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META-ANALYSIS

# Recent evidence for subcutaneous drains to prevent surgical site infections after abdominal surgery: A systematic review and metaanalysis

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#### **Abstract**

#### **BACKGROUND**

Surgical site infections (SSIs) increase mortality, hospital stays, additional medical treatment, and medical costs. Subcutaneous drains prevent SSIs in gynecological and breast surgeries; however, their clinical impact in abdominal surgery remains unclear.

To investigate whether subcutaneous drains were beneficial in abdominal surgery using a systematic review and meta-analysis.

#### **METHODS**

The database search used PubMed, MEDLINE, and the Cochrane Library. The following inclusion criteria were set for the systematic review: (1) Randomized controlled trial studies comparing SSIs after abdominal surgery with or without subcutaneous drains; and (2) Studies that described clinical outcomes, such as SSIs, seroma formation, the length of hospital stays, and mortality.

### RESULTS

Eight studies were included in this meta-analysis. The rate of total SSIs was significantly lower in the drained group (54/771, 7.0%) than in the control group (89/759, 11.7%), particularly in gastrointestinal surgery. Furthermore, the rate of superficial SSIs was slightly lower in the drained group (31/517, 6.0%) than in the control group (49/521, 9.4%). No significant differences were observed in seroma formation between the groups. Hospital stays were shorter in the drained group than in the control group.

#### **CONCLUSION**

Subcutaneous drains after abdominal surgery prevented SSIs and reduced hospital stays but did not significantly affect seroma formation. The timing of drain removal needs to be reconsidered in future studies.

Key Words: Abdominal surgery; Mortality; Seroma formation; Subcutaneous drain; Surgical site infections

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Core Tip: This review supports the beneficial effects of subcutaneous drains after abdominal surgery. Subcutaneous drains may not prevent seroma formation. Most studies removed drains within 3 d regardless of the amount of fluid discharge. The timing of drain removal may affect the clinical outcome. Nevertheless, subcutaneous drains can prevent surgical site infections and shorten the length of hospital stays after abdominal surgery.

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#### INTRODUCTION

Surgical site infections (SSIs) are a common complication after gastrointestinal surgery and increase patient mortality[1, 2]. They were previously reported to occur in approximately 20% of patients after colorectal and hepatobiliary surgeries [3-5]. SSIs prolong hospital stays and increase additional medical management with high medical costs[6]. Therefore, their prevention during the perioperative period after surgery is essential.

Fluid collection in subcutaneous tissue is a risk factor for the development of SSIs through its provision of an environment for bacterial growth[7]. The Centers for Disease Control and Prevention guidelines recommend the use of preoperative antimicrobial agents, the removal of serous fluid with drains, including negative pressure wound therapy, and antibacterial-coated absorbent sutures for the prevention of SSIs[8]. The World Health Organization global guidelines also recommend the use of negative pressure wound therapy and antibacterial, absorbent sutures in any surgical procedure[9]. Subcutaneous drains are commonly used after gynecological and breast surgeries[10]; however, conflicting findings have been reported on their clinical impact on SSIs after abdominal surgery[11-15].

The majority of previous studies that examined the clinical benefits of subcutaneous drains were retrospective analyses without cause responsiveness. Therefore, further evidence is needed from randomized controlled trials (RCTs). This systematic review and meta-analysis were designed to compare clinical outcomes among subcutaneous drained and control groups after abdominal surgery.

#### MATERIALS AND METHODS

#### Search strategy

The review followed the statement of Preferred Reporting Items for Systematic Reviews and Meta-analyses [16]. The protocol was registered in INPLASY (INPLASY No. 202350115). Ethical approval was not required for this review because of the observational meta-analysis. The protocol was augmented and evaluated with the peer review of electronic search strategies guidelines before performing the search[17]. A comprehensive literature search was conducted using PubMed, MEDLINE, and the Cochrane Library for articles published between January 1, 1999 and April 1, 2023, and the search strategy is described in Supplementary Table 1.

#### Screening and eligibility

Five independent authors (Ishinuki T, Kouzu K, Kobayashi Mo, Suzuki K, and Yamashita C) reviewed the title and abstract of each article based on the following criteria: (1) RCT studies published in 1999 or thereafter; (2) Patients underwent abdominal surgery, defined as gastrointestinal, hepatobiliary, and hernia repair surgery; (3) Comparisons between subcutaneous drains and no subcutaneous drains; and (4) Incidence of SSIs was presented. Exclusion criteria were duplicate studies and studies in the same database or population. In the case of a conflict of agreement among authors, a group consensus was used to reach acceptance or rejection. Six authors (Ishinuki T, Goda E, Kitagawa Y, Mohri Y, Uchino M, and Haji S) reviewed the full texts of studies that passed the first screening. In addition, references were checked to ensure that all studies were included in eligible studies.

#### Data selection and quality assessment

Data selection was performed by four independent authors (Ishinuki T, Shinkawa H, Suzuki K, and Yoshida M). A data entry form was prepared in advance. The following information was selected: study details (title, first author, journal name, and year of publication), study design (purpose, study period, eligibility and exclusion criteria, age, and total number of participants), interventions delivered (procedure, surgical site, type of drain, timing of drain removal, length of hospital stays, and type of antimicrobial agents), and study results [number of SSIs, type of SSI (superficial or deep/ organ), number of seroma formed, sample size, and P value]. The authors independently assessed the risk of bias for studies using the criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions and Cochrane's effective practice and organization of care guidance, such as random sequence generation, allocation concealment, blinding of participants, blinding of personnel, blinding of outcome assessments, incomplete outcome data, selective reporting, and other bias [18]. Conflicts of opinion among authors were discussed with all authors, and a consensus was reached.

#### Statistical analysis

The primary outcome was the rate of SSIs, including individual superficial or deep/organ SSIs. Secondary outcomes were the rate of seroma formation, the length of hospital stays, and mortality. Dichotomous data were analyzed for risk ratios using a random effects model and the Mantel-Haenszel method. Continuous data, such as the length of hospital stays, were analyzed using non-parametric tests[19-21]. Data were presented as means with standard deviations using a random effects model. Median and interquartile range data were calculated as means and standard deviations[22]. In addition, a subgroup analysis of SSIs was performed according to each type of drain or surgical site. Data synthesis and statistical analyses were performed with Review Manager (version 5.4; The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark).

#### **RESULTS**

#### **Findings**

The Preferred Reporting Items for Systematic Reviews and Meta-analyses flow diagram for this review is shown in Figure 1. Database search results showed that 9462 studies were eligible, with two additional studies being added to the references. We excluded 834 studies because of duplication, and 8621 were excluded after the screening of titles and abstracts. As a result, nine studies were reviewed as full texts[11,19-21,23-27]. Eight studies were ultimately included in the meta-analysis[11,19-21,23-26] after the exclusion of one study without SSI data[27]. The bias summary is shown in Supplementary Figure 1.

#### Summary and characteristics of studies

A summary of data in each study is shown in Table 1. Five studies disclosed the outcomes of superficial or deep/organ SSIs[19,23,24,26]. Three studies reported the number of seromas formed[21,24,25], and three described the length of hospital stays[19-21]. Although three studies discussed mortality[19,25,26], only one mortality occurred in the drained group; therefore, a further analysis of mortality was impossible [25,26].

The characteristics of each study are shown in Supplementary Table 2. There were three studies on lower gastrointestinal surgery [21,24,26], one on hepatobiliary surgery [19], three on mixed surgery [11,20,23], and one on hernia repair[25]. The types of drains were the Redon drain[23], Hemovac drain[11], Blake drain[19,26], Penrose drain[24], and Tubular drain[25]. Two studies did not specify the type of drain used[20,21]. The timing of drain removal ranged between 2-5 postoperative days or when the drainage volume was less than 40 mL/day. Cefuroxime and metronidazole were used in one study[23], cefazoline in three[11,19,25], cefmetazole in one[24], ampicillin/sulbactam in one[21], and flomoxef in one [26]. One study did not describe the type of antibiotic prophylaxis [20]. An intent-to-treat analysis was performed in three out of seven studies[19,23,25].

#### Results on the primary outcome

The rate of total SSIs was significantly lower in the drained group (54/771, 7.0%) than in the control group (89/759, 11.7%) without heterogeneity (*I*<sup>2</sup> = 0%) [risk ratio (RR): 0.63, 95% confidence interval (95%CI): 0.45-0.87, *P* = 0.005] (Figure 2A). Furthermore, the rate of superficial SSIs was slightly lower in the drained group (31/517, 6.0%) than in the control group (49/521, 9.4%) (RR: 0.64, 95%CI: 0.37-1.11, P = 0.11) (Figure 2B). In addition, no significant differences were observed in deep/organ SSIs between the groups (Figure 2C). Publication bias of the SSIs was assessed by the funnel plot (Supplementary Figure 2).

#### Results on secondary outcomes

No significant differences were observed in seroma formation between the drained and control groups (RR: 1.21, 95%CI: 0.65-2.26, P = 0.54) (Figure 3). However, the length of hospital stays significantly differed (mean difference: -1.34, 95%CI: -2.33 to -0.34, P = 0.008) (Figure 4). Publication bias of the seroma formation and the hospital stays were assessed by the funnel plot (Supplementary Figures 3 and 4, respectively).

#### Results of subgroup analyses

The results of subgroup analyses of the types of drains are shown in Figure 5. SSIs with the Blake drain (RR: 0.56, 95%CI: 0.24-1.29, P = 0.18) and other closed suction methods (RR: 0.71, 95%CI: 0.47-1.07, P = 0.52) did not significantly differ from those with the control, whereas SSIs using passive drainage significantly decreased more than with the control (RR: 0.33, 95% CI: 0.11-0.99, P = 0.05) (Figure 5). The results of subgroup analyses of surgical procedures are shown in Figure 6. Subcutaneous drains in gastrointestinal surgery decreased SSIs more than the control (RR: 0.48, 95%CI: 0.26-0.88, P = 0.02), whereas those in the hepatobiliary surgery (RR: 0.82, 95%CI: 0.37-1.83, P = 0.63), mixed surgery (RR: 0.64, 95%CI: 0.33-1.24, *P* = 0.22), and hernia repair surgery (RR: 0.80, 95%CI: 0.25-2.57, *P* = 0.71) did not (Figure 6).

#### DISCUSSION

We identified eight RCTs that compared SSIs after abdominal surgery with or without subcutaneous drains. Although the rate of total SSIs was significantly lower in the drained group than in the control group, no significant differences were observed in superficial or deep/organ SSIs because of statistical power. According to the surgical site, drains effectively prevented SSIs in gastrointestinal surgery. No significant differences were observed in SSIs among the drain types examined. We also showed that seroma formation did not significantly differ between the drained and control groups. On the other hand, subcutaneous drains effectively reduced hospital stays.

Subcutaneous drains remove interstitial fluid from a wound thereby reducing the risk of SSIs[28]. Watanabe et al[26] showed the benefits of subcutaneous drains in preventing SSIs after colorectal surgery, and putative reasons for reducing SSIs were proposed. The first reason is the specific shape of the drain itself. The classic shape of a subcutaneous drain is a tube with multiple small holes[11,21,23,25]. This drain type may damage the hypodermis because of high negative pressure from the holes[29]. The Blake drain is a closed suction drain made of a silicone elastomer with a solid core in the center and four slits along the sides. Since the Blake drain was developed to drain without causing tissue damage, it may be more beneficial than other drains[26]. Therefore, this review investigated whether the Blake drain significantly reduced SSIs; however, no significant differences were observed between the drain types examined. The small holes of a

Table 1 Summary of clinical outcomes in each study for the subcutaneous drain group vs the control group after abdominal surgery

Ref.	Year	Drained,	Control,	Total SSI,	Superficial SSI,	Deep/organ SSI,	Seroma,	Hospital stay, mean	Mortality,
		n	n	n	n	n	n	± SD	n
Baier et al[23]	2010	100	100	10:9	9:6	1:3	ND	ND	ND
Kaya et al[11]	2010	210	192	12:19	ND	ND	ND	ND	ND
Nakayama <i>et al</i> [19]	2014	131	129	10:12	10:12	0:0	ND	$26.3 \pm 39.7 : 30.3 \pm 49.5$	1:0
Numata et al[24]	2014	124	122	4:12	4:12	0:0	0:0	ND	ND
Westphalen <i>et al</i> [25]	2015	21	21	4:5	ND	ND	11:9	ND	0:0
Arer et al[20]	2016	23	25	2:8	ND	ND	ND	$5.9 \pm 2.4 : 7.9 \pm 3.8$	ND
Lauscher et al[21]	2016	50	53	7:9	4:7	3:2	1:1	$8.3 \pm 2.3 : 9.3 \pm 3.8$	ND
Watanabe et al [26]	2017	112	117	5:15	4:12	1:3	ND	ND	0:0

ND: Not described; SD: Standard deviation; SSI: Surgical site infection.

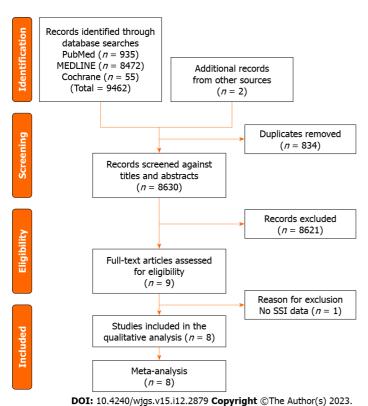
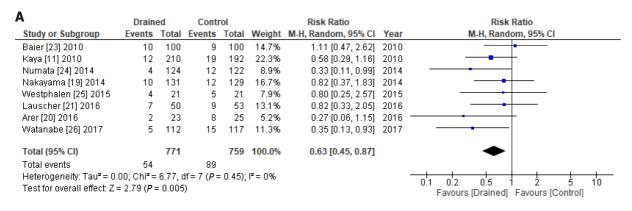
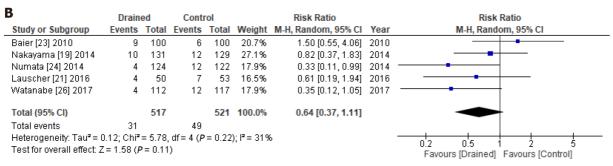


Figure 1 Flow diagram of systematic reviews and meta-analyses. SSI: Surgical site infection.

drain may become blocked with fat tissue during the flow of fluid, which eventually prevents drainage[30]. Therefore, drainage methods that are less likely to become blocked need to be developed.

The second proposed reason is the timing of drain removal. Long-term drain placement may increase the risk of contamination[26]. A previous study published in 2004 reported a high infection rate associated with drain placement [31]. On the other hand, studies published from the 2010s demonstrated that a sufficiently long drain time, such as longer than 72 h, prevented wound infection [12,30]. The majority of studies analyzed in the present study removed drains within 72 h, which may have been too short to prevent superficial infection[11,19,21,23,24]. Nakayama et al[19] also reported that the timing of drain removal was too early to detect clinical effects and showed that 41% of SSIs occurred within 72 h of drain removal. Watanabe et al [26] removed drains 120 h after surgery and found no incidence of SSIs. Therefore, the timing of drain removal needs to be investigated in further studies.







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Figure 2 Surgical site infections in the subcutaneous drain group vs the control group after abdominal surgery. A: Total surgical site infections; B: Superficial surgical site infections; C: Deep surgical site infections. CI: Confidence interval.

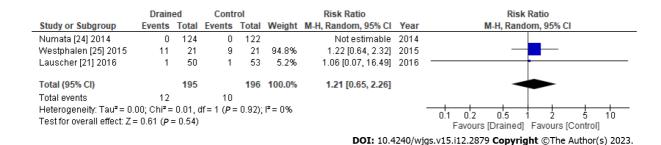
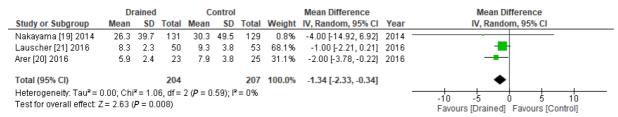


Figure 3 Seroma formation in the subcutaneous drain group vs the control group after abdominal surgery. Cl: Confidence interval.

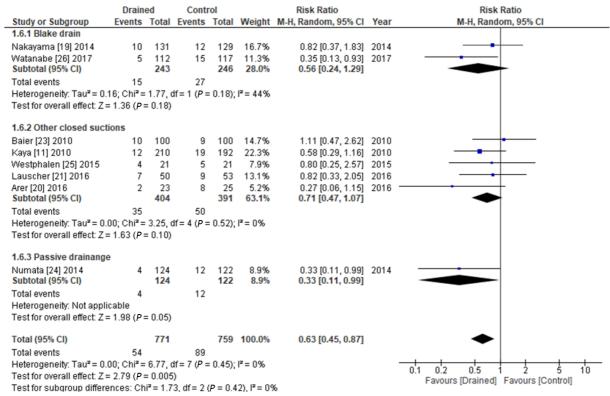
Although subcutaneous drains significantly decreased the rate of total SSIs, no significant differences were observed in the rate of superficial or deep/organ SSIs. Since two previous studies did not describe data on superficial or deep/organ SSIs, the statistical power in the subgroup analysis may have been lower than that in the total analysis [11,25]. The present study also examined clinical effects, which were slightly better in the drained group than in the control group. This result may be attributed to improvements in drain materials and management.

This review showed that the effectiveness of subcutaneous drains was dependent on the surgical site. The usefulness of subcutaneous drains for the prevention of SSIs has been demonstrated in cholecystectomy[32] and gastrointestinal surgery[11,23]. Baier et al[23] reported no benefit of subcutaneous drains in the abdominal field. On the other hand, Kaya et al[11] showed a significant reduction in SSIs after surgery for colorectal malignancies and lower abdominal incisions in their subgroup analysis. Previous studies also found that drains prevented SSIs in contaminated surgery, such as lower



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Figure 4 Hospital stays in the subcutaneous drain group vs the control group after abdominal surgery. Cl: Confidence interval.



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Figure 5 Subgroup analysis of surgical site infections depending on drain types. CI: Confidence interval.

gastrointestinal surgery[33,34]. The present results provide support for the use of drains in lower gastrointestinal surgery. The meta-analysis showed that subcutaneous drains did not significantly prevent seroma formation. Westphalen et al [25] noted that seroma formation mostly occurred after drain removal. The peak incidence of seroma formation was previously reported to be approximately 2 wk after surgery, at which time the majority of drains had already been removed[35-37]. Shima et al[12] demonstrated that the timing of drain removal in breast cancer surgery was important to avoid wound complications. They found that seroma formation may be prevented when subcutaneous drains were removed after 7 d or later without an increase in SSIs. Therefore, the timing of drain removal needs to be individually selected for specific surgical procedures.

The use of subcutaneous drains affects the length of hospital stays. The length of hospital stays is a socioeconomic factor that is increased by any complication[21]. Hospital stays were prolonged by SSIs, large seromas, hematomas, and other complications[21]. Therefore, the prevention of SSIs by appropriately placing a subcutaneous drain may shorten hospital stays.

To ensure the quality of evidence, this review performed a meta-analysis of RCTs only. However, the interpretation of the present results was limited. The small number of studies included and insufficient published data affected the statistical results obtained. Therefore, a subgroup analysis of factors, such as the material of the drain and the timing of drain removal, was not possible. In addition, surgical techniques may have improved over the study period. Furthermore, putative adverse effects, such as pain, cosmetic evaluations, and management costs, were not analyzed due to the lack of data. It was not possible to investigate a publication bias due to the lack of sufficiently large publications to estimate. A limitation of the present study was that some factors may not have been included in the analysis, such as the age of patients, preoperative conditions, the length of surgery, the surgical technique, and the surgeon's experience.

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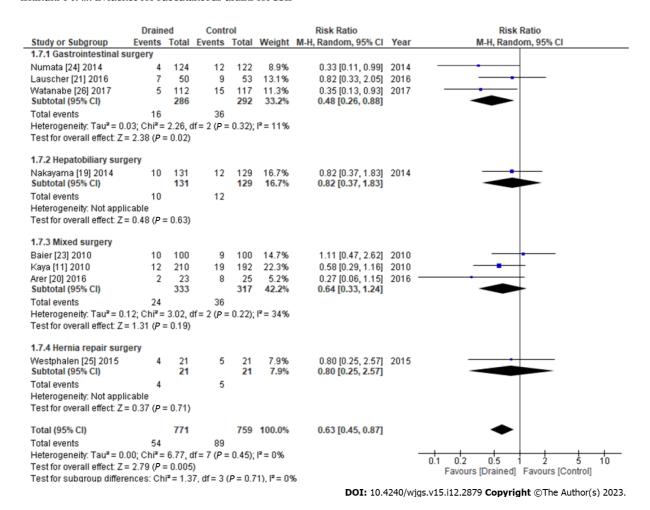


Figure 6 Subgroup analysis of surgical site infections depending on surgical procedures. CI: Confidence interval.

#### CONCLUSION

In conclusion, the present study supports the use of subcutaneous drains to prevent SSIs and shorten the length of hospital stays after abdominal surgery. On the other hand, subcutaneous drains may not prevent seroma formation. Several specific clinical outcomes, such as the timing of drain removal, pain control, cosmetic evaluations, medical cost, and the quality of life of patients need to be clarified in future studies.

### ARTICLE HIGHLIGHTS

#### Research background

Surgical site infections (SSIs) are a common complication after gastrointestinal surgery and result in a worse clinical prognosis for the patients. Subcutaneous drains are commonly used after abdominal surgery to prevent SSIs. Nevertheless, further evidence is needed about subcutaneous drains. Therefore, this systematic review and meta-analysis were designed to compare clinical outcomes among subcutaneous drains and control groups after abdominal surgery.

#### Research motivation

There is a shortage of evidence as to whether subcutaneous draining is beneficial in preventing the development of SSIs, and the results are different in each of the previous studies.

#### Research objectives

The objective for this review was to determine whether subcutaneous drainage is beneficial in preventing the development of SSIs.

#### Research methods

Independent authors reviewed the previous studies and data selection. The primary outcome was the rate of SSIs, including individual superficial or deep/organ SSIs. Secondary outcomes were the rate of seroma formation, the length of hospital stays, and mortality. Data were presented as means with standard deviations using a random effects model.

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#### Research results

We identified eight RCTs that compared SSIs after abdominal surgery with or without subcutaneous drains. Although the rate of total SSIs was significantly lower in the drained group than in the control group, no significant differences were observed in superficial or deep/organ SSIs because of statistical power. According to the surgical site, drains effectively prevented SSIs in gastrointestinal surgery. No significant differences were observed in SSIs among the drain types examined. We also showed that seroma formation did not significantly differ between the drained and control groups. On the other hand, subcutaneous drains effectively reduced hospital stays.

#### Research conclusions

This review supports the use of subcutaneous drains to prevent SSIs and shorten the length of hospital stays after abdominal surgery. On the other hand, subcutaneous drains may not prevent seroma formation.

#### Research perspectives

Impact of subcutaneous drains for pain control, cosmetic evaluations, medical cost, and the quality of life of patients need to be clarified.

#### **FOOTNOTES**

Author contributions: Ishinuki T conducted the acquisition of data, abstract evaluation, full-text evaluation, interpretation of data, result discussion, and drafting the article; Shinkawa H conducted the acquisition of data, interpretation of data, and drafting the article; Kouzu K conducted the acquisition of data, abstract evaluation, and result discussion; Shinji S conducted the acquisition of data bias evaluation; Goda E conducted the full-text evaluation and graphic design; Ohyanagi T conducted statistical analyses and graphic design; Kobayashi Ma conducted the acquisition of data and bias evaluation; Kobayashi Mo conducted the abstract evaluation and bias evaluation; Suzuki K conducted the abstract evaluation and interpretation of data; Kitagawa Y conducted the full-text evaluation and bias evaluation; Yamashita C conducted the abstract evaluation and bias evaluation; Mohri Y conducted the full-text evaluation and bias evaluation; Shimizu J conducted the abstract evaluation and bias evaluation; Uchino M conducted the full-text evaluation and graphic design; Haji S conducted the full-text evaluation; Yoshida M conducted the interpretation of data and statistical analyses; Ohge H conducted result discussion; Mayumi T conducted a design of the review and result discussion; Mizuguchi T conducted conception of the review and result discussion.

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