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SSAT QUICK SHOT PRESENTATION

Sugarbaker Versus Keyhole Repair for Parastomal Hernia: a Systematic Review and Meta-analysis of Comparative Studies

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Abstract

Introduction Parastomal hernia is a debilitating complication of stoma creation. Parastomal hernia repair with mesh reduces recurrence rates in open and laparoscopic settings. Recent comparative studies conflict with previously pooled data on optimal mesh repair technique. The objective of this study is to examine parastomal hernia recurrence rates after Sugarbaker and keyhole repairs by performing an updated systematic review and meta-analysis of comparative studies.

Methods A systematic review of PubMed, MEDLINE, EMBASE, the Cochrane database, SCOPUS, and the PROSPERO registry was performed according to PRISMA 2020 guidelines (PROSPERO ID: CRD42021290483). Studies comparing parastomal hernia recurrences after Sugarbaker and keyhole repairs were included. Studies with overlapping patient cohorts (duplicate data), non-comparative studies, studies that did not report the primary outcome of interest, and studies not in the English language were excluded. Study bias was assessed using the Newcastle–Ottawa scale. Pooled mean differences (MD), odds ratios (OR), and risk ratios (RR) with 95% confidence intervals (CI) were calculated. Heterogeneity was assessed using the I^2 statistic. Forest plots and funnel plots were generated. Study quality was analyzed using MINORS. Additional subgroup analysis of modern studies was performed.

Results Ten comparative studies published between 2005 and 2021 from 5 countries were included for analysis comprising 347 Sugarbaker repairs and 246 keyhole repairs. There were no differences in patient age, sex, or BMI between the groups. There was no difference between the groups regarding surgical site infection (OR 0.78; CI 0.31–1.98; $P=0.61$) or postoperative bowel obstruction (OR 0.76; CI 0.23–2.56; $P=0.66$). Sugarbaker repairs were significantly less often associated with parastomal hernia recurrence when compared to keyhole repairs (OR 0.38; CI 0.18–0.78; $P=0.008$). There was no significant heterogeneity among the studies comparing parastomal hernia recurrence ($I^2=32\%$; $P=0.15$). Quality analysis revealed a median MINORS score of 11 (range 6–16). Subgroup analysis of studies performed after the previously published pooled analysis (2015–2021) revealed no significant difference in parastomal hernia recurrence between the two groups (OR 0.58; CI 0.24–1.38; $P=0.22$) with a significant subgroup effect ($P=0.05$).

Conclusions Though there were lower rates of parastomal hernia recurrence with Sugarbaker repairs on overall analysis, this phenomenon disappeared on subgroup analysis of modern studies. Randomized controlled trials with contemporary cohorts would help further evaluate these repairs and minimize potential bias.

Keywords Hernia · Herniorrhaphy · Ostomy

Introduction

The creation of a diverting stoma for any reason is accompanied by substantial risk of parastomal hernia (PSH) which is subsequently associated with significant patient morbidity and distress.[1,2] Diabetes, elevated BMI, and emergent stoma creation have been identified as risk factors significantly associated with the development of PSH.[3] Outcomes of PSH repair remain poor, and these procedures are often accompanied by complications.[4] However, PSH repair with mesh has been shown to improve recurrence rates in both open and laparoscopic settings.[2,5,6] The Sugarbaker (SB) repair involves the placement of an underlay mesh over the lateralized bowel, thus avoiding exposure of a prosthetic material

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to enteric contents[7,8] . The keyhole (KH) repair utilizes a slit in the mesh to allow maneuverability circumferentially around the stoma.[9,10] Both approaches have modifications for laparoscopy.

Concerns regarding PSH recurrence rates and late mesh-related morbidity prompted numerous single cohort studies and comparative analyses.[8,11–24] A 2015 meta-analysis concluded that KH repair has a significantly higher rate of recurrence.[25] However, more recent studies have conflicted these pooled data, and the majority of the previously included studies were non-comparative cohorts or, when comparative, provided only limited demographic data to assess comparability of the treatment groups.[26–28]

In the context of new and conflicting data regarding PSH recurrence rates associated with SB and KH repairs, and by utilizing the Population, Intervention, Comparison, Outcome (PICO) framework,[29] this study aims to perform an updated systematic review and meta-analysis of comparative studies to answer the following question: In patients with parastomal hernias, is the SB repair more effective than the KH repair in preventing PSH recurrence?

Materials and Methods

Institutional Review Board Approval and Prospective Registration

The UTHSC institutional review board (IRB) determined this study to be Not Human Subjects Research (NHSR) status (IRB number: 21–08472-NHSR). This study was registered through the International Prospective Register of Systematic Reviews (PROSPERO ID: CRD42021290483).

Eligibility Criteria

Studies were included for analysis if they were comparative studies or randomized controlled trials (RCTs) examining PSH recurrence after SB or KH techniques for PSH repair. Studies were excluded from consideration if they were non-comparative studies (including case reports and case series), if they did not report rates of parastomal hernia recurrence for both SB and KH repairs, if there was overlap between patient cohorts in other included studies (duplicate data), or if the studies were not available in the English language.

Information Sources

This systematic review comprised a comprehensive online search of PubMed, MEDLINE, EMBASE, the Cochrane database, and SCOPUS for all published articles reporting the surgical outcomes of parastomal hernia repairs in the English language. The PROSPERO international prospective register of systematic reviews was also queried for published or ongoing reviews of similar scope.

Search Strategy

The search was performed by two authors (AMF and ALP) independently and in a blinded manner. The text words "parastomal hernia repair" were utilized alone and in combination with the text words "Sugarbaker," "keyhole," and "laparoscopic repair" and the Medical Subjects Headings (MeSH) terms "Herniorrhaphy" and "laparoscopy" utilizing the Boolean logic term "OR." Additional search terms including the text words "Mesh" and "Complications" and the MeSH terms "Reoperation," "Recurrence," and "Morbidity" were added alone and in combination to the original search utilizing the Boolean logic term "AND" to augment the search results. The search was refined further by toggling the "comparative studies" and "randomized controlled trials" filter options. All citations and abstracts identified were thoroughly reviewed, and the search was further expanded utilizing the "related articles" function during review of each relevant study. Additional eligible literature was identified during a screen of the bibliographies of the retrieved papers. A complete list of text words and MeSH terms can be found in the prospectively registered search strategy document on PROSPERO (https://www.crd.york.ac.uk/PROSPEROFILES/290483_STRATEGY_20211109.pdf).

Selection Process

Abstracts and full texts of selected studies were reviewed in detail by three independent reviewers (AMF, ALP, and EHW) to determine if they met inclusion criteria. Disagreements between two reviewers were resolved by consensus or by the decision of the third independent reviewer.

Data Collection Process

After the selection process, two reviewers (AMF and ALP) abstracted data regarding the primary and secondary outcomes of interest in each of the included studies (PSH recurrence, SSI, bleeding, bowel obstruction, perioperative mortality, MI, PE, pneumonia, UTI). Study characteristics were abstracted into the standardized data collection spreadsheet (first author, year of publication, location of study institutions, journal of publication, study design). Important population characteristics were also abstracted from the included studies including total number of patients, number of patients in each cohort, demographics of patients in each cohort, and details of PSH repair techniques. A quality assessment of non-randomized studies was performed utilizing the methodological index for non-randomized studies (MINORS) scoring criteria.[30]

Data Items

Primary outcomes of interest included the following:

- PSH recurrence after modified SB repair
- PSH recurrence after KH repair

Secondary outcomes of interest included the following:

- Surgical complications
  - Surgical site infections (SSI)
  - Bleeding
  - Bowel obstruction
  - Perioperative mortality
- Medical complications
  - Myocardial infarction (MI)
  - Pulmonary embolus (PE)
  - Pneumonia
  - Urinary tract infections (UTI)

Any results that were compatible with an outcome of interest were sought in each study if they occurred at time points relevant to the patient's PSH repair. Variables examined as potential sources of heterogeneity warranting evaluation included stoma type (colostomy, ileostomy, ileal conduit), stoma indication (trauma, benign disease, cancer), surgical approach (open laparotomy, laparoscopic), other patient factors (nutritional status, steroid usage), and mesh types (synthetic, biologic).

Study Risk of Bias Assessment

The Newcastle–Ottawa scale (NOS) was utilized to assess the risk of bias.[31]

Certainty of Evidence

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework was implemented to assess confidence in the body of evidence for all pooled analyses.[32]

Effect Measures

Patient characteristics (number, age, sex) were analyzed using descriptive statistics where applicable. If indicated, conversion of variables from median and range to mean and standard deviation was performed according to the method by Hozo et al.[33] Conversion of standard error of the mean to standard deviation was performed by multiplying the standard error by the square root of the sample size ($SD = SE \times \sqrt{N}$).[34] P values of ≤ 0.05 (two-tailed) were used to denote statistical significance. Dichotomous variables (PSH recurrence, SSI, bowel obstruction, mortality) were analyzed by calculating odds ratios (OR) and risk ratios (RR) with corresponding 95% confidence intervals (CI) as summary statistics. Continuous variables were analyzed by calculating pooled mean differences (MD) with 95% CI.

Synthesis Methods

The Review Manager (RevMan) 5.4 software (www.cochrane.org) was used to perform all pooled statistical analyses. Studies were determined to be eligible for synthesis for a particular outcome if they included data regarding that outcome for both interventions (SB and KH) at timepoints relevant to the PSH repair. Study characteristics, patient characteristics, details of surgery, and rates of PSH recurrence were tabulated for reference, and forest plots were generated to visually display results of individual studies and syntheses.

Random-effects model-based meta-analyses were performed for all outcomes of interest with available data.[35] The I^2 index was used to quantify heterogeneity by estimating the percentage of variability across studies not due to chance.[36] Studies were determined to have significant heterogeneity if they had an I^2 of $> 50\%$ or if the associated P value was < 0.1[37] . Subgroup analyses were performed to help determine potential causes of heterogeneity.[36,37] Sensitivity analyses were performed by repeating the meta-analysis of the primary outcome of interest after excluding studies that included mixed cohorts of open and laparoscopic,[27,28] and studies including urinary conduits.[13,19,26,38]

Reporting Bias Assessment

Reporting bias was assessed for the primary outcomes of interest by generating funnel plots with pseudo 95% confidence limits and assessing for symmetry.[34,39,40]

Results

Study Selection

Only 4 of the 15 studies included in the previous meta-analysis by DeAsis et al. met inclusion criteria for this updated review, as the remainder did not report comparative data regarding SB and KH repairs.[13,17,19,20,25] The results of our updated search protocol are depicted in Fig. 1. Our review initially yielded 1789 articles. Of these, 1264 articles were excluded prior to screening as duplicates or due to not being comparative studies. A total of 525 articles were reviewed in more detail. Of these, 516 were excluded, as they were

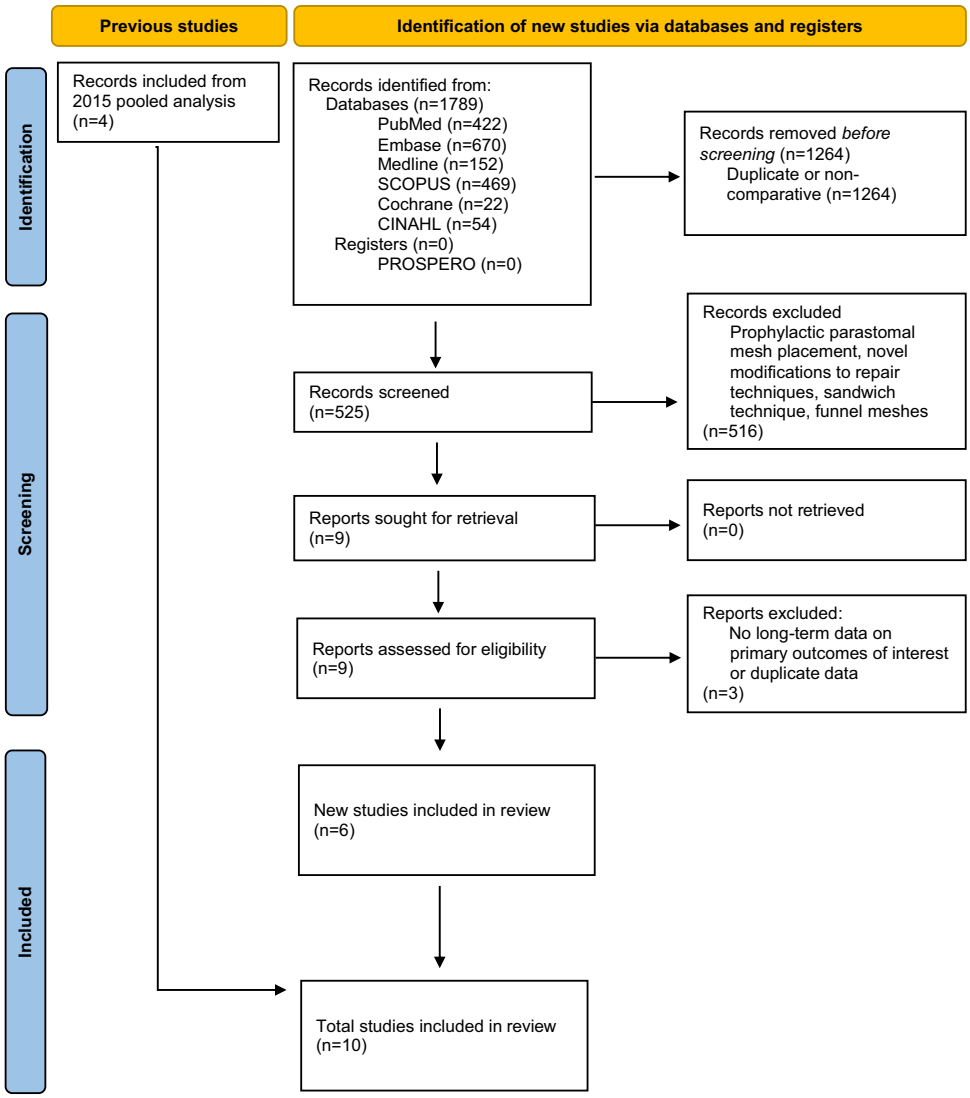

Fig. 1 Study flow diagram

off topic (examining prophylactic parastomal mesh placement, examining incisional hernias), contained significant modifications of the repair techniques, utilized other repair techniques (sandwich repair, top hat repair), or employed funnel meshes for repair. Out of the remaining studies, one was excluded due to lack long-term follow-up data regarding parastomal hernia recurrences,[16] while another was excluded for overlapping authors and institutions (duplicate data).[23] Ten articles ultimately met inclusion criteria and were incorporated into the final analysis.[13,17,19,20,26–28,38,41,42]

Study Characteristics

Characteristics of the 10 included studies are depicted in Table 1. The final analysis reviewed a total of 593 patients from Austria, Denmark, Finland, France, and the USA. A total of 347 patients underwent SB repairs while 246 underwent KH repairs. Age was heterogeneously reported, with 4 studies including information about age for both groups.[26–28,42] There was no significant difference in patient age between the two groups among these studies. Eight studies reported percentage female sex, with 4 studies including information regarding patient sex for both study groups.[26–28,42] Among these studies, there were no significant differences regarding percentage female sex between the two groups. Eight studies reported indications for ostomy creation, with all 8 of these studies including a mixed cohort of malignancy, inflammatory bowel disease, and other indications.[17,19,20,26–28,38,41] Among these studies, other indications included diverticulitis, GIST, Paget's disease, radiation proctitis, strangulated abdominal wall abscess, anal incontinence, and anismus. All 10 studies included colostomies and ileostomies, while 4 studies also included ileal conduits constructed for urinary diversion.[13,19,26,38] Eight studies exclusively examined

Table 1 Study characteristics, patient characteristics, and details of surgery among studies comparing parastomal hernia repair recurrence rates between Sugarbaker repairs and keyhole repairs. *SB*, Sugarbaker; *KH*, keyhole; *IBD*, inflammatory bowel disease; *CA*, cancer; *Lap*, laparoscopic; *Conduit*, ileal conduit for urinary diversion; *ePTFE*, expanded polytetrafluoroethylene; *PVDF*, polyvinylidene fluoride. Merged cells indicate when a value was reported for the overall study cohort and not for each repair type. The bold horizontal line indicates the timing of the previous pooled analysis in 2015. Where indicated, conversion of median and range to mean and standard deviation was performed via the method by Hozo et al.,[33] and conversion of standard error to standard deviation was performed by multiplying by the square root of the sample size.[34] *Other indications included diverticulitis, GIST, Paget's disease, radiation proctitis, strangulated abdominal wall abscess, and anismus

Year	Author	Country	Study design	Number of patients		Patient age in years, mean (SD)		Female sex, %		Indication for ostomy	Type of ostomy	Lap vs open repair	Mesh composition	Parastomal hernia recurrence (%)	
				SB	**KH**	**SB**	**KH**	**SB**	**KH**					**SB**	**KH**
2005	LeBlanc[13]	United States	Prospective	5	7	Range: 42–89		Not reported		Not reported	Colostomy, ileostomy, conduit	Lap	ePTFE	0%	14%
2008	Muysoms[17]	France	Retrospective	13	11	70 (14.5)		45.8%		IBD, CA, other*	Colostomy, ileostomy	Lap	Composite, ePTFE	15%	73%
2008	Craft[19]	United States	Retrospective	16	5	66 (11.5)		Not reported		IBD, CA, other*	Colostomy, ileostomy, conduit	Lap	ePTFE	0%	20%
2009	Pastor[20]	United States	Retrospective	7	3	56.25 (16.0)		58.3%		IBD, CA, other*	Colostomy, ileostomy	Lap	ePTFE	29%	67%
2013	Helgstrand[41]	Denmark	Prospective	56	57	65 (10.5)		51.7%		IBD, CA, other*	Colostomy, ileostomy	Lap	Not reported	0%	5%
2015	DeAsis[42]	United States	Prospective	25	18	62.4 (11.2)	66.2 (11.6)	52%	38.9%	Not reported	Colostomy, ileostomy	Lap	ePTFE	16%	61%
2015	Kohler[38]	Austria	Retrospective	4	22	68.4 (26.1)		45.9%		CA, other*	Colostomy, ileostomy, conduit	Lap	Composite	50%	45%
2018	Oma[28]	Denmark	Retrospective	69	10	70.9 (16.2)	61.4 (10.5)	45%	60%	IBD, CA, other*	Colostomy, ileostomy	Lap, open	Composite	9%	10%
2020	Gameza[26]	Denmark	Prospective	61	74	63 (16)	62 (8.3)	56%	50%	IBD, CA, other*	Colostomy, ileostomy, conduit	Lap	Composite, ePTFE	10%	7%
2021	Mäkäräinen-Uhlbäck[27]	Finland	Retrospective	91	39	68.4 (10.6)	67.1 (9.9)	53.8%	56.7%	IBD, CA, other*	Colostomy, ileostomy	Lap, open	Polypropylene, polyester, PVDF	22%	36%

laparoscopic PSH repairs,[13,17,19,20,25,26,38,41] while 2 studies examined both laparoscopic and open repairs.[27,28]

Diagnostic criteria for PSH recurrence differed slightly among studies but tended to include a combination of findings on physical examination and/or imaging studies.[16,17,23,26–28,38,41,42] There were no data regarding specific findings on computerized tomography utilized to define PSH, such as diameter of fascial defect, contents of hernia, or patient symptomology.

Time to PSH recurrence was captured by a minority of the included studies which varied in their conclusions.[26,27,42] DeAsis et al. utilized a formal time-to-event analysis and demonstrated a significantly higher recurrence-free probability in the SB repair group,[42] whereas Mäkäräinen-Uhlbäck et al. demonstrated no significant difference in time to recurrence among the repair types. Gameza et al. reported time to PSH recurrence ranging from 1 to 84 months for KH repairs and 6 to 65 months for SB repairs.[26]

Six studies commented on rates of repair of recurrent PSH.[23,26,28,38,41,42] Only 1 study (Asif et al.) reported a significant difference between the groups regarding rates of recurrent PSH repairs. (64% SB vs 37% KH).[23]

Risk of Bias in Studies

Individual risk of bias assessments revealed a median NOS score of 4 (range 3–6). One study was noted to have very high risk of bias (scores 0–3), while all other studies were noted to have high risk of bias (scores 4–6). Common sources of bias risk included selection bias given the lack of randomization and lack of allocation concealment, and lack of comparability between the groups (not controlling for BMI, diabetes, or emergent nature of stoma creation).

Results of Synthesis

All 10 of the included studies reported data regarding PSH recurrence.[13,17,19,20,26–28,38,41,42] PSH recurrence rates for each individual study are displayed in Table 1. SB repairs were significantly less often associated with PSH recurrence when compared to KH repairs (OR 0.38; CI 0.18–0.78; $P=0.008$) (Fig. 2). There was no significant heterogeneity among the studies when examining PSH recurrence ($I^2=32\%$; $P=0.15$). A funnel plot generated for our primary outcome of interest revealed no significant asymmetry concerning for publication bias (Fig. 3). Only 1 study fell outside of the pseudo 95% confidence interval lines.

Sensitivity analysis revealed no difference in the results of the meta-analysis of the primary outcome of interest after exclusion of studies reporting mixed cohorts of laparoscopic and open repairs (OR 0.29; CI 0.10–0.82; $P=0.02$) versus including them (OR 0.38; CI 0.18–0.78; $P=0.008$).[27,28] Additional sensitivity analysis revealed no difference in the results of the meta-analysis of the primary outcome of interest after exclusion of studies that analyzed PSH with urinary conduits (OR 0.26; CI0.12–0.58; $P=0.0009$) versus including them (OR 0.38; CI 0.18–0.78; $P=0.008$).[13,19,26,38]

Four studies reported comparative data on surgical site infections (SSI), including superficial incision SSI, peristomal abscesses, and mesh infections.[26–28,42] Meta-analysis of these studies revealed no difference in overall rate of SSI between those who underwent SB repairs and those who underwent KH (OR 0.78; CI 0.31–1.98; $P=0.61$) (Fig. 4). There was no significant heterogeneity among the studies comparing rates of SSI ($I^2=0\%$; $P=0.69$).

Five studies included data regarding post-operative bowel obstruction.[26–28,38,42] There were no significant differences between SB and KH repairs regarding rates of post-operative bowel obstruction (OR 0.76; CI 0.23–2.56; $P=0.66$) (Fig. 5). There was no significant heterogeneity among the studies comparing rates of bowel obstruction ($I^2=0\%$; $P=0.52$).

Comparative data regarding other post-operative complications were few. Three studies reported data for both groups regarding post-operative bleeding, without any significant differences.[26,27,42]

Individual data regarding medical complications were similarly sparse, and none showed significant differences between the SB and KH repair groups. One study reported a single MI in the keyhole repair group (1.35%) versus none in the SB group (0.0%).[26] One study reported a single PE in the KH repair group (1.4%),[26] while another study reported 3 thromboembolic events in the SB group (4.4%)[27] Two studies reported rates of post-operative pneumonia with no significant differences.[26,28] Three studies discussed rates of UTI, and none was significantly different between the groups.[26,27,42]

Perioperative mortality rarely occurred and was not commonly reported. Köhler et al. found that emergent repair was associated with a mortality rate of 28.6%, while there were no mortalities in the elective group.[38]

Study Quality Analysis

Study quality analysis revealed a median MINORS score of 11 (range 6–16) among the included studies.[30]

Subgroup Analyses

Subgroup analysis performed by era (before and after the previous pooled analysis in 2015) revealed that among studies performed after the previous pooled analysis, there was no significant difference between SB and KH repairs regarding rates of PSH recurrence (OR 0.58; CI 0.24–1.38;

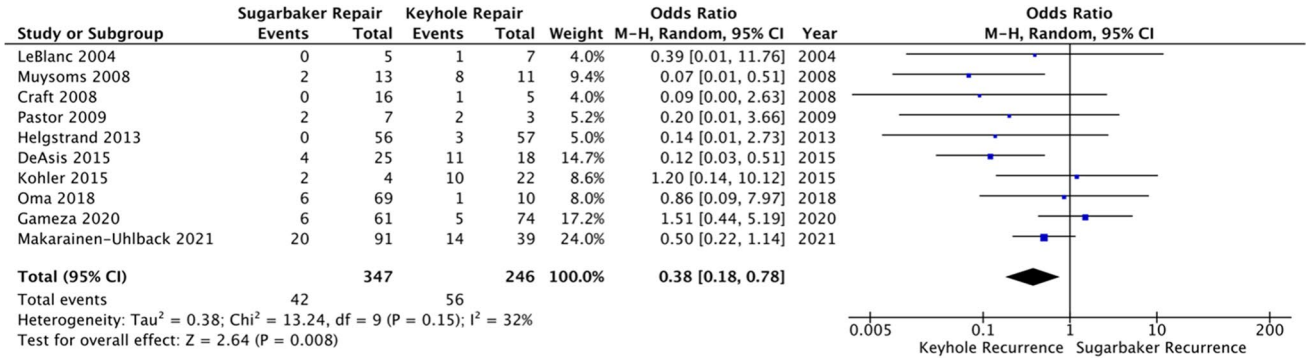

Fig. 2 Forest plot of studies comparing rates of parastomal hernia recurrence associated with keyhole repairs and modified Sugarbaker repairs. Meta-analysis revealed significantly more parastomal hernia recurrences among the keyhole repair group than the Sugarbaker repair group

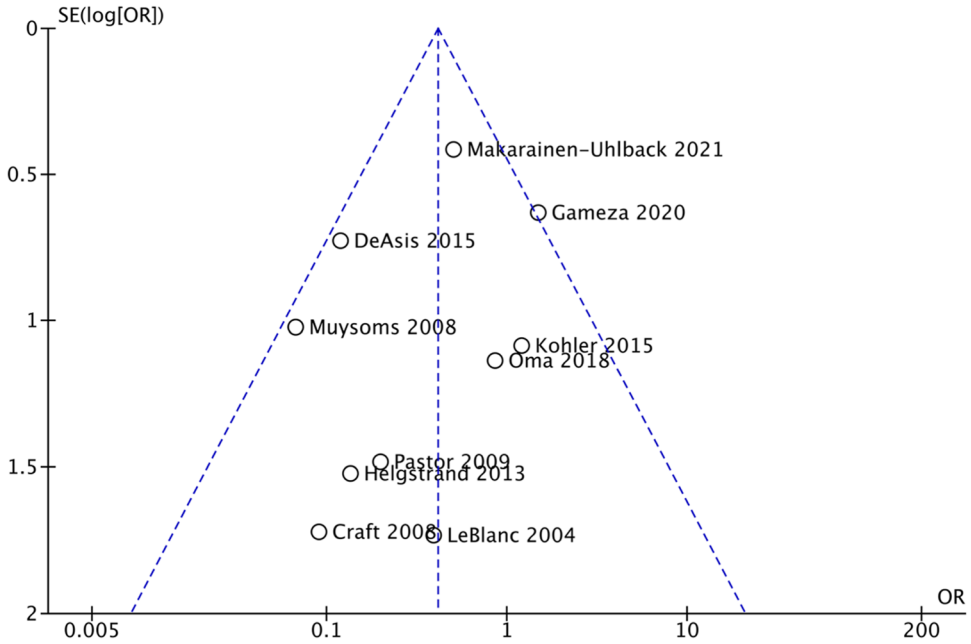

Fig. 3 Funnel plot of studies comparing rates of parastomal hernia recurrence associated with keyhole repairs and modified Sugarbaker repairs. The symmetry of the funnel plot did not indicate significant publication bias among the studies. SE, standard error; OR, odds ratio

$P = 0.22$) with no significant heterogeneity among these studies ($I^2 = 47\%$; $P = 0.11$) (Fig. 6). There was significant subgroup effect between the subgroups on the test for subgroup differences ($P = 0.05$), and there was significant heterogeneity between the subgroups ($I^2 = 75\%$) (Fig. 6). There was equal covariate distribution between the subgroups analyzed ($n = 5$ in each subgroup).

Six studies exclusively employed a single mesh type throughout the duration of their study, allowing for analysis of hernia recurrence with relation to mesh type. Studies that employed multiple types of meshes throughout the study period or did not report mesh type were excluded from this subgroup analysis. Four studies exclusively utilized expanded polytetrafluoroethylene (ePTFE) meshes,[13,19,20,42] and two exclusively used composite antiadhesive polyester meshes.[28,38] When ePTFE was employed, SB repairs were significantly less often associated with PSH recurrence (OR 0.14; CI 0.05–0.45; $P = 0.0008$) (Fig. 7). When composite antiadhesive polyester meshes were utilized, there was no significant difference in PSH recurrence between the groups (OR 1.02; CI 0.22–4.77; $P = 0.98$). There was no significant heterogeneity among the studies within either subgroup (ePTFE $I^2 = 0\%$; $P = 0.92$; composite $I^2 = 0\%$; $P = 0.83$). There was a significant subgroup effect ($P = 0.04$). There was not equal covariate distribution between the subgroups analyzed ($n = 4$ ePTFE, $n = 2$ composite).

Certainty of Evidence

Using the GRADE framework, we evaluated the certainty of evidence for our pooled analyses, including parastomal hernia recurrence, surgical site infection, and bowel obstruction after SB and KH repairs (Table 2). This

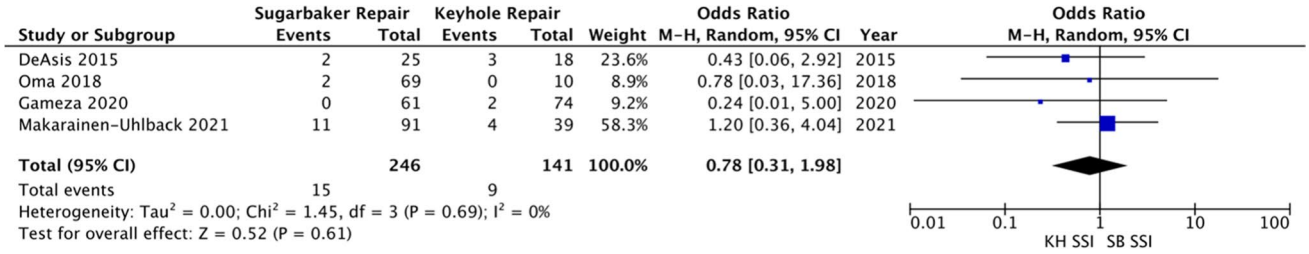

Fig. 4 Forest plot of studies comparing rates of surgical site infections associated with keyhole repairs and modified Sugarbaker repairs. Meta-analysis revealed no significant difference in rates of SSI between the two groups and no significant heterogeneity among the studies reporting this outcome. SB, Sugarbaker; KH, keyhole; SSI, surgical site infection; M-H, Mantel–Haenszel; CI, confidence interval

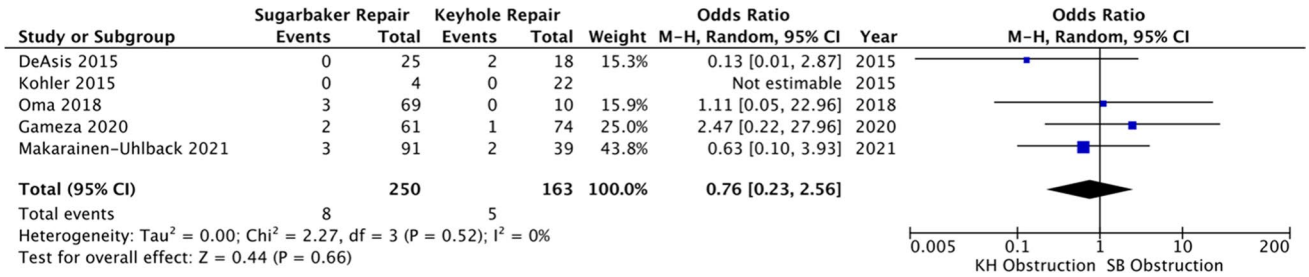

Fig. 5 Forest plot of studies comparing rates of post-operative bowel obstruction associated with keyhole repairs and modified Sugarbaker repairs. Meta-analysis revealed no significant difference in rates of bowel obstruction between the two groups and no significant heterogeneity among the studies reporting this outcome. SB, Sugarbaker; KH, keyhole; M-H, Mantel–Haenszel; CI, confidence interval

revealed moderate certainty in evidence supporting that SB repair results in a large reduction in parastomal hernia recurrence. There was very low certainty in evidence evaluating surgical site infections and bowel obstructions between the two groups.

Discussion

The management of PSH continues to challenge surgeons. Overall, our analysis revealed that PSH recurrence was significantly less in patients undergoing SB repair compared to KH repair with similar complication profiles. This was found to have evidence of moderate certainty and is congruent with previously published pooled analyses by DeAsis et al.[25] However, there are several important considerations when interpreting these data.

First, there is significant risk of selection bias in every study included in this analysis, as no studies were randomized and few studies controlled for factors associated with increased risk of developing PSH, such as diabetes, increased BMI, and emergent stoma creation.[3] Prospective, randomized trials will be critical to adequately account for these factors. Fortunately, one such clinical trial is now registered and is recruiting patients at the Cleveland Clinic (ClinicalTrials.gov Identifier: NCT03972553). The results of this trial will prove invaluable in the study of parastomal hernia repair.

Another variable worth considering is mesh composition, as this was not consistent across studies. Four studies exclusively utilized ePTFE, while others used composite antiadhesive polyester mesh, polypropylene mesh, or polyvinylidene fluoride (PVDF) mesh. Our subgroup analysis revealed that SB repairs had lower rates of recurrence in the ePTFE group but not in the group employing composite antiadhesive meshes. While the number of studies was small when examining this outcome, this emphasizes the importance of maintaining a consistent mesh type throughout the study period when assessing hernia outcomes, especially given previous analyses regarding mesh shrinkage (and its potential effects on mesh keyhole enlargement) as well as mesh erosion.[43,44] Further recommendations regarding mesh would be best informed by prospective analyses to limit the effects of confounding variables.

Only two studies out of 10 examined both laparoscopic and open approaches for SB and KH repairs,[27,28] so there was not adequate covariate distribution for a pooled analysis examining laparoscopic versus open technique. Laparoscopic versus open PSH repairs have been previously examined in retrospective analyses with variable

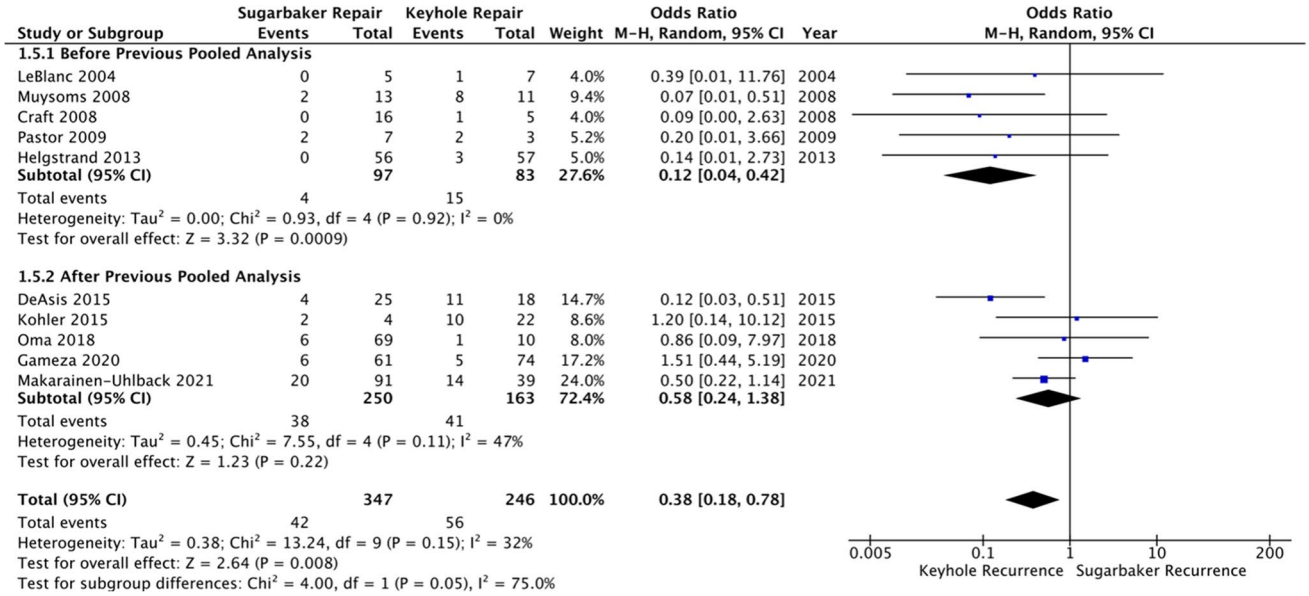

Fig. 6 Forest plot of subgroup analysis of studies comparing rates of parastomal hernia recurrence associated with keyhole repairs and modified Sugarbaker repairs stratified by era (before and after the previous pooled analysis in 2015). The modern study group revealed no significant difference between the two repair groups regarding PSH recurrence. The test for subgroup differences revealed a significant subgroup effect. While there was no significant heterogeneity among the trials in each subgroup, there was significant heterogeneity between the subgroups. SB, Sugarbaker; KH, keyhole; M-H, Mantel–Haenszel; CI, confidence interval

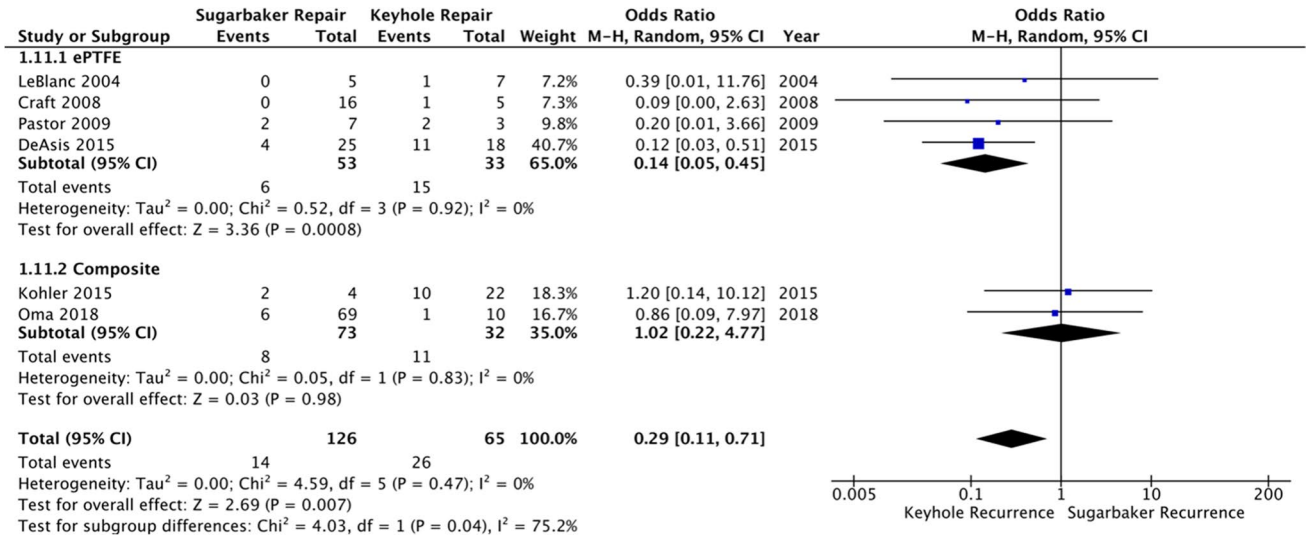

Fig. 7 Forest plot of subgroup analysis of studies comparing rates of parastomal hernia recurrence associated with keyhole repairs and modified Sugarbaker repairs stratified by mesh type. The ePTFE subgroup revealed fewer recurrences in those undergoing Sugarbaker repairs, while the composite mesh group revealed no significant difference. M-H, Mantel–Haenszel; CI, confidence interval

conclusions.[23,45,46] Keller et al. utilized a time-to-event analysis which did reveal increased repair longevity in a cohort of laparoscopic SB repairs.[45] The open repairs performed by Asif et al. were not captured in our analysis as they were open primary repairs.[23] Oma et al. reported that the open approach was utilized when laparoscopic surgery was not feasible, or when a concomitant incisional hernia repair was planned, and that open mesh fixation was achieved via a similar procedure to their laparoscopic approach.[28] Additionally, there was not a significant difference between the rates of open approaches in the KH group (10%) versus the SB group (9%) in their dataset. However, they did not perform

Table 2 GRADE assessment of evidence

Sugarbaker repair compared to keyhole repair for parastomal hernia						
Patient or population: Parastomal hernia **Setting: Hospital** **Intervention:** Sugarbaker repair **Comparison:** Keyhole repair						
Outcomes	**Anticipated absolute effects*** (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with keyhole repair	**Risk with Sugarbaker repair**				
Parastomal hernia recurrence (PSHR) assessed with: physical exam / imaging	219 per 1000	**103 per 1000** (65 to 158)	**OR 0.41** (0.25 to 0.67)	603 (10 observational studies)	⨁⨁⨁◯ Moderate	Sugarbaker repair probably results in a large reduction in parastomal hernia recurrence
Surgical site infection (SSI) assessed with: physical exam / cultures	64 per 1000	**50 per 1000** (21 to 119)	**OR 0.78** (0.31 to 1.98)	387 (4 observational studies)	⨁◯◯◯ Very low	The evidence is very uncertain about the effect of Sugarbaker repair on surgical site infection
Post-operative bowel obstruction (obstruction) assessed with: physical exam / imaging	31 per 1000	**23 per 1000** (7 to 75)	**OR 0.76** (0.23 to 2.56)	413 (5 observational studies)	⨁◯◯◯ Very low	The evidence is very uncertain about the effect of Sugarbaker repair on post-operative bowel obstruction

GRADE, Grading of Recommendations Assessment, Development and Evaluation; *CI*, confidence interval; *OR*, odds ratio

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI)

GRADE Working Group grades of evidence

High certainty: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate certainty: We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low certainty: Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect

Very low certainty: We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect

subgroup analysis examining open versus laparoscopic repairs.[28] Mäkäräinen-Uhlbäck et al. found a trend toward higher rates of recurrence in the laparoscopic KH and SB groups when compared to their open counterparts, while all enterocutaneous fistulae in their experience occurred after open repairs.[27]

Finally, the lower rates of PSH recurrence with SB repairs disappeared when analyzing comparative studies performed after the original meta-analysis in 2015. This subgroup analysis, which analyzed significantly more patients and provided more robust analyses of patient characteristics, ultimately revealed no significant difference regarding PSH recurrence. Whether this phenomenon is due to improved KH surgical technique over time, changes in mesh selection, or more rigorous experimental design is difficult to determine from the current data. Additionally, the majority of the studies that were published after the original meta-analysis were conducted in Europe, and patient characteristics may be different compared to the patients who underwent PSH repair in the earlier studies conducted in the USA. Overall, the results of any subgroup analyses should be interpreted with caution, as all subgroup analyses are observational in nature and are subject to the same limitations of any observational investigation.[34,47]

While our analysis is consistent with that of DeAsis et al.,[25] more needs to be known about the characteristics of the patients and their hernias prior to determining a method of repair. For example, there may be a benefit in repairing a PSH before it becomes symptomatic, and there may be a size of hernia where a particular type of repair is more beneficial. One limitation of this analysis is that we lack knowledge regarding the surgical techniques employed, which could contribute to the risk of PSH, such as the size and morphology of the fascial opening, the creation of a rosette stoma versus a flush stoma, or whether subcutaneous fat was cored out of the abdominal wall. Another point of consideration

is regarding the definition of parastomal hernia recurrence, which remained ambiguously defined in most studies. A more rigorous set of diagnostic criteria including objective radiographic findings or patient symptomatology would help clarify this point in future prospective, randomized trials to eliminate current biases. Finally, due to the variable length of follow-up in the included studies, it is possible that PSH recurrence after either type of repair is higher than currently reported. Additional studies are needed to determine what would be an acceptable recurrence-free period after repair.

Conclusions

PSH causes significant patient distress, and multiple approaches have been described in the literature with variable success. SB repairs, whether performed with an open or minimally invasive approach, have previously been reported to have lower recurrence rates for the repair of PSH. However, the results of our subgroup analysis of more modern studies call this conclusion into question. The results of the ongoing randomized controlled trial will help address concerns regarding experimental design with patient randomization, contemporary patient cohorts, and consistent mesh composition.

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Declarations

Conflict of Interest The authors declare no competing interests.

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