Double balloon enteroscopy in the old: Experience from China

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Abstract

AIM: To evaluate the safety, efficacy and management of double balloon enteroscopy (DBE) carried out in those aged individuals with suspicious small intestine diseases.

METHODS: DBE is a wonderful invention of the past decade and is widely used as an examination tool for the gastrointestinal tract. From January 2003 to July 2011, data from patients who were ≥ 65 years old and underwent DBE examination in the Nanfang Hospital were included in a retrospective analysis.

RESULTS: Fifty-nine individuals were found and subsequently analyzed. The mean age was 69.63 ± 3.89 years (range 65-84), 34 were males. Indications for DBE were melena/hematochezia (36 cases), abdominal pain (15 cases), diarrhea (3 cases), stool change (1 case), weight loss (1 case), vomiting (2 cases), and debilitation (1 case). The average duration of symptoms was 33.34 ± 64.24 mo. Twenty-seven patients suffered from age-related diseases. Severe complications were not found during and after DBE. Comparison between systolic and diastolic blood pressure before and after DBE was statistically significant (mean ± SD, \( P < 0.01 \), \( P < 0.05 \), respectively). Small bowel pathologies were found by DBE in 35 patients, definite diagnoses were made in 31 cases, and detection rate and diagnostic yield for DBE were 68.6% and 60.8%, respectively.

CONCLUSION: DBE is a safe and effective method for gastrointestinal examination in the aged population. Aging alone is not a risk factor for elderly patients with suspicious gastrointestinal diseases and thorough preparation prior to the DBE procedure should be made for individuals with multiple diseases especially cardiovascular disorders.

Key words: Double balloon enteroscopy; Capsule endoscopy; Small bowel diseases; Multiple systematic diseases

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INTRODUCTION

As the world population is aging, age-related diseases continue to increase and utilization of endoscopic techniques is rising[3], but the feasibility, safety, and effectiveness of endoscopic use for the elderly are still unknown, and there are still concerns about the use of clinical endoscopy in the elderly. Double balloon enteroscopy (DBE) is a wonderful invention in the past decade[3] and widely used as an examination tool in the gastrointestinal tract, which has the double advantages of being useful for diagnosis and interventional management. Use of DBE has mainly been in the small bowel in the past few years[3-10].

Compared to esophagogastroduodenoscopy (EGD), colonoscopy, and push endoscopy, clinical endoscopists are usually uncertain or perplexed about whether elderly individuals who are suspect for small bowel disorders could endure and be investigated by DBE with prolonged duration examination. There are a number of clinical studies regarding DBE performed in adults[11-13] and clinical trials using DBE performed in children[14-18], but little data concerning DBE exclusively used in the aged population. Therefore, the safety, efficacy, diagnosis and therapeutic management of DBE carried out in those aged subjects were assessed.

MATERIALS AND METHODS

Inclusion criteria were senile patients who were ≥ 65 years old and underwent DBE from January 2003 to July 2011 at Department of Gastroenterology, Nanfang Hospital (a tertiary center and university hospital), Southern Medical University, Guangzhou, China. The records of all patients were included in a retrospective analysis. This work was approved by Institutional Review Board of Nangfang hospital, Southern Medical University.

All procedures were performed by DBE with no obvious absolute contraindications and carried out after written informed consent from patients and/or their guardians. A low residue and liquid diet were required and colored foods were avoided as far as possible at least one day prior to the test. All patients finished a bowel cleansing preparation by ingesting a 1.8-2 L polyethylene-glycol solution followed by overnight fasting (if the test was carried out in the morning), at least 6 h prior to the start of the procedure.

The Fujinon system (EN-450P5/20, Fuji Photo Optical Incorporated Company, Fujinon Inc, Japan) was used. This system consists of an endoscope at a working length of 200 cm with an outer diameter of 8.5 mm, and a flexible overtube 140 cm in length and 12 mm in outer diameter. By inflating the overtube balloon enough to grip the intestinal wall, the endoscope can be inserted further without forming redundant loops in the small bowel, and then the overtube can in turn be inserted while the endoscope balloon is inflated. DBE could be moved back and forth in a controlled manner by experienced endoscopists and an assistant to produce observations of the bowel.

Preparations and evaluation before and during the DBE procedure were as follows: (1) comprehensive assessment was carried out combining medical history and physical examination of the patients, individuals with suspected small bowel lesions and without absolute contraindications were included in the DBE investigation; (2) all subjects without other systematic diseases were evaluated prior to DBE operation, including vital signs (body temperature, blood pressure, pulse, respiration); hemoglobin (if this was abnormally low; it had to be corrected to a value > 80 g/L); electrolytes in serum (these also had to be corrected to normal range if abnormal levels were detected); electrocardiograph, chest X-ray, abdominal ultrasound were performed as regular examinations. Combined advice from other medical professionals was considered if unusual manifestations were found and the trans-oral or anal route or a combination of the two approaches was taken into account; (3) patients receiving pharmacotherapy for other known diseases were asked to discontinue administration the day before starting the test (steroid hormones, nonsteroidal anti-inflammatory drugs, and anticoagulant drugs had to be discontinued for at least a week). Experts in other professional departments, including anesthesiologists, were invited to participate in diagnosis and treatment of patients who suffered from concomitant diseases. The risk of DBE manipulation was decided in combination with endoscopists. Cases who were at extremely high risk were required to be treated by medical means in stable conditions if DBE was necessary; according to the suggestions of other professionals; (4) endoscopists, clinicians, anesthesiologists, and endoscopic nurses jointly participated in the DBE process. Concurrently, real-time monitoring equipment, resuscitative devices and necessary drugs were always ready for use in case of emergency. DBE was implemented in the operating room with full equipped medical measures being used when it was necessary; (5) antegrade, retrograde or a combination of the two approaches was performed with or without intervention under conscious or deep sedation, or general anesthesia (antegrade approaches generally included mechanical ventilation); and (6) specific management was individualized on the basis of different conditions in distinct patients before and during DBE procedure.

Observations were followed after DBE exploration, as described above, related laboratory parameters, and serious complications were monitored and managed accordingly.

Statistical analysis

Statistical analysis was performed using SPSS version 17.0 for Windows software. Continuous data were represented as means, mean ± SD or range and categorical variables were expressed as frequency or percentages. Student’s test was used to compare continuous variables. The χ² test or Fisher exact probability test were used to compare differences in categorical variables examined.
Negative 69.63 ± 3.89 (65-84) 1

15
3
34/25
5
3
50
2
20
1
1
52
1
19
1
9
1
6
58
19
5

Prior surgery (Y/N) 19/40
Abdominal operation 15
Thoracic operation 1
Other operation 3

Table 1  Characteristics of included elderly patients (n = 59)

| Features                              | n |
|---------------------------------------|---|
| Gender (M/F)                          | 34/25 |
| Age (yr, mean ± SD, range)            | 69.63 ± 3.89 (65-84) |
| Age group (yr) ≥ 65                    | 58   |
| Age group (yr) ≥ 80                    | 1    |
| Complaints                            |     |
| Melena/hematochezia                   | 36   |
| Abdominal pain                        | 15   |
| Diarrhea                              | 3    |
| Vomiting                              | 2    |
| Weight loss                           | 1    |
| Stool change                          | 1    |
| Debilitation                          | 1    |
| Duration of symptoms                  | 33.34 ± 64.24 (0.10-324.00) |
| Other medical examination             |     |
| Esophagogastroduodenoscopy            | 52   |
| Colonoscopy                           | 50   |
| Computed tomography                   | 14   |
| Barium study                          | 8    |
| Digital subtraction angiography       | 4    |
| Magnetic resonance imaging            | 3    |
| Mekel’s scan                          | 3    |
| Bone marrow aspiration                | 3    |
| Position-emission tomography          | 1    |
| Capsule endoscopy                     | 20   |
| Other diseases                        | 27   |
| Hypertension                          | 19   |
| Coronary diseases                     | 2    |
| Hypertension + coronary diseases      | 1    |
| Hypertension + chronic bronchitis     | 1    |
| Diabetes mellitus                     | 2    |
| Chronic bronchitis                    | 1    |
| Blood systemic diseases               | 1    |
| Blood transfusion (Y/N)               | 29/30 |
| Hemoglobin level (g/L)                | 96.00 ± 26.40 (39.00-160.00) |
| (mean ± SD, range)                    |     |
| Prior surgery (Y/N)                   | 19/40 |
| Thoracic operation                    | 15   |
| Other operation                       | 3    |

Table 2  Capsule endoscopy vs double balloon enteroscopy for examination of gastrointestinal tract in this study (n = 19)

| CE Findings | DBE Findings | Total |
|-------------|--------------|-------|
| Positive    | 5            | 1     | 6    |
| Negative    | 9            | 4     | 13   |
| Total       | 14           | 5     | 19   |

CE: Capsule endoscopy; DBE: Double balloon enteroscopy. \( P = 0.021; \kappa = 0.10. \)

McNemar’s \( \chi^2 \) test was used in comparison of diagnosis between capsule endoscopy (CE) and DBE. Agreement analysis between CE and DBE was assessed by the kappa statistic. \( P < 0.05 \) (two-sided) was considered statistically significant.

RESULTS

Characteristics of patients

Fifty-nine individuals who were aged ≥ 65 years were found and subsequently analyzed; only one patient was ≥ 80 years. The mean age was 69.63 ± 3.89 years (range 65-84), 34 were males. Indications for DBE were melena/hematochezia (36 cases), abdominal pain (15 cases), diarrhea (3 cases), stool change (1 case), weight loss (1 case), vomiting (2 cases), and debilitation (1 case). The average duration of symptoms was 33.34 ± 64.24 mo (range 0.10-324.00 mo). Prior blood transfusion had been performed at least once in 29 subjects. Almost half the patients (27 cases) suffered from age-related diseases, including cardiovascular diseases, respiratory diseases, cardiopulmonary sickness, endocrine illnesses, etc. Hypertension and coronary disease were the main cardiovascular diseases and the most common respiratory illness was chronic bronchitis. Anticoagulant drugs were used in 1 case and 19 individuals had a prior surgical procedure. The mean hemoglobin level in plasma at initial examination was 96.00 ± 26.40 g/L (range 39.00-160.00 g/L). The demographic information was listed in Table 1.

Twenty individuals had prior CE investigation. Inspection time between CE and DBE was within 1-13 d of the DBE procedure. One patient did not complete the entire CE process because the CE battery ran out. CE was successfully discharged through the anus. The remaining patients accomplished examinations without any complications. Abnormities were seen in 17 patients, clear diagnoses were established in 6. Comparison between CE and DBE was given in Table 2.

Safety and efficacy of DBE

In this review, the mean levels of systolic and diastolic blood pressure in patients before the DBE procedure were 130.49 ± 17.19 mmHg (range 98-171 mmHg), 76.56 ± 10.70 mmHg (range 55-105 mmHg), respectively. Low levels of hemoglobin and abnormal levels of electrolytes were all corrected prior to DBE; heart rate remained in the normal range. The mean level of oxygen saturation before the test was 99.15% ± 1.54 % (range 92%-100%).

All patients received atropine prior to the DBE procedure. Administration of benzodiazepines such as diazepam or midazolam, meperidine or fentanyl, rocuronium, and propofol were used for sedation, induction and maintenance of narcosis through injection; real-time blood pressure control for patients undergoing DBE was maintained according to the distinct conditions of different patients; drug use was under real-time monitoring by electrocardiography, and measurement of transdermal oxygen saturation during the intervention process and carried out by professional anesthetists.

All patients completed the DBE procedures whether a peroral, peranal or combination approach was chosen. Severe complications were not found during and after DBE. Only a few patients complained of slight discomfort after DBE, and the symptoms soon disappeared.
withou medical treatment. The average levels of systolic and diastolic blood pressure in patients after DBE were 124.15 ± 17.18 mmHg (range 88-170 mmHg) and 72.34 ± 9.88 mmHg (range 50-92 mmHg), respectively. The mean level of oxygen saturation after the test was 99.76% ± 0.47% (range 98%-100%). There was a statistically significant change in systolic and diastolic blood pressure before and after DBE examination.

**Diagnosis of gastrointestinal pathologies via DBE**

Fifty-nine cases underwent 81 DBE procedures, including 27 performed by the antegrade approach, 10 by the retrograde approach, and 22 by combining the two approaches. Total enteroscopy combining the 2 approaches which could scrutinize the whole small bowel was achieved in 12 patients. The mean insertion depth was 278.37 ± 102.68 cm (from the pylorus to the furthest distance, performed by antegrade DBE), and 305.00 ± 97.72 cm (from the ileum valve to the furthest distance, performed by retrograde DBE) respectively; the mean total procedure time was 112.61 ± 39.32 min (antegrade DBE) and 119.50 ± 37.52 min, respectively. Twenty subjects received endoscopic biopsy and definite positive findings were made in 3 individuals. Lesions detected in the gastrointestinal tract were found in 42 patients and the diagnosis yield was 64.4% (35/54). Twenty-three individuals underwent surgical procedures and one person underwent intra-operative enteroscopy.

| Findings                        | n = 51 |
|---------------------------------|--------|
| Location                        |        |
| Duodenum                        | 9      |
| Jejunum                         | 14     |
| Ileum                           | 7      |
| Cecum                           | 1      |
| Multiple segments of small bowel| 4      |
| Final diagnoses                 |        |
| Primary or metastatic tumors    | 15     |
| Diverticula                     | 7      |
| Single ulcer                    | 5      |
| Angiectasis                     | 4      |
| Erosions                        | 2      |
| Angioma                         | 1      |
| Lymphangiectasis                | 1      |
| Lymphangiomat                   | 1      |
| Single stenosis                 | 1      |
| Crohn’s disease                 | 1      |
| Functional gastrointestinal diseases| 13    |

With advances in society and development of medical science, aging of the world’s population is an inevitable trend. According to the latest demographic data, released on August 16, 2011 in Beijing, the China Committee on Aging’s Office “2010 Annual Statistical Bulletin of China Aging Development” showed that in developing countries such as China, 180 million of the population were aged ≥ 60 years and 120 million were aged ≥ 65 years. An increasingly aging population is bound to be accompanied by rises in age-related disorders. Gastrointestinal diseases are very common in children, adults and the elderly; consequently, the frequency of use of gastrointestinal endoscopy which can visualize the digestive tract is rising sharply.

Traditional and conventional upper gastrointestinal endoscopy and colonoscopy could scrutinize only the proximal small bowel and distal ileum owing to their limitations of length; the mid gut which spans the stomach and the colon is the longest part of the intestinal tract and could not be directly observed for examination, diagnosis and even intervention. Even if traditional techniques such as push enteroscopy, barium meal and advanced methods such as computed tomography (CT), magnetic resonance imaging, positron emission tomography could make correct diagnoses of gastrointestinal diseases, their limitations, such as length, and the difficulty of smaller lesions, make therapeutic management impossible, especially in the small bowel. That fact, coupled with unspecific clinical symptoms presented by small bowel diseases, misdiagnosis, missed lesions, delayed diagnosis and treatment usually promote poor prognosis and increase mortality. Over the past decade, there have been two significant inventions, namely CE and DBE, which have been applied in practice and revolutionized gastrointestinal diseases, particularly in the small intestine. Screening and/or diagnosis of patients with intestinal illnesses have been greatly improved by CE and DBE.

With aging, the deterioration of physiological function in various organs also gradually becomes clear and
increases in age-related systemic diseases such as cardiovascular diseases, lung diseases, malignant tumors, etc. A number of clinical studies showed that EGD, colonoscopy, and endoscopic retrograde cholangiopancreatography were safe and effective methods for use in the aged [1,23-26]. CE was considered a non-invasive method for screening the gastrointestinal tract [6,27,28]; nevertheless, the lower specificity [29,30] and inability of its use for therapeutic management [31] were regarded as its shortcomings.

Plentiful studies confirmed excellent safety, effectiveness, and appreciable benefits for adults investigated by DBE, and these results were reported in published literature. Diagnosis, treatment and safety of DBE for children who were aged ≥ 3 years were also demonstrated in clinical trials [16,17,18]. In contrast to other endoscopic methods, DBE with prolonged performance which is used in the elderly is usually performed more meticulously by clinicians and endoscopists due to safety concerns. This is partly because intervention costs significantly rise and, if necessary, anesthesia itself may also have moderate or severe side effects [1]. Clinicians are likely to choose non-invasive and relatively safe methods to investigate gastrointestinal pathogenesis that have given rise to various manifestations; patients are also likely to undergo a number of medical examinations as well but unclear diagnosis is obtained.

Patients with heart- or lung-related diseases for DBE must be taken into detailed consideration; insufficient preparations for those with poor health status are hazardous during and after DBE investigation. In this ret-
As the world population is aging, age-related diseases continue to increase and utilization of endoscopic techniques is raising, but few studies about the feasibility, safety, and effectiveness of double balloon enteroscopy (DBE) for the elderly have been performed, and there is still concern about its use in the elderly.

**Research frontiers**

The invention of balloon assisted enteroscopy was first reported in 2001 by Yamamoto. A growing number of studies were chiefly focused on research of whole small bowel diseases, in order to facilitate earlier diagnoses and intervention in disorders of the mid gut. This study investigated the value of DBE for examination of an older population with suspected small bowel disease.

**Innovations and breakthroughs**

Although the prevalence of small intestine diseases is not as high as that of colon disease, its manifestations are always unspecific and can even be fatal because of delayed diagnosis. The present study suggests that a higher proportion of the Chinese elderly population has tumors in the small bowel or functional gastrointestinal diseases. The results show that DBE is a safe and effective method in the older population.

**Applications**

DBE-based examination can be used safely and effectively in older patients for diagnosis and treatment of small bowel diseases.

**Peer review**

This retrospective study of DBE in the old is of significant interest in clinical practice. The safety and efficacy of DBE confirmed in this study may result in...
wider use of balloon-assisted enteroscopy for exploration of the small intestine when older patients are suspected of having small bowel disorders.

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