

# Efficacy of scissor-type knife for endoscopic submucosal dissection: a systematic review and meta-analysis

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## Abstract

**Background** Endoscopic submucosal dissection (ESD) is an effective resection technique for early cancers and large gastrointestinal luminal lesions. However, ESD is technically challenging, with the potential for severe adverse events. Scissor-type ESD (ST-ESD) knives with an inner cutting edge and an electrically insulated external coating could mitigate some of these risks. This study aimed to evaluate the performance of ST electro-surgical knives when used for ESDs.

**Methods** Electronic databases were queried for studies from January 2005 through December 2022 evaluating the performance of ST-ESD knives. Fixed- and random-effects models were used to calculate pooled proportions. Heterogeneity was assessed using the  $I^2$  test and by constructing funnel plots, while bias was calculated using Egger and Harbord bias indicators.

**Results** Final analysis included data from 17 studies comprising 1652 ESD procedures. The pooled *en bloc* resection rate and R0 resection rate were 97.94% (95% confidence interval [CI] 97.20-98.57) and 94.32% (95%CI 93.11-95.43), respectively. The main adverse events were perforation and delayed post-procedural bleeding, with pooled rates of 1.07% (95%CI 0.63-1.62) and 1.86% (95%CI 1.26-2.56), respectively. There was no heterogeneity, as indicated by an  $I^2$  score of 0% (95%CI 0-44.50%). The mean procedure time was 67.45 min (95%CI 58.01-76.89).

**Conclusions** Our analysis shows that ST-ESD knives deliver consistently good performance across various locations in the gastrointestinal lumen and lesion sizes, with a good safety profile. This could be particularly appealing to newer adopters of ESD.

**Keywords** Endoscopic submucosal dissection, ESD knife, scissor-type knife, grasping-type knife

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## Introduction

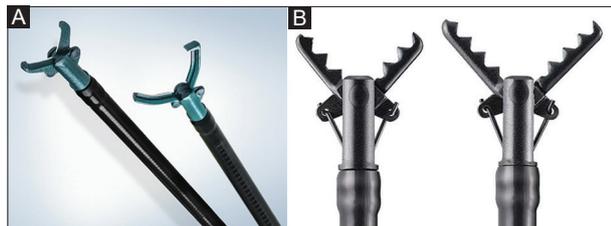
Endoscopic submucosal dissection (ESD) enables the operator to achieve an *en bloc* resection regardless of lesion “size” with complete (R0) resection [1]. This allows for comprehensive pathological tumor staging and treatment of early-stage carcinomas of the gastrointestinal tract [1,2]. Use of ESD in the west, particularly in the United States of America (USA), has remained limited mainly to major academic high-volume centers, where the procedure is performed by therapeutic endoscopists [3,4]. With the establishment of its efficacy, advancements in technology, and accessibility to training, ESD is gaining more acceptance among gastroenterologists in the USA. However, ESD is a highly technical, complex advanced endoscopic resection technique with the potential for severe adverse events, particularly in the early part of the learning curve [5,6]. The risk of adverse events, including perforation and severe bleeding, is highest during the submucosal dissection step, when the endoscopist must perform precise movements to keep

the tip moving along the dissection plane at the appropriate pace. Addressing intraprocedural and postprocedural complications when they occur is also an important determinant of successful ESD outcomes. Hence dissection and hemostasis devices play a very crucial role. Several ESD electro-surgical knives are available, with the earlier and conventional ones being needle-type. These include non-insulated tip knives (e.g., HookKnife, Triangle tip knife, DualKnife, FlushKnife) and insulated-tip knives (e.g., IT-2 Knife, IT-2 NanoKnife) [5]. With the evolution of ESDs from a procedure initially limited to gastric lesions, to the more challenging and less forgiving colorectal lesions, a new grasping type or scissor-type ESD (ST-ESD) knife was developed in the late 2000s in Japan to overcome some of the limitations of needle-type knives [7,8]. The ST-ESD knives are unique in their ability to grasp and pull the target tissue away from the deeper muscle layer before electro-surgical cutting or coagulation [6,9]. ST-ESD knives have an external electrically insulated coating, and sharp jagged or smooth, non-insulated inner cutting jaws [7]. This mechanism allows selective delivery of electro-surgical current to the grasped tissue between the upper and lower electrodes while sparing the adjacent regions and deeper *muscularis propria*. This ST-ESD knife design could decrease adverse effects, primarily when non-experts perform ESDs. The 2 main ST-ESD knives are the “stag beetle (SB) knife” (Sumitomo Bakelite, Tokyo, Japan) and the “ClutchCutter (CC) knife” (Fujifilm Medical, Tokyo, Japan) [7,8]. These are shown in Fig. 1. The first ST knife was the CC knife, introduced in 2007. CC is a thicker knife with a serrated jaw, while SB knives are thinner. This difference makes CC knives more efficient in managing periprocedural bleeding, while SB knives are better suited for sharp mucosal incisions [7]. Multiple studies have evaluated these knives, including studies that compared ST-ESD knives to non-ST (NST)-ESD knives [9–26]. The results have supported the use of ST-ESD knives, even by endoscopists with limited ESD experience. With the growing acceptance and increasing availability of ESD training in the USA, we decided to perform this systematic review and conduct a meta-analysis of all currently available data on the efficacy and safety of ST-ESD knives.

## Materials and methods

### Search methodology

A literature search was conducted using the electronic database engines MEDLINE through PubMed, Ovid, Cochrane



**Figure 1** The 2 main scissor-type endoscopic submucosal dissection knives. (A) Stag beetle knife and (B) ClutchCutter knife

library (Cochrane Central Register of Controlled Trials and Cochrane Database of Meta-Analysis), EMBASE, ACP journal club, and Database of Abstracts of Reviews of Effects (DARE), according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines, to identify studies from January 2005 through October 2022 that evaluated the performance of ST-ESD knives. The keywords used were “endoscopic submucosal dissection”, “ESD”, “ESD Knife”, “grasping-type ESD knife”, “scissor-type ESD knife”, “ClutchCutter”, and “SB knife”. References of reviewed articles were further scanned for additional studies. The retrieved studies were carefully examined to exclude potential duplicates or overlapping data.

### Study eligibility

Published studies were eligible if they reported the use of grasping or ST knives for the performance of ESD. Articles were excluded if they were not in the English language. Studies in animal models, editorials, abstracts with incomplete data, and comments were excluded. Two authors (HG, IV) reviewed full-text articles independently. Differences were resolved by mutual agreement or review by a third author (SP). The agreement was evaluated using Cohen’s  $\kappa$ .

### Data extraction and quality assessment

The following data were independently abstracted by 2 authors (HG, IV) into a standardized form: (a) study characteristics (primary author, period of study, year of publication, and country of the population studied); (b) study design; (c) baseline characteristics of the study population (number of patients enrolled, participant demographics); (d) intervention details (number of ESD procedures, size, location, indication, operator experience); (e) outcomes (*en bloc* resection, R0 resection, duration of procedures, speed of procedure); and (f) adverse events (perforations, delayed bleeding).

### Outcomes evaluated

The outcomes evaluated were *en bloc* resection rates, R0 resection rates, total procedure time, and adverse events.

### Statistical analysis

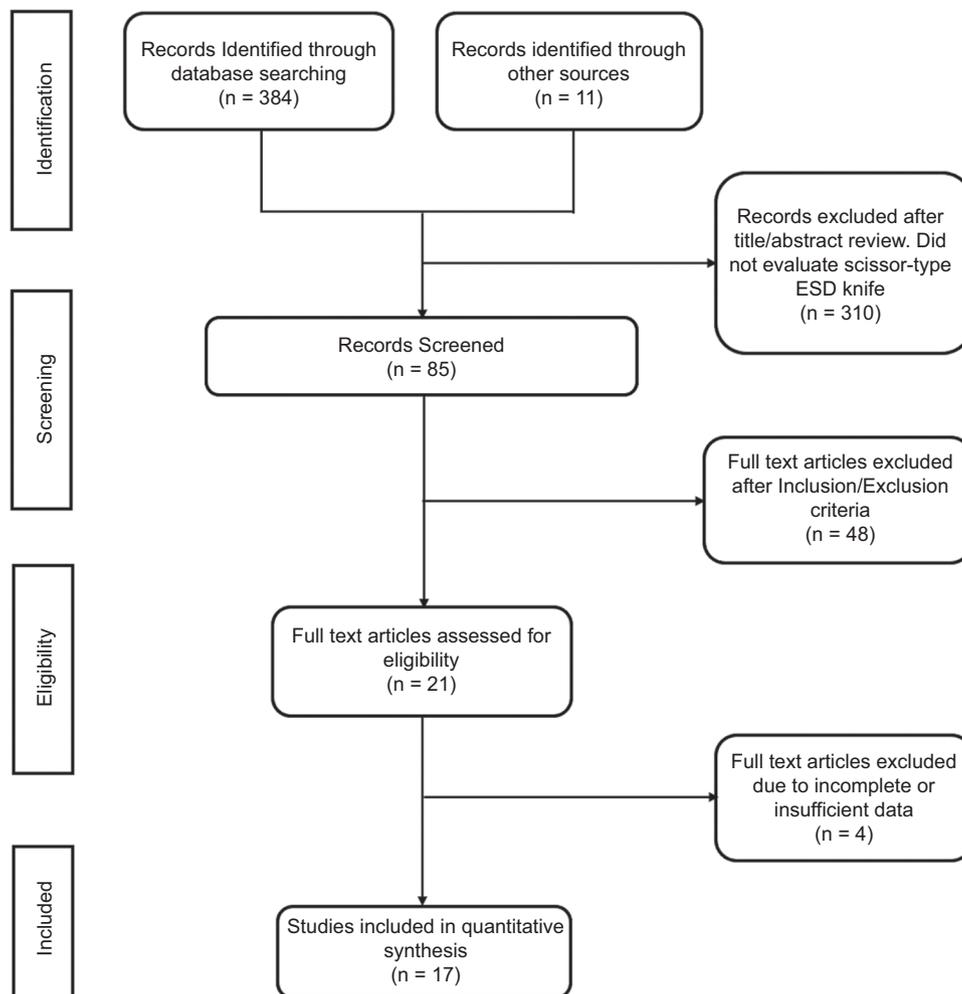
This meta-analysis was performed by calculating weighted pooled effects. Individual study proportions were transformed into a quantity using the Freeman-Tukey variant of the arcsine square-root transformed proportion. The pooled proportion is calculated as the back-transform of the weighted mean of the transformed proportions, using inverse arcsine variance weights for the fixed-effects model and the DerSimonian-Laird

method for the random-effects model. The heterogeneity of the studies was evaluated using Cochran's Q test, based on inverse variance weights, and by calculating the  $I^2$  statistic.  $I^2$  values of 0-39% were considered as non-significant heterogeneity; 40-75% as moderate heterogeneity; and 76-100% as considerable heterogeneity. A P-value >0.10 rejects the null hypothesis that the studies are heterogeneous. The findings of this meta-analysis are reported using the fixed-effects model, as there was no statistically significant heterogeneity. Forest plots were drawn to show the point estimates in each study in relation to the summary of pooled estimate. The width of point estimates in the Forest plots indicates the assigned weight to that study. The Egger bias indicator and Begg-Mazumdar bias indicator tested the effects of publication and selection bias on the summary estimates. Funnel plots were constructed to assess potential publication bias. A leave-out sensitivity analysis, excluding studies with a high risk of inducing bias (RoB), and a "per-knife" sensitivity analysis, based on the type of ST-ESD knife used, were also conducted to further validate the results of this meta-analysis. The quality of the included studies was evaluated using the Newcastle-Ottawa scale for

non-randomized studies and the Jadad scale for randomized control trials. Microsoft Excel 2019 was used for the statistical analysis.

## Results

The initial search identified 384 studies, from which 85 relevant articles were reviewed. Data were extracted from 17 studies, comprising 1558 patients, that met the inclusion criteria and were included in the final analysis. The PRISMA diagram showing the details of the review process is given in Fig. 2. All the included studies are available in full-text articles. The characteristics of the included studies are given in Table 1. The quality of studies was good, as evaluated using the Newcastle-Ottawa and Jadad scales. All the pooled estimates given are estimates calculated using the fixed-effects model. The estimates calculated using fixed- and random-effects models were similar. The agreement between reviewers was 1.0, as measured by Cohen's  $\kappa$ .



**Figure 2** Study flow diagram according to the PRISMA guidelines  
ESD, endoscopic submucosal dissection

**Table 1** Characteristics of studies included in this meta-analysis

Author [ref.], year	Study design, location	Patients, lesions (n)	Male (n)	Location of lesion	ST-ESD knife***	Number of operators
Akahoshi <i>et al</i> [10], 2010	Single-center Prospective, Japan	10, 10	6	Colon and rectum	CC	1 Expert*
Akahoshi <i>et al</i> [11], 2011	Single-center Prospective, Japan	35, 35	23	Stomach	CC	1 Expert*
Homma <i>et al</i> [12], 2012	Multi-center Prospective, Japan	100, 102	NA	Colon and rectum	SB Jr	11 Non-experts*
Oka <i>et al</i> [13], 2012	Single-center Retrospective, Japan	39, 39	NA	Colon	SB Jr	1 Expert*
Komori <i>et al</i> [14], 2014	Single-center Prospective, Japan	7, 7	4	Rectum	CC	1 Expert*
Fujinami <i>et al</i> [15], 2014	Single-center Retrospective, Japan	15, 17	15	Esophagus	SB	1 Expert*
Nagai <i>et al</i> [16], 2016	Single-center Prospective RCT, Japan	56, 56	49	Stomach	CC	3 Non-experts**
Yamashina <i>et al</i> [17], 2017	Single-center Prospective RCT, Japan	39, 39	24	Colon and rectum	SB Jr	2 Non-experts**
Akahoshi <i>et al</i> [18], 2017	Single-center Prospective, Japan	122, 122	78	Stomach	CC	2 Non-experts
Sugihara <i>et al</i> [19], 2017	Single-center Prospective RCT, Japan	20, 20	8	Colon and rectum	SB Jr	2 Non-experts**
Kuwai <i>et al</i> [20], 2018	Single-center Retrospective, Japan	70, 96	59	Esophagus	SB and SB Jr	4 Non-experts*
Dohi <i>et al</i> [21], 2019	Single-center Retrospective, Japan	61, 61	42	Stomach	CC	1 Expert and 8 Non-experts*
Esaki <i>et al</i> [22], 2020	Multi-center Prospective, Japan	36, 36	29	Esophagus	CC	5 Experts and 10 Non-experts**
Miyakawa <i>et al</i> [23], 2020	Single-center Retrospective, Japan	464, 507	297	Colon and rectum	SB Jr	1 Expert*
Inoue <i>et al</i> [24], 2021	Single-center Retrospective, Japan	49, 49	27	Colon	CC	2 Experts and 5 Non-experts*
Kuwai <i>et al</i> [25], 2022	Multi-center Retrospective, Japan	386, 407	235	Colon	SB Jr and CC	49 Operators, varying levels of experience
Tamaru <i>et al</i> [26], 2022	Multi-center Prospective RCT, Japan	49, 49	29	Colon	SB Jr	7 Experts*

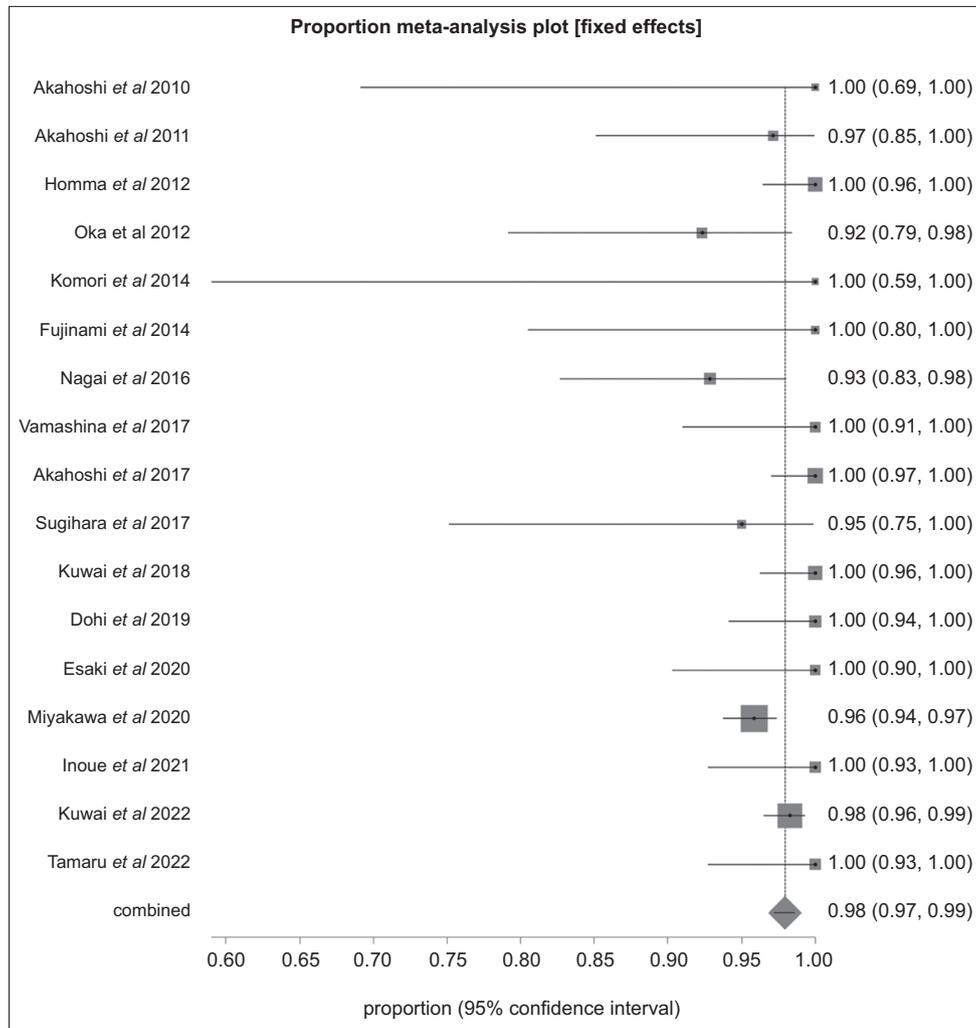
\*No standard definition for Expert or non-Expert. This was assigned based on what each study considered its operators to be

\*\*Endoscopic submucosal dissection procedures were performed primarily by non-expert trainees with an expert supervisor available for assistance when needed  
SB, Stag-Beetle Knife, Sumitomo Bakelite, Tokyo, Japan; SB Jr, Stag-Beetle Knife Jr, Sumitomo Bakelite, Tokyo, Japan; CC, ClutchCutter, Fujifilm Co., Tokyo, Japan

The total sample size was 1652 ESD procedures performed in 1558 patients. Mean patient age was 69.62±2.64 years and females constituted 39.53% of the study population. These data included ESDs performed in the esophagus, stomach, colon and rectum. The mean lesion size was 24.24±4.58 mm for esophageal lesions, 35.12±3.78 mm for gastric lesions, and 30.72±3.53 mm for colonic lesions. The ST knives used were the CC knife in 8 studies (25% of ESDs) and the SB Knife/SB Knife Jr in the other 9 studies (75% of ESDs). In 9 of these studies, all the steps using ESD knives were performed using an ST-ESD knife, while argon plasma coagulation and Hook knives were used for marking the circumference in 4. Only 1 study reported using an NST-

ESD knife for mucosal incision. All the studies were conducted in various high-volume referral centers across Japan. The ESD operators comprised a combination of experts and non-experts. The definition of experts and non-experts varied among the studies. In studies that evaluated trainees, there was at least one expert for supervision and procedure takeover if needed.

The pooled *en bloc* resection rate and R0 resection rate were 97.94% (95% confidence interval [CI] 97.20-98.57) and 94.32% (95%CI 93.11-95.43), respectively. The forest plot showing individual study estimates and the pooled estimate for *en bloc* resection is shown in Fig. 3. There was no publication bias according to the Egger bias indicator, -0.24 (95%CI -1.30-0.80, P=0.62), and the Harbord bias indicator, 0.71 (95%CI -0.62-



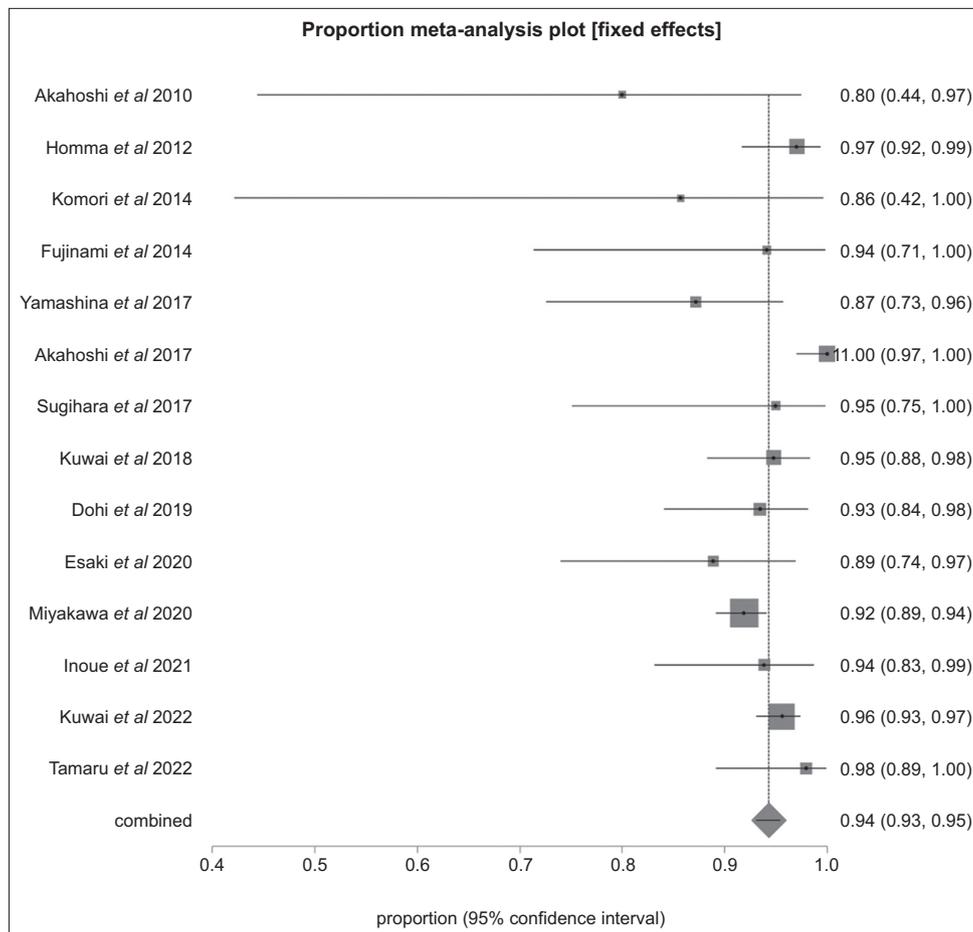
**Figure 3** Forest plot showing individual and pooled estimates of *en bloc* resection rate with the scissor-type endoscopic submucosal dissection knife

2.04,  $P=0.32$ ). The forest plot for R0 resection is shown in Fig. 4. The Harbord bias indicator calculated for R0 resection was  $-0.41$  (95%CI  $-1.83-0.99$ ), showing no publication bias. The pooled *en bloc* resection rate was 98.20% (95%CI 97.48-98.81) and the pooled R0 resection rate was 94.45% (95%CI 93.24-95.55) on a leave-out sensitivity analysis that excluded high-RoB studies. A “per-knife” sensitivity analysis was also performed on the primary outcomes by calculating the rates of *en bloc* and R0 resection based on whether the SB knife or CC knife was used for performing ESD. The pooled rate of *en bloc* resection using the SB knife alone was 97.66% (95%CI 96.76-98.41) while the pooled rate of *en bloc* resection using CC knife alone was 98.77% (95%CI 97.42-99.63). Pooled rates of R0 resection were 93.86% (95%CI 92.45-95.12) and 96.13% (95%CI 93.60-98.04) using the SB knife and CC knife, respectively. Outcomes based on the location of lesions showed that the *en bloc* resection rates for esophageal, gastric and colorectal lesions were 100% (95%CI 97-100), 98.60% (95%CI 96.88-99.64), and 97.49 (95%CI 96.55-98.29), respectively. The R0 resection rates were 92.68% (95%CI 87.99-96.28) for esophageal lesions and 93.65% (95%CI 92.20-94.96) for colorectal lesions. The main adverse events were perforation

and delayed postprocedural bleeding, with pooled rates of 1.07% (95%CI 0.63-1.62) and 1.86% (95%CI 1.26-2.56), respectively. The forest plot showing the individual study estimates and the pooled estimate for perforation rate is shown in Fig. 5. There was no heterogeneity, with an  $I^2$  score of 0% (95%CI 0-44.50%). The pooled mean procedure time for the entire cohort was 67.45 min (95%CI 58.01-76.89). Procedure time was also calculated based on the location of the lesion resected and was  $93.95 \pm 30.85$  min for esophageal ESDs,  $73.51 \pm 17.27$  min for gastric ESDs, and  $62.89 \pm 14.35$  min for colorectal ESDs.

## Discussion

The results of this meta-analysis show that ST-ESD knives can consistently achieve good *en bloc* and R0 resection rates comparable to those of conventional needle-type ESD knives. Achieving an *en bloc* and potentially R0 resection, regardless of the lesion size, is the principal advantage of ESD over other endoscopic resection techniques, such as endoscopic mucosal resection [1,4].



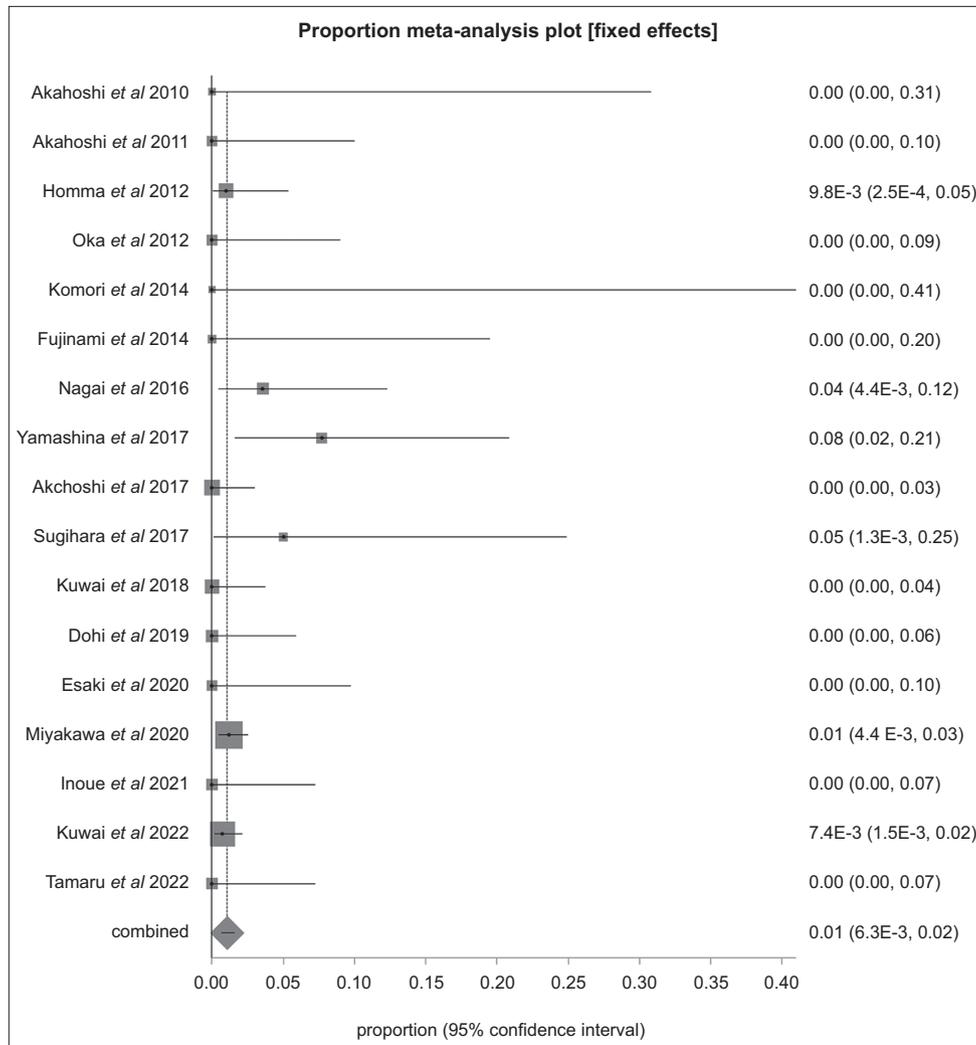
**Figure 4** Forest plot showing individual and pooled estimates of R0 resection rate with scissor-type endoscopic submucosal dissection knife

In one of the largest prospective studies of colonic ESDs by Saito *et al*, which involved 1111 colonic lesions, the reported *en bloc* and R0 resection rates were 88% and 89%, respectively [27]. A meta-analysis by De Ceglie *et al*, involving 66 studies, showed an *en bloc* resection rate of 91% with colonic ESD [28]. The *en bloc* resection rate of 98% and an R0 resection rate of 94% found in our study are comparable to, if not better than those reported in prior studies that primarily used NST-ESD knives. Additionally, 9 studies included in this meta-analysis reported using an ST-ESD knife for all the steps involving an electrosurgical knife [10,12,14,16,18,22,24-26], with only 1 study reporting the use of an NST-ESD knife to perform the mucosal incision step [19].

Our pooled analysis included ESDs performed by experts, gastroenterologists with varying levels of ESD experience, and trainees with no previous ESD experience. Dohi *et al*, in their study comparing ST-ESD knives to NST-ESD knives in gastric ESDs, found no significant difference in R0 resection between the 2 groups when experts performed the procedure [21]. However, ST-ESD knives showed significant superiority in both self-completion rates and mean procedure time when non-experts performed the procedures [21]. A study by Yamashina *et al* also found a better self-completion rate when trainees used ST-ESD knives [17]. Two other studies also compared procedure completion time between experts and non-experts

when ST-ESD knives were used. Esaki *et al* found no significant difference in median procedure completion time, while Inoue *et al* observed that, among less-experienced endoscopists, the mean procedure time was significantly shorter in the ST-ESD knife group than in the NST-ESD knife group [22,24]. Other studies have not consistently shown this difference, but data are limited, and head-to-head comparison of these 2 types of ESD knives in trainees is scarce, as most available studies are drawn from expert experience. Our data showing a good aggregate *en bloc* and R0 resection from a pool that included different tiers of experience warrant further studies directly comparing these 2 types of knives, mainly when used by trainees.

Another significant finding from this meta-analysis is the low rates of delayed bleeding and perforation with ST-ESD knives. Bleeding is the most common complication of ESD, and can be immediate or delayed [5]. Delayed bleeding is defined as a drop in hemoglobin by 2 g or more after being stable for the initial 24 h [5]. Delayed bleeding rates can differ significantly based on the location of the lesion, with studies reporting rates of 4-9% for gastric ESDs [29-31] and 0.5-2.70% for colonic ESDs [32-34]. The pooled delayed bleeding rate of 1.80% from this meta-analysis falls within the lower range of those reported in previous studies. The reason may be ST-ESD knives' ability to grasp vasculature and function as a coagulation grasper, utilizing



**Figure 5** Forest plot showing individual and pooled estimates of perforation with scissor-type endoscopic submucosal dissection knife

soft coagulation settings without the need for switching devices. This may encourage the more robust use of coagulation settings to treat vessels in the resection bed effectively. Perforation is more common with ESD than other endoscopic resection techniques [5]. It can be intraprocedural or delayed. Tumor size, location, fibrosis, procedure duration and operator inexperience are known risk factors for perforation [35]. Previous studies have reported varying rates of perforation, from 4.30-8.20%, with gastric ESDs [30,35], around 4% with esophageal ESDs [36], and about 5% with colonic ESDs [27,33,34,37]. Duodenal ESDs carry the highest risk for perforation, with wide variability in the reported rates [38]. The pooled perforation rate of 1% noted in this study is lower than those typically reported for ESDs and suggests that ST-ESD knives could potentially lower the risk of perforation. This difference is probably related to the ability of an ST-ESD knife to grasp and pull tissue away from the underlying *muscularis propria* before delivering the electrosurgical current. In addition, the electrically insulated outer coating also further protects the underlying and adjacent tissue from unintended thermal injury. Kuwai *et al*, in the largest study comparing ST-ESD knives to NST-ESD knives,

involving 1221 propensity score-matched colorectal ESDs, found that the rates of perforation and delayed bleeding were significantly lower in the ST group [25]. Other studies involving trainees, however, have not consistently noted this difference. However, it is also important to note that none of the studies reported a greater incidence of adverse events with ST-ESD knives, including when used by less experienced endoscopists.

The findings from this meta-analysis thus suggest a need for further prospective studies to clarify whether there are any safety advantages with the use of ST-ESD knives, especially in new adopters. To the best of our knowledge, this is the first systematic review and meta-analysis of all currently available data on the efficacy of ST knives for ESD. The findings from this study show that ST-ESD knives can be a feasible alternative or adjunct to conventional needle-type or blade-type ESD knives. Further studies are needed to define the role of this relatively new style of ESD knife and evaluate whether there is a significant difference in the learning curve if ST-ESD knives are used in the early part of ESD training.

There are a few limitations to this study. All the studies evaluated were performed in Japan, where the technique of ESD

was pioneered and has been in practice for over 2 decades. There is also a risk of selection bias in some of the included studies, as only 3 were randomized controlled trials, whereas the others were single or multicenter prospective or retrospective studies. This could have affected patient selection for the performance of ESD using ST knives. Furthermore, the results of this meta-analysis include a combination of data from studies of the CC knife and SB knife (which includes both SB knife and SB Knife Jr). Although they are all ST knives, they have differences, which could affect some of the outcomes evaluated and may have introduced moderate heterogeneity to our findings. However, the similar findings for *en bloc* and R0 resection rates seen on a sensitivity analysis, excluding high RoB studies, and a per-knife sensitivity analysis further indicate that the findings from this study are robust.

Our analysis shows that the ST knife delivers consistent performance across a wide range of ESD procedures in various locations of the gastrointestinal tract. ST-ESD knives have a good safety profile, comparable to conventional needle-type ESD knives. Additionally, there seems to be a potential for reduced rates of adverse events and perhaps greater ease of use in the hands of less experienced operators during ESD procedures. These findings suggest that ST-ESD knives could be an alternative or adjunct to traditional NST knives for ESDs. More head-to-head studies are warranted, particularly including less experienced operators of ESD.

### Summary Box

#### What is already known:

- Endoscopic submucosal dissection (ESD) is a complex advanced endoscopic resection technique with the potential for severe adverse events, particularly in the early part of the learning curve
- Scissor-type ESD (ST-ESD) knives have a mechanism that allows selective delivery of electrosurgical current to the grasped tissue between the upper and lower electrodes while sparing the adjacent regions and deeper *muscularis propria*
- This ST-ESD knife design has been purported to decrease adverse effects, primarily when non-experts perform ESDs

#### What the new findings are:

- The ST knife delivers consistent performance across a wide range of ESD procedures in various locations of the gastrointestinal tract
- ST-ESD knives have a good safety profile, comparable to conventional needle-type ESD knives
- There seems to be a potential for reduced rates of adverse events and perhaps greater ease of use in the hands of less experienced operators of ESD procedures, suggesting that ST-ESD knives could be an alternative or adjunct to traditional non-ST knives for ESDs

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