix 1 – Inclusion criteria for each cohort group****Pre and post endotherapy for DBO cases**

- Patients with known Barrett's dysplasia or neoplasia which was amenable to endoscopic therapy were eligible (dysplasia included indefinite for dysplasia, low grade dysplasia, high grade dysplasia and cancer if appropriate for endotherapy).
- Patients were approached at least 6 weeks prior to their endotherapy appointment either in clinic or by post and given the questionnaire pack.
- Participant logs were screened by the study team on regular intervals to determine when participants had completed their treatment and follow up questionnaires (post treatment) were sent by post to the individuals who had completed a pre-treatment questionnaire.

Treatment completion was defined as:

- For an endoscopic resection (ER) the end point of their treatment was deemed to be the completion of the ER, i.e. the endoscopic submucosal dissection or endoscopic mucosal resection procedure. If the participant was having radiofrequency ablation only completion was either their 360 HALO RFA treatment procedure or when no further HALO 90 RFA was required at the latest check endoscopy. Questionnaires were sent to participants after 6 weeks following the completion of their treatment and fewer than 6 months after the end of their treatment completion.
- Non-responders were contacted 2 times via phone and further questionnaires sent if required.

**Non-dysplastic Barrett's oesophagus.**

- Any patient with a diagnosis of non-dysplastic BO enrolled in surveillance was included.
- No evidence of intestinal metaplasia(IM) on latest biopsies was not a reason for exclusion as by virtue of their continuation on surveillance, suggesting prior IM on biopsies historically or clinically significant reason for them to continue on surveillance.

#### **Barrett's oesophagus with dysplasia or early OAC.**

- A retrospective group of patients who had previously had endotherapy was also included in the recruitment. This involved any patient who had previously had a diagnosis of DBO (dysplasia includes indefinite for dysplasia, low grade dysplasia, high grade dysplasia) or early OAC which had been previously treated with endotherapy (ER or RFA).

#### **Gastroesophageal reflux disease.**

- Included participants who have been diagnosed with any of the following in primary or secondary care without the presence of BO; "gastroesophageal reflux with oesophagitis", "gastroesophageal reflux without oesophagitis", "gastroesophageal reflux disease", "GORD", "acid reflux", "heartburn" or "dyspepsia".
- Participants were recruited from both primary and secondary care. Primary care participants were identified and invited postally from a single GP surgery. Secondary care participants were identified via hospital coding systems and postally invited or identified at the time of a hospital appointment (clinic or endoscopy) and recruited in person.

**Colonic polyp surveillance.**

- Participants in this group were included if they had a known histology of adenomatous colonic polyps and had further endoscopic surveillance planned without a concurrent diagnosis of BO.
- Patients on colonoscopy surveillance for other reasons, e.g. IBD CRC cancer risk, previous personal history of CRC, were excluded.
- All participants were recruited via postal invite or in person in the outpatient clinic.

**Healthy Volunteers**

- To be used as a control group, participants without significant chronic disease were identified from primary care coding and recruited via postal invite. Members of hospital staff without significant chronic disease were eligible for inclusion also.

**Appendix 2 – group specific additional data collected.***Pre-treatment and post treatment DBO group*

- This group were recruited prior to their ET, completed the first questionnaire pack prior to their treatment, then another pack between 6 weeks to 3 months after their endoscopic therapy.
- Prague classification and histological grade pre-endoscopic therapy.
- ET modality; RFA, endoscopic resection (ER) (endoscopic mucosal resection (EMR) or endoscopic submucosal dissection (ESD)) or APC.
- *After treatment:*

- Number of endoscopic therapy sessions required.
- Time since completing successful endoscopic therapy.
- Timing of prior and next surveillance endoscopy.
- Timing of previous BO clinic attendance.

**Non-dysplastic BO**

- Prague classification.
- Timing of prior and next surveillance endoscopy.
- Timing of previous BO clinic attendance.

**Colonic polyp surveillance**

- British Society of Gastroenterology colonic polyp risk stratification
- Timing of prior and next surveillance endoscopy.

**Gastroesophageal reflux disease**

- Timing of prior endoscopy, if undertaken.
- Findings at prior endoscopy (e.g. erosive GORD, non-erosive GORD +/- other confounding findings)

**Dysplastic BO retrospective only group**

- A Cohort recruited after their endoscopic therapy and single questionnaire booklet completed.
- Prague classification and histological grade pre-endoscopic therapy.

- ET modality; RFA, EMR, ESD or APC
- Number of ET sessions required.
- Time since completing successful ET.
- Timing of prior and next surveillance endoscopy.
- Timing of previous BO clinic attendance.

### Appendix 3

	Dysplastic pre-endothrapy responder (n=69)	Dysplastic pre-endothrapy Non responder (n=28)
Age – mean (range)	70.7 (33-92)	65.9 (44-83)
Sex (% male)	87%	82%
Comorbidities		
- None	14.4%	5
- 1-2	42%	9
- 3-4	28.9%	11
- More than 5	14.4%	3
Prague (M) – mean (range)	6.2 (1- 18)	4 ( 0-12)

Details of non-responder characteristics for all groups is available on reasonable request.

### Appendix 4 – follow up care outcomes Barrett’s cohorts

	NDBE	Pre-treatment DBO	Post treatment DBO	Retrospective DBO only
Outpatient appointment provided (yes)	212/376 (56.4%)	49/64(76.6%)	30/31 (96.8%)	48/54 (88.9%)
Appointment within 6 weeks of endoscopy (yes)	173/199 (88.7%)	46/54 (85%)	24/30(80%)	43/54(79.6%)

Follow up by who	0 = 161/191 (84.3%)	0= 52/60 (86.7%), 1=2/60(3.3%), 2= 6/60 (10%)	0=27/28 (96%), 2= 1/28 (3.6%)	0 = 44/49(90%) 1= 3/49 (6%) 2= 2/49 (4%)
Consultant=0, Nurse=1, Speciality trainee (registrar) =2	1=16/191 (8.4%), 2 = 14 /199 (7.3%)			
Medication discussed (Yes)	196/215 (91.2%)	46/57(80.7%)	27/31 (87%)	46/49(94%)
Lifestyle discussion (Yes)	140/208 (67.3%)	25/56(44.6%)	13/29(44.8%)	28/50 (56%)
Cancer risk discussed (Yes)	175/211(82.9%)	39/57(68.4%)	23/30 (76.7%)	37/49 (75.5%)
Advantages of surveillance discussed (Yes)	195/210 (92.9%)	44/58 (75.9%)	23/29(79%)	46/50 (92%)
Limitations of surveillance discussed (Yes)	97/207 (46.9%)	19/56(33.9%)	9/28 (32.1%)	17/47(36%)
Future treatments discussed (Yes)	80/209 (38.3%)	28/56(50%)	18/29 (62.1%)	34/49(69%)
Written information provided (Yes)	146/209 (69.9%)	45/58(77.6%)	20/29(69%)	41/50 (82%)
Online information provided (Yes)	67/210 (31.9%)	15/57(26.3%)	6/27(22%)	19/51 (37%)
Information	256/363 (70.5%)	59/64(92%)	29/30(96.7%)	50/53 (94%)

provided face to face at clinic appointment (Yes)				
Information from face to face at endoscopy (Yes)	264/365(72.3%)	50/63(79.4%)	24/28(86%)	51/54 (94%)
Information leaflet provided (Yes)	251/365(68.8%)	52/63(82.5%)	22/27(81.5%)	49/53 (92%)
Information self-taught (Yes)	109/352 (31%)	22/60 (36.7%)	7/26(27%)	14/52(27%)
Satisfied with information provided (0=satisfied – 4 = unsatisfied)	0-1 = 279/368 (73.2%)	0-1 60/63 (95%)	0-1 28/31 (90%)	0-1 = 52/55 (94.5%)
Satisfaction with follow up care (0=satisfied – 4 = unsatisfied)	0-1 = 272 (74.9%)	0-1= 56/61 (91.8%)	0-1 = 28/31(90%)	0-1 = 55/55 (100%)
Unanswered questions (Yes)	113/365 (31%)	18/64 (28.1%)	9/29(31%)	6/52 (11.5%)

**Appendix 4 table - Summarises the outcome of questions relating to follow up care and satisfaction with patient education for the cohorts of Barrett's patients. NDBO= Non-dysplastic Barrett's oesophagus, DBO = Dysplastic Barrett's oesophagus.**