RESEARCH

How does tolerability of double balloon enteroscopy compare to other forms of endoscopy?

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ABSTRACT

Background and aims Gastrointestinal endoscopy can be difficult for patients to tolerate. Studies on endoscopic tolerability mainly focus on gastroscopy or colonoscopy with a paucity of data on double balloon enteroscopy (DBE). We aimed to prospectively evaluate tolerability in patients undergoing several forms of endoscopy including DBE.

Methods Consecutive patients undergoing colonoscopy, flexible sigmoidoscopy, gastroscopy, endoscopic retrograde pancreatography (ERCP), capsule endoscopy (CE) and DBE were prospectively recruited. A questionnaire recorded demographics, procedural data, patient tolerability (pain, discomfort and distress recorded on numerical rating scales) and the Hospital Anxiety and Depression Scale (HADS).

Results 956 patients were recruited (512 women; median age 57 years). The median pain score for DBE was poor with a score of 5 compared with 1 and 0 for oesophagogastroduodenoscopy and ERCP, respectively ($p<0.001$). Colonoscopy and retrograde DBE scores were not dissimilar. CE was well tolerated with a median pain score of 0. Patients with DBE required significantly higher doses of sedation and analgesia than other patients. The HADS Anxiety Score was also associated with poorer tolerability.

Conclusions DBE is poorly tolerated when compared with other forms of endoscopy despite higher doses of sedation. Increasing demand to improve tolerability of DBE in the UK may be addressed with the use of propofol.

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INTRODUCTION

Tolerability in endoscopy is a well-researched area with a multitude of papers examining different aspects of the patient experience. Much of this research centres around the more common endoscopic procedures such as oesophagogastroduodenoscopy (OGD) and colonoscopy with much less published literature regarding procedures such as endoscopic retrograde cholangiopancreatography (ERCP) and double balloon enteroscopy (DBE). The vast majority of studies focus on a single procedure leading to a paucity of relative tolerability data which makes it difficult to compare the patient experience between individual endoscopic procedures. As such it is not clear how patients undergoing DBE or capsule endoscopy (CE) fare compared with patients undergoing other procedures such as OGD and colonoscopy.

DBE was invented by Yamamoto in 2001.[1 2] The availability of DBE has revolutionised the investigation of the small bowel allowing diagnostic and therapeutic capabilities to treat small bowel pathology. The procedure takes on average of over an hour to perform.[3]

While propofol and general anaesthetic is used for DBE in the USA and some centres in Europe, it is predominantly performed using conscious sedation in the UK.[4 5] Published literature on DBE mainly focuses on the diagnostic and therapeutic utility of the procedure.[2 5–8] There has been one published study that investigated tolerability of DBE when compared with OGD and colonoscopy.[9] While no differences in tolerability were found between colonoscopy and retrograde DBE, over half of the patients did not reach a satisfactory level of sedation at antegrade DBE and had poorer tolerability than during their OGD. In addition, significantly higher doses of sedation were used during the DBE procedures. The literature suggests that patient response to midazolam is widely

varied.[10 11] The finding that only 16 of 36 patients with antegrade DBE achieved a satisfactory level of sedation may suggest that benzodiazepine sedation is not adequate for DBE. The authors however concluded that if an adequate level of sedation (benzodiazepine ±opiate) is reached, then tolerability of DBE can be comparable with that of traditional endoscopy techniques.

CE, a wireless endoscopic method to investigate the small bowel, has been accepted as a well-tolerated procedure with low levels of discomfort.[12] As such few tolerability studies have been conducted. The tolerability data that have been published are very favourable towards CE. Velayos *et al*[13] analysed 54 patients who had undergone CE. Of these 54 patients only 5.56% found the procedure very hard to tolerate. Over 61% described the procedure as 'tolerable, went through it without any major complications'.

The primary aim of this study was to ascertain the relative tolerability of DBE compared with other forms of endoscopic procedures and factors affecting tolerance of endoscopic procedures.

METHODS

Patients

Consecutive patients attending for routine endoscopy including OGD, colonoscopy, flexible sigmoidoscopy (FS), ERCP, DBE or CE were invited to participate in this prospective study. Informed consent was obtained for all procedures. Participation involved the completion of a questionnaire comprising both preprocedure and postprocedure elements. Technical data on the procedure were collected by the lead researcher after the procedure.

Preprocedure details included patient demographics (gender, height, weight and age) as well as the Hospital Anxiety and Depression Scale (HADS). The HADS is a validated tool for screening patients for anxiety and depression in an outpatient setting.[14]

The postprocedure section asked the patient to score their procedural pain, discomfort (defined as ache, uneasiness and suffering) and distress (defined as anxiety, physical or mental suffering) on a numerical rating scale from 0 to 10, where 0 was no pain/discomfort/distress and 10 was the worst pain/discomfort/distress imaginable. Both the endoscopist and assisting nurse were asked to rate patient tolerability. The data collection tool has previously been validated in another study assessing tolerability.[15]

Endoscopic procedures

All procedures were performed by trained endoscopists including nurse endoscopists and trainee gastroenterologists with appropriate supervision and consultants from either medical or surgical specialties. DBE was carried out by two consultant gastroenterologists (RS and DSS). Participation in the study did not affect clinical management in any way. Patients who opted to have sedation were given intravenous benzodiazepines by the endoscopist, with the majority receiving midazolam and a small minority receiving diazepam. Analgesia consisted of fentanyl or pethidine as required or patient administered nitrous oxide gas.

Bowel cleansing (Kleen Prep, Norgine, UK) was routinely used for colonoscopy, DBE and CE. Picolax (Ferring, UK) was used for FS in accordance with local protocol. The study was registered with both the research ethics and the local clinical audit and effectiveness departments.

Statistical analysis

The data were analysed using SPSS V.20. Non-parametric tests (Mann–Whitney U) were used to compare sedation and analgesia use between the groups. A two-sided p value of <0.05 was deemed significant. Where multiple analyses were made upon the same data, the Bonferroni correction was used. A binary logistical regression was used to identify factors associated with tolerability.

RESULTS

During the study period of 10 months from September 2011 to June 2012, 956 patients were recruited to the study. Table 1 shows the distribution of these patients across the range of endoscopic procedures. The majority (53.5%, n=510) were women, while 46.5% were men. The median age of patients was 57 years with a range of 17–92 years. A total of 56.5% of female patients had previously undergone abdominal surgery in comparison with only 37.4% of male patients ($p<0.001$). Median body mass index (BMI) was 25.97 kg/m^2 for men and 25.84 kg/m^2 for women ($p=0.287$).

Sedation was used in 39.5% (n=121) of OGD patients, 45.1% (n=137) of colonoscopy patients and 23.0% (n=23) of FS patients. Analgesia was used in 4.2% (n=13) of OGD patients, 13.8% (n=42) of

Table 1 Number of procedures and duration for each endoscopic modality

Procedure	Number of procedures	Mean duration of procedure (min)
OGD (oesophagogastroduodenoscopy)	306	5.9
Colonoscopy	304	26.2
FS (flexible sigmoidoscopy)	100	11.9
ERCP (endoscopic retrograde cholangiopancreatography)	100	20.3
DBE (double balloon enteroscopy), total	53	
Antegrade	(36)	67.0
Retrograde	(17)	115.0
CE (capsule endoscopy)	91	N/A
Total	954	

colonoscopy patients and 2.0% (n=2) of FS patients. A total of 99% of patients (n=99) received sedation for ERCP with the remaining patient refusing sedation, while 91% of patients (n=99) undergoing ERCP received intravenous analgesia. All patients undergoing DBE received both sedation and analgesia. The vast majority of sedated patients received midazolam with only five (1.2%) receiving diazepam. All but 39 patients who received analgesia were given fentanyl with the remaining 39 patients (19.7%) receiving pethidine. No sedation or analgesia was required for swallowing CE.

The median scores for pain, discomfort and distress for each procedure are tabulated in table 2. In addition, the median doses of sedation (midazolam and diazepam) and analgesia (fentanyl and pethidine) were calculated from those who received sedation and analgesia, respectively; patients not receiving sedation/analgesia were removed from the analysis. (see supplementary table 1). Patients undergoing OGD or colonoscopy received median doses of 2mg of Midazolam for their procedure in comparison to patients undergoing oral DBE who received 6mg and those undergoing anal DBE who received 8mg. A similar pattern is seen with analgesia where OGD and colonoscopy patients received median doses of 50 micrograms of Fentanyl whereas patients undergoing DBE by either route received a median dose of 100 micrograms. It can be seen that tolerability scores for DBE were generally worse despite the higher doses of sedation and analgesia used suggesting poorer tolerance, when compared with other procedures. The scores for CE were the lowest. From here on all analyses include only sedated patients.

Of all the examinations undertaken, 69 were dual procedures consisting of OGD with either colonoscopy (65) or FS.[4] There were no significant differences in tolerability between examinations undertaken as single procedures and those that were part of dual examinations.

In OGD examinations carried out wholly or in part by trainees, there were higher levels of pain (0 vs 2, p=0.004), discomfort (3 vs 5, p=0.004) and distress (2 vs 4, p=0.011). For all other endoscopic modalities there were no differences in tolerability between examinations carried out by trainees or more senior endoscopists.

Table 2 Median tolerability scores for each procedure grouped by sedation use

	Procedural pain (median)	Procedural discomfort (median)	Procedural distress (median)
OGD			
Sedated	0	2	2
Unsedated	2	5	5
Colon			
Sedated	5	6	3
Unsedated	4	4	2
FS			
Sedated	5	5	4
Unsedated	3	4	1
ERCP			
Sedated	0	2	0
Unsedated	2	7	4
DBE oral			
Sedated	4	5	4
DBE anal			
Sedated	7	6	3
CE			
Unsedated	0	0	0

CE, capsule endoscopy; DBE, double balloon enteroscopy; ERCP, endoscopic retrograde pancreatography; FS, flexible sigmoidoscopy; OGD, oesophagogastroduodenoscopy.

Comparisons of tolerability between DBE and other endoscopic procedures

Table 3 shows that DBE (by either route) was found to be significantly more painful and uncomfortable than OGD, more painful and uncomfortable than ERCP and less tolerable than CE across all domains of tolerability. In addition, antegrade DBE was found to be more distressing than ERCP. There were no significant differences between DBE when compared with colonoscopy or FS. It is important to remember that patients undergoing DBE by either route received significantly higher doses of sedation and analgesia than patients undergoing any other procedure.

Tolerability scores in relation to HADS Anxiety Score

Mann–Whitney U analysis was conducted for comparisons of pain, discomfort and distress scores between patients who scored <11 on the HADS Anxiety Scale with those who scored ≥11, for all sedated endoscopic procedures. Outcomes were significantly worse for patients with anxiety scores of over 11 for all tolerability domains (see supplementary table 2).

Factors associated with tolerability of endoscopy

Binary logistical regression (table 4) was carried out to identify factors associated with tolerability of DBE and other endoscopic procedures. For the variables of pain, discomfort and distress the patients were grouped in those who scored 0–4 (low) and those who scored 5–10 (high) and the analysis was conducted for each variable. Factors included in the analyses were age, gender, BMI, previous abdominal surgery, HADS Anxiety Score, duration, sedation and analgesia.

An important predictor of poorer tolerability of OGD was younger age, whereas factors associated with poor tolerance for colonoscopy were female

Table 3 A comparison of tolerability between DBE and conventional endoscopy

	Pain	Discomfort	Distress
OGD vs DBE oral	0 vs 4 (p<0.001)	2 vs 5 (p=0.003)	2 vs 4 (p=0.040)
Colon vs DBE anal	5 vs 7 (p=0.122)	6 vs 6 (p=0.341)	3 vs 3 (p=0.802)
FS vs DBE anal	5 vs 7 (p=0.034)	5 vs 6 (p=0.075)	4 vs 3 (p=0.857)
ERCP vs DBE oral	0 vs 4 (p<0.001)	2 vs 5 (p<0.001)	0 vs 4 (p<0.001)
ERCP vs DBE anal	0 vs 7 (p<0.001)	2 vs 6 (p<0.001)	0 vs 3 (p=0.030)
CE vs DBE oral	0 vs 4 (p<0.001)	0 vs 5 (p<0.001)	0 vs 4 (p<0.001)
CE vs DBE anal	0 vs 7 (p<0.001)	0 vs 6 (p<0.001)	0 vs 3 (p<0.001)

Significance value is set at p<0.007 due to a Bonferroni correction for multiple testing of data.
CE, capsule endoscopy; DBE, double balloon enteroscopy; ERCP, endoscopic retrograde pancreatography; FS, flexible sigmoidoscopy; OGD, oesophagogastroduodenoscopy.

gender and longer duration. High anxiety levels were adversely associated with tolerability of OGD and ERCP. Other factors important in the tolerability of ERCP were longer duration, younger age and a lack of analgesia use. No factors were found to be significantly associated with poor tolerability of FS or DBE via either route.

DISCUSSION

This is the first study to examine the relative tolerability of DBE compared with a range of endoscopic procedures.

It has previously been reported that DBE can be carried out comfortably using benzodiazepine and opiate medication.[9] We have shown that tolerability to DBE is worse than OGD, ERCP and CE, despite higher levels of sedation. While no significant differences were found between DBE and colonoscopy or FS, significantly higher doses of sedation were required to achieve this level of tolerability. Significantly higher doses of analgesia were also required, potentiating the risks posed by the sedation. Thus, patients undergoing DBE may be at increased risk of hypotension, respiratory depression and even cardiorespiratory arrest.[16 17]

Propofol is an anaesthetic drug, which can be used to achieve deep sedation or complete anaesthesia. It has been widely used for endoscopic procedures in Europe and the USA, although its use is still limited in the UK. Propofol has a short half life and high lipid solubility and therefore brings advantages of rapid induction of sedation and fast recovery. When used for gastrointestinal endoscopy, patient satisfaction and tolerance have been shown to be superior to benzodiazepines and narcotics.[18 19] Studies have also shown that it can be safely administered by endoscopists.[20 21] There are variations in propofol use across the world with many countries using it more widely than the UK. This is partly due to the fact that UK guidelines produced by the Royal College of Anaesthetists state that propofol administration can only be carried out by an anaesthetist due to the risks involved.[22] This has posed a logistical and financial barrier which perhaps has limited the use of propofol for endoscopic procedures in the UK. A recent study from Liverpool, UK, showed that dedicated day endoscopy lists with propofol administered by anaesthetists, achieved good levels of satisfaction for patients, endoscopists and anaesthetists.[23] The deeper level of sedation afforded by propofol

Table 4 Factors associated with tolerability

	Factors associated with increased pain		Factors associated with increased discomfort		Factors associated with increased distress	
	Factor	p Value	Factor	p Value	Factor	p Value
OGD	Younger age	0.016	Younger age	0.001	Younger age	0.001
	HADS anxiety score of 11+	0.048				
Colonoscopy	Female gender	0.012	Longer duration	0.001	Longer duration	0.029
	Longer duration	<0.001				
Flexible sigmoidoscopy	None		None		None	
Endoscopic retrograde cholangiopancreatography	HADS anxiety score of ≥11	0.011	Younger age	0.019	Younger age	0.013
	Longer duration	0.002	HADS anxiety score of 11+	0.011	Lack of analgesia	0.007
			Longer duration	0.001		
			Lack of analgesia	0.007		
Double balloon enteroscopy (antegrade)	None		None		None	
Double balloon enteroscopy (retrograde)	None		None		None	

HADS, Hospital Anxiety and Depression Scale; OGD, oesophagogastroduodenoscopy.

over benzodiazepine sedation is likely to improve the tolerability of DBE while the additional support would enhance patient safety.

CE was extremely well tolerated with median values of 0 for pain, discomfort and distress without the use of sedation or analgesia, making the procedure significantly more tolerable than all of the other procedures. CE has already cemented its place in assessment of small bowel pathology. There has been promising results from studies comparing Pillcam Colon versus colonoscopy.[24 25] Hence, there may be a role for Pillcam colon after failed colonoscopy, but comparative studies with radiology are required. Another benefit of CE is that sedation is not required and as such any risks from this are negated.

Several previous studies have identified factors associated with tolerability of endoscopic procedures. However, the majority of studies tend to examine factors related to a single procedure alone.[15 26 27] This is the first study to identify factors associated with tolerability across a wide range of endoscopic procedures in a single study. Unfortunately due to the low numbers of DBE examinations in this study, no factors were found to be significantly associated with tolerability of the procedure.

Another novel finding in this study is factors associated with distress during endoscopy. Distress has been show to be an important aspect of the patient experience of endoscopy,[27 28] yet it is still underestimated and perhaps under-researched. Younger patients were at risk of increased distress during OGD, while longer procedure duration was an important factor for colonoscopy. For OGD distress scores were higher than pain scores, reinforcing the fact that this often overlooked marker of tolerability would be a useful inclusion in further tolerability studies.

Elphick *et al*[15] found that patients who scored above the validated cut-off of ≥11 on the anxiety portion of the HADS questionnaire suffered from increased levels of discomfort at colonoscopy. Using the HADS anxiety questionnaire, we have shown that patients who score ≥11 had a worse experience at endoscopy in terms of pain, discomfort and distress. This has potentially useful implications to identify patients who are more likely to tolerate endoscopy suboptimally. In our experience, the HADS is an easy questionnaire that patients are able to complete without assistance in <5 min. As such this useful tool is not time consuming and could enable targeted intervention to those patients at risk of poor tolerability.

One limitation of this study is the lower sedation rates for endoscopy compared with national audits.[29] However, the main aim of this study focussed on comparisons of tolerability of endoscopic procedures in sedated patients only. A further limitation of this study is the small number of patients in the DBE group. However, the number of patients who underwent DBE is similar to the only other published study on DBE tolerability.[9] In addition, in this study, comparisons are made between DBE and all other forms of endoscopy which has never been done before. The results are fairly striking and less favourable for DBE. DBE is still a highly specialist procedure reserved for particular cases and as such fewer procedures are carried out. It would be useful to repeat the analysis using data from multiple centres to increase the number of procedures in an attempt to identify factors associated with poor tolerability.

In summary, this study has shown that DBE is poorly tolerated compared with other forms of endoscopy, despite higher doses of standard sedation used. Higher anxiety levels appear to have an adverse effect on patient tolerability. There is an increasing need and demand to improve tolerability of DBE in the UK and expansion of the use of drugs such as propofol for prolonged endoscopic procedures. This analysis goes some way to help identify patients at risk of poor tolerability, allowing us to manage them more appropriately.

Key messages

- DBE is poorly tolerated compared to other endoscopy modalities despite higher sedation levels.
- Factors associated with the tolerability of endoscopy include age, HADS anxiety score, gender and duration of procedure.
- A HADS anxiety score of 11 or more is associated with increased pain, discomfort and distress at endoscopy.

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