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Acceptability to patients of screening disposable transnasal endoscopy: qualitative interview analysis

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Abstract

Objectives

Screening in selected at-risk populations for Barrett's oesophagus (BO) and oesophageal varices (OVs) has been proposed, but there are obstacles with conventional oesophagogastroduodenoscopy (C-OGD), including patient acceptability. Portable and disposable office-based transnasal endoscopy (TNE) is a feasible and accurate alternative to C-OGD that may have use in primary and secondary care. This article outlines a qualitative analysis of patient experiences of TNE and C-OGD in order to gain an insight into an acceptable delivery of an endoscopic screening service.

Design

Purposeful sampling identified 23 participants who then underwent semi-structured interviews to determine their experiences of both procedures. Thematic analysis was conducted to derive meaning from their lived experiences.

Setting

A secondary care endoscopy unit, clinic room and interview room.

Participants

Patients referred for BO or OV surveillance and for endoscopy to investigate dyspepsia underwent unsedated TNE using the EG Scan II device followed by C-OGD with or without sedation, as part of a clinical trial(1,2).

Results

The themes that arose from our analysis were: inclusivity in one's own health care; comfort level and convenience; validity of the procedure and application to a screening population; and a sense of altruism and reciprocity.

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3 Positive aspects of TNE included participant empowerment, reduced discomfort and
4 avoidance of conscious sedation. Participants felt that if TNE screening was of proven
5 efficacy it would be welcomed, though views on use in a community setting were
6 mixed.
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12 **Conclusions**

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14 Most patients preferred TNE to unsedated C-OGD and the reasons they gave featured
15 strongly in the emerging themes. This information identifies opportunities and
16 challenges in establishing an endoscopic screening service.
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28 Keywords: endoscopy, oesophageal disease, hepatology
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32 **Strengths and Limitations of the study**

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- The size of the original study, in which 100 patients from this centre alone allowed for a broad stated aim and collection of participants until data saturation was reached.
 - Every participant had clinic-based TNE before C-OGD so their experiences of the TNE would reflect that of a person undergoing screening more so than if C-OGD was done first.
 - The advantage in performing thematic analysis on this group of patients is that it allowed us to develop clear themes with supporting data, which could allow transferability to other potential screening populations. It is highly likely the same themes would have been derived from interviews of participants from any

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3 of the study centres and the conclusions could apply to many locations or
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5 healthcare systems.
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- 8 • Qualitative research can be prone to claims of poor scientific rigour; however,
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10 the framework by which the validity and reliability of a study is evaluated is
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12 subject to standard quantitative criteria. To maximise the credibility and
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14 dependability of the findings, reflexivity, in which the impact of the researcher
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16 and social environment on each other is acknowledged and managed, was
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18 employed at each stage. Care was taken not to manipulate participants into
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20 giving accounts that favoured or condemned either endoscopic test.
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 - 23 • The index of transferability for the findings within this study for other screening
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25 modalities and investigations is limited.
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Introduction

Several authorities have highlighted the need to identify alternative, minimally-invasive screening tests for Barrett's oesophagus (BO) and oesophageal varices (OV) which are precursor conditions for oesophageal adenocarcinoma (OAC) and variceal bleeding, respectively(3–6). The incidence and mortality from OAC has risen rapidly over the last few decades(7). This has prompted efforts to screen at risk patients who are white, male, age 55 or over, with chronic reflux symptoms for BO(6). Similarly, incidence and mortality from chronic liver disease is also rising, with one of the major contributors being variceal haemorrhage(6). It is recommended practice to screen for varices using endoscopy in all patients with cirrhosis but the cost-effectiveness of this approach has been questioned(5).

Currently, the standard of care for assessing BO and OVs is hospital-based conventional oesophagogastroduodenoscopy (C-OGD). This requires a fully equipped endoscopy department, complete with nursing support, recovery facilities, monitoring, and decontamination rooms(9). Patients frequently require conscious sedation(10). C-OGD can be perceived to be an uncomfortable experience for the patient which may prompt those eligible for screening not to attend(11,12). These features of C-OGD fail to meet screening principles of cost-effectiveness and acceptability.

To overcome this, various alternative screening tools have been proposed and remain largely the preserve of research studies. Portable and disposable transnasal endoscopy (TNE) is one such tool that has been proposed as a solution. The suggested benefits of TNE over C-OGD include allowing the patient to speak during the examination, increased comfort levels and avoidance of sedation. It has been shown to be both accurate and cost-effective as a potential screening tool(1,2,13,14).

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3 The EG scan™ II system (Intromedic Ltd., Seoul, South Korea) is a transnasal
4 endoscopic device with a disposable 6mm diameter probe. It has an air insufflation
5 channel but no biopsy or irrigation port and is designed to be a method of visualising
6 various upper gastrointestinal conditions (Figure 1). The apparatus has been designed
7 for use in a consultation room, as a 'clinic-based' procedure, with potential for use in
8 general practice.
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21 The tolerability of TNE compared with that of C-OGD has been studied using visual
22 scales and questionnaires in randomised trials, assessing attitudes towards and
23 experience of sedated C-OGD and unsedated TNE(15). To date, we have no
24 knowledge of any qualitative studies that have considered the acceptability of TNE to
25 patients who have undergone both it and C-OGD in a controlled environment. The
26 lived experiences of those who undergo these procedures can inform preference and
27 identify the challenges or opportunities for healthcare systems.
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38 Tolerability and preference scores like the visual analogue scale (VAS) and the
39 Spielberg State Trait Anxiety Inventory (STAI-6) questionnaire are helpful ways of
40 assessing the impressions of large populations of patients towards a healthcare
41 experience(16,17). They do not however permit reflection, nuance and richer insights
42 into the experiences of individuals and therefore do not inform service development in
43 the same way that qualitative methods do.
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52 The aims of this study were to explore the expectations and experiences of patients
53 who underwent both TNE in an outpatient setting and C-OGD on the same day through
54 qualitative analysis, and to determine the factors that impact on the acceptability of
55 these procedures.
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Methods

Study Design and Setting

A qualitative methodology was employed, with the analysis of experiences and perceptions of both C-OGD and clinic-based TNE, using face-to-face interviews. This builds on wider research examining the technical feasibility, quality, safety, acceptability (through scoring measures) and accuracy of clinic-based TNE using the EG Scan compared to C-OGD as the reference standard(1). The procedure for endoscopic examination using the EG Scan™ is outlined in Figure 1 and Box 1. Whereas the original research was conducted in three different centres, the collection of information with respect to this qualitative study was done at one centre (Nottingham, UK) with all patients having undergone endoscopy at that location.

The East Midlands division of the Research Ethics Committee granted approval for the study (REC reference 12/EM/0100). It was prospectively registered (ISRCTN registry identifier: 70595405). Specific consent forms for these interviews were devised and confirmation of consent was sought during each interview. Interview transcripts have been stored on an encrypted secure drive at the study site.

Box 1. Use of the EG Scan probe for oesophageal visualisation

1. Patients given 100ml liquid drink comprising water, orange cordial flavouring, a mucolytic (10ml of 200mg/ml N-acetylcysteine) and an anti-foaming agent (1ml of Simeticone 40mg/ml) to improve mucosal visualisation
2. A topical aerosol spray (Lidocaine Hydrochloride 5% and Phenylephrine Hydrochloride 0.5% is applied to the nares (3-4 sprays), 3-5 minutes prior to the procedure
3. The probe is introduced into the right or left nare and advanced into the proximal oesophagus under direct vision
4. The oesophagus and gastro-oesophageal junction are inspected both in forward and retro-flexion views
5. Following the procedure the probe is disconnected from the hand-held controller and discarded

Participants and Recruitment

Purposeful sampling took place, in which most of the individuals involved in the wider research project (47/50) were identified as potential participants before being contacted by telephone within four weeks of the day of endoscopy. Three distinct patient groups were identified: those with histologically confirmed BO, those warranting OV screening or surveillance, and those with dyspepsia referred for diagnostic endoscopy. At the time of their recruitment to the original study comparing clinic-based TNE with C-OGD, these individuals agreed to be contacted in the future to further explore their experiences of the procedure for the purposes of research, which would include interview at a site that maximised confidentiality and was agreeable to interviewer and participant. Those who could not tolerate both endoscopic examinations or who underwent variceal band ligation during C-OGD were excluded from recruitment to interview as their lived experiences were deemed to be considerably different from the rest.

It was anticipated that a minimum of twenty interviews would have to be conducted to gather sufficient information. This was informed in part by existing literature(18). By the 24th participant interview, it was determined that data saturation had been reached (as no new themes were being identified) and that no further participants would be required.

Data Collection

The interviews were conducted with interviewers guided by a structured written interview schedule. Both interviewers were female registered research nurses independent of the main study team and blinded to the patients' tolerability scores.

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3 The study was conducted and reported according to the COREQ standards for
4 qualitative research(19).
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9 The interview schedule included broad exploration of participants' prior understanding
10 and expectations of undergoing both forms of endoscopy procedure, their experiences
11 of the procedures and factors influencing this, and their recommendations for future
12 service provision, including any information or support needs.
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18 Interviews were recorded on an encrypted device and all lasted less than one hour.
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20 Following this, recordings were transcribed to Microsoft Word documents undertaken
21 by a professional transcriber who ensured that the transcripts were anonymised.
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26 27 **Data Analysis**

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29 Transcribed interviews underwent thematic analysis by one researcher (JM) who was
30 not involved in the study beforehand but fully briefed of the processes. Transcripts
31 were read at least twice with broad notes being made of possible themes(20). The
32 transcripts were then entered into NVivo version 12 (QSR International, Melbourne,
33 Australia) software for analytical support. This program helped to identify the
34 frequency of language used, its relation to other statements and along with human
35 interpretation, to determine the relevance of the language used to the research aims.
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47 Themes were checked with the supporting text and interpretations drawn.
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50 51 **Rigour**

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53 In order to ensure scientific rigour, checks were made at each stage of this study, while
54 taking care not to compromise the unique contribution that good quantitative research
55 can bring to scientific progress(21). As well as the sampling methods described above,
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60 we used existing theoretical frameworks to aid data collection and analysis. Our

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3 transcripts were analysed for deviant cases, which were noted but acknowledged not
4 to represent the majority of participants' experiences. Reflexivity was undertaken in
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6 which researchers considered the impact they had on recruitment, responses and
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8 analysis.
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11 12 13 **Patient and Public Involvement** 14

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16 Following TNE and C-OGD patients were asked to complete a questionnaire on their
17 experiences of these tests. Analysis of the questionnaires and encounters between
18 researchers and patients during this time strongly informed the preparation for semi-
19 structured interviews, as part of the overall iterative process. In addition, throughout
20 this process the input of the Patient and Public Involvement group at Nottingham
21 Biomedical Research Centre was taken into consideration in terms of aims, design,
22 patient consent and information leaflets. Details of the research study are to be made
23 available to participants on request.
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40 **Results** 41

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43 Twenty-three interviews took place, with participants having BO (n=11), OV's (n=8) or
44 neither of these (those referred for investigation of dyspepsia) (n=4). Given the
45 standard approach of the two endoscopic procedures, excluding those having had
46 variceal band ligation, it was determined that all participants shared a similar lived
47 experience and could all give accounts that can provide insights into the acceptability
48 of TNE as a screening tool for either BO or OV's. More details on the backgrounds of
49 these 23 interview participants are outlined in Table 1.
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Basic Demographics of Interview Participants	
Males (n/23)	17
Sedation for C-OGD (n/23)	13
Median Age (range)	66 (48-83)
Barrett's Oesophagus (n/23)	11
Liver Disease warranting Varices Screening/Surveillance (n/23)	8
Dyspepsia (n/23)	4

Table 1. Demographic and sedation details of 23 interview participants

Four dominant themes were identified after careful thematic analysis, using NVivo™ software. The four themes were: i) inclusivity in one's own health care; ii) comfort level and convenience; iii) validity of the procedure and application to a screening population; iv) a sense of altruism and reciprocity. The evidence supporting these four themes is outlined below, illustrated with excerpts from transcripts.

Inclusivity in one's own healthcare

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3 Every participant acknowledged that they had consented with appropriate knowledge
4 of each procedure. The existence of established guidelines, best practice and trust in
5 the decision-making of medical professionals prompted attendance for endoscopic
6 tests, with one participant summarising the feelings of many others by saying *"If you've*
7 *got to have a test, you've got to have a test."* Another participant said of C-OGD, *"I*
8 *know it's part of the care, that you've got to have it done"*. The language used by them
9 indicates a disinclination to undergo C-OGD, while they described TNE as
10 *"empowering"*, *"fascinating"* and that they would *"definitely"* have it done again.
11
12 Participants used their knowledge of their chronic conditions and their symptoms as
13 accompanying motives for having endoscopic tests. On attending for the dual
14 endoscopic tests as part of a research study, most participants described feeling well-
15 informed of the procedures and involved in the decision-making process. Two people
16 expressed initial wariness of TNE as they did not know what to expect but felt
17 reassured after a fuller explanation. In contrast, with the *"impersonal"* C-OGD where
18 they felt *"trapped...claustrophobic"* or like in *"a production line"* most of the participants
19 praised the level of empowerment and control they had with TNE where they could
20 speak with the operator, sit up in a chair and view their endoscopic images if they
21 wished.
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46 **Comfort level and convenience**

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49 As part of the original study, every participant completed visual analogue scales of
50 their experiences of each endoscopic procedure. This was revisited at interview and
51 affirmed that the majority preferred TNE to unsedated C-OGD. Among those having
52 sedation for C-OGD, the preference for TNE remained but this was less strong. A
53 sizeable number of individuals chose sedation following past experiences of
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3 undergoing C-OGD without. All TNEs were performed without sedation, which was
4 reported as acceptable by all participants, who described minor nasal discomfort as
5 the predominant uncomfortable element. They had insight that having an unsedated
6 procedure would mean *“you can go straight home”* afterwards, making it more time-
7 efficient and convenient. For those who had unsedated C-OGD, excessive gagging
8 featured almost universally as well as a measure of distress that caused one patient
9 to cry and another to state *“I wouldn’t recommend that to anyone.”*

20 **Validity of the procedure and application to a screening population**

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23 The EG scan has been shown to have accuracy in the detection of BO and
24 medium/large OVs(1,2). Participants were informed of the outcome of their own
25 endoscopic examinations but were unaware of the study findings that TNE and C-
26 OGD results were in concordance. Participants were however encouraged to use their
27 lived experience to give an account of how important test accuracy would be to them
28 and to others. The premise was that of TNE being extended to screening individuals
29 in a community setting.

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32 For those who had a history of undergoing C-OGDs for BO and OVs, the potential
33 accuracy of TNE was important. They described C-OGD as a *‘necessary evil’* but an
34 informative test for their condition which they have little choice but to undergo given
35 the reasons above. While most acknowledged TNE as more comfortable, they
36 suggested that it would only be an acceptable alternative if its ability to detect
37 abnormalities matched that of C-OGD. Based on his experience one participant
38 declared, *“I do believe the gastroscopy one is more thorough.”* Alongside this, the
39 participants emphasised the requirement for adequately trained endoscopists to
40 perform TNE and some expressed reservations over their general practitioners taking

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3 up the role- “As long as you had proficient GPs doing it” “As long as he (GP) can do
4 *it...properly.*” For this reason, opinion was divided on the location of the test, with
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6 some preferring the specialist nature of secondary care and others espousing the
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8 greater convenience and comfort of having TNE in the community.
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13 **Sense of altruism and reciprocity**

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16 Participants used their experiences as patients and as study participants to deliver
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18 unique insights into how endoscopic screening would be received by the target
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20 populations. For many patients, their positive experiences of healthcare informed their
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22 decision-making in becoming a research participant. “*I was most grateful for what the*
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24 *hospital had done for me previously*”, “*I ought to try and put something back in*” and
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26 “*I’m always ready to help in the progress of science*” were some statements that clearly
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28 showed the willingness of participants to use their experiences for the betterment of
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30 others.
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36 The involvement of those who have undergone the procedure is an important factor in
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38 establishing a screening programme. Participants suggested that prospective patients
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40 would be reassured by engaging with someone who had already undergone the
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42 procedure, reflecting the place of social constructionism in society’s view towards
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44 healthcare screening in an overt fashion(22).
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48 **Discussion**

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51 This research represents the first time that a qualitative study has been conducted into
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53 the experiences of patients undergoing transnasal endoscopy. The additional
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55 information derived from a qualitative as compared to a quantitative means of
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57 assessing acceptability (eg VAS or structured questionnaire) allows for deeper
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3 interpretation of a patient's perspective. The themes identified in this study encourage
4 the view that TNE could be acceptable to a screening population, thus fulfilling an
5 important principle of a viable screening programme(23). To the participants, the
6 notion of an accurate test that was superior in comfort and convenience was
7 appealing. They could see the benefits that this could bring a wider population and
8 were pleased to be part of a community that could enhance other patients'
9 experiences. The greater mutualism and control that TNE seems to bring in contrast
10 to C-OGD made it more appealing, which could be important in achieving adequate
11 uptake of in a screening population. Questions for the use of TNE as a screening tool
12 remain. The inability of the EG Scan system to allow biopsies is one recurring concern
13 for participants, and nasal discomfort is a significant drawback. There is evidence for
14 higher comfort levels during endoscopy when thinner endoscopes (6 mm or less in
15 diameter) are used, whether transnasally or transorally(24).

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34 Contradicting views emergent from the data also provide important insights. The
35 minority of participants who did not wish to view endoscopic images, those who would
36 prefer C-OGD as a screening tool because of its established nature and individuals
37 who would prefer to attend hospital for TNE rather than the community, all had valid
38 reasons that warrant consideration. The participants realised that, as individuals who
39 had pre-existing conditions or symptoms requiring OGD examination, they differed
40 from a screening population, making direct comparisons impossible. Some of the
41 reasons given for preferring aspects of C-OGD over TNE are indeed based in existing
42 practices e.g. oesophageal biopsies in BO using C-OGD.

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56 Patient acceptability has been studied through qualitative means in related areas of
57 gastrointestinal practice. The Cytosponge TFF-3 test is a means of diagnosing BO
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3 through non-endoscopic means. A study using semi-structured interviews and focus
4 groups analysed responses from Cytosponge-naïve but eligible patients to gauge their
5 impression of this test versus endoscopy, using videos and explanation of the clinical
6 problem by a researcher(25). Qualitative research of patients undergoing C-OGD for
7 BO reflect themes of comfort and control being important to them, which aligns well
8 with our findings(26). Additionally, qualitative analysis of interviews has been
9 conducted to gain an insight into factors affecting adherence to endoscopic screening,
10 which would be a major factor in establishing an effective service(27).
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22 **Conclusions**

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26 The information collected in this patient-centred qualitative study has identified four
27 main themes underlying the expectations and experiences of those undergoing TNE
28 and C-OGD. They are inclusivity in one's own health care, comfort level and
29 convenience, validity of the procedure and application to a screening population, and
30 a sense of altruism and reciprocity. We believe that this analysis is a reliable
31 reflection of the experiences of the patients involved and that it provides insights into
32 the opportunities and challenges for interventions offered to patients selected as 'at
33 risk' and therefore considered for screening. The themes align with quantitative
34 acceptability outcomes and are likely to reflect the experiences of at-risk screening
35 populations within the wider community.
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49 **Author Contributions**

50
51 John J. McGoran: contributed to analysis, interpretation of data and drafted the
52 manuscript.
53

54
55 Andrea Bennett: contributed to the acquisition of data and critical revision of the
56 manuscript for important intellectual content.
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3 Joanne Cooper: contributed to acquisition of data, interpretation of data and critical
4
5 revision of the manuscript for important intellectual content.
6

7
8 John de Caestecker: contributed to the study supervision, interpretation of data and
9
10 critical revision of the manuscript for important intellectual content.
11

12
13 Laurence B. Lovat: contributed to the study supervision, interpretation of data and
14
15 critical revision of the manuscript for important intellectual content.
16

17
18 Indra Neil Guha: contributed to the acquisition of data, study supervision,
19
20 interpretation of data and critical revision of the manuscript for important intellectual
21
22 content.
23

24
25 Krish Ragunath: contributed to the conception, design and supervision of the study,
26
27 acquisition of data, study supervision, interpretation of data and critical revision of
28
29 the manuscript for important intellectual content.
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31
32 Sarmed S. Sami: contributed to the conception, design and supervision of the study,
33
34 acquisition of data; analysis; interpretation of data; and critical revision of the
35
36 manuscript for important intellectual content.
37

38 **Potential Conflicts of Interest**

39
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41
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43
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45

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48
49 South Korea.
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51
52 The other authors have no conflicts of interest to declare relevant to this publication.
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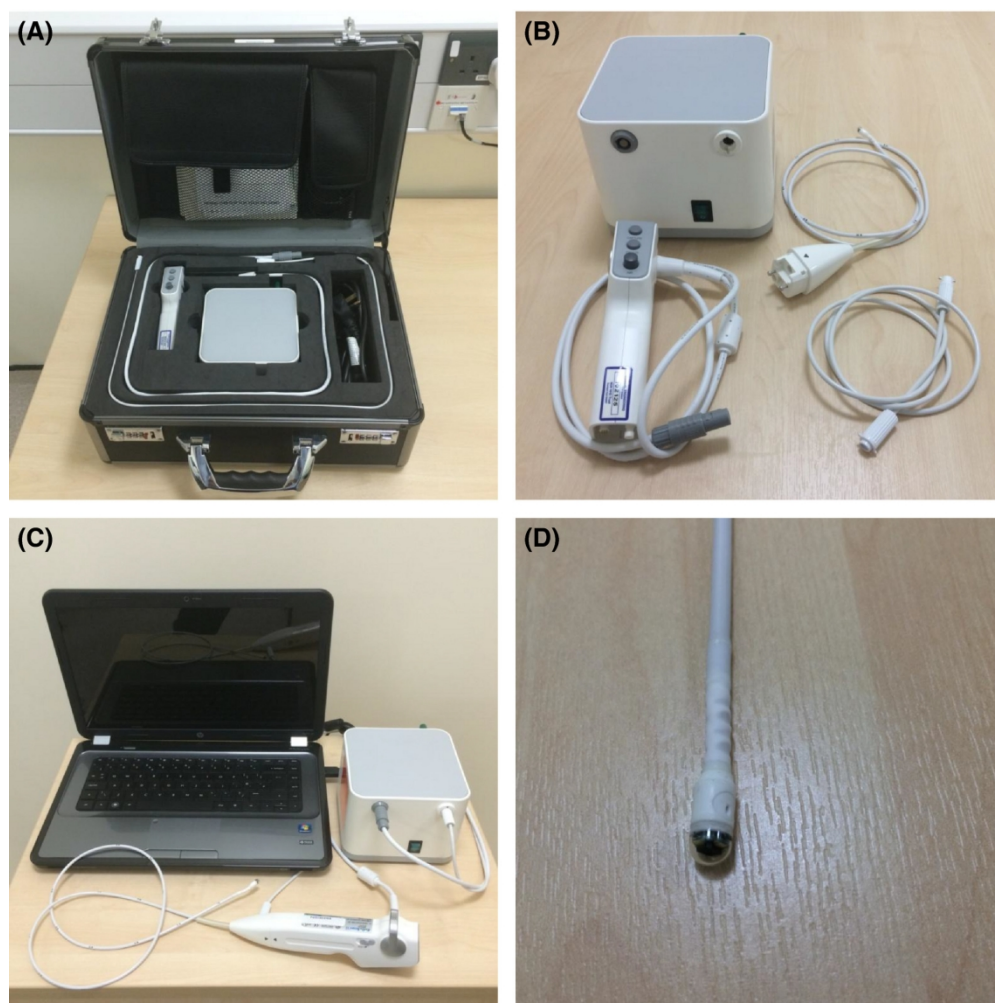


Figure 1. The EG ScanTM II system. (A) the portable case with four main parts; (B) the image processor (top left), disposable probe (top right), air tube (bottom right) and hand-held controller (bottom left); (C) the system connected and ready for use; (D) close view of the capsule probe tip. (Reproduced with permission from Sami SS, et al. Copyright John Wiley and Sons).

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COREQ (CONsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
<i>Personal characteristics</i>			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	
Occupation	3	What was their occupation at the time of the study?	
Gender	4	Was the researcher male or female?	
Experience and training	5	What experience or training did the researcher have?	
<i>Relationship with participants</i>			
Relationship established	6	Was a relationship established prior to study commencement?	
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	
Interviewer characteristics	8	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	
Domain 2: Study design			
<i>Theoretical framework</i>			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	
<i>Participant selection</i>			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	
Sample size	12	How many participants were in the study?	
Non-participation	13	How many people refused to participate or dropped out? Reasons?	
<i>Setting</i>			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	
<i>Data collection</i>			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	
Repeat interviews	18	Were repeat interviews carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	
Field notes	20	Were field notes made during and/or after the interview or focus group?	
Duration	21	What was the duration of the interviews or focus group?	
Data saturation	22	Was data saturation discussed?	
Transcripts returned	23	Were transcripts returned to participants for comment and/or	

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
<i>Data analysis</i>			
Number of data coders	24	How many data coders coded the data?	
Description of the coding tree	25	Did authors provide a description of the coding tree?	
Derivation of themes	26	Were themes identified in advance or derived from the data?	
Software	27	What software, if applicable, was used to manage the data?	
Participant checking	28	Did participants provide feedback on the findings?	
<i>Reporting</i>			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	
Data and findings consistent	30	Was there consistency between the data presented and the findings?	
Clarity of major themes	31	Were major themes clearly presented in the findings?	
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

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BMJ Open

Acceptability to patients of screening disposable transnasal endoscopy: qualitative interview analysis

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Acceptability to patients of screening disposable transnasal endoscopy: qualitative interview analysis

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Abstract

Objectives

Screening in selected at-risk populations for Barrett's oesophagus (BO) and oesophageal varices (OVs) has been proposed, but there are obstacles with conventional oesophagogastroduodenoscopy (C-OGD), including patient acceptability. Portable and disposable office-based transnasal endoscopy (TNE) is a feasible and accurate alternative to C-OGD that may have use in primary and secondary care. This article outlines a qualitative analysis of patient experiences of TNE and C-OGD in order to gain an insight into an acceptable delivery of an endoscopic screening service.

Design

Purposeful sampling identified 23 participants who then underwent semi-structured interviews to determine their experiences of both procedures. Thematic analysis was conducted to derive meaning from their lived experiences.

Setting

A secondary care endoscopy unit, clinic room and interview room.

Participants

Patients referred for BO or OV surveillance and for endoscopy to investigate dyspepsia underwent unsedated TNE using the EG Scan II device followed by C-OGD with or without sedation, as part of a clinical trial.

Results

The themes that arose from our analysis were: inclusivity in one's own health care; comfort level and convenience; validity of the procedure and application to a screening population; and a sense of altruism and reciprocity.

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3 Positive aspects of TNE included participant empowerment, reduced discomfort and
4 avoidance of conscious sedation. Participants felt that if TNE screening was of proven
5 efficacy it would be welcomed, though views on use in a community setting were
6 mixed.
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12 **Conclusions**

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14 Most patients preferred TNE to unsedated C-OGD and the reasons they gave featured
15 strongly in the emerging themes. This information identifies opportunities and
16 challenges in establishing an endoscopic screening service.
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28 Keywords: endoscopy, oesophageal disease, hepatology
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32 **Strengths and Limitations of the study**

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- The size of the original study, in which 100 patients from this centre alone allowed for a broad stated aim and collection of participants until data saturation was reached.
 - Every participant had clinic-based TNE before C-OGD so their experiences of the TNE would reflect that of a person undergoing screening more so than if C-OGD was done first.
 - The advantage in performing thematic analysis on this group of patients is that it allowed us to develop clear themes with supporting data, which could allow transferability to other potential screening populations. It is highly likely the same themes would have been derived from interviews of participants from any

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3 of the study centres and the conclusions could apply to many locations or
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5 healthcare systems.
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- 8 • Qualitative research can be prone to claims of poor scientific rigour; however,
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10 the framework by which the validity and reliability of a study is evaluated is
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12 subject to standard quantitative criteria. To maximise the credibility and
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14 dependability of the findings, reflexivity, in which the impact of the researcher
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16 and social environment on each other is acknowledged and managed, was
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18 employed at each stage. Care was taken not to manipulate participants into
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20 giving accounts that favoured or condemned either endoscopic test.
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 - 23 • The index of transferability for the findings within this study to non-research
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25 settings and for other screening modalities and investigations is limited.
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Introduction

Portable and disposable office-based transnasal endoscopy (TNE) is a feasible and accurate alternative to conventional oesophagogastroduodenoscopy (C-OGD) that may have use in primary and secondary care(1,2). Several authorities have highlighted the need to identify alternative, minimally-invasive screening tests for Barrett's oesophagus (BO) and oesophageal varices (OV) which are precursor conditions for oesophageal adenocarcinoma (OAC) and variceal bleeding, respectively(3–6). The incidence and mortality from OAC have risen rapidly over the last few decades(7). This has prompted efforts to screen at risk patients who are white, male, age 55 or over, with chronic reflux symptoms for BO(6). Similarly, incidence and mortality from chronic liver disease is also rising, with one of the major contributors being variceal haemorrhage(8). It is recommended practice to screen for varices using endoscopy in all patients with cirrhosis but the cost-effectiveness of this approach has been questioned(5).

Currently, the standard of care for assessing BO and OVs is hospital-based conventional oesophagogastroduodenoscopy (C-OGD). This requires a fully equipped endoscopy department, complete with nursing support, recovery facilities, monitoring, and decontamination rooms(9). Patients frequently require conscious sedation(10). C-OGD can be perceived to be an uncomfortable experience for the patient which may prompt those eligible for screening not to attend(11,12). These features of C-OGD fail to meet screening principles of cost-effectiveness and acceptability.

To overcome this, various alternative screening tools for high risk groups have been proposed and remain largely the preserve of research studies. Portable and disposable transnasal endoscopy (TNE) as a method of screening for BO and OVs is

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3 one such tool that has been proposed as a solution. The suggested benefits of TNE
4 over C-OGD include allowing the patient to speak during the examination, increased
5 comfort levels and avoidance of sedation. It has been shown to be both accurate and
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10 cost-effective as a potential screening tool(1,2,13,14). The EG scan™ II system
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12 (Intromedic Ltd., Seoul, South Korea) is a transnasal endoscopic device with a
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14 disposable 6mm diameter probe. It has an air insufflation channel but no biopsy or
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16 irrigation port and is designed to be a method of visualising various upper
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18 gastrointestinal conditions (Figure 1). The apparatus has been designed for use in a
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20 consultation room, as a 'clinic-based' procedure, with potential for use in general
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practice.

The tolerability regarding comfort levels of TNE compared with that of C-OGD has
been studied using visual scales and questionnaires in randomised trials, assessing
attitudes towards and experience of sedated C-OGD and unsedated TNE that allow a
simple measure of preference between the two(15). Acceptability is a deeper concept,
that takes into consideration not only comfort scores but the global patient experience
and willingness to undergo the intervention. It may act as an indicator of patient uptake
and inform strategies for recruitment on a population level. To date, we have no
knowledge of any qualitative studies that have considered the acceptability of TNE to
patients who have undergone both it and C-OGD in a controlled environment. The
lived experiences of those who undergo these procedures can inform preference and
identify the challenges or opportunities for healthcare systems.

Tolerability and preference scores like the visual analogue scale (VAS) and the
Spielberger State Trait Anxiety Inventory (STAI-6) questionnaire are helpful ways of
assessing the impressions of large populations of patients towards a healthcare

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3 experience(16,17). They do not however permit reflection, nuance and richer insights
4 into the experiences of individuals and therefore do not inform service development in
5 the same way that qualitative methods do. A deeper analysis of this could add to the
6 clinical community's understanding of patients' sense-making process and enhance
7 human factors in screening or surveillance such as recruitment and retention.
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16 The aims of this study were to explore the expectations and experiences of patients
17 who underwent both TNE in an outpatient setting and C-OGD on the same day through
18 qualitative analysis, and to determine the factors that impact on the acceptability of
19 TNE as a potential screening and surveillance tool.
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26 **Methods**

27 **Study Design and Setting**

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33 A qualitative methodology was employed, with the analysis of experiences and
34 perceptions of both C-OGD and clinic-based TNE, using face-to-face interviews. This
35 builds on wider research examining the technical feasibility, quality, safety,
36 acceptability (through scoring measures) and accuracy of clinic-based TNE using the
37 EG Scan compared to C-OGD as the reference standard(1). The procedure for
38 endoscopic examination using the EG Scan™ is outlined in Figure 1 and Box 1.
39 Whereas the original research was conducted in three different centres, the collection
40 of information with respect to this qualitative study was done at one centre
41 (Nottingham, UK) with all patients having undergone endoscopy at that location.
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55 The East Midlands division of the Research Ethics Committee granted approval for
56 the study (REC reference 12/EM/0100). It was prospectively registered (ISRCTN
57 registry identifier: 70595405). Specific consent forms for these interviews were
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3 devised and confirmation of consent was sought during each interview. Interview
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5 transcripts have been stored on an encrypted secure drive at the study site.
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13 **Box 1. Use of the EG Scan probe for oesophageal visualisation**

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- 15 1. Patients given 100ml liquid drink comprising water, orange cordial flavouring,
16 a mucolytic (10ml of 200mg/ml N-acetylcysteine) and an anti-foaming agent
17 (1ml of Simeticone 40mg/ml) to improve mucosal visualisation
- 18 2. A topical aerosol spray (Lidocaine Hydrochloride 5% and Phenylephrine
19 Hydrochloride 0.5% is applied to the nares (3-4 sprays), 3-5 minutes prior to
20 the procedure
- 21 3. The probe is introduced into the right or left nare and advanced into the
22 proximal oesophagus under direct vision
- 23 4. The oesophagus and gastro-oesophageal junction are inspected both in
24 forward and retro-flexion views
- 25 5. Following the procedure the probe is disconnected from the hand-held
26 controller and discarded
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33 **Participants and Recruitment**

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35 Purposeful sampling took place, in which most of the individuals in one centre involved
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37 in the wider research project were identified as potential participants before being
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39 contacted by telephone within four weeks of the day of endoscopy. This is a common
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41 recruitment approach in qualitative research which contrasts with random sampling in
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43 quantitative research that seeks to reduce selection bias. Three patient groups were
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45 identified: those with histologically confirmed BO, those warranting OV screening or
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47 surveillance, and those with dyspepsia referred for diagnostic endoscopy. The
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49 experiences of all 47 patients were considered valid for an analysis of acceptability,
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51 with three out of 50 ineligible because of ill health. Recruitment approaches for the
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53 quantitative and qualitative studies were done in parallel, with individuals consenting
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55 to involvement in an interview-based research study at a time following the day they
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3 underwent endoscopic examination. Those who could not tolerate both endoscopic
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5 examinations or who underwent variceal band ligation during C-OGD were excluded
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7 from recruitment to interview as their lived experiences were deemed to be
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9 considerably different from the rest.
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13 It was anticipated that a minimum of twenty interviews would have to be conducted to
14
15 gather sufficient information. This was informed in part by existing literature(18). By
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17 the 23rd participant interview, it was posed that data saturation had been reached and
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19 no further participants would be required. This conclusion was supported following
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21 thematic analysis of the existing interview transcripts and it was agreed by the
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23 research team that further significant insights were unlikely to be gained from
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25 additional interviews.
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30 **Data Collection**

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33 The interviews were conducted with interviewers guided by a topic schedule, that was
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35 agreed by consensus of the researchers. The scheduled questions related to the
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37 consenting process, the experiences of each endoscopic procedure and views over
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39 the use of TNE in the community. The semi-structured nature of the interviews allowed
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41 the skilled researchers to explore the given answers with further probing and
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43 digression from the core topics. The topics and questions arose from the experiences
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45 of the researcher as clinicians in caring for patients undergoing endoscopy and
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47 knowledge of the processes of the original study where there was significant Patient
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49 and Public Involvement. Both interviewers were female registered research nurses
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51 independent of the main study team and blinded to the patients' tolerability scores.
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53 The study was conducted and reported according to the COREQ standards for
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55 qualitative research(19).
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3 The interview schedule included broad exploration of participants' prior understanding
4 and expectations of undergoing both forms of endoscopy procedure, their experiences
5 of the procedures and factors influencing this, and their recommendations for future
6 service provision, including any information or support needs.
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13 Interviews were recorded on an encrypted device and all lasted less than one hour.
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15 Following this, recordings were transcribed to Microsoft Word documents undertaken
16 by a professional transcriber who ensured that the transcripts were anonymised.
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20 21 **Data Analysis**

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24 Transcribed interviews underwent thematic analysis by one researcher (JM) who was
25 not involved in the study beforehand but fully briefed of the processes. Transcripts
26 were read at least twice with broad notes being made of recurrent words, phrases and
27 sentiments from which possible themes could arise(20). The transcripts were then
28 entered into NVivo version 12 (QSR International, Melbourne, Australia) software,
29 which helped to identify the frequency of language used and its relation to other
30 statements, to determine the relevance of the language used to the research aims.
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32 These patterns were again considered by the researcher and the themes were arrived
33 at. Themes were again checked with the supporting text and interpretations drawn.
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46 **Rigour**

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49 In order to ensure scientific rigour, checks were made at each stage of this study by
50 primarily referring to the COREQ criteria, while taking care not to compromise the
51 unique contribution that good quantitative research can bring to scientific
52 progress(19)(21). The research team also discussed the analysis frequently, using
53 existing theoretical frameworks to ensure competent data collection and analysis. Our
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3 transcripts were analysed for deviant cases, which were noted but acknowledged not
4 to represent the majority of participants' experiences. Reflexivity was undertaken in
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6 which researchers considered the impact they had on recruitment, responses and
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8 analysis. Specifically, awareness of the VAS for comfort from the original study was
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10 noted and care taken not to apply this to the qualitative analysis. The researchers are
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12 aware of the requirements for a good screening tool so carefully considered that the
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14 themes that arose did so from the participants' accounts and not from a predetermined
15
16 agenda. In considering all of the factors that might have affected the analysis a
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18 reflexivity diary was kept until the conclusions were drawn upon.
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25 **Patient and Public Involvement**

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28 Following TNE and C-OGD patients were asked to complete a questionnaire on their
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30 experiences of these tests. Analysis of the questionnaires and encounters between
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32 researchers and patients during this time strongly informed the preparation for semi-
33
34 structured interviews. In addition, throughout this process the input of the Patient and
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36 Public Involvement group at Nottingham Biomedical Research Centre was taken into
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38 consideration in terms of aims, design, patient consent and information leaflets.
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41 Details of the research study are to be made available to participants on request.
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49 **Results**

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52 Twenty-three interviews took place, with participants having BO (n=11), OV's (n=8) or
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54 neither of these (those referred for investigation of dyspepsia) (n=4).(Table 1) Given
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56 the standard approach of the two endoscopic procedures, excluding those having had
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58 variceal band ligation, it was determined that all participants shared a similar lived
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experience and could all give accounts that can provide insights into the acceptability of TNE as a screening tool for either BO or OVs. For the purposes of the thematic analysis it was therefore not thought necessary to divide the groups according to their indication for endoscopy. The majority (17/23) of participants were men, which somewhat represents the gender balance in those having endoscopic examination for BO and OVs. The presence of sedation for C-OGD was a factor in participants' lived experiences and this was taken into account during interview of each individual.

Basic Demographics of Interview Participants	
Males (n/23)	17
Sedation for C-OGD (n/23)	13
Median Age (range)	66 (48-83)
Barrett's Oesophagus (n/23)	11
Liver Disease warranting Varices Screening/Surveillance (n/23)	8
Dyspepsia (n/23)	4

Table 1. Demographic and sedation details of 23 interview participants

Four dominant themes were identified after careful thematic analysis, using NVivo™ software. The four themes were: i) inclusivity in one's own health care; ii) comfort level and convenience; iii) validity of the procedure and application to a screening

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3 population; iv) a sense of altruism and reciprocity. The evidence supporting these four
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5 themes is outlined below, illustrated with excerpts from transcripts.
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8 9 **Inclusivity in one's own healthcare**

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12 Every participant acknowledged that they had consented with appropriate knowledge
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14 of each procedure. The principle of autonomy was underlined in the response of
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16 participants to a question of how involved they felt in the decision making process- "*I*
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18 *could have said no. But I came looking for help.*", "*as a patient, I have the ultimate*
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20 *say.*" The existence of established guidelines, best practice and trust in the decision-
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22 making of medical professionals prompted attendance for endoscopic tests, with one
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24 participant summarising the feelings of many others by saying "*If you've got to have a*
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26 *test, you've got to have a test.*" Another participant said of C-OGD, "*I know it's part of*
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28 *the care, that you've got to have it done*". The language used by them indicates a
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30 disinclination to undergo C-OGD, while they described TNE as "*empowering*",
31
32 "*fascinating*" and that they would "*definitely*" have it done again. Participants used their
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34 knowledge of their chronic conditions and their symptoms as accompanying motives
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36 for having endoscopic tests. On attending for the dual endoscopic tests as part of a
37
38 research study, most participants described feeling well-informed of the procedures
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40 and involved in the decision-making process. Two people expressed initial wariness
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42 of TNE as they did not know what to expect but felt reassured after a fuller explanation.
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44 In contrast, with the "*impersonal*" C-OGD where they felt "*trapped...claustrophobic*" or
45
46 like in "*a production line*" most of the participants praised the level of empowerment
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48 and control they had with TNE where they could speak with the operator, sit up in a
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50 chair and view their endoscopic images if they wished ("*I could watch it on the*
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52 *monitor*").
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Comfort level and convenience

As part of the original study, every participant completed visual analogue scales of their experiences of each endoscopic procedure. This was revisited at interview and affirmed that the majority preferred TNE to unsedated C-OGD. Among those having sedation for C-OGD, the preference for TNE remained but this was less strong. A sizeable number of individuals chose sedation following past experiences of undergoing C-OGD without. All TNEs were performed without sedation, which was reported as acceptable by all participants, who described minor nasal discomfort as the predominant uncomfortable element. They had insight that having an unsedated procedure would mean *“you can go straight home”* afterwards, making it more time-efficient and convenient. For those who had unsedated C-OGD, excessive gagging featured almost universally as well as a measure of distress that caused one patient to cry and another to state *“I wouldn’t recommend that to anyone.”* Gagging was less of an issue for TNE as described by the individual who reported, *“not so much with the nasal one but with the, with the oral one, it was very bad gagging reflex.”*

Validity of the procedure and application to a screening population

The EG scan has been shown to have accuracy in the detection of BO and medium/large OVs(1,2). Participants were informed of the outcome of their own endoscopic examinations but were unaware of the study findings that TNE and C-OGD results were in concordance. Participants were however encouraged to use their lived experience to give an account of how important test accuracy would be to them and to others. The premise was that of TNE being extended to screening individuals in a community setting.

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3 For those who had a history of undergoing C-OGDs for BO and OV, the potential
4 accuracy of TNE was important. They described C-OGD as a 'necessary evil' but an
5 informative test for their condition which they have little choice but to undergo given
6 the reasons above. Having been briefed on the devices, one participant recognised a
7 possible limitation of the EG Scan probe- *"The nasal one, you can't actually take*
8 *biopsies from, you can't use that to take samples."* While most acknowledged TNE as
9 more comfortable, they suggested that it would only be an acceptable alternative if its
10 ability to detect abnormalities matched that of C-OGD. Based on his experience, (*"the*
11 *day I had them both done, I think the nasal one, I think it missed something out"*) one
12 participant declared, *"I do believe the gastroscopy one is more thorough."* Alongside
13 this, the participants emphasised the requirement for adequately trained endoscopists
14 to perform TNE and some expressed reservations over their general practitioners
15 taking up the role- *"As long as you had proficient GPs doing it"* *"As long as he (GP)*
16 *can do it...properly."* For this reason, opinion was divided on the location of the test,
17 with some preferring the specialist nature of secondary care and others espousing the
18 greater convenience and comfort of having TNE in the community.
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41 **Sense of altruism and reciprocity**

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44 Participants used their experiences as patients and as study participants to deliver
45 unique insights into how endoscopic screening would be received by the target
46 populations. For many patients, their positive experiences of healthcare informed their
47 decision-making in becoming a research participant. *"I said yes because I was most*
48 *grateful for what the hospital had done for me previously", "I ought to try and put*
49 *something back in"* and *"I'm always ready to help in the progress of science"* were
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3 some statements that clearly showed the willingness of participants to use their
4 experiences for the betterment of others.
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9 The involvement of those who have undergone the procedure is an important factor in
10 establishing a screening programme. Participants suggested that prospective patients
11 would be reassured by engaging with someone who had already undergone the
12 procedure, reflecting the place of social constructionism in society's view towards
13 healthcare screening in an overt fashion(22).
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20 21 **Discussion**

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25 This research represents the first time that a qualitative study has been conducted into
26 the experiences of patients undergoing transnasal endoscopy on this level. The
27 interview participants' reflections on TNE were supported by the narrative of having
28 had C-OGD on the same day but the aim of this research was not to contrast one
29 endoscopic mode with the other, as each has its own applicability in clinical practice.
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32 The additional information derived from a qualitative as compared to a quantitative
33 means of assessing acceptability (eg VAS or structured questionnaire) allows for
34 deeper interpretation of a patient's perspective. The themes identified in this study
35 encourage the view that TNE could be acceptable to a screening population, thus
36 fulfilling an important principle of a viable screening programme(23).
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49 The community of inquiry theory is a concept that unites the themes arrived at in this
50 study (24). The background is that TNE is shown to be accurate and safe in the
51 delivery of BO and OV assessment but the problem remains that not enough is deeply
52 understood about its acceptability to a population. To explore the challenges and
53 advantages offered by TNE in the screening of BO and OVs, participants from different
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3 backgrounds and for different reasons underwent the same procedure. Their individual
4 perspectives were all considered and conclusions that reflect this community's
5 account were arrived at, which will hopefully contribute to improved delivery of patient
6 care. For the purposes of this study all of the accounts were communicated through
7 the researchers but they are reflective of the conversations that may exist in the
8 greater population.
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12 To the participants, the notion of an accurate test that was superior in comfort and
13 convenience was appealing. They could see the benefits that this could bring a wider
14 population and were pleased to be part of a community that could enhance other
15 patients' experiences. The greater mutualism and control that TNE seems to bring in
16 contrast to C-OGD made it more appealing, which could be important in achieving
17 adequate uptake of in a screening population. It must of course be noted that the
18 theme of 'inclusivity in one's own healthcare' that arose from the interviews is within a
19 study setting of voluntary participants, in contrast with a screening population who may
20 feel less able to decline. The evidence from the accounts nevertheless supports the
21 impression that TNE can enhance a feeling of involvement, which is an important
22 factor in uptake and concordance. Questions for the use of TNE as a screening tool
23 remain. The inability of the EG Scan system to allow biopsies is one recurring concern
24 for participants, and nasal discomfort is a significant drawback. There is evidence for
25 higher comfort levels during endoscopy when thinner endoscopes (6 mm or less in
26 diameter) are used, whether transnasally or transorally(25).
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53 Contradicting views emergent from the data also provide important insights. The
54 minority of participants who did not wish to view endoscopic images, those who would
55 prefer C-OGD as a screening tool because of its established nature and individuals
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3 who would prefer to attend hospital for TNE rather than the community, all had valid
4 reasons that warrant consideration. The participants realised that, as individuals who
5 had pre-existing conditions or symptoms requiring OGD examination, they differed
6 from a screening population, making direct comparisons impossible. Some of the
7 reasons given for preferring aspects of C-OGD over TNE are indeed based in existing
8 practices e.g. oesophageal biopsies in BO using C-OGD.
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12 Patient acceptability has been studied through qualitative means in related areas of
13 gastrointestinal practice. The Cytosponge TFF-3 test is a means of diagnosing BO
14 through non-endoscopic means. A study using semi-structured interviews and focus
15 groups analysed responses from Cytosponge-naïve but eligible patients to gauge their
16 impression of this test versus endoscopy, using videos and explanation of the clinical
17 problem by a researcher(26). Qualitative research of patients undergoing C-OGD for
18 BO reflect themes of comfort and control being important to them, which aligns well
19 with our findings(27). Additionally, qualitative analysis of interviews has been
20 conducted to gain an insight into factors affecting adherence to endoscopic screening,
21 which would be a major factor in establishing an effective service(28).
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Conclusions

The information collected in this patient-centred qualitative study has identified four main themes underlying the expectations and experiences of those undergoing TNE and C-OGD. They are inclusivity in one's own health care, comfort level and convenience, validity of the procedure and application to a screening population, and a sense of altruism and reciprocity. We believe that this analysis is a reliable reflection of the experiences of the patients involved and that it provides insights into the opportunities and challenges for interventions offered to patients selected as 'at risk' and therefore considered for screening. These insights could not have arisen from quantitative analyses of acceptability and highlight the strengths of thematic analysis in optimising clinical care. The themes align with the original study's VAS outcomes in suggesting that unsedated TNE is widely acceptable and are likely to reflect the experiences of at-risk screening populations within the wider community.

Figure 1. The EG ScanTM II system. (A) the portable case with four main parts; (B) the image processor (top left), disposable probe (top right), air tube (bottom right) and hand-held controller (bottom left); (C) the system connected and ready for use; (D) close view of the capsule probe tip. (Reproduced with permission from Sami SS, et al. Copyright John Wiley and Sons).

Author Contributions

John J. McGoran: contributed to analysis, interpretation of data and drafted the manuscript.

Andrea Bennett: contributed to the acquisition of data and critical revision of the manuscript for important intellectual content.

Joanne Cooper: contributed to acquisition of data, interpretation of data and critical revision of the manuscript for important intellectual content.

John de Caestecker: contributed to the study supervision, interpretation of data and critical revision of the manuscript for important intellectual content.

Laurence B. Lovat: contributed to the study supervision, interpretation of data and critical revision of the manuscript for important intellectual content.

Indra Neil Guha: contributed to the acquisition of data, study supervision, interpretation of data and critical revision of the manuscript for important intellectual content.

Krish Ragunath: contributed to the conception, design and supervision of the study, acquisition of data, study supervision, interpretation of data and critical revision of the manuscript for important intellectual content.

Sarmed S. Sami: contributed to the conception, design and supervision of the study, acquisition of data; analysis; interpretation of data; and critical revision of the manuscript for important intellectual content.

Potential Conflicts of Interest

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The other authors have no conflicts of interest to declare relevant to this publication.

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Data Availability

The data are interview transcripts which are held on a secure server based in Nottingham University Hospitals. Material is intellectual property of S Sami et al. and requests should be made to the corresponding author.

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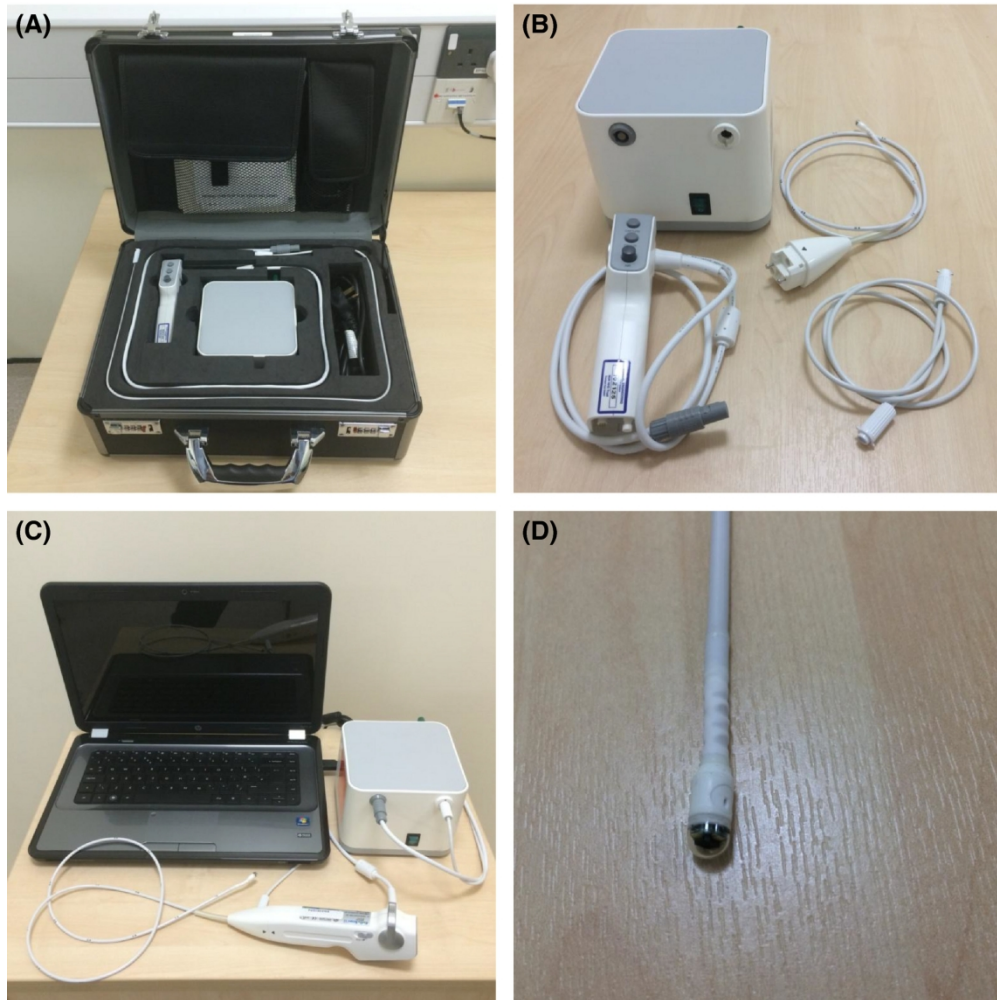


Figure 1. The EG ScanTM II system. (A) the portable case with four main parts; (B) the image processor (top left), disposable probe (top right), air tube (bottom right) and hand-held controller (bottom left); (C) the system connected and ready for use; (D) close view of the capsule probe tip. (Reproduced with permission from Sami SS, et al. Copyright John Wiley and Sons).

COREQ (CONsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
<i>Personal characteristics</i>			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	
Occupation	3	What was their occupation at the time of the study?	
Gender	4	Was the researcher male or female?	
Experience and training	5	What experience or training did the researcher have?	
<i>Relationship with participants</i>			
Relationship established	6	Was a relationship established prior to study commencement?	
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	
Interviewer characteristics	8	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	
Domain 2: Study design			
<i>Theoretical framework</i>			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	
<i>Participant selection</i>			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	
Sample size	12	How many participants were in the study?	
Non-participation	13	How many people refused to participate or dropped out? Reasons?	
<i>Setting</i>			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	
<i>Data collection</i>			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	
Repeat interviews	18	Were repeat interviews carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	
Field notes	20	Were field notes made during and/or after the interview or focus group?	
Duration	21	What was the duration of the interviews or focus group?	
Data saturation	22	Was data saturation discussed?	
Transcripts returned	23	Were transcripts returned to participants for comment and/or	

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
<i>Data analysis</i>			
Number of data coders	24	How many data coders coded the data?	
Description of the coding tree	25	Did authors provide a description of the coding tree?	
Derivation of themes	26	Were themes identified in advance or derived from the data?	
Software	27	What software, if applicable, was used to manage the data?	
Participant checking	28	Did participants provide feedback on the findings?	
<i>Reporting</i>			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	
Data and findings consistent	30	Was there consistency between the data presented and the findings?	
Clarity of major themes	31	Were major themes clearly presented in the findings?	
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

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Acceptability to patients of screening disposable transnasal endoscopy: qualitative interview analysis

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Acceptability to patients of screening disposable transnasal endoscopy: qualitative interview analysis

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Abstract

Objectives

Screening in selected high risk populations for Barrett's oesophagus (BO) and oesophageal varices (OVs) has been proposed, but there are obstacles with conventional oesophagogastroduodenoscopy (C-OGD), including patient acceptability. Portable and disposable office-based transnasal endoscopy (TNE) is a feasible and accurate alternative to C-OGD that may have use in primary and secondary care. This article outlines a qualitative analysis of patient experiences of TNE and C-OGD in order to gain an insight into an acceptable delivery of an endoscopic screening service.

Design

Purposeful sampling identified 23 participants who then underwent semi-structured interviews to determine their experiences of both procedures. Thematic analysis was conducted to derive meaning from their lived experiences.

Setting

A secondary care endoscopy unit, clinic room and interview room.

Participants

Patients referred for BO or OV surveillance and for endoscopy to investigate dyspepsia underwent unsedated TNE using the EG Scan II device followed by C-OGD with or without sedation (patient choice), as part of a clinical trial.

Results

The themes that arose from our analysis were: inclusivity in one's own health care; comfort level and convenience; validity of the procedure and application to a screening population; and a sense of altruism and reciprocity.

Positive aspects of TNE included participant empowerment, reduced discomfort and avoidance of conscious sedation. Participants felt that if TNE screening was of proven

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3 efficacy it would be welcomed, though views on use in a community setting were
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5 mixed.
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7 **Conclusions**

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10 Most patients preferred TNE to unsedated C-OGD and the reasons they gave featured
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12 strongly in the emerging themes. Preferences between TNE and sedated C-OGD
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14 were more subtle, with equivalent comfort scores but merits and drawbacks of both
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16 being discussed. This information identifies opportunities and challenges in
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18 establishing an endoscopic screening service.
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28 Keywords: endoscopy, oesophageal disease, hepatology
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32 **Strengths and Limitations of the study**

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- The size of the original study, in which 100 patients from this centre alone allowed for a broad stated aim and collection of participants until data saturation was reached.
 - Every participant had clinic-based TNE before C-OGD so their experiences of the TNE would reflect that of a person undergoing screening more so than if C-OGD was done first.
 - The advantage in performing thematic analysis on the data gathered from interviews is that it allowed us to develop clear themes, which could allow transferability to other potential screening populations however this may be limited in non-research settings and other screening modalities.

- To maximise the credibility and dependability of the findings, reflexivity, in which the impact of the researcher and social environment on each other is acknowledged and managed, was employed at each stage. Care was taken not to manipulate participants into giving accounts that favoured or condemned either endoscopic test.
- An ordering effect cannot be quantified as all participants had TNE first and C-OGD second but we suggest that this order could have an impact on their perceptions of the endoscopic examinations.

Introduction

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3 Portable and disposable office-based transnasal endoscopy (TNE) is a feasible and
4 accurate alternative to conventional oesophagogastroduodenoscopy (C-OGD) that
5 may have use in primary and secondary care(1,2). Several authorities have
6 highlighted the need to identify alternative, minimally-invasive screening tests for
7 Barrett's oesophagus (BO) and oesophageal varices (OV) which are precursor
8 conditions for oesophageal adenocarcinoma (OAC) and variceal bleeding,
9 respectively(3–6). The incidence and mortality from OAC have risen rapidly over the
10 last few decades(7). This has prompted efforts to screen high risk patients who are
11 predominantly white, male, age 55 or over, with chronic reflux symptoms for BO(6).
12 The prevalence in women is lower but exact proportions are unclear. Similarly,
13 incidence and mortality from chronic liver disease is also rising, with one of the major
14 contributors being variceal haemorrhage(8). It is recommended practice to screen for
15 varices using endoscopy in all patients with cirrhosis but the cost-effectiveness of this
16 approach has been questioned(5).

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Currently, the standard of care for assessing BO and OVs is hospital-based
conventional oesophagogastroduodenoscopy (C-OGD). This requires a fully equipped
endoscopy department, complete with nursing support, recovery facilities, monitoring,
and decontamination rooms(9). Patients frequently require conscious sedation(10). C-
OGD can be perceived to be an uncomfortable experience for the patient which may
prompt those eligible for screening not to attend(11,12). These features of C-OGD fail
to meet screening principles of cost-effectiveness and acceptability.

To overcome this, various alternative screening tools for high risk groups have been
proposed and remain largely the preserve of research studies. Portable and
disposable transnasal endoscopy (TNE) as a method of screening for BO and OVs is

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3 one such tool that has been proposed as a solution. The suggested benefits of TNE
4 over C-OGD include allowing the patient to speak during the examination, increased
5 comfort levels and avoidance of sedation. It has been shown to be both accurate and
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10 cost-effective as a potential screening tool(1,2,13,14). The EG scan™ II system
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12 (Intromedic Ltd., Seoul, South Korea) is a transnasal endoscopic device with a
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14 disposable 6mm diameter probe. It has an air insufflation channel but no biopsy or
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16 irrigation port and is designed to be a method of visualising various upper
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18 gastrointestinal conditions (Figure 1). The apparatus has been designed for use in a
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20 consultation room, as a 'clinic-based' procedure, with potential for use in general
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practice.

The tolerability regarding comfort levels of TNE compared with that of C-OGD has
been studied using visual scales and questionnaires in randomised trials, assessing
attitudes towards and experience of sedated C-OGD and unsedated TNE that allow a
simple measure of preference between the two(15). Acceptability is a deeper concept,
that takes into consideration not only comfort scores but the global patient experience
and willingness to undergo the intervention. It may act as an indicator of patient uptake
and inform strategies for recruitment on a population level. To date, we have no
knowledge of any qualitative studies that have considered the acceptability of TNE to
patients who have undergone both it and C-OGD in a controlled environment. The
lived experiences of those who undergo these procedures can inform preference and
identify the challenges or opportunities for healthcare systems.

Tolerability and preference scores like the visual analogue scale (VAS) and the
Spielberger State Trait Anxiety Inventory (STAI-6) questionnaire are helpful ways of
assessing the impressions of large populations of patients towards a healthcare

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3 experience(16,17). They do not however permit reflection, nuance and richer insights
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5 into the experiences of individuals and therefore do not inform service development in
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7 the same way that qualitative methods do. A deeper analysis of these experiences
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9 could add to the clinical community's understanding of a patient's decision-making
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11 process and enhance human factors in screening or surveillance such as recruitment
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13 and retention.
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18 The aims of this study were to explore the expectations and experiences of patients
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20 who underwent both TNE in an outpatient setting and C-OGD on the same day through
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22 qualitative analysis, and to determine the factors that impact on the acceptability of
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24 TNE as a potential screening and surveillance tool.
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58 **Methods**

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Study Design and Setting

A qualitative methodology was employed, with the analysis of experiences and perceptions of both C-OGD and clinic-based TNE, using face-to-face semi-structured interviews. This builds on wider research examining the technical feasibility, quality, safety, acceptability (through scoring measures) and accuracy of clinic-based TNE using the EG Scan compared to C-OGD as the reference standard(1). A pictorial outline of this equipment is represented in Figure 1. Whereas the original research was conducted in three different centres, the collection of information with respect to this qualitative study was done at one centre (Nottingham, UK) with all patients having undergone both endoscopic procedures at that location.

The East Midlands division of the Research Ethics Committee granted approval for the study (REC reference 12/EM/0100). It was prospectively registered (ISRCTN registry identifier: 70595405). Specific consent forms for these interviews were devised and confirmation of consent was obtained prior to each interview. Interview transcripts have been stored on an encrypted secure drive at the study site.

Participants and Recruitment

Purposeful sampling took place, in which most of the individuals in one centre involved in the wider research project were identified as potential participants before being contacted by telephone within four weeks of the day of endoscopy. This is a common recruitment approach in qualitative research which contrasts with random sampling in quantitative research that seeks to reduce selection bias. Three patient groups were

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3 identified: those with histologically confirmed BO, those warranting OV screening or
4 surveillance, and those with dyspepsia referred for diagnostic endoscopy. The
5 experiences of all 47 patients were considered valid for an analysis of acceptability as
6 they reflected a suitably healthy and communicative cohort, with three out of 50
7 ineligible because of ill health. Recruitment approaches for the quantitative and
8 qualitative studies were done in parallel, with individuals approached for their consent
9 to participate in an interview-based research study at the same time as for the
10 quantitative study. They were then followed up within four weeks to ensure willingness
11 to proceed with interview. Only the three individuals mentioned above withdrew
12 consent or were withdrawn because of ill health. Those who could not tolerate both
13 endoscopic examinations or who underwent variceal band ligation during C-OGD were
14 excluded from recruitment to interview as their lived experiences were deemed to be
15 considerably different from the rest. Sedated and unsedated patients were considered
16 equally valid as this variation is reflected in clinical practice.

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It was anticipated that a minimum of twenty interviews would have to be conducted to
gather sufficient information. This was informed in part by existing literature(18). After
23 interviews were conducted, the researchers reviewed the merits of conducting
further data collection as it would have required further appointments. After a
preliminary period of data analysis it was proposed that saturation had been reached
and no further participants would be required. The full thematic analysis of the existing
interview transcripts supported this and it was agreed by the research team that further
significant insights were unlikely to be gained from additional interviews.

Data Collection

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3 The interviews were conducted with interviewers guided by a topic schedule, that was
4 agreed by consensus of the researchers. The scheduled questions related to all
5 aspects of the endoscopic procedures and participants' views on the use of TNE in
6 the community. Broad points included exploration of participants' prior understanding
7 and expectations of undergoing both forms of endoscopy procedure, their experiences
8 of the procedures and factors influencing this, and their recommendations for future
9 service provision, including any information or support needs. Box 1 outlines the
10 interview schedule further. The semi-structured nature of the interviews allowed the
11 skilled researchers to explore the given answers with further probing and digression
12 from the core topics. The topics and questions arose from the experiences of the
13 researcher as clinicians in caring for patients undergoing endoscopy and knowledge
14 of the processes of the original study where there was significant Patient and Public
15 Involvement (1,2). Both interviewers were female registered research nurses
16 independent of the main study team and blinded to the patients' tolerability scores.
17 The interviewers received site training to familiarise themselves with qualitative
18 research and are subject to regular appraisal and research training, with oversight
19 from a research team that includes an academic with a nursing background. The study
20 was conducted and reported according to the COREQ standards for qualitative
21 research(19).

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48 Interviews were recorded on an encrypted device and lasted between twenty and thirty
49 five minutes. Following this, recordings were transcribed to Microsoft Word documents
50 undertaken by a professional transcriber who consciously checked their actions in
51 retrospect and ensured that the transcripts were anonymised.

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59 **Box 1. Schedule for use by research nurses conducting semi-structured interview**

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- Explore events that led to participant requiring endoscopy- ideas, concerns, expectations
 - Explore experiences of both tests to compare and contrast; short description
 - Ask about environment in which each test took place- description; feelings
 - Revisit visual analogue score to allow discussion over preferred test and explore

Data Analysis

Transcribed interviews underwent thematic analysis by one researcher (JM) who was not involved in the study beforehand but fully briefed of the processes. Transcripts were read at least twice with broad notes being made of descriptions and sentiments from which possible recurrent themes could arise(20). The transcripts were then entered into NVivo version 12 (QSR International, Melbourne, Australia) software, which helped to identify the frequency of language used and its relation to other statements, to determine the relevance of the language used to the research aims. These patterns were again considered by the researcher and the themes were arrived at. Themes were again checked with the supporting text and interpretations drawn.

Rigour

In order to ensure scientific rigour, checks were made at each stage of this study by primarily referring to the COREQ criteria, while taking care not to compromise the unique contribution that good quantitative research can bring to scientific progress(19)(21). The research team also discussed the analysis frequently, using existing theoretical frameworks to ensure competent data collection and analysis. Our transcripts were analysed for deviant cases, which were noted to be equally valid to

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3 majority perspectives. As clinicians delivering endoscopic examination in daily
4 practice, it was important for the team undertaking this qualitative analysis to exercise
5 reflexivity. Consideration was made to the data collection, interpretation and arrival at
6 themes through reflective discussion and self-analysis. Specifically, awareness of the
7 VAS for comfort from the original study was noted and care taken not to apply this to
8 the qualitative analysis. With an acknowledgement of individual and collective biases
9 and motives, the researchers carefully tried to ensure that the themes arose from the
10 participants' accounts alone. There may be a significant ordering effect resulting from
11 TNE being performed before C-OGD in all cases. The quantitative study which
12 analysed the diagnostic accuracy, safety, cost-effectiveness and tolerability using VAS
13 required this specific ordering. It does however represent a limitation in the case of the
14 qualitative analysis. Involvement of the lead author (JM) who has no conflict of interest
15 of note pertaining to device manufacturers, served to reduce the impact of apparent
16 interpretative bias.

35 36 **Patient and Public Involvement**

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39 The participants in this analysis were part of a larger study as noted earlier. Following
40 TNE and C-OGD patients were asked to complete a questionnaire on their
41 experiences of these tests. Analysis of the questionnaires and encounters between
42 researchers and patients during this time strongly informed the preparation for semi-
43 structured interviews. In addition, throughout this process the input of the Patient and
44 Public Involvement group at Nottingham Biomedical Research Centre was taken into
45 consideration in terms of aims, design, patient consent and information leaflets.
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For peer review only

Results

Twenty-three interviews took place, with participants having BO (n=11), OVs (n=8) or neither of these (those referred for investigation of dyspepsia) (n=4).(Table 1) Given

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3 the standard approach of the two endoscopic procedures, excluding those having had
4 variceal band ligation, it was determined that all participants shared a similar lived
5 experience and could all give accounts that can provide insights into the acceptability
6 of TNE as a screening tool for either BO or OVs. For the purposes of the thematic
7 analysis it was therefore not thought necessary to divide the groups according to their
8 indication for endoscopy. The majority (17/23) of participants were men, which
9 somewhat represents the gender balance in those having endoscopic examination for
10 BO and OVs. The presence of sedation for C-OGD was a factor in participants' lived
11 experiences and this was taken into account during interview of each individual. Recall
12 of events differed between participants because of sedation however the absence of
13 perceived discomfort is as important a feature of acceptability as conscious and
14 remembered tolerability, when considering attitudes towards this test. The
15 inconvenient aspects of intravenous sedation such as increased length of clinical
16 observation and a 'hangover effect' were also discussed.
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Basic Demographics of 23 Interview Participants

Males (n/23)	17
Sedation for C-OGD (n/23)	13
Median Age (range)	66 (48-83)
Barrett's Oesophagus (n male)	11 (9)
Liver Disease warranting Varices Screening/Surveillance (n male)	8 (6)
Dyspepsia (n male)	4 (2)

Table 1. Demographic and sedation details of 23 interview participants. Reflective of the general population for BO and cirrhotic liver disease, males represent the majority of participants. Sedation status for C-OGD was decided on by fully informed participants.

Four themes were identified after thematic analysis. The four themes were: i) inclusivity in one's own health care; ii) comfort level and convenience; iii) validity of the procedure and application to a screening population; iv) a sense of altruism and reciprocity. The evidence supporting these four themes is outlined below, illustrated with excerpts from transcripts.

Inclusivity in one's own healthcare

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3 On attending for the dual endoscopic tests as part of a research study, most
4 participants described feeling well-informed of the procedures and involved in the
5 decision-making process. Two people expressed initial wariness of TNE as they did
6 not know what to expect but felt reassured after a fuller explanation. Every participant
7 acknowledged that they had consented with appropriate knowledge of each
8 procedure. TNE was described as “*empowering*”, “*fascinating*” and a participant stated
9 that they would “*definitely*” have it done again. Specific comments regarding TNE’s
10 merits included that they could speak with the operator, sit up in a chair and view their
11 endoscopic images if they wished- “*I could watch it on the monitor*” (male, 70,
12 *dyspepsia*).
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27 By contrast, the “impersonal” C-OGD made participants feel “trapped” and
28 “claustrophobic” or like in “a production line”. Comments were highly suggestive of a
29 disinclination to undergo C-OGD. Unfavourable comments about C-OGD were
30 underlined by participants’ responses to queries over their involvement in the decision
31 making process- “*I could have said no. But I came looking for help* (male, 70,
32 *dyspepsia*).”, “*as a patient, I have the ultimate say* (male, 66, *liver disease*).” The
33 existence of established guidelines, best practice and trust in the decision-making of
34 medical professionals prompted attendance for endoscopic tests, with one participant
35 summarising the feelings of many others by saying “*If you’ve got to have a test, you’ve*
36 *got to have a test.*” Another participant said of C-OGD, “*I know it’s part of the care,*
37 *that you’ve got to have it done*” (female, 83, *Barrett’s*). Participants used their
38 knowledge of their chronic conditions and their symptoms as accompanying motives
39 for having endoscopic tests.
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58 **Comfort level and convenience**

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3 As part of the original study, every participant completed visual analogue scales of
4 their experiences of each endoscopic procedure. The interviewers had access to the
5 VAS for each participants and reminded them of the score out of ten they gave, before
6 exploring the reason for this and any change in attitude made in retrospect. This part
7 of the data collection reaffirmed that the majority preferred TNE to unsedated C-OGD.
8 Among those having sedation for C-OGD, the preference for TNE remained but this
9 was less strong. Of the thirteen who chose sedation, all but one had experienced a C-
10 OGD in the past and some stated this choice was informed by past experiences of
11 undergoing endoscopy without. All TNEs were performed without sedation, which was
12 reported as acceptable by all participants, who described minor nasal discomfort as
13 the predominant uncomfortable element. They had insight that having an unsedated
14 procedure would mean *“you can go straight home”*(female, 83, Barrett’s) afterwards,
15 making it more time-efficient and convenient. For those who had unsedated C-OGD,
16 excessive gagging featured almost universally as well as a measure of distress that
17 caused one patient to cry and another to state *“I wouldn’t recommend that to anyone”*
18 (male, 65, dyspepsia). Gagging was less of an issue for TNE as described by the
19 individual who reported, *“not so much with the nasal one but with the, with the oral*
20 *one, it was very bad gagging reflex”* (male, 75, dyspepsia). Beyond this theme, patient
21 experiences and accounts did not appear to be affected by their sedation status.
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48 **Validity of the procedure and application to a screening population**

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51 The EG scan has been shown to have accuracy in the detection of BO and
52 medium/large OVs(1,2). Participants were informed of the outcome of their own
53 endoscopic examinations but were unaware of the study findings that TNE and C-
54 OGD results were in concordance. Participants were however encouraged to use their
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3 lived experience to give an account of how important test accuracy would be to them
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5 and to others. The premise was that of TNE being extended to screening individuals
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7 in a community setting.
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11 For those who had a history of undergoing C-OGDs for BO and OVAs, the potential
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13 accuracy of TNE was important. They described C-OGD as a *'necessary evil'* but an
14
15 informative test for their condition which they have little choice but to undergo given
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17 the reasons above. Having been briefed on the devices, one participant recognised a
18
19 possible limitation of the EG Scan probe- *"The nasal one, you can't actually take*
20
21 *biopsies from, you can't use that to take samples."* (male, 72, Barrett's) While most
22
23 acknowledged TNE as more comfortable, they suggested that it would only be an
24
25 acceptable alternative if its ability to detect abnormalities matched that of C-OGD.
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27 Based on his experience, (*"the day I had them both done, I think the nasal one, I think*
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29 *it missed something out"* (male, 58, Barrett's)) one participant declared, *"I do believe*
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31 *the gastroscopy one is more thorough"* (male, 71, liver disease). Alongside this, the
32
33 participants emphasised the requirement for adequately trained endoscopists to
34
35 perform TNE and some expressed reservations over their general practitioners taking
36
37 up the role- *"As long as you had proficient GPs doing it"* *"As long as he (GP) can do*
38
39 *it...properly"* (male, 68, Barrett's). For this reason, opinion was divided on the location
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41 of the test, with some preferring the specialist nature of secondary care and others
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43 espousing the greater convenience and comfort of having TNE in the community.
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51 **Sense of altruism and reciprocity**

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54 Participants used their experiences as patients and as study participants to deliver
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56 unique insights into how endoscopic screening would be received by the target
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58 populations. For many patients, their positive experiences of healthcare informed their
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3 decision-making in becoming a research participant. *“I said yes because I was most*
4 *grateful for what the hospital had done for me previously” (female, 59, Barrett’s), “I*
5 *ought to try and put something back in” (female, 60, liver disease) and “I’m always*
6 *ready to help in the progress of science” (male, 65, dyspepsia) were some statements*
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8 that clearly showed the willingness of participants to use their experiences for the
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10 betterment of others.
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18 The involvement of those who have undergone the procedure is an important factor in
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20 establishing a screening programme. Participants suggested that prospective patients
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22 would be reassured by engaging with someone who had already undergone the
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24 procedure, reflecting the place of social constructionism in society’s view towards
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26 healthcare screening in an overt fashion(22).
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Discussion

This research represents the first time that a qualitative study has been conducted into the experiences of patients undergoing transnasal endoscopy for screening of gastrointestinal conditions. The aim of this research was not to contrast one endoscopic mode with the other, as each has its own applicability in clinical practice, but to consider the acceptability of TNE in screening of high risk individuals. The additional information derived from a qualitative as compared to a quantitative means of assessing acceptability (eg VAS or structured questionnaire) allows for deeper interpretation of a patient's perspective. The themes identified in this study support the view that TNE could be acceptable to a screening population, thus fulfilling an important principle of a viable screening programme(23).

The community of inquiry theory is a concept that unites the themes identified in this study(24). The background is that TNE is shown to be accurate and safe in the delivery of BO and OV assessment but the problem remains that not enough is deeply understood about its acceptability to a population. To explore the challenges and advantages offered by TNE in the screening of BO and OVs, male and female participants of different ages and for different reasons underwent the same procedure. Their individual perspectives were all considered and conclusions that reflect this community's account were arrived at, which will hopefully contribute to improved delivery of patient care. For the purposes of this study all of the accounts were communicated through the researchers but they are reflective of the conversations that may exist in the greater population.

To the participants, the notion of an accurate test that was superior in comfort and convenience was appealing. They could see the benefits that this could bring a wider

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3 population and were pleased to be part of a community that could enhance other
4 patients' experiences. The greater mutualism and control that TNE seems to bring in
5 contrast to C-OGD made it more appealing, which could be important in achieving
6 adequate uptake of in a screening population. It must of course be noted that the
7 theme of 'inclusivity in one's own healthcare' that arose from the interviews is within a
8 study setting of participants who volunteered to undergo TNE, in contrast with a
9 screening population who may feel less able to decline. The evidence from the
10 accounts nevertheless supports the impression that TNE can enhance a feeling of
11 involvement, which is an important factor in uptake and concordance. In a public health
12 setting, inclusivity and a sense of community of which altruism is a component, are
13 essential factors affecting patient involvement. Questions for the use of TNE as a
14 screening tool remain. The inability of the EG Scan system to allow biopsies was one
15 recurring concern for participants, and nasal discomfort is a significant drawback.
16 There is evidence for higher comfort levels during endoscopy when thinner
17 endoscopes (6 mm or less in diameter) are used, whether transnasally or transorally
18 and a different device might be used to achieve this(25).

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41 Contradicting views emergent from the data also provide important insights. The
42 minority of participants who did not wish to view endoscopic images, those who would
43 prefer C-OGD as a screening tool because of its established nature and individuals
44 who would prefer to attend hospital for TNE rather than the community, all had valid
45 reasons that warrant consideration. The participants realised that, as individuals who
46 had pre-existing conditions or symptoms requiring OGD examination, they differed
47 from a screening population, making direct comparisons impossible. Some of the
48 reasons given for preferring aspects of C-OGD over TNE are indeed based in existing
49 practices e.g. oesophageal biopsies in BO using C-OGD.
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3 Qualitative research of patients undergoing C-OGD alone for BO reflect themes of
4 comfort and control being important to them, which aligns well with our findings(26).
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7 Additionally, qualitative analysis of interviews has been conducted to gain an insight
8 into factors affecting adherence to endoscopic screening, which would be a major
9 factor in establishing an effective service(27). A clearer view of the population's
10 interpretation of such an intervention may enhance the confidence of healthcare
11 providers to establish a screening programme with TNE at its core.
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23 **Conclusions**

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27 The information collected in this patient-centred qualitative study has identified four
28 main themes underlying the expectations and experiences of those undergoing TNE
29 and C-OGD. They are inclusivity in one's own health care, comfort level and
30 convenience, validity of the procedure and application to a screening population, and
31 a sense of altruism and reciprocity. We believe that this analysis is a credible
32 reflection of the experiences of the patients involved and that it provides insights into
33 the opportunities and challenges for interventions offered to patients selected as
34 'high risk' and therefore considered for screening. These insights could not have
35 arisen from quantitative analyses of acceptability and highlight the strengths of
36 qualitative methods to optimise clinical care. The themes align with the original
37 study's VAS outcomes in suggesting that unsedated TNE is potentially acceptable
38 and may reflect the experiences of high risk screening populations within the wider
39 community.
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3 **Figure 1. The EG Scan™ II system. (A) the portable case with four main parts;**
4 **(B) the image processor (top left), disposable probe (top right), air tube**
5 **(bottom right) and hand-held controller (bottom left); (C) the system connected**
6 **and ready for use; (D) close view of the capsule probe tip. (Reproduced with**
7 **permission from Sami SS, et al. Copyright John Wiley and Sons).**
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14 **Author Contributions**

15
16
17 John J. McGoran: contributed to analysis, interpretation of data and drafted the
18 manuscript.
19

20
21 Andrea Bennett: contributed to the acquisition of data and critical revision of the
22 manuscript for important intellectual content.
23

24
25 Joanne Cooper: contributed to acquisition of data, interpretation of data and critical
26 revision of the manuscript for important intellectual content.
27

28
29 John de Caestecker: contributed to the study supervision, interpretation of data and
30 critical revision of the manuscript for important intellectual content.
31

32
33 Laurence B. Lovat: contributed to the study supervision, interpretation of data and
34 critical revision of the manuscript for important intellectual content.
35

36
37 Indra Neil Guha: contributed to the acquisition of data, study supervision,
38 interpretation of data and critical revision of the manuscript for important intellectual
39 content.
40

41
42 Krish Ragnath: contributed to the conception, design and supervision of the study,
43 acquisition of data, study supervision, interpretation of data and critical revision of
44 the manuscript for important intellectual content.
45

46
47 Sarmed S. Sami: contributed to the conception, design and supervision of the study,
48 acquisition of data; analysis; interpretation of data; and critical revision of the
49 manuscript for important intellectual content.
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Potential Conflicts of Interest

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The other authors have no conflicts of interest to declare relevant to this publication.

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Data Availability

Extra data can be accessed via the Dryad data repository at <http://datadryad.org/> with the doi: doi:10.5061/dryad.wdbrv15jb

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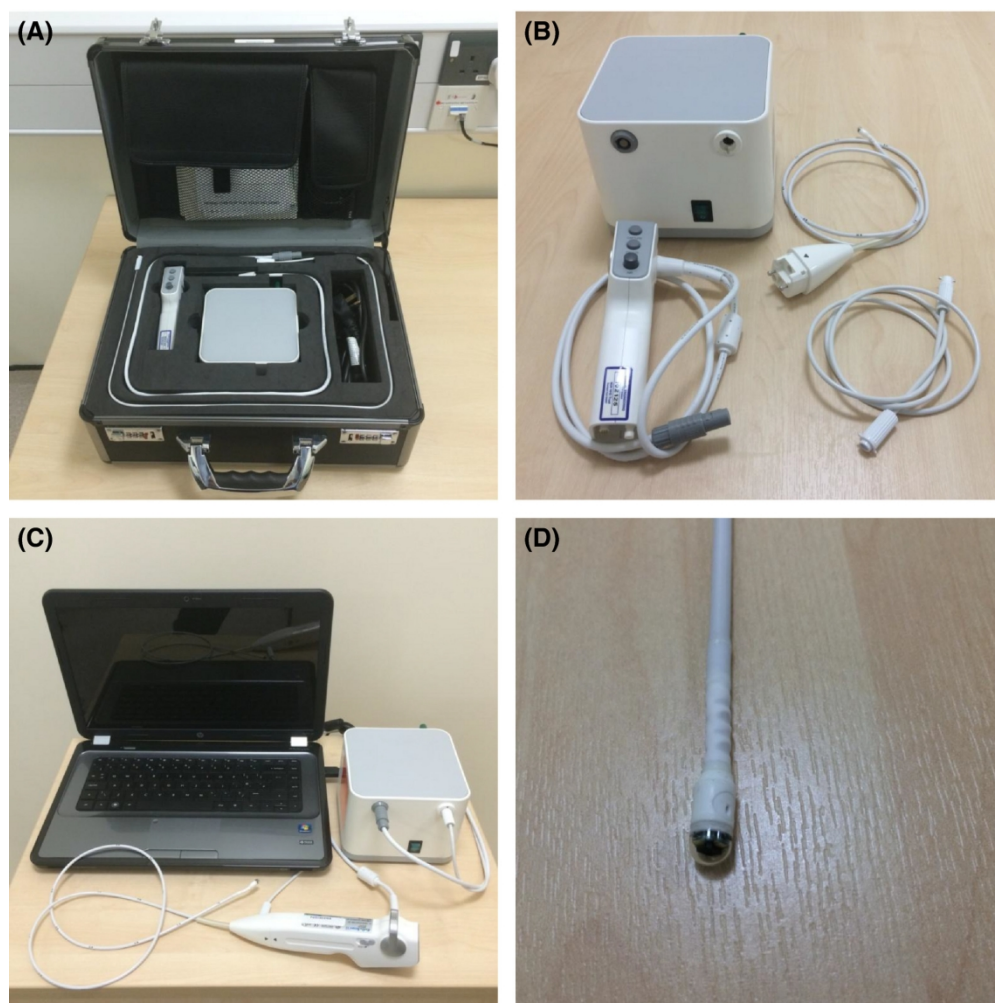


Figure 1. The EG ScanTM II system. (A) the portable case with four main parts; (B) the image processor (top left), disposable probe (top right), air tube (bottom right) and hand-held controller (bottom left); (C) the system connected and ready for use; (D) close view of the capsule probe tip. (Reproduced with permission from Sami SS, et al. Copyright John Wiley and Sons).

COREQ (CONsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
<i>Personal characteristics</i>			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	
Occupation	3	What was their occupation at the time of the study?	
Gender	4	Was the researcher male or female?	
Experience and training	5	What experience or training did the researcher have?	
<i>Relationship with participants</i>			
Relationship established	6	Was a relationship established prior to study commencement?	
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	
Interviewer characteristics	8	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	
Domain 2: Study design			
<i>Theoretical framework</i>			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	
<i>Participant selection</i>			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	
Sample size	12	How many participants were in the study?	
Non-participation	13	How many people refused to participate or dropped out? Reasons?	
<i>Setting</i>			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	
<i>Data collection</i>			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	
Repeat interviews	18	Were repeat interviews carried out? If yes, how many?	
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	
Field notes	20	Were field notes made during and/or after the interview or focus group?	
Duration	21	What was the duration of the interviews or focus group?	
Data saturation	22	Was data saturation discussed?	
Transcripts returned	23	Were transcripts returned to participants for comment and/or	

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
<i>Data analysis</i>			
Number of data coders	24	How many data coders coded the data?	
Description of the coding tree	25	Did authors provide a description of the coding tree?	
Derivation of themes	26	Were themes identified in advance or derived from the data?	
Software	27	What software, if applicable, was used to manage the data?	
Participant checking	28	Did participants provide feedback on the findings?	
<i>Reporting</i>			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	
Data and findings consistent	30	Was there consistency between the data presented and the findings?	
Clarity of major themes	31	Were major themes clearly presented in the findings?	
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

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