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Contents

Bimonthly Volume 8 Number 2 April 28, 2020

OPINION REVIEW

REVIEW

MINIREVIEWS

SYSTEMATIC REVIEWS

META-ANALYSIS

SCIENTOMETRICS

Contents

World Journal of Meta-Analysis

Volume 8 Number 2 April 28, 2020

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META-ANALYSIS

Single-balloon and spiral enteroscopy may have similar diagnostic and therapeutic yields to double-balloon enteroscopy: Results from a meta-analysis of randomized controlled trials and prospective studies

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Abstract

BACKGROUND

Double-balloon, single-balloon, and spiral enteroscopy (DBE, SBE, and SE) have revolutionized the management of intestinal diseases. However, evidence about efficacies of these methods is lacking. We aimed to conduct a meta-analysis comparing the clinical outcomes among DBE, SBE, and SE.

METHODS

We searched randomized controlled trials and prospective studies in MEDLINE, PubMed, EMBASE, Cochrane Library, and Chinese CQVIP database. Studies referencing the comparison of at least two of these three methods were included. Primary outcome was diagnostic yield. Other outcomes were therapeutic yield, total enteroscopy, examination time, time to maximum insertion, and depth of maximal insertion (DMI).

RESULTS

Eleven studies including 727 patients were identified: DBE *vs* SE (n = 6), DBE *vs* SBE (n = 4), and SBE *vs* SE (n = 1). The diagnostic and therapeutic yields did not differ significantly when comparing DBE with SE [odds ratio (OR) = 1.19, 95% confidence interval (CI): 0.68-2.08; OR = 1.17, 95%CI: 0.61-2.23] and DBE with SBE

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(OR = 0.85, 95%CI: 0.55-1.33; OR = 1.71, 95%CI: 0.64 - 4.60). Total enteroscopy, examination time, time to maximum insertion, and DMI were similar between SBE and DBE. DBE was superior to SE with regard to DMI [mean difference (MD) = 36.76, 95%CI: 5.09-68.43], with longer time to maximum insertion (MD = 15.14, 95%CI: 12-18.27) and examination time (MD = 12.98, 95%CI: 9.57-16.38).

CONCLUSION
DBE and SBE have similar clinical outcomes. Compared with DBE, SE seems to have similar diagnostic and therapeutic yields, but shorter procedural time in cost of less depth of insertion. SE needs further evaluation *vs* SBE. DBE is recommended for complete enteroscopy.

Key words: Double-balloon enteroscopy; Single-balloon enteroscopy; Spiral enteroscopy; Meta-analysis; Randomized controlled trials

Core tip: We conducted a meta-analysis to compare the effectiveness of double-balloon, single-balloon, and spiral enteroscopy. We found that double-balloon enteroscopy may have similar clinical outcomes to single-balloon enteroscopy, and spiral enteroscopy seems to have similar diagnostic and therapeutic yields, but shorter procedural time in cost of less depth of insertion when compared with double-balloon enteroscopy.

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INTRODUCTION

When double-balloon enteroscopy (DBE) was introduced into the clinic by Yamamoto in 2001[1], dramatic changes have happened in the diagnosis and management of disorders in the distant part of small bowel, which were dependent on surgically assisted enteroscopy or rope guided enteroscopy before. Currently, there are another two different systems: Single-balloon enteroscopy (SBE) and spiral enteroscopy (SE). Although the balloon-assisted enteroscopy techniques follow the push-and-pull principle, SE is dependent on a new system: Pleating of the small bowel *via* rotation[2].

There have been several randomized controlled trials (RCTs) comparing DBE with SBE[3-6]. In these studies, DBE has been shown to be similar to SBE with regard to diagnostic/therapeutic yield, depth of maximal insertion, and procedure time, but superior to SBE in terms of total enteroscopy. There have been seven studies including four RCTs and three prospective studies comparing DBE with SE[2,7-12]. In these studies, diagnostic yield was supposed to be similar between DBE and SE. Two recent meta-analyses only compared DBE with SBE, and did not evaluate SE[13,14]. Another meta-analysis compared balloon enteroscpy (combined DBE with SBE) with SE[15]. Moreover, these three meta-analyses included May's study, in which SBE was not really applied but by detaching one balloon from double-balloon enteroscope[16,17]. In addition, they did not include Chinese studies due to language barrage.

Therefore, we conducted a meta-analysis aimed to evaluate the efficacy of DBE, SBE, and SE for the management of small bowel diseases.

MATERIALS AND METHODS

The methodology and reporting of this study followed the PRISMA statement guidelines recommended by Cochrane collaboration for meta-analysis[18].

Data sources and searches

A comprehensive literature search was independently performed by two authors. The

search was performed on MEDLINE, PubMed, EMBASE, Cochrane Library, and Chinese CQVIP database (http://en.cqvip.com/) from January 2008 to October 2018, using the search terms "balloon enteroscopy", "single balloon enteroscopy", "double balloon enteroscopy", and "spiral enteroscopy". Boolean operators AND, OR, and NOT were used. Meanwhile, abstracts from the conference proceedings were also retrieved.

Study selection

RCTs and prospective studies comparing DBE, SBE, and SE were eligible for inclusion. Retrospective studies and non-comparative studies that used only DBE, SBE, or SE were excluded. The studies were restricted to studies performed in human and published in English and Chinese. And a manual search of the references of all retrieved studies was performed in case of omission of the ongoing or completed trials. Two investigators independently assessed the eligibility and validity of each study. Queries concerning inclusion were resolved by discussion and consensus between the two reviewers.

Outcome measures

The primary outcome evaluated in this study was diagnostic yield rate, defined as the percentage of enteroscopy procedures with findings relevant to the indication of the procedure[10]. Other outcomes were therapeutic yield rate, total enteroscopy rate, depth of maximal insertion (DMI), time to maximum insertion, and examination time (per-oral and per-anal).

Data extraction

The following data from each study were extracted: First author's name, publication year, country, study design, interventions, patient demographics, indications, number of endoscopies, diagnostic and therapeutic yields, DMI, time to maximum insertion, and examination time (per-oral and per-anal). Different opinions between the reviewers were revolved through discussion.

Risk of bias assessment

As described in the Cochrane Handbook for Systematic Reviews of Interventions[19], we assessed the quality of RCT based on random sequence generation, allocation concealment, blinding of participants and investigators, blinding of outcome assessment, incomplete outcome data, selective reporting, and other bias. We used the Newcastle-Ottawa Scale to assess the quality of prospective study[20]. Any disagreement was resolved *via* discussions.

Statistical analysis

Statistical analyses were performed using RevMan software (version 5.3; Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014). Standard deviation was obtained from the range and interquartile range as recommended[21,22]. Results are expressed as odds ratio (OR) for categorical variables or mean difference (MD) for continuous variables with 95% confidence interval (CI). Heterogeneity was assessed using I^2 test. $P < 0.05$ or $I^2 > 50\%$ was considered as significant heterogeneity. A fixed- or random-effects model was used, depending on the absence or presence of significant heterogeneity. Potential for publication bias was assessed by funnel plot. $P < 0.05$ was considered statistically significant.

RESULTS

Description of studies

The detailed steps of our literature search are shown in Figure 1. Briefly, a total of 384 articles were identified. After screening, 22 potentially relevant articles and abstracts were retrieved from the electronic databases. After excluding 11 studies based on the predefined inclusion criteria, 11 studies were identified. Six trials compared DBE with SE[2,8-12], four compared DBE with SBE[3-6], and one compared SBE with SE[7], which were evaluated separately in the meta-analysis. Baseline characteristics and outcome measures are shown in Tables 1 and 2. The risks of bias of the RCTs included in this meta-analysis are detailed in Supplementary Figure 1. Each prospective study achieved eight points in assessing quality according to the Newcastle-Ottawa Scale.

DBE vs SE

There were six comparisons of DBE *vs* SE: Five from Europe and one from Asia[2,8-12]. Three were RCTs[2,8,11] and three were prospective studies[9,10,12]. A total of 370 procedures were analyzed, including 255 DBE and 115 SE procedures.

Table 1 Study characteristics

Ref.	Country	Study design	Intervention	No. of patients	Male/Female	Age	Indications (OGIB/others)
Moran *et al*[7], 2018	United States	RCT	SBE	17	3/14	55.8 ± 20.3	8/9
			SE	13	10/3	53.1 ± 18.3	7/6
Oka *et al*[8], 2015	Japan	RCT	DBE	10	6/4	63.9 ± 12.8	0/10
			SE	10	6/4	63.9 ± 12.8	0/10
Despott *et al*[9], 2015	United Kingdom	Prospective	DBE	15	5/10	51.4 ± 5.4	0/15
			SE	15	5/10	51.4 ± 5.4	0/15
Messer *et al*[2], 2013	Germany	RCT	DBE	13	6/7	47.6 ± 20/7	7/6
			SE	13	7/6	61.2 ± 18.6	12/1
Rahmi *et al*[10], 2013	France	Prospective	DBE	191	76/115	59.0 ± 15.9	151/40
			SE	50	25/25	58.4 ± 14.3	43/7
May *et al*[11], 2011	Germany	RCT	DBE	10	6/4	69 ± 12	10/0
			SE	10	6/4	69 ± 12	10/0
Frieling *et al*[12], 2010	Germany	Prospective	DBE	17	7/10	61 ± 17	14/3
			SE	18	10/8	58 ± 25	11/7
Efthymiou *et al*[3], 2012	Australia	RCT	DBE	57	24/33	61 (49-68)[1]	44/13
			SBE	50	19/31	67 (51-72)[1]	40/10
Domagk *et al*[6], 2011	Germany	RCT	DBE	65	32/33	52 (18-84)[2]	29/36
			SBE	65	35/30	53 (21-80)[2]	26/39
Takano *et al*[5], 2011	Japan	RCT	DBE	20	15/5	62.7 ± 16.1	13/7
			SBE	18	13/5	64.9 ± 14.7	10/8
Ren *et al*[4], 2011	China	RCT	DBE	50	35/15	42.3	25/25
			SBE				

[1]Median (IQR).
[2]Median (range). RCT: Randomized controlled trial; SBE: Single-balloon enteroscopy; SE: Spiral enteroscopy; DBE: Double-balloon enteroscopy; OGIB: Obscure gastrointestinal bleeding.

As shown in Figure 2, there was no significant difference in diagnostic yield (OR = 1.19, 95%CI: 0.68-2.08) or therapeutic yield (OR = 1.17, 95%CI: 0.61-2.23) between DBE and SE. DBE resulted in deeper DMI (MD = 36.76, 95%CI: 5.09-68.43), corresponding to longer time to maximum insertion (MD = 15.14, 95%CI: 12.00-18.27) and examination time (MD = 12.98, 95%CI: 9.57-16.38). There was no statistical heterogeneity between the studies with regard to diagnostic yield, therapeutic yield, DMI, time to maximum insertion, and examination time ($P > 0.05$). The funnel plot did not show publication bias in terms of diagnostic yield between DBE and SE (Supplementary Figure 2).

DBE vs SBE

There were four RCTs comparing DBE with SBE[3-6]. A total of 327 procedures were analyzed, including 171 DBE and 156 SBE procedures.

As shown in Figure 3, there were no significant differences in diagnostic yield (OR = 0.85, 95%CI: 0.55-1.33), therapeutic yield (OR = 1.71, 95%CI: 0.64-4.60), total enteroscopy (OR = 6.10, 95%CI: 0.31-118.52), DMI (MD = -20.42, 95%CI: -89.29-48.45), per-oral examination time (MD = -7.45, 95%CI: -36.60-21.16), or per-anal examination time (MD = 2.48, 95%CI: -6.49-11.44). There was no statistical heterogeneity between the studies with regard to diagnostic yield, therapeutic yield, or per-anal examination time ($P > 0.05$). The funnel plot did not show publication bias in terms of diagnostic yield between DBE and SBE (Supplementary Figure 3).

SBE vs SE

We could not conduct a meta-analysis since there was only one trial comparing SBE *vs* SE. In the single trial[7], patients needed for an anterograde enteroscopy were randomized to receive SBE ($n = 17$) or SE ($n = 13$), thus evaluating a direct comparison between SBE and SE. However, this was insufficient to compare these modalities using meta-analysis. In this trial which ceased without reaching the required sample size, there were no significant differences identified between SBE and SE with regard to diagnostic yield (41% *vs* 69%, $P = 0.16$), therapeutic yield (24% *vs* 46%, $P = 0.26$), DMI (285.3 ± 80.8 cm *vs* 330.0 ± 88.2 cm, $P = 0.16$), or procedure time (38.3 ± 12.4 *vs*

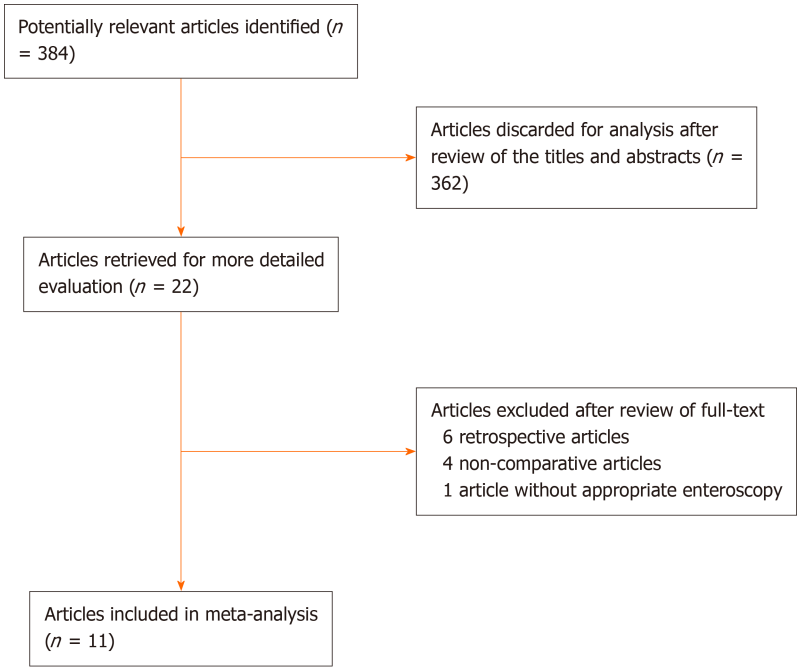

Figure 1 Flow chart.

37.0 ± 10.5, $P = 0.76$).

Sensitivity/subgroup analysis

We did not perform additional sensitivity or subgroup analysis to assess the observed heterogeneity due to limited number of studies.

DISCUSSION

Although the small intestine has long been considered the final frontier of endoscopy, significant progress in small-bowel enteroscopy techniques has led to increased diagnostic and therapeutic capabilities[23]. This meta-analysis including 727 patients, to our knowledge, is the first systemic meta-analysis comparing DBE, SBE, and SE with regard to clinical outcomes. Our study showed that DBE and SBE had similar clinical outcomes. We also identified that the diagnostic and therapeutic yields were comparable between DBE and SE. It was noteworthy that compared with DBE, SE had shorter procedural time but less depth of insertion. However, SE needs further evaluation vs SBE for clinical outcomes.

In our meta-analysis, double- and single-balloon systems showed similar performance in diagnostic and therapeutic yields, DMI, time to maximum insertion, and examination time. As for diagnostic yield, these four RCTs included in our study showed no significant difference. But in two retrospective studies we excluded[24,25], diagnostic yields were significantly higher in SBE, compared to the DBE group (61.7% *vs* 48.2%, $P < 0.001$; 62.0% *vs* 35.6%, $P = 0.014$). Nevertheless, retrospective studies easily suffered from patient selection bias, which was also declared by the author. These findings are consistent with previous meta-analyses[13,14]. However, the two meta-analyses included May's study[17] which was based on the P-type Fujinon instrument for both DBE and SBE. Although the P-type enteroscope allowed deeper intubation in the small bowel, therapeutic maneuvers were difficult to perform using this instrument in comparison with the T-type[26]. Lipka *et al*[14] mentioned that the P-system was less comparable to the Olympus system used in the other trials. Although results were similar to the previous, our study excluding that trial may be more credible. It is interesting that these two meta-analyses included the same four RCTs but reached the controversial conclusion in terms of total enteroscopy rate. Wadhwa *et al* concluded that DBE was superior to SBE with regard to complete small bowel visualization (relative risk [RR] = 0.37, 95%CI: 0.19-0.73), while Lipka not (RR 1.73, 95%CI: 0.86-3.48). The recommendation to prefer DBE in patients in whom total enteroscopy is desired may be based on the feeling of many endoscopists. In our study, total enteroscopy rate tended to be higher in DBE than SBE, although the difference was not significant (OR = 6.10, 95%CI: 0.31-118.52). Complete enteroscopy

Table 2 Outcome measures of enteroscopy

Ref.	Intervention	No. of endoscopy	Diagnostic yield, *n* (%)	Therapeutic yield, *n* (%)	Total enteroscopy, *n* (%)	DMI, mean ± SD (cm)	Time to maximum insertion, mean ± SD (min)	Examination time, mean ± SD (min)	
								Oral	Anal
Moran *et al*[7], 2018	SBE	17	7/17 (41.2)	4/17 (24)	NA	285.3 ± 80.8	NA	36.1 ± 11.4	NA
	SE	13	9/13 (69.2)	6/13 (46)	NA	330.0 ± 88.2	NA	34.8 ± 4.7	NA
Oka *et al*[8], 2015	DBE	10	10/10 (100)	NA	NA	228 ± 22.0	32.9 ± 5.2	38.9 ± 5.0	NA
	SE	10	9/10 (90)	NA	NA	214 ± 16.9	19.5 ± 2.6	28.2 ± 4.3	NA
Despott *et al*[9], 2015	DBE	14	NA	NA	NA	265 (227-324)[3]	45 (35-53)[3]	54 (45-62)[3]	NA
	SE	14	NA	NA	NA	175 (132-212)[3]	24 (20-28)[3]	28 (27-36)[3]	NA
Messer *et al*[2], 2013	DBE	13	6/13 (46)	12/13 (92)	12/13 (92.3)	346.2 ± 63.3	46.2 ± 12.5	59.6 ± 14.5	76.1 ± 21.8
	SE	13	9/13 (69)	12/13 (92)	1/13 (7.7)	268.5 ± 76.3	26.2 ± 7.7	43.4 ± 10.2	51.9 ± 11.0
Rahmi *et al*[10], 2013	DBE	191	143/191 (74.9)	133/191 (69.6)	NA	200 (150-300)[2]	NA	60 (45-80)[2]	NA
	SE	50	35/50 (70.0)	33/50 (66)	NA	220 (200-300)[2]	NA	55 (45-80)[2]	NA
May *et al*[11], 2011	DBE	10	NA	14[1]	NA	310 (220-430)[3]	46.5 ± 19.3	65.0 ± 12.8	NA
	SE	10	NA	9[1]	NA	250 (200-340)[3]	24.3 ± 11.8	43.3 ± 9.3	NA
Frieling *et al*[12], 2010	DBE	17	8/17 (47.1)	NA	NA	265 ± 88.1	NA	41.8 ± 9.5	
	SE	18	6/18 (33.4)	NA	NA	216 ± 54.1	NA	46.5 ± 12	
Efthymiou *et al*[3], 2012	DBE	66	35/66 (53)	17/66 (26)	0/5	234.1 ± 99.3	NA	60 (45-70)[2]	
	SBE	53	30/53 (57)	16/53 (30)	0/1	203.8 ± 87.6	NA	60 (45-67)[2]	
Domagk *et al*[6], 2011	DBE	65	28/65 (43)	6/65 (9)	12/65 (18)	253 (120-450)[3]	NA	105 (40-140)[3]	
	SBE	65	24/65 (37)	3/65 (5)	7/65 (11)	258 (100-560)[3]	NA	96 (35-135)[3]	
Takano *et al*[5], 2011	DBE	20	10/20 (50)	7/20 (35)	8/14 (57)	NA	NA	70.4 ± 26.5	90.4 ± 13.7
	SBE	18	11/18 (61)	5/18 (28)	0/14	NA	NA	92.8 ± 20.6	93.1 ± 22.6
Ren *et al*[4], 2011	DBE	20	12/20 (60)	NA	0/6	328 (200-450)[3]	NA	70.3 (41-123)[3]	81.4 (55-141)[3]
	SBE	20	18/20 (90)	NA	0/5	360 (300-450)[3]	NA	63.7 (38-112)[3]	73.1 (45-132)[3]

[1]Angiodysplasias treated with APC.
[2]Median (IQR).
[3]Median (range). SBE: Single-balloon enteroscopy; SE: Spiral enteroscopy; DBE: Double-balloon enteroscopy; NA: Not available; DMI: Depth of maximal insertion; SD: Standard deviate.

may not be necessary to make a diagnosis, but it plays a role in determining the extension of a known disease and the number of the lesions, especially for the fact that many small bowel diseases are not solitary but multiple, such as vascular malformations, polyps in polyposis syndrome, or Crohn's stenosis[27]. Similarly, previous studies have shown that the rate of complete enteroscopy by using the DBE method is approximately 40% to 80%[28], while the rates of SBE decreased to approximately 5% to 25%[29,30]. If complete enteroscopy is needed for identifying the extent and number of the lesions, specifically for those once diagnosed by capsule endoscopy with multiple lesions, we recommended DBE technique because it provides a higher rate of complete enteroscopy at present[27].

Spiral enteroscopy, first reported in 2009[31], is another newly developed enteroscopy, which was found to have the advantages of shorter examination time and being more stable within the bowel, thus allowing controlled examination of the intestinal mucosa[31-33]. The previous meta-analysis conducted by Baniya *et al*[15] combined prospective and retrospective studies, demonstrating that balloon enteroscopy (DBE + SBE) and SE were similar with regard to diagnostic and therapeutic success rates and DMI, but the procedure time was significantly less for the SE group. Excluding retrospective study, we identified three RCTs and three prospective studies comparing DBE with SE, and found that there were no significant differences between DBE and SE with regard to diagnostic and therapeutic yields. However, our study showed that DBE resulted in deeper DMI, in cost of longer procedure time, which is consistent with previous studies[2,9,11]. Although the difference was not significant, DBE tended to achieve deeper small bowel insertion compared to SE[8,12]. Only one study compared DBE and SE in terms of total enteroscopy, and the total enteroscopy rate was 92% in the DBE group and 8% in the SE group (P = 0.002)[2]. Compared with SE, we also recommended DBE if complete

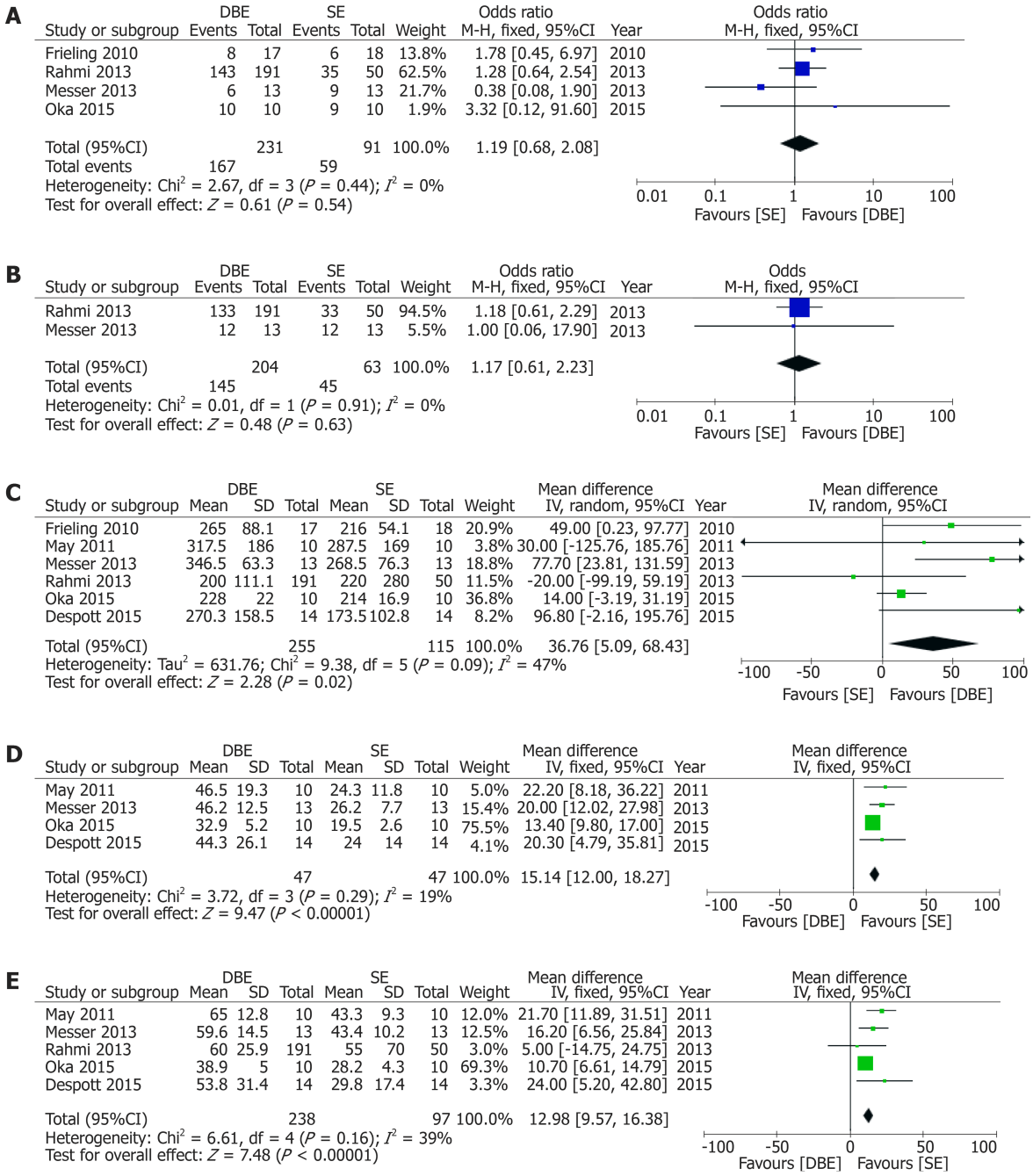

Figure 2 Outcome measures between double-balloon enteroscopy and spiral enteroscopy. A: Diagnostic yield; B: Therapeutic yield; C: Depth of maximal insertion; D: Time to maximum insertion; and E: Examination time.

enteroscopy was needed.

Up to now, there have been only two studies testing SE *vs* SBE. One RCT conducted by Moran *et al*[7] showed no significant differences between SE and SBE with respect to diagnostic yield, therapeutic yield, DMI, and procedure time. One retrospective study conducted by Khashab *et al*[23] showed that SE and SBE were similar in diagnostic yield but the insertion depth was significantly higher in SE. Small sample size and retrospective design prevented giving a definitive judgement, and future adequately powered prospective study is required to confirm these findings.

Recently, a novel motorized spiral endoscope has been introduced into clinical evaluation[34]. This novel enteroscopy is currently been evaluated for its efficacy and safety in three prospective clinical trials. It seems to provide a faster and deeper approach to the small bowel with similar safety and efficacy to balloon enteroscopy[35].

There were some limitations to the current study. First, the sample sizes of studies we included were small and we lacked high-quality prospective randomized multicenter trials. Second, a limited number of studies obstructed subgroup and sensitivity analyses. Third, there was no uniform method for insertion depth

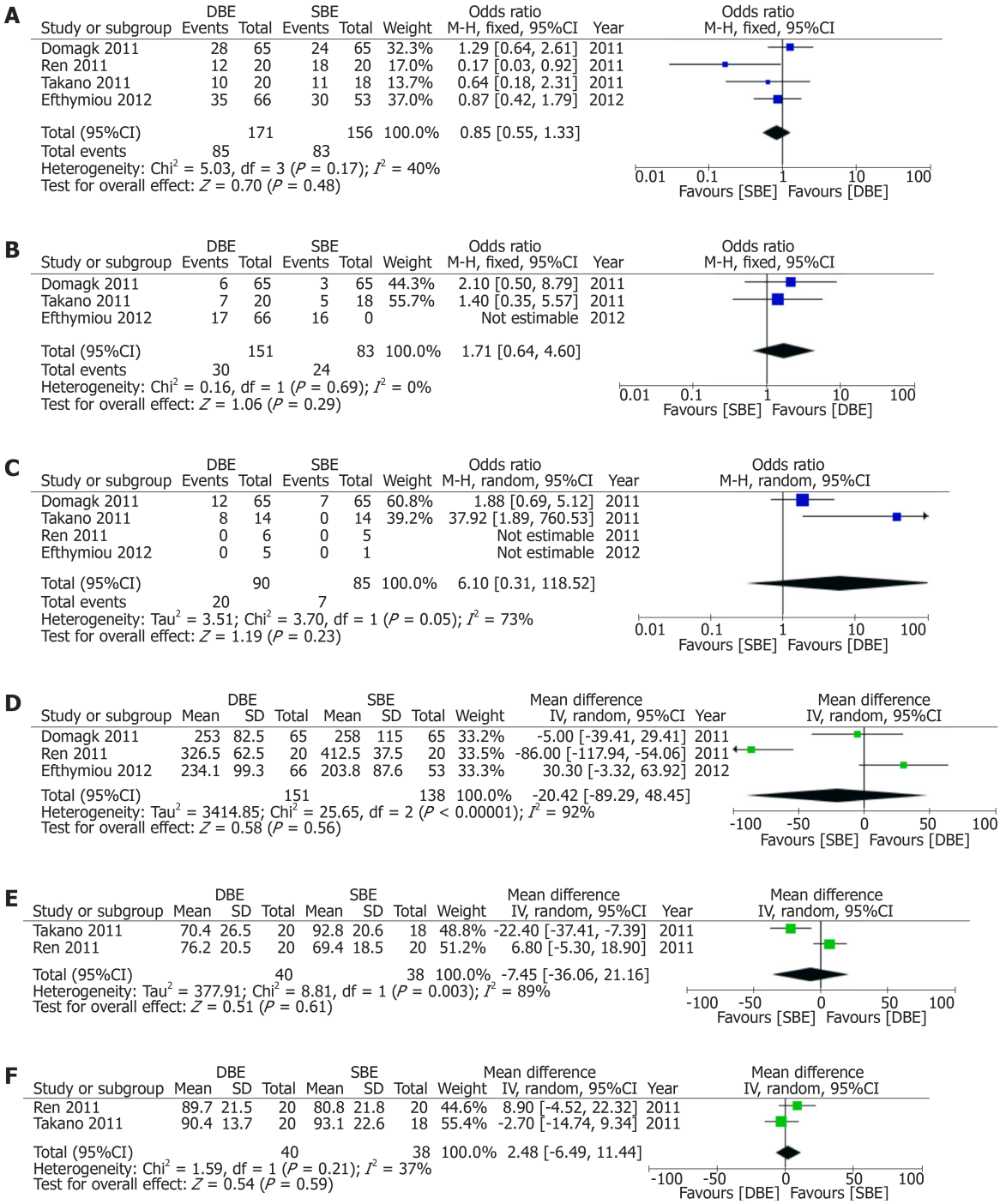

Figure 3 Outcome measures between double-balloon enteroscopy and single-balloon enteroscopy. A: Diagnostic yield; B: Therapeutic yield; C: Total enteroscopy; D: Depth of maximal insertion; E: Examination time (per-oral); and F: Examination time (per-anal).

estimation and different methods of enteroscopic distance estimation were used, which may have an impact on the results[23]. Fourth, due to limited studies comparing SBE with SE, we could not conduct a meta-analysis. Fifth, we only identified and included those studies that were published in English and Chinese because of the language barrier for the authors. Therefore, our meta-analysis may not include some useful published in other kinds of languages. Finally, peroral enteroscopy tended to provide higher diagnostic and therapeutic yields than peranal method. However, a limited number of studies also obstructed separate analysis.

In conclusion, the present meta-analysis has demonstrated that DBE and SBE have similar clinical outcomes. Compared with DBE, SE seem to have similar diagnostic and therapeutic yields, but shorter procedural time in cost of less depth of insertion. SE needs further evaluation *vs* SBE for clinical outcomes. DBE is recommended for complete enteroscopy.

ARTICLE HIGHLIGHTS

Research background

There are three different methods for the management of disorders in the distant part of small bowel: Double-balloon enteroscopy (DBE), single-balloon enteroscopy (SBE), and spiral enteroscopy (SE).

Research motivation

The efficacy of the three methods in terms of diagnostic and therapeutic yield rates, total enteroscopy rate, depth of maximal insertion, time to maximum insertion, and examination time remains unclear.

Research objectives

We aimed to compare the efficacy of DBE, SBE, and SE for the management of small bowel diseases.

Research methods

We searched randomized controlled trials and prospective studies in MEDLINE, PubMed, Embase, Cochrane Library, and Chinese CQVIP database. Statistical analyses were performed *via* RevMan software.

Research results

The diagnostic and therapeutic yields did not differ significantly when comparing DBE with SE and DBE with SBE. Total enteroscopy, examination time, time to maximum insertion, and depth of maximal insertion were similar between SBE and DBE. DBE was superior to SE with regard to depth of maximal insertion, with longer time to maximum insertion and examination time.

Research conclusions

DBE and SBE may have similar clinical outcomes. Compared with DBE, SE seems to have similar diagnostic and therapeutic yields, but shorter procedural time in cost of less depth of insertion.

Research perspectives

SE needs further evaluation *vs* SBE. DBE is recommended for complete enteroscopy.

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