Comparison of patient tolerance and acceptability of magnet-controlled capsule endoscopy and flexible endoscopy in the investigation of dyspepsia

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ABSTRACT

Background and study aims Oropharyngeal intubation during Esophagogastroduodenoscopy (EGD) is uncomfortable, associated with aerosol generation and transmission of airborne microbes. Less-invasive alternatives may be better tolerated. In this study, patient tolerance and acceptability of EGD and transnasal endoscopy (TNE) have been compared with magnet-controlled capsule endoscopy (MACE).

Patients and methods A comparison of MACE with EGD and TNE in the investigation of dyspepsia was performed. Factors affecting patient tolerance and acceptability were examined using the Endoscopy Concerns Scale (ECS) and Universal Patient Centeredness Questionnaire (UPC-Q).

Results Patients were significantly more distressed (scoring least to most distress: 1–10) by gagging (6 vs 1), choking (5 vs 1), bloating (2 vs 1), instrumentation (4 vs 1), discomfort during (5 vs 1) and after (2 vs 1) EGD compared to MACE (all $P<0.0001$). Patients were more distressed by instrumentation (5 vs 1) and discomfort during (5 vs 1) TNE compared to MACE ($P=0.001$). Patients were more accepting of MACE than EGD and TNE with a UPC-Q score (scoring least to most acceptable: 0–100) lower for EGD (50 vs 98, $P<0.0001$) and TNE (75 vs 88, $P=0.007$) than MACE, and a post-procedure ECS score (scoring most to least acceptable: 10–100) higher for EGD (34 vs 11, $P<0.0001$) and TNE (25 vs 10.5, $P=0.001$) than MACE. MACE would be preferred by 83% and 64% of patients even if EGD or TNE respectively was subsequently recommended to obtain biopsies in half of examinations.

Conclusions Gagging and choking during instrumentation, the main causes of patient distress during EGD, occurred less during TNE but tolerance, acceptability and patient experience favored MACE.

Introduction

Esophagogastroduodenoscopy (EGD) is performed in 3% of Medicare beneficiaries per year [1]. It is uncomfortable and many patients require intravenous sedation or general anesthesia. Adverse events occur in up to 1 in 200 EGDs and 60% are cardiopulmonary events related to sedation and intubation [2, 3]. It is, therefore, understandable that patients may delay seeking medical advice for symptoms due to fear of investigation [4]. The COVID-19 pandemic has prompted consideration of the risks to endoscopy staff of aerosol-generating proce-

dures [5]. These concerns underlie a continuing search for less invasive upper gastrointestinal investigative tools which are effective, safe and acceptable to patients.

Transnasal endoscopy (TNE) using ultrathin instruments is better tolerated than EGD [6]. Capsule endoscopy does not involve intubation and the capsule can be moved and rotated in a stream of swallowed water to achieve gastric visualization using external magnetic control. Studies suggest that patients may prefer magnet-controlled capsule endoscopy (MACE) to EGD [7–10].

Our understanding of patients' upper gastrointestinal endoscopy experiences is mostly limited to procedural tolerance [11] and no studies have yet been designed to primarily examine patient experience of EGD and TNE by comparison to MACE. In addition to comparing tolerance for EGD, TNE, and MACE, we have also compared the broader experience with each using two patient-reported experience measures (PREMs): the Endoscopy Concerns Scale (ECS) and the Universal Patient Centeredness Questionnaire (UPC-Q) [12, 13].

Patients and methods

Patients

Patients between 18 and 80 years of age referred to Sheffield Teaching Hospitals for the endoscopic investigation of dyspepsia were invited to participate [14]. Those expressing interest in participating were consecutively screened for eligibility. Contraindications to MACE included a history of dysphagia, Crohn's disease, small bowel resection or previous abdominopelvic irradiation, long term (over six months) daily consumption of a nonsteroidal anti-inflammatory drugs and implanted metallic devices.

Interventions

Patients were offered the choice of EGD (with or without sedation) or TNE and invited to have MACE in the 2 weeks preceding their flexible endoscopy. Procedures were described and patients given standardized hospital information leaflets. Participants who agreed to have both MACE and flexible endoscopy were included in the study.

Robot-controlled MACE was performed using the NaviCam (AnX Robotica Corp, Texas, United States). The system comprises two joysticks which control an external magnet suspended on a robot arm above the patient recumbent on an examination couch. All examinations were performed by the same endoscopist. Prior to the examination, patients ingested 80 mg simethicone (Infacol, Teva UK) in 100 mL of water, followed by a series of position changes to wash the stomach and then consumed a further 500 to 1000 mL of water to distend the stomach before swallowing the capsule endoscope (AKEM-11SW; AnX Robotica Corp, Texas, United States). The procedure controls and maneuvers are described in detail elsewhere [15].

Flexible endoscopy was performed within 2 weeks of MACE by accredited endoscopists. All patients had oropharyngeal topical anesthesia and were offered benzodiazepine (midazolam) sedation prior to EGD (Olympus H260 or H290 or Pentax EC34-i10F gastroscope) or 5 % lidocaine/0.5 % phenylephrine nasal spray (Alliance Healthcare Ltd, UK) 15 minutes prior to TNE (Olympus XP290N). TNE was performed by one endoscopist. Patients were excluded from the study if either MACE or flexible endoscopy were incomplete; if there was food in the stomach, the MACE procedure time was less than 10 minutes, or nasal intubation was not possible.

Data collection and analysis

Knowledge of what patients anticipate in advance of their investigation is necessary to understand their health seeking behavior and compliance. Prior to each examination patients were asked to score their anxiety on a visual analog scale (1–10: not at all to extremely), as well as 13 endoscopy-related concerns previously described by Condon et al. in their development of the ECS, namely: telling friends about, fasting and discomfort prior to, the test; intravenous cannulation, instrumentation (insertion of flexible endoscope or swallowing the capsule), expressions of emotions, the endoscopist seeing food in the stomach and feelings of gagging, choking, vomiting, bloating, discomfort during the test [13]. The instrumentation criterion in the ECS was adapted for MACE by asking the patient to score their experience of swallowing the capsule rather than insertion of the flexible endoscope. Summation of each of these 13 scores was used as a measure of pre-procedure acceptance (13–130: most to least acceptable).

Measures of patient acceptance were collected after the procedure.

1. An ECS questionnaire scoring 10 of 13 items described earlier quantified patients' actual experience. The three pre-procedural items (concerns related to telling friends about, fasting and discomfort prior to, the test) were not repeated. These 10 items were added together to provide a measure of acceptability in light of their actual experience (post-procedure ECS: 10–100 most to least acceptable).
2. Patients were asked to consider three scenarios: whether or not they would undergo the test again or advise a friend to do so in similar medical circumstances or have the test as a screen for cancer in 5 years. Patients were regarded as finding the test acceptable if they answered in the affirmative to all three questions.

   The UPC-Q was used to assess and compare patient global experience with each form of endoscopy [12]. Each patient was asked to identify three aspects of the overall pathway that were most important to them. They were asked to rate their experience with each aspect (1–5: poor to excellent). They were then asked to rank the level of importance of the three aspects relative to each other by allocating a total of six points between the three aspects. Aspects of the care pathway listed as important to patients were categorized according to subject matter and reported. The overall UPC-Q score (of 0–100: least to most acceptable) was obtained using the following equation (where A_1, A_2 and A_3 are the three most important aspects of the pathway chosen by each patient):

   $$\text{UPC-Q score} = [\,(\text{Rate } A_1 \times \text{Rank } A_1/6) + (\text{Rate } A_2 \times \text{Rank } A_2/6) + (\text{Rate } A_3 \times \text{Rank } A_3/6) - 1] \times 25$$

3. Patients were asked to express a preference for one or the other test. EGD could be recommended following MACE if biopsies were needed. Therefore, patients were also asked to express a preference for the primary diagnostic test based on the probability of requiring a second procedure to obtain biopsies.

In a subset of patients, tandem recordings of MACE and flexible endoscopy were reviewed by a blinded expert endoscopist. Endoscopic findings and agreement between modalities are reported.

Outcome measures

The primary outcomes were to examine overall acceptability and experience with MACE compared to EGD or TNE. These were defined as pre-procedure patient anxiety and ECS scores, and post-procedure as the UPC-Q and post-procedure ECS scores. The secondary (tolerance) outcomes were to quantify the level of distress caused by each item of the ECS (13 pre-procedure and 10 post-procedure items).

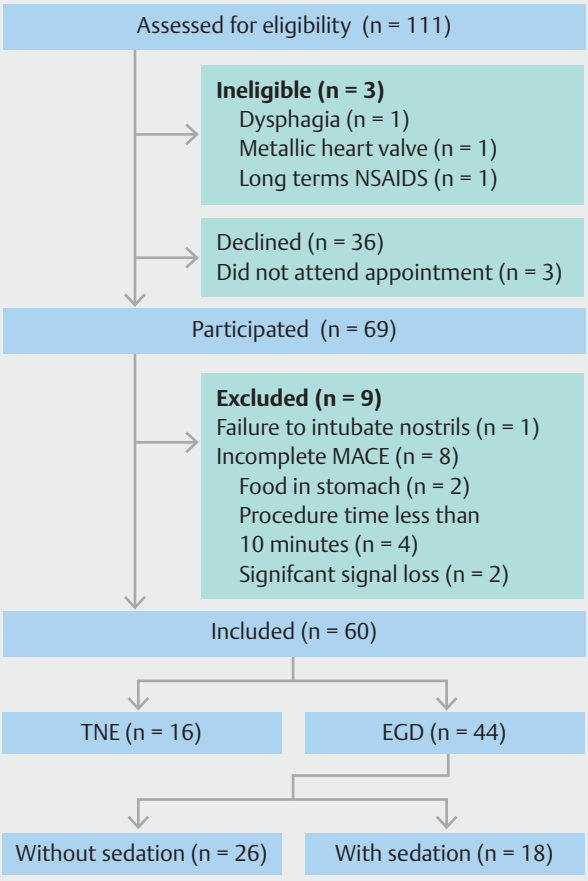
Advice was sought from the Statistical Services Unit at the University of Sheffield. A single point (10 %) difference in patient distress scores between groups was considered to be clinically significant. A sample of 44 per group would have a 90 % power to detect a difference in distress scores of 1 between MACE and flexible endoscopy assuming a standard deviation of 2 using a paired t-test with a 0.05 two-sided significance level. A sample of 48 patients would allow for an a priori interim analysis to be performed after 16 transnasal gastroscopies which would have a 90 % power to detect a difference in mean distress score of 2 and satisfy the requirements of full power.

Statistical methods

IBM SPSS Statistics for Macintosh, Version 24.0.0 (Armonk, New York, United States: IBM Corp) was used for statistical analysis. Continuous data was represented as median and interquartile range (IQR) respectively as the distribution among the majority of patient questionnaire data were non-parametric (Shapiro-Wilk test $P > 0.05$). Non-parametric paired differences in central tendencies were examined using Wilcoxon signed rank tests. Unpaired differences were examined using Mann Whitney U or Kruskal-Wallis H test. Categorical data is presented as number and percentages: n (%), and McNemar test was used to compare paired dichotomous variables. Statistical significance is defined as $P < 0.05$ and significance levels of multiple comparisons for primary and secondary outcomes were subjected to the Bonferroni correction. Construct validity of the UPC-Q was examined by Pearson's correlation of convergent and discriminant factors.

Ethics

This study was approved and conducted in accordance with the ethical standards of the South Central – Berkshire B Research Ethics Committee (16/SC/0606. ClinicalTrials.gov NCT03420729), and the 1964 declaration of Helsinki and its later amendments.



▶ **Fig. 1** Participants in the trial.

Results

Participants

Of 111 patients who expressed an interest, 69 participated and 60 were included in the study (▶ **Fig. 1**). Characteristics of included patients undergoing MACE and EGD or TNE are reported in ▶ **Table 1**. MACE was complete in 61 (88 %), EGD in 47 (100 %), and TNE in 21 patients (95 %). Nine patients were excluded. One converted to EGD following failed nasal intubation and eight had incomplete gastric MACE (▶ **Fig. 1**). Eighteen patients (40.9 %) opted for sedation with EGD (median midazolam dose 2 mg (range 1.5–4); fentanyl 50 mcg (range 25–75).

Patient anxiety, anticipatory concerns and views on acceptability of their proposed investigations

Before the procedure, patients were more anxious about having EGD than MACE, with median state anxiety scores of 5 and 2 ($P < 0.0001$) respectively, but not significantly more anxious about having TNE than MACE (▶ **Table 2**). Trait anxiety did not differ significantly between EGD and TNE cohorts (▶ **Table 1**). Median pre-procedure ECS scores were higher before EGD (39 vs 26, $P < 0.0001$) and TNE (42 and 32, $P = 0.04$) than MACE (▶ **Table 2**). Median distress scores were significantly more in anticipation of EGD compared to MACE with regard to procedure-related

▶ **Table 1 Characteristics of included patients undergoing MACE followed by EGD or TNE**. Age, gender, Hospital Anxiety and Depression scores (HADS), use of anxiolytics or antidepressants, body mass index (BMI) and previous experience of endoscopy reported in median (IQR) or n (%).

	MACE followed by		
	EGD	TNE	p
N (%)	44	16	
Age	53.0 (22)	52.5 (23)	0.77
Female gender, n (%)	27 (66)	6 (55)	0.50
HADS			
Anxiety score	5 (8)	2 (6)	0.81
Score > 8, n (%)	12 (29)	3 (27)	0.90
Anxiolytic use, n (%)	0 (0)	0 (0)	–
Depression score	1 (5)	0 (4)	0.10
Score > 8, n (%)	3 (7.3)	0 (0)	0.36
Anti-depressant use, n (%)	8 (18)	3 (19)	0.81
BMI kg/m^2	24 (10)	23 (9)	0.40
Previous EGD experience, n (%)	18 (41)	2 (12.5)	0.08
Previous TNE experience, n (%)	0 (0)	0 (0)	–

factors (gagging (5 vs 2, $P<0.0001$) and procedural discomfort (5 vs 2, $P<0.0001$). By comparison, discussing the procedure with friends, fasting pre-procedure, potential for intravenous cannulation, displays of emotions and the endoscopist seeing food in the stomach caused negligible distress. No statistically significant differences were seen in anticipatory concerns prior to TNE and MACE after Bonferroni's correction. There was a trend suggesting TNE might cause more distress than MACE when patients anticipated instrumentation (7.5 vs. 2.5, $P=0.008$) and procedural discomfort (6.5 vs. 3, $P=0.005$) (▶ **Table 2**).

Patient tolerance and factors causing distress during EGD, TNE and MACE

After their procedure, patients reported experiencing significantly more distress (median score) due to gagging (6 vs 1, $P<0.0001$), choking (5 vs 1, $P<0.0001$), instrumentation (4 vs 1, $P<0.0001$), discomfort during (5 vs 1, $P<0.0001$) and after (2 vs 1, $P<0.0001$) EGD when compared to MACE (▶ **Table 3**). Similarly, patients reported significantly more distress due to instrumentation (4.5 vs 1, $P=0.001$) and discomfort during (5 vs 1, $P=0.001$) TNE compared to MACE (▶ **Table 3**). In those undergoing EGD with sedation, MACE was still significantly better tolerated (▶ **Table 4**).

No significant differences were found between pre- and post-EGD or TNE distress scores, suggesting patients correctly anticipated which procedural factors would cause them distress (▶ **Table 5**). However, factors related to tolerance of MACE (gagging, choking, abdominal bloating, instrumentation, discomfort during and after MACE) caused significantly less actual distress than anticipated.

Patient acceptance of EGD, TNE and MACE and effect of mucosal biopsies on patient preference MACE and flexible endoscopies

The UPC-Q was completed appropriately by 95 % of participants (n = 57/60). For the purpose of data analysis, drinking the water, swallowing the capsule, procedural discomfort, and test duration were all categorized as being related to procedural tolerance; having sufficient information and being informed about test progress as being related to communication and having a comfortable environment and adverse effects as being related to procedural recovery and aftercare. Aspects identified by patients for EGD, TNE, and MACE (respectively) related to procedural tolerance in 67 %, 54 %, and 54 % of patients; communication in 4 %, 18 %, and 8 %; aftercare and recovery in 7 %, 9 %, and 5 %; test results in 13 %, 14 %, and 18 %; test accuracy in 2 %, 4 %, and 5 %, and other concerns in 8 %, 0 %, and 10 %.

Median ECS scores were significantly higher after EGD (34 vs 11, $P<0.0001$) and TNE (25 vs 10.5, $P=0.001$) compared to MACE. UPC-Q score was lower for EGD (50 vs 98, $P<0.0001$) and TNE (75 vs 88, $P=0.007$) than MACE. In the subgroup of 40.9 % of patients who opted to have sedation with their EGD, MACE had a higher UPC-Q (100 vs 54, $P=0.003$) and lower post-procedure ECS score (10.5 vs. 25, $P<0.0001$), suggesting a greater acceptance of MACE than sedated EGD (▶ **Table 4**). As defined by affirmative answers to all three questions regarding preparedness to undergo the same test again or to recommend the test, 100 %, 94 % and 64 % of patients found MACE, TNE and EGD respectively acceptable. However, all patients preferred MACE to EGD and 94 % preferred MACE to TNE.

If tissue biopsies were necessary after MACE and the chance of requiring biopsies (requiring flexible endoscopy as a second test) was 1 in 20, 1 in 10, 1 in 5, 1 in 4 or 1 in 2, 100 %, 100 %, 94 %, 94 % and 83 % would prefer MACE followed by EGD, rather than a direct to EGD strategy and 94 %, 94 %, 81 %, 75 % and 63 % would prefer MACE followed by TNE rather than a direct to TNE strategy.

Performance characteristics of UPC-Q and ECS

The UPC-Q correlated with post-procedure ECS after both MACE ($r=-0.32$ $P=0.01$) and gastroscopy ($r=-0.40$ $P=0.002$) demonstrating convergent validity, but not with pre-procedure ECS ($P=0.49$ and $P=0.29$) nor state anxiety scores ($P=0.25$ and $P=0.26$) providing some evidence of discriminant validity.

Endoscopic findings

Twenty-three patients with tandem recording of EGD and MACE were included in the analysis of endoscopic findings. There was complete agreement in findings between MACE and EGD in 65 % of patients (15/23) (▶ **Table 6**). Eight patients (35 %) had normal examinations on both MACE and EGD. Thirty endoscopic findings were found in total: 66 % of findings (20/30) were seen by both MACE and EGD, 16.7 % (5/30) by MACE alone, and 16.7 % (5/30) by EGD alone.

▶ **Table 2 Comparison of patient pre-procedure anticipation when undergoing EGD or TNE vs MACE.** Pairwise comparison of median (IQR) pre-procedure anxiety (1 – 10: Least to most) and pre- procedure endoscopic concern scale (ECS) score (most to least acceptable: 13–130). Components of the pre- procedure ECS distress scores (1 – 10: Least to most) are compared for description. Only p values for clinically significant differences (≥ 1 point difference) are reported.

	EGD (n = 44)			TNE (n = 16)		
	EGD	MACE	p	TNE	MACE	p
Pre procedure anxiety	5 (5)	2 (2)	<0.0001[1]	4.5 (5)	4 (4)	0.57
Pre procedure ECS	39 (41)	26 (7)	<0.0001[1]	42 (25)	32 (19)	0.04
Telling friends/colleagues about test	1 (0)	1 (3)	–	1 (1)	1 (2)	–
Fasting	1 (1)	1 (2)	–	1.5 (3)	1.5 (3)	–
Discomfort prior to procedure	1 (1)	1 (2)	–	1 (1)	1 (2)	–
Gagging	5 (4)	2 (5)	<0.0001*	3 (5)	3.5 (6)	–
Choking	5 (2)	2 (5)	0.05	3 (5)	3.5 (6)	–
Bloating	2 (2)	2 (4)	–	1 (1)	2 (2)	0.13
Vomiting	4 (2)	1 (6)	0.19	1.5 (1)	1 (3)	–
Doctor seeing food in stomach	1 (0)	1 (0)	–	1 (0)	1 (0)	–
Displaying emotions during the test	1 (1)	1 (3)	–	1 (1)	1 (3)	–
Instrumentation	5 (4)	3 (5)	0.03	7.5 (4)	2.5 (3)	0.008
Intravenous catheter	1 (1)	1 (3)	–	1 (1)	1 (2)	–
Discomfort during procedure	5 (3)	2 (6)	<0.0001[2]	6.5 (3)	3 (4)	0.005
Discomfort after procedure	2 (2)	2 (4)	–	4 (3)	3 (5)	0.40

[1] For primary outcomes, P<0.01 considered as statistically significant after Bonferroni correction for 4 comparisons.
[2] For descriptive outcomes, P<0.002 considered as statistically significant after Bonferroni correction for 26 comparisons

▶ **Table 3 Comparison of patient experience when undergoing EGD or TNE vs MACE.** Pairwise comparison of median (IQR) universal patient centredness questionnaire (UPC-Q) score (least to most acceptable: 0–100) and post-procedure endoscopic concern scale (ECS) score (most to least acceptable: 10–100). Components of the post- procedure ECS distress scores (1 – 10: Least to most) are also compared for description. Only p values for clinically significant differences (≥ 1 point difference) are reported.

	EGD (n = 44)			TNE (n = 16)		
	EGD	MACE	p	TNE	MACE	p
UPC-Q	50 (50)	98 (25)	<0.0001[1]	75 (67)	88 (37)	0.007[1]
Post procedure ECS	34 (32)	11 (1)	<0.0001[1]	25 (15)	10.5 (5)	0.001[1]
Gagging	6 (6)	1 (0)	<0.0001[2]	1.5 (2)	1 (0)	–
Choking	5 (6)	1 (0)	<0.0001[2]	1.5 (2)	1 (0)	–
Bloating	2 (4)	1 (0)	0.08	1 (3)	1 (1)	–
Vomiting	1 (3)	1 (0)	–	1 (0)	1 (0)	–
Doctor seeing food in stomach	1 (0)	1 (0)	–	1 (0)	1 (0)	–
Displaying emotions during the test	1 (4)	1 (0)	–	1 (1)	1 (0)	–
Instrumentation	4 (7)	1 (1)	<0.0001[2]	4.5 (4)	1 (0)	0.001[2]
Intravenous catheter	1 (1)	1 (0)	–	1 (0)	1 (0)	–
Discomfort during procedure	5 (5)	1 (0)	<0.0001[2]	5 (5)	1 (0)	0.001[2]
Discomfort after procedure	2 (4)	1 (0)	<0.0001[2]	2 (3)	1 (0)	0.01

[1] For primary outcomes, P<0.01 considered as statistically significant after Bonferroni correction for 4 comparisons.
[2] For descriptive outcomes P<0.002 considered as statistically significant after Bonferroni correction for 20 comparisons.

▶ **Table 4 Comparison of patient experience of subgroup of patients undergoing EGD with and without sedation compared to MACE.** Unpaired comparison of median (IQR) universal patient centredness questionnaire (UPC-Q) score (least to most acceptable: 0–100) and post-procedure endoscopic concern scale (ECS) score (most to least acceptable: 10–100). Components of the post- procedure ECS distress scores (1 – 10: Least to most) are also compared for description. Only p values for clinically significant differences (≥1 point difference) are reported.

	EGD (n = 44)					
	Sedated (n = 18)			Unsedated (n = 26)		
	EGD	MACE	p	EGD	MACE	p
UPC-Q	54 (52)	100 (19)	0.003[1]	46 (50)	92 (25)	0.001[1]
Post procedure ECS	25 (26)	10.5 (1.5)	<0.0001[1]	34 (36)	11 (2)	<0.0001[1]
Gagging	6 (6.3)	1 (0)	0.001[2]	7 (5)	1 (0)	<0.0001[2]
Choking	4 (5.3)	1 (0)	0.001[2]	5 (5)	1 (0)	<0.0001[2]
Bloating	1 (2)	1 (0)	–	4 (5)	1 (0)	0.001[2]
Vomiting	1 (1.5)	1 (0)	–	1 (4)	1 (0)	–
Doctor seeing food in stomach	1 (0)	1 (0)	–	1 (0)	1 (0)	–
Displaying emotions during the test	1 (4.3)	1 (0)	–	2 (4)	1 (0)	0.001[2]
Instrumentation	3 (4.5)	1 (1)	0.008	5 (7)	1 (1)	<0.0001[2]
Intravenous catheter	2 (3)	1 (0)	0.005	1 (0)	1 (0)	–
Discomfort during procedure	4 (6.3)	1 (0)	0.001[2]	6 (5)	1 (0)	<0.0001[2]
Discomfort after procedure	2 (3.3)	1 (0)	0.005	3 (4)	1 (0)	<0.0001[2]

[1] For primary outcomes, P<0.01 considered as statistically significant after Bonferroni correction for 4 comparisons
[2] For descriptive outcomes P<0.002 considered as statistically significant after Bonferroni correction for 20 comparisons.

▶ **Table 5 Comparison of pre-procedural anticipation and patient experience undergoing EGD, TNE and MACE.** Paired comparison of median (IQR) scores of distress cause by anticipation (before) and actual (after) endoscopy causing distress for each endoscopic modality (1 – 10: Least to most)

	EGD (n = 44)			TNE (n = 16)			MACE (n = 60)		
	Before	After	p	Before	After	p	Before	After	p
Gagging	5 (5)	6 (6)	0.22	3 (5.5)	1.5 (2)	0.10	3 (4)	1 (0)	<0.0001[1]
Choking	5 (5)	5 (5.5)	–	3 (5.5)	1.5 (2)	0.05	2 (3)	1 (0)	<0.0001[1]
Bloating	2 (4)	2 (3.5)	–	1 (1.8)	1 (2.8)	–	2 (2)	1 (1)	<0.0001[1]
Vomiting	4 (6)	1 (3)	0.08	1.5 (2.8)	1 (0)	–	1 (2)	1 (0)	–
Doctor seeing food in stomach	1 (0)	1(0)	–	1 (0)	1 (0)	–	1 (0)	1 (0)	–
Displaying emotions during the test	1 (2.5)	1 (4)	–	1 (2.8)	1 (1)	–	1 (1)	1 (0)	–
Instrumentation	5 (5)	4 (6.5)	0.16	7.5 (3)	4.5 (4)	0.04	3 (4)	1 (1)	<0.0001[1]
Intravenous catheter	1 (3)	1 (1)	–	1 (1.8)	1 (0)	–	1 (1)	1 (0)	–
Discomfort during procedure	5 (6)	5 (5)	–	6.5 (3.8)	5 (4.5)	0.14	3 (2.5)	1 (0)	<0.0001[1]
Discomfort after procedure	2 (4)	2 (4)	–	4 (3.8)	2 (2.8)	0.09	2 (3)	1 (0)	<0.0001[1]

[1] For descriptive outcomes P<0.004 considered as statistically significant after Bonferroni correction for 10 comparisons.

Discussion

The anticipation of EGD caused more distress in comparison to MACE due to concerns related to procedural tolerance (intubation and discomfort during EGD) and these were matched by actual patient experience. This may explain why patients were much more anxious before EGD than MACE. Patients favored MACE over both EGD and TNE by some margin and by most tolerance measures, by acceptability, overall experience, and preference. The majority of patients would prefer MACE initially to

▶ **Table 6** Comparison of endoscopic findings of MACE and EGD

Case	MACE and EGD	MACE only	EGD only
1	Normal		
2		Fundal polyp	
3	Normal		
4	Antral angioectasia	Antral erosion	
5		(antral bulge)[1]	Esophagitis
6	Normal		
7	Normal		
8	2 prepyloric erosions		
9	D2 angioectasia		
10	Antral gastritis[2]	Prepyloric erosion	
11	Antral erosion and a fundal polyp		
12			Pyloric erosion
13	Normal		
14	Normal		
15	Normal		
16	Oesophagitis[2] and Fundal polyp		
17	Duodenditis		
18	Antral erosions		Duodenitis
19	Normal		
20	Esophagitis[2]	Fundal polyp	Hiatus hernia, duodenitis
21	Fundal polyp x2, Antral gastritis		
22	Esophagitis[2], cluster of polyps on lower posterior body of stomach		
23	Antral gastritis, multiple > 20 flat polyps on body of stomach, hiatus hernia	Linear ulcer along lesser curve	

[1] Antral bulge not seen on EGD
[2] Not seen on live MACE examination, but seen on retrospective review of capsule video.

either EGD or TNE, even if there were a 50 % chance of requiring further visits (and pre-procedure preparation) for a flexible endoscopy as a second test to obtain biopsies.

The aerosols generated by gagging and choking increase the risk of transmitting COVD-19 to endoscopy staff and patients [5]. This study suggests that compared to conventional EGD, risks could be mitigated by use of TNE, which induced less of an oropharyngeal reflex and consequent gagging and choking, or MACE, during which such a reflex was virtually absent. There are currently no published studies of aerosol generation in transnasal gastrointestinal endoscopy. A systematic review of nasal endoscopy report mixed findings with regard to aerosol generation during nasal procedures, but concluded that nasal anesthetics and decongestants are significantly aerosol-generating above baseline [16]. Furthermore, it was recently shown that joystick-controlled MACE could be performed on a patient in a separate room with audiovisual links to the endoscopist, control station, and monitor, therefore eliminating the need for personal protective equipment [17].

EGD is the accepted gold standard in upper gastrointestinal investigation and TNE has comparable diagnostic accuracy in the esophagus [18, 19]. However, about 10 % of early cancers are missed at initial EGD. [20] Proximal lesions identified during push enteroscopy [21] and capsule endoscopy [22] are presumed to have been missed by prior EGD. Recent studies of MACE using a handheld magnet suggest at least diagnostic equivalence with EGD (although both modalities missed pathology) [9, 10]. Moreover, in a 350 multicentre Chinese study the sensitivity, specificity, positive and negative predictive values of MACE compared to esophagogastroduodenoscopy (EGD) were 90.4 % (84.7–96.1), 94.7 % (91.9–97.5), 87.9 % (81.7–94.0), and 95.9 % (93.4–98.4), irrespective of site and size of focal gastric lesion [8]. MACE has been reported as taking between 14 and 26 minutes [15]. It has been shown that EGD last-

ing over 7 minutes has a threefold diagnostic yield of early cancer [23]. The relative benefit, therefore, of more responsive instrument control offered by EGD compared to a longer examination allowed by less-invasive or noninvasive tests needs further investigation.

Along with clinical effectiveness, patient experience is a further pillar in quality of care [24]. Studies of patient experience with endoscopy have focused on procedural tolerance and satisfaction [11, 24]. However, this study shows that over one-third of the concerns volunteered by patients were unrelated to their procedural tolerance. That test results are important to patients is unsurprising, but many also expressed an interest in the overall investigative pathway, the detail (sensations experienced) and duration of the test. Patients valued a comfortable environment during recovery and information about potential adverse effects. A measure of satisfaction is unidimensional and conveys patient overall contentedness with their experience, but in contrast to PREMs, does not encompass all aspects of care nor discriminate which aspects are important [25].

Patient experience may affect compliance with investigation and participation in screening programs and services responsive to feedback can improve patient outcomes [25, 26]. Therefore, we chose to use two PREMs, the ECS and UPC-Q. The ECS comprised aspects of patient concerns before, during, and after endoscopy, and the score derived was shown to demonstrate good construct validity and to correlate with patient acceptance of EGD [13]. The UPC-Q is a patient-generated index based on each individual's concerns, priorities, and experiences and serves to examine patient acceptability of a healthcare experience beyond the constraints set by an endoscopy paradigm. It performs reliably and correlates well against known measures of patient satisfaction in other inpatient and outpatient settings [12]. That it correlates with the ECS, an experience score designed for, and validated in, endoscopic practice, suggests that it could be used as a patient-related experience measure in this setting.

Our results are consistent with previous studies of tolerance and preference for capsule endoscopy over EGD [7–10, 27, 28] and TNE [29]. Patients are thought to formulate a notion of acceptability by comparing their expectation with actual experience [30]. Our patients accurately anticipated the unpleasant aspects of EGD, yet only 64 % of patients regarded it as acceptable and it performed comparatively poorly in the UPC-Q. This contrasts with the 95 % acceptability rate for EGD identified in the study by Condon et al [13]. However, acceptability is defined by the context in which it is assessed, and the experience of a less-invasive or noninvasive alternative in this study is likely to have adversely affected the acceptability and tolerability of conventional EGD, especially when patients had better MACE experience than they anticipated. This may, in part, also explain why transnasal endoscopy in this study may be more poorly tolerated than reported in previous studies in which patients were randomized to only one intervention. Finally, acceptability might also be affected by the cost of the investigative procedure in fee-for-service health care systems: a cost analysis of the different modalities is needed.

Conscious sedation for EGD had a disappointing impact. However, systematic review and meta-analysis showed that compared to no sedation, use of midazolam alone only improves patient satisfaction and willingness to repeat the procedure (not any aspect of tolerance nor overall experience) [31] at mean doses of 4.8 to 10.3 mg, far greater than would be used in current practice. That patients may not always feel "conscious" sedation is adequate may explain the move toward anesthetist-directed sedation using propofol [32]. Immediate serious adverse events of EGD are rare, occurring in between 0.32–0.39 % of a recently described series of 1.38 million procedures [32]. Wang et al, however, showed that 1 % of patients were treated for infection within 30 days of EGD [33] and therefore complications of EGD and sedation may be delayed and not always recognized.

The primary aim of the study was to compare patient experience with the three modalities. Patients were eligible if they needed investigation for dyspepsia, a cohort known to have a low yield of pathology [34]. Consistent with other studies comparing MACE and flexible endoscopy in recurrent iron deficiency [9] and upper gastrointestinal bleeding [10], both MACE and EGD miss lesions. No major adverse events have been reported following MACE, although experience with this technology is still limited. In the largest series of MACE procedures reported (n = 3182), there were no reported cases of capsule retention [15]. Capsule aspiration may occur in 0.1 % of patients at most, usually in men over 80 years of age. Devices were spontaneously expectorated by half the patients, the remainder needed bronchoscopic removal and no fatalities were reported [35]. Regarding TNE, minor epistaxis affects 5 % of patients, but adverse cardiopulmonary events are significantly less than with EGD [36, 37].

The ability to obtain biopsies remains an important advantage of flexible endoscopy. However, we previously found that while 84 % of 500 patients having EGD to investigate dyspepsia had biopsies taken, they contributed to management in only 16 % beyond empirical treatment with proton pump inhibitors or *Helicobacter pylori* "test and treat" strategies [38]. Even with a 50 % chance that a second procedure would be required to obtain biopsies, most patients still preferred to have MACE as the initial investigation.

Conclusions

MACE is better tolerated and more acceptable than EGD and TNE. Although procedural tolerance was the major contributor to test acceptability, other factors related to the care pathway were identified by patients in one-third of cases. Patients expressed a preference for MACE followed by fiberoptic gastroscopy if biopsies were required.

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Competing interests

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