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Observational Study

**Clinical Profile, Diagnostic Yield and Procedural Outcomes of Patients undergoing
Single Balloon Enteroscopy - A Tertiary Care Hospital Experience**

Single Balloon Enteroscopy

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Abstract

BACKGROUND

Single-Balloon Enteroscopy (SBE) allows ease of access for small bowel visualization and has multiple diagnostic and therapeutic indications. It provides the advantage of performing various therapeutic interventions alongside the diagnostic procedure. SBE has also been considered a relatively safe procedure with no major complications.

AIM

To investigate the indications, safety, and clinical yield of SBE, and determine its effect on disease outcome.

METHODS

A retrospective, descriptive study was conducted at a tertiary care hospital in Karachi, Pakistan. Medical records of all 56 adult patients (≥ 18 years) who underwent SBE between July 2013 and December 2021 were reviewed and data was collected using a structured proforma. A descriptive analysis of the variables was performed using Statistical Package of Social Sciences (SPSS) Version 19. Results were reported as mean \pm standard deviation for quantitative variables and numbers and percentages for qualitative variables. Missing data was reported as unknown.

RESULTS

56 patients who underwent 61 SBE procedures were included. The mean age was 50.93 ± 16.16 years, with 53.6% males. Hypertension (39.3%) and diabetes mellitus (25.0%) were the most common pre-existing comorbidities. Obscure gastrointestinal bleed (39.3%) was the most common indication for enteroscopy, followed by chronic diarrhea (19.7%) and unexplained anemia (16.4%). A majority of procedures were performed in the endoscopy suite (90.2%) under monitored anaesthesia care (93.4%). Most procedures were diagnostic (91.8%) and completed without complications (95.1%). The depth of examination ranged from 95 cm to 500 cm with a mean of 282.05 ± 90.04

cm. The most common findings were inflammation and ulcerations (29.5%), followed by masses (19.7%) and vascular malformations (14.8%). As a result of the findings, a new diagnosis was made in 47.5% of the cases and a previous one was ruled out in 24.6% of them. 65.6% of the cases had a change in management.

CONCLUSION

SBE is a suitable modality for investigating diseases in the small bowel. It is shown to be technically efficient and reasonably safe and is associated with high diagnostic and therapeutic yield.

Key Words: Single balloon enteroscopy; Small bowel diseases; Gastrointestinal bleed; Small bowel endoscopy; Small bowel; Balloon-assisted enteroscopy

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Core Tip: Single Balloon Enteroscopy (SBE) is a safe and effective modality which allows ease of access for small bowel visualization. The procedure has multiple diagnostic and therapeutic indications. However, there is insufficient data published reporting its efficacy and impact. In this study, we analysed our single centre data of adults who underwent SBE between 2013 and 2021. We report patient demographics, procedure indications and procedure findings. Based on our results, we can assess the indications, safety, and clinical yield of SBE, and determine its effect on disease outcome.

INTRODUCTION

For decades, gastroenterologists have been challenged by the lack of proper visualization provided by standard endoscopies to the small intestine, with many of its areas being difficult to access without an intra-operative endoscopy procedure.^[1] Enteroscopy has been a significant breakthrough in this field, allowing access to most of the small bowel using endoscopic techniques without the need for surgery.^[2] Initially, Push Enteroscopy was established in the 1980s. However, it was associated with a limited depth of penetration into the small bowel, up till the level of the proximal jejunum, due to difficulty in manoeuvring it further. This was followed by the advent of the Push and Pull Enteroscopy in 2001, also known as the Double Balloon Enteroscopy (DBE). DBE, as its name suggests, consists of two balloons: one on the tip of the enteroscope and the other on an overtube at the scope's distal end. The controlled inflation and deflation of the balloons allows the enteroscope to properly proceed without causing over-looping of the intestine. The volumes and pressures in the balloons are also measurable and are monitored throughout the procedure. As a result, DBE furthered the reach of the enteroscope and was seen to improve diagnostic yield, thereby overcoming the limitations of its preceding modality.^[1-4]

The Single Balloon Enteroscopy (SBE) system was launched in 2007 as an alternative to DBE. SBE consists of only one balloon attached to the overtube at the scope's distal end and is relatively easier to use. The tip of the enteroscope is angled during withdrawal of the scope in the small bowel to achieve stable positioning and insufflation of the overtube is performed using a pressure-controlled pump.^[5] Both methods have been shown to yield significant and similar therapeutic and diagnostic yield.^[6-9]

⁴ Small bowel capsule endoscopy is currently the first-line recommended technique for investigation of the small bowel in patients with obscure gastrointestinal bleed. This is often used as a preliminary examination prior to device assisted enteroscopy (DAE) if further investigation is clinically indicated.^[10,11] According to the most recent European Society of Gastrointestinal Endoscopy guidelines, DAE is also particularly

recommended in patients with co-morbidities and/or those undergoing a therapeutic procedure since all endoscopic therapeutic procedures can be undertaken at the time of DAE.^[12]

The most common indication for small bowel enteroscopy is ³obscure gastrointestinal bleeding, defined as bleeding from the GI tract that persists or recurs without an obvious cause after esophagogastroduodenoscopy (EGD), colonoscopy, and radiographic evaluation of the small bowel.^[13] Other indications include chronic diarrhea, Crohn disease, refractory celiac disease, small bowel malignancies, suspected nonsteroidal anti-inflammatory drug-induced small bowel injury, suspicion of small bowel obstruction, and detection of polyps in patients with polyposis syndromes.^[7] Enteroscopy can also be performed in lieu of patients presenting with several different symptoms, with no specific diagnostic results yielding from regular endoscopy. The advantage of SBE compared to other techniques for visualizing the small bowel, such as capsule endoscopy and radiologic methods, is in the ability to perform a wide variety of therapeutic interventions alongside the diagnostic procedure.^[14] SBE has also been considered a relatively safe procedure with no major complications. The safety profile has been shown to match that of DBE overall, and the only major complications seen have been those that have resulted due to perforations.^[15]

While existing literature has highlighted great diagnostic and therapeutic benefits of SBE, the data regarding its outcomes is scarce and not widely generalizable. The equipment costs and specialized training requirements could be reasons as to why SBE is not a commonly practiced procedure.

There is currently limited published data from developing countries detailing enteroscopy utility and outcomes. We aimed to explore the role of small bowel push enteroscopy in our population and study its indications, safety, findings, complications, diagnostic yield, and effect on disease outcome, in order to increase the body of knowledge regarding this procedure

MATERIALS AND METHODS

This was a retrospective observational study conducted in a tertiary care referral centre in Karachi, the largest and most populated metropolitan city of Pakistan. Ethical approval and exemption were granted by the Ethical Review Committee of the institution on 31st December 2020 (2020-5760-15324).

Medical records of all adult patients above the age of 18 years who underwent a SBE procedure at the Aga Khan University Hospital (AKUH) from 3rd July 2013 to 31st December 2021 were identified by random sampling, using the hospital's information medical record system. A chart review was conducted for all eligible patients. For each medical record, a proforma was completed regarding patient demographics, comorbidities, clinical presentation, medication history, procedure details and enteroscopy and biopsy findings. In order to determine the procedures yield, a through chart review of the in and out patient hospital course was conducted. (See Appendix: Enteroscopy Questionnaire)

Our inclusion criteria were all adult patients over the age of 18 years who underwent a SBE procedure in the hospital within our study period. There were no exclusion criteria. All patients signed an informed consent form prior to the procedure. (See Appendix: Consent Form). Patient outcomes were defined as a change or otherwise in the patient's diagnosis and management as a result of the findings of the procedure.

A descriptive analysis was performed for patient demographics, clinical characteristics and enteroscopy details. Data was analysed descriptively. Results were reported as mean \pm standard deviation for quantitative variables and numbers and percentages for qualitative variables. Missing data was reported as unknown. Data was analysed using Statistical Package of Social Sciences (SPSS) Version 19. The statistical methods of this study were reviewed by Safia Awan of the Aga Khan University Hospital.

RESULTS

Our final study population comprised of a total of 56 patients (Table 1) who underwent a total of 61 procedures. The mean age of our sample was 50.93 ± 16.16 years, with a majority of males (53.6%, $n = 30$). Hypertension (39.3%, $n = 22$) and diabetes mellitus (25.0%, $n = 14$) were the most common pre-existing comorbidities. Prior medication use included antiplatelet (5.4%, $n = 3$) and non-steroidal anti-inflammatory drug (NSAID) (3.6%, $n = 2$) therapy, which is known to be associated with gastrointestinal (GI) injury such as obscure bleeding and inflammation.¹³⁻¹⁴ No patient in our study sample was on anticoagulation medications.

The clinical findings and outcomes of the 61 enteroscopy procedure are outlined in Table 2. Obscure gastrointestinal bleed was the most common enteroscopy indication (39.3%, $n = 24$), followed by chronic diarrhea (19.7%, $n = 12$). Other indications included unexplained anemia (16.4%, $n = 10$), enteric thickening and inflammatory changes on imaging (11.5%, $n = 7$), small intestine space occupying lesion (11.5%, $n = 7$), persistent vomiting (9.8%, $n = 6$), weight loss (6.6%, $n = 4$), and malabsorption syndrome (6.6%, $n = 4$). Most of the procedures were performed in the endoscopy suite (90.2%, $n = 55$) under monitored anaesthesia care (93.4%, $n = 57$). However, 9.8% ($n = 6$) of cases were done in the main operating room, with 8.2% ($n = 5$) due to patient comorbidities and 1.6% ($n = 1$) in conjunction with an additional surgical procedure.

The majority of the enteroscopy procedures were diagnostic (91.8%, $n = 56$). Interventions were carried out following 27.8% of the cases. Out of these, 13.1% ($n = 8$) were enteroscopic interventions like polypectomy, argon plasma coagulation, adrenaline sclerotherapy, hemoclip attachment and stent removal, 9.8% ($n = 6$) were surgical interventions and 4.9% ($n = 3$) were radiological interventions like angioembolization, which followed post procedure.

The depth of the enteroscopy examination ranged from 95 cm to 500 cm with a mean of 282.05 ± 90.04 cm. Enteroscopy examination was normal in 44.3% ($n = 27$) of the cases, while inflammation and ulcerations were seen in 29.5% ($n = 18$), space occupying lesions and masses were found in 19.7% ($n = 12$), vascular malformations in 14.8% ($n = 9$) and active bleeding was seen in 8.2% ($n = 5$) of the cases. A biopsy was obtained in 33 (54.1%) cases and the results included non-specific inflammation (63.6%, $n = 21$), malignancies or dysplasia (27.2% $n = 9$), villous atrophy (3.0% $n = 1$) and presence of Giardia (3.0%, $n = 1$). Out of the malignancies/dysplasia, 15.2% ($n = 5$) of the cases were of an adenocarcinoma, and there was one case of each of, adenomatous polyp (3.0%), inflammatory polyp (3.0%), hamartomatous polyp (3.0%) and lymphoma (3.0%).

There was no mortality recorded in our study. Most procedures were successfully completed without any complications, while complications were seen in three (4.9%) procedures. All complications were either conservatively managed or resolved spontaneously following the procedure.

One patient had premature ventricular contractions during the procedure which were conservatively managed and resolved while another developed hemodynamic instability which resolved spontaneously post procedure. The third patient developed aspiration pneumonia post procedure which resolved with antibiotics.

The clinical yield of the SBE procedures in our study was determined by quantifying the change in diagnosis and management. A classification of a change in diagnosis was made when a diagnosis which was made prior to the enteroscopy procedure was either modified or disproven following the procedure findings. There was a change in diagnosis in 72.1% ($n = 44$) of the cases. Out of these, a new diagnosis was made in 47.5% ($n = 29$) of the cases (termed as positive changes) while a previous diagnosis was disproven in 24.6% ($n = 15$) of the cases (termed as negative changes). A classification of a change in management was made when a management plan which was made prior

to the enteroscopy procedure was either modified or disproven following the procedure findings. There was a change in management in 65.6% ($n = 40$) of the cases.

DISCUSSION

Our study adds to the limited published literature regarding Single Balloon Enteroscopy (SBE) experience from a tertiary care hospital in a developing country. A few studies analysing the indications, efficacy, outcomes, and safety of enteroscopy procedures have been carried out in various countries. The efficacy of SBE was also compared with that of double balloon enteroscopy in several retrospective studies and meta-analyses.^[18–20] Moreels *et al*^[21] conducted a case series in 2016 evaluating the therapeutic actions of SBE using a new prototype and highlighting its benefits. Studies have also been carried out to evaluate the efficacy of SBE in non-invasive evaluation of, obscure gastrointestinal bleeding, and Crohn disease^[22–24], but there was a dearth of data describing experiences over many years for all cause indications, which additionally limits data providing information regarding the safety and efficacy of the procedure.

The demographics of our patient population are comparable to other studies from Korea and India, which report a mean age of 50-55 years and a majority of males (52.9% - 69.1%). However, a study conducted in the United States had a higher mean age, at 62 ± 17 years.^[25] In agreement with our results, published studies report obscure GI bleeding as the most common indication, ranging from 48% to 97% in patients undergoing SBE. Other common indications included anemia, chronic diarrhea, lesions, polyposis and Crohn's, amongst others, within various proportions.^[18,22,25]

Ulcers (19.6%), tumors (16.7%) and vascular malformations (14.7%) were the most common findings in a single-centre retrospective study conducted in China to test the diagnostic yield and safety of SBE.^[23] Overall, the findings reported in literature are similar and proportional to those seen in our study population.

We determined a high safety profile of SBE in our patients, with non-severe complications arising in only three (4.9%) of the cases, which were subsequently conservatively managed. There were no cases of severe complications reported in our patients. This is in accordance with previous literature which shows very low incidence of any adverse effects following SBE. A meta-analysis including four studies showed no evidence of any severe adverse effects such as bowel perforation, bleeding or pancreatitis.^[26] It has also been previously reported that the adverse effects seen in SBE procedures were comparable to those seen in DBE procedures, with both being marked as safe according to a single-centre retrospective analysis. However, the study accounted for a performance bias as all the procedures were carried out by a single endoscopist, who was trained in the procedure.^[20] One study on the usage of emergency SBE concluded that the incidence of adverse effects was lower when general anaesthesia was used as compared to when it was performed under conscious sedation.^[23] Our SBE procedures were always performed by the same team of endoscopists with significant expertise as well, resulting in no major adverse effects.

A similar study reported mean depth as 23 ± 87 cm beyond the ligament of Treitz with a range of 20 – 400 cm, in accordance with our findings.^[22] In a randomized controlled trial, the mean depth of insertion of anterograde SBE procedures was found to be 203.8 cm.^[24] A previous study has also been shown to explain a method used by endoscopists to assess the depth of insertion which is based on advancement with each push-and-pull manoeuvre in cases of DBE.^[25]

In our study, 65.6% ($n = 40$) of the procedures resulted in a change in management and 72.1% ($n = 44$) had a change in diagnosis following enteroscopy findings. Literature reports diagnostic yields of SBE ranging from 47% to 65%, and therapeutic yields from 25% to 42%.^[18,20,22,25]

A single centre retrospective study published in 2020 studied the safety and diagnostic yield of capsule endoscopy in the investigation of obscure gastrointestinal bleeds.^[10] The study population included 58.6% males with a mean age of 67.7 ± 14.4 years. The results showed diagnostic yield as 73.8%, revealing clinically significant bleeds which were missed at gastroscopy or colonoscopy in 30.3% of patients.

The limitations of our study include a retrospective, single-centre analysis. While our sample size is relatively smaller compared to other similar studies, it includes all patients who underwent a SBE procedure at our institution over an eight-year period. However, our study findings are solely representative of a South Asian population in a low-middle income country. Our study also notes a lack of a standardized reporting template for SBE depth of examination that may be used internationally.

Our observed findings can be used to guide further research, as current literature on the clinical indications, safety profile, diagnostic yield, and patient outcomes of enteroscopy is not sufficient to provide the basis of guidelines, especially in LMIC's. Additional prospective studies with larger sample sizes are recommended to grasp a thorough understanding of the indications and efficacy of SBE. Long-term follow up studies will also be beneficial in demonstrating the clinical impact of SBE.

CONCLUSION

Our study reports an encouraging single centre tertiary care experience of SBE over an eight-year period. We conclude that SBE is a safe and effective method with high clinical impact of precise diagnosis and management of small bowel diseases.

ARTICLE HIGHLIGHTS

Research background

Single- Balloon Enteroscopy (SBE) is a procedure that has greatly improved the access to small bowel visualization, particularly of the mid and distal parts of the small bowel.

In addition to being used as a diagnostic tool, SBE can also be used to perform a number of therapeutic interventions. SBE is a relatively safe procedure with a low incidence of complications and a good diagnostic and therapeutic yield. One of the most common indications generally seen is intestinal bleeding.

Research motivation

Since SBE is a relatively new procedure, there is still an absence of viable literature about it from the developing world countries like Pakistan. Due to the good yields from this procedure, proper adaptation of this technique in these places can greatly be used to improve healthcare outcomes particularly pertaining to small bowel problems by improving timely diagnosis and management.

Research objectives

The aim of our study was to look at outcomes following SBE procedures over a longer period of 8 years. We aimed to investigate the indications, procedures, findings, and safety of SBE procedures and to correlate their effects on the disease outcomes.

Research methods

We performed ¹ a retrospective descriptive study at a tertiary care hospital in Pakistan and investigated all the SBE procedures carried out between July 2013 and December 2021. A total of 56 patients underwent 61 SBE procedures during this time period. We collected data using patient files and electronic health records using a structured proforma. It was interpreted and was then categorized and analyzed using the SPSS software.

Research results

Our study population consisted of 56 patients who underwent 61 SBE procedures at a tertiary care hospital over the study period. The mean age of the sample was 50.93 ± 16.16 years and 53.6% of the sample was male. The most common comorbidities in the

patient population were hypertension (39.3%) and diabetes mellitus (25.0%). The most common indications for conducting the SBE procedure were found to be obscure gastrointestinal bleed (39.3%), chronic diarrhea (19.7%) and unexplained anemia (16.4%). Other indications included enteric thickening or inflammatory changes on imaging, space occupying lesions, persistent vomiting, weight loss and malabsorption syndromes. Most of the procedures were conducted in the endoscopy suite while 9.8% ($n = 6$) required the operation room due to patient comorbidities or being in conjunction with a surgical procedure. A majority of the procedures were carried under monitored anesthesia care (93.4%) while the rest were done under general anesthesia. Most procedures were diagnostic (91.8%) and completed without complications (95.1%). The depth of examination ranged from 95 cm to 500 cm with a mean of 282.05 ± 90.04 cm. The most common enteroscopy findings were inflammation and ulcerations (29.5%), followed by masses (19.7%) and vascular malformations (14.8%). Biopsy samples were taken in 33 of the cases and the most common biopsy finding was non-specific inflammation (63.6%). As a result of the findings, a new diagnosis was made in 47.5% of the cases and a previous one was ruled out in 24.6% of them. 65.6% of the cases had a change in management.

Research conclusions

Through our study findings we concluded that SBE is a useful method in diagnosing small bowel problems with a good yield. It is also relatively safe and has a low risk of complications.

Research perspectives

More research needs to be conducted on the usage and yields from SBE procedures in LMICs with larger samples. There also needs to be a standardized method to record the details of enteroscopy procedures.

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