



Incidence, risk factors and prevention of stoma site incisional hernias: a systematic review and meta-analysis

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Received 8 May 2018; accepted 16 July 2018; Accepted Article Online 9 August 2018

Abstract

Aim Stoma reversal might lead to a stoma site incisional hernia. Recently, prophylactic mesh reinforcement of the stoma site has gained increased attention, supporting the need for accurate data on the incidence of and risk factors for stoma site incisional hernia and to identify high-risk patients. The aim of this study was to assess incidence, risk factors and prevention of stoma site incisional hernias.

Method Embase, MEDLINE, Web of Science, Cochrane and Google Scholar databases were searched. Studies reporting the incidence of stoma site incisional hernia after stoma reversal were included. Study quality was assessed with the Newcastle–Ottawa Scale and Cochrane risk of bias tool. Data on incidence, risk factors and prophylactic mesh reinforcement were extracted.

Results Of 1440 articles found, 33 studies comprising 4679 reversals were included. The overall incidence of incisional hernia was 6.5% [range 0%–38%, median follow-up 27.5 (17.54–36) months]. Eleven studies

assessed stoma site incisional hernia as the primary endpoint, showing an incidence of 17.7% [range 1.7%–36.1%, median follow-up 28 (15.25–51.70) months]. Body mass index, diabetes and surgery for malignant disease were found to be independent risk factors, as derived from eight studies. Two retrospective comparative cohort studies showed significantly lower rates of stoma site incisional hernia with prophylactic mesh reinforcement compared with nonmesh controls [6.4% *vs* 36.1% ($P = 0.001$); 3% *vs* 19% ($P = 0.04$)].

Conclusion Stoma site incisional hernia should not be underestimated as a long-term problem. Body mass index, diabetes and malignancy seem to be potential risk factors. Currently, limited data are available on the outcomes of prophylactic mesh reinforcement to prevent stoma site incisional hernia.

Keywords Stoma site incisional hernias, incidence, risk factors, prevention

Introduction

Temporary stomas are frequently constructed to defunction a low colorectal anastomosis and during surgery for acute complicated diverticulitis, inflammatory bowel disease and traumatic intestinal injury [1–8]. Subsequent stoma reversal is associated with surgical site infection (SSI), anastomotic leakage, postoperative ileus and development of stoma site or midline incisional hernia (MIH) [9–13]. Stoma site incisional hernia

(SSIH) can cause pain, disfiguration, incarceration and strangulation [14,15].

Recent research has shown that prophylactic mesh reinforcement (PMR) in midline laparotomies in high-risk patients significantly decreases the incidence of MIH [16,17], and PMR at the stoma site during permanent stoma construction has been considered to reduce rates of parastomal hernia [18–21]. Considering the largely comparable pathophysiology, PMR during temporary ostomy takedown to prevent SSIH could also be beneficial by potentially obviating complications and re-operations, and has gained increased attention amongst surgeons [17]. Accurate data on incidence and risk factors for the development of SSIH are of importance to correctly assess the clinical value of PMR to prevent SSIH, to facilitate selection of high-risk patients and to aid clinical and shared decision-making [22].

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Therefore, the aims of this study were to systematically investigate the literature regarding the incidence of SSIH after stoma reversal, to evaluate potential risk factors for SSIH and to assess the effectiveness of PMR in preventing SSIH.

Method

The protocol of this study was registered in PROSPERO (CRD42016053347). This study was conducted following the MOOSE guidelines and PRISMA statement [23,24]. Furthermore, decisions on the content were based on items proposed by Wille-Jørgensen *et al.* [25].

Study design and participants

Randomized controlled trials (RCTs) and prospective or retrospective cohort or case-control studies providing data on the incidence of SSIH were included. Case reports, reviews, letters, abstracts or comments were excluded. Studies were included if they met the following criteria: (1) patients ≥ 16 years of age, (2) participants underwent stoma reversal via laparotomy, laparoscopy or local surgery, (3) study outcome included data on the occurrence of SSIH and (4) follow-up duration. Studies reporting on $> 10\%$ of patients with abdominal wall trauma; only reporting on duodeno-/gastro-/oesophago- or urostomies; and only including stoma revisions or re-siting were excluded.

Systematic literature search

A systematic search was performed by a biomedical information specialist. On 4 July 2017, the Embase, MEDLINE, Cochrane, Web of Science and Google Scholar databases were searched. Full search syntaxes and results per database are shown in Appendix S1 in the online Supporting Information. There was no limit on publication date. Identified articles were reviewed independently by two reviewers (GS and DL) after duplicates were removed on title and abstract, followed by full-text review using EndNote X7®. Differences in article selection were discussed and inclusion or exclusion was performed after consensus was reached between reviewers.

Data extraction

Data extraction was performed by two researchers (GS and DL) and checked by a third independent researcher (RB). Discrepancies were discussed amongst all three researchers, and decisions were made when consensus

was reached. In case of uncertainties on reported study results, corresponding authors were contacted if possible. Two researchers (GS and DL) independently assessed the quality of included studies by assessing level of evidence [26], Newcastle-Ottawa Scale (NOS) criteria (nonrandomized studies)[27] and risk of bias (RCTs) [28].

Primary and secondary outcomes

The following outcome variables were extracted: study characteristics (author, year, design, level of evidence, risk of bias, NOS, SSIH detection methods), baseline characteristics [number of patients, gender, age, body mass index (BMI), smoking status, chemotherapy, surgical type and approach, indication, follow-up duration], stoma characteristics [numbers constructed and closed, stoma type (loop colostomy (LC) or ileostomy (LI) and end colostomy (EC) or end ileostomy (EI)), time to closure, closure method and surgical site infection (SSI) after closure] and SSIH characteristics (number of SSIH, SSIH per stoma type and SSIH repairs). Median follow-up for reported cumulative SSI and SSIH rates was calculated based on available follow-up data.

Data synthesis

A Mantel-Haenszel random-effects model was used to calculate pooled odds ratios (ORs), while taking between-study variance and within-study variance into account. ORs with 95% CIs were calculated to assess outcome differences after ileostomy or colostomy reversal. Q statistics and I^2 were calculated to evaluate heterogeneity. All analyses were performed with RevMan 5.3 (Cochrane Centre, Denmark), except for the cumulative meta-analysis, which was performed using R (version 3.4.1.).

Results

Search

A PRISMA flow diagram of the full search results is shown in Fig. 1. After fulfilling the search, a total of 2458 articles were identified, of which 1440 remained after removal of duplicates. After screening on title and abstract and full-text reading, 33 articles were included for qualitative and quantitative analyses [3–8,29–55]. Four articles provided data on outcomes after PMR for prevention of SSIH [45,46,56,57], of which two had a nonmesh control group and could therefore be included in quantitative synthesis [45,46].

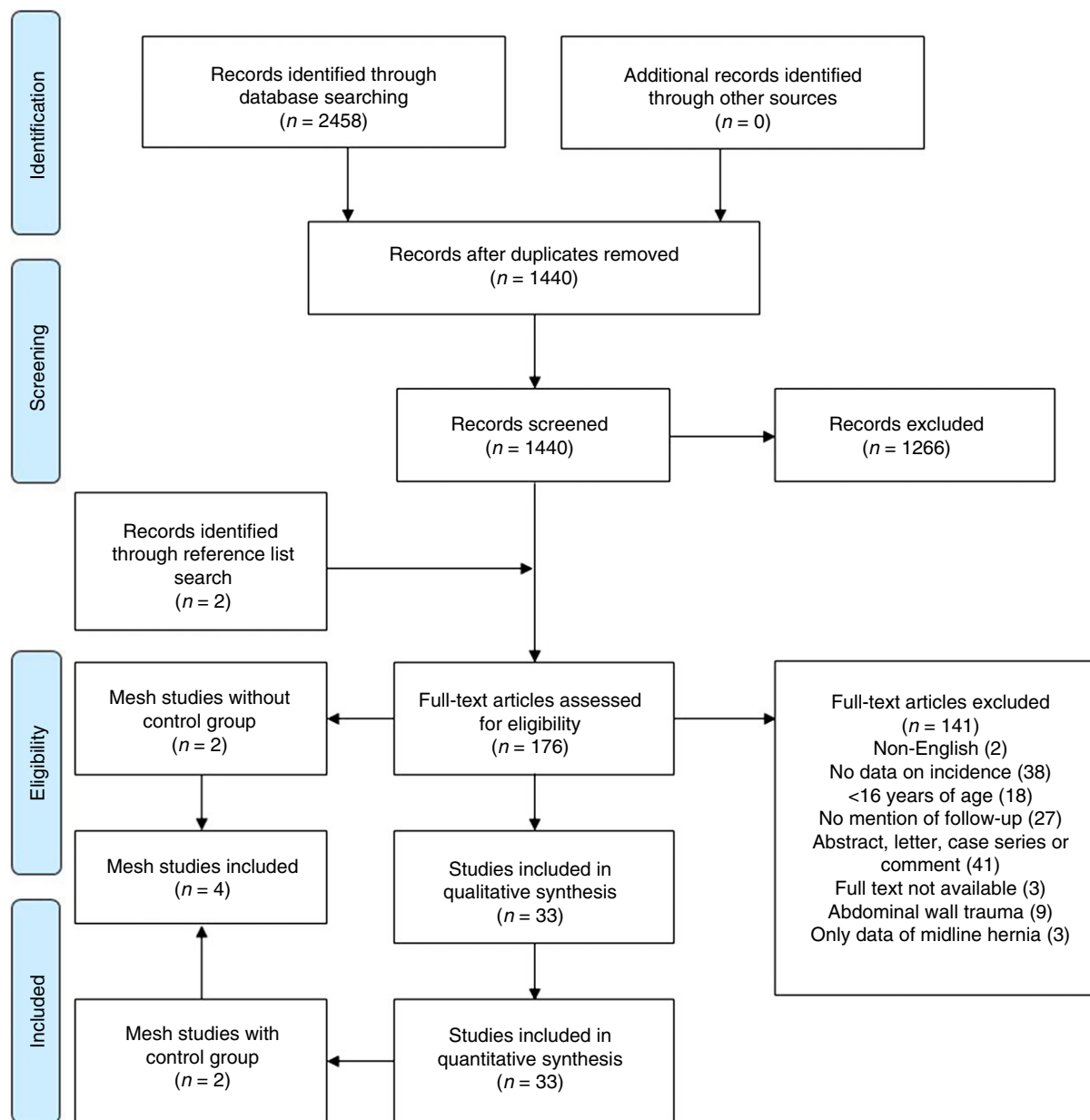


Figure 1 Preferred items for reporting of systematic reviews and meta-analyses (PRISMA) flow diagram.

Study characteristics

Study characteristics are shown in Table 1. Two articles were RCTs, 7 were prospective, 23 were retrospective cohort studies and 1 study was case-matched. A total of 6594 nonmesh and 77 mesh patients were available. The majority of studies (20/33) did not specify the SSIH detection method. Two studies specifically mentioned the use of clinical examination and 11 reported on imaging [ultrasound (US), CT or MRI].

Stoma characteristics

An overview of stoma characteristics is shown in Table 2. Overall, 5289 stomas were constructed, of which 4679 (88.5%) were closed. In three studies, the type of colostomy or ileostomy was not clearly described and was therefore reported as total number of colostomies or ileostomies. In all other studies, LI was the most investigated stoma type (28/30), followed by LC (8/30), EC (6/30) and EI (5/30).

Table 1 Study characteristics.

Author	Study details				Patients				
	Year	Design	LOE	NOS	Number	Male gender (%)	Age (years)	BMI (kg/m ²)	Smoking (%)
Bakx [29]	2004	R	2b	6	69	53.6	57 (28–83)	–	–
Bhangu [30]	2012	R	2b	6	59	76	62.7 (13.4)	–	–
Brook [5]	2016	R	2b	8	193	59.6	66 (20–92)	25 (16–44)	16
Cingi [31]	2008	P	2b	6	31	48.4	Hernia: 60.9 (11.0) No hernia: 68 (14.3)	Hernia: 30.1 (6.2) No hernia: 26.2 (4.9)	–
De Keersmaecker [32]	2016	R	2b	6	153	60.1	67.1 (11.6)	–	–
D'Haeninck [33]	2011	R	2b	6	197	54.8	56.2 (15.4)	23.8 (3.8)	–
Edwards [34]	2001	RCT*	1b	–	LC: 36 LI: 34	LC: 79.4 LI: 61.1	LC: 68 (32–90) LI: 63 (40–85)	–	–
El-Hussuna [35]	2012	R	2b	5	159	67.3	65 (39–88)	24 (16.4–35.9)	17.6
Fiscon [36]	2014	P	2b	6	20	75	65.4 (53.1–72.1)	25.8 (23.9–28)	–
Garcia-Botello [6]	2004	R	2b	6	127	57.5	54 (18.58)	–	–
Giannakopoulos [7]	2009	R	2b	5	119	57.1	55 (39–66)	24.4 (22.3–26.8)	–
Guzman-Valdivia [37]	2008	R	2b	6	70	59	61 (36–87)	36 (25–52)	–
Hasegawa [38]	2000	RCT*	1b	–	27	7.7	45.7 (23–76)	–	–
Holmgren [39]	2017	R	2b	8	316	56.7	67 (37–86)	–	–
Köhler [40]	2014	R	2b	6	14	57.1	66 (43–86)	26.7 (20.4–31.8)	–
Krand [41]	2008	P	2b	7	50	68	61 (23–78)	–	–
Lewis [42]	1990	P	2b	6	50	65	35 (17–71)	–	–
Li [43]	2017	R	2b	9	SSE: 139 NSSE: 599	SSE: 43.2 SSE: 57.8	SSE: 40.7 (13.4) NSSE: 42.8 (15.9)	SSE: 25.5 (5.6) NSSE: 25.9 (5.9)	–
Liang [44]	2013	R	2b	6	No SSI: 82	No SSI: 94	No SSI: 64 (9.3)	No SSI: 27 (6.3)	–
Liu [45]	2013	R	2b	9	SSI: 46 Mesh: 47 Control: 36	SSI: 95.6 Mesh: 63.8 Control: 58.3	SSI: 59 (10.9) Mesh: 69.6 (57.9–76.0) Control: 65.0 (57.8–70.5)	SSI: 31 (6.1) Mesh: 9 patients > 30 Control: 12 patients > 30	–
Luglio [8]	2011	P	2b	5	944	56.9	47.2 (16.8)	25.7 (5.2)	–
Maggiori [46]	2015	CM	3b	9	Mesh: 30 Control: 64	Mesh: 60 Control: 62	Mesh: 61 (13, 25–79) Control: 61 (13, 28–84)	Mesh: 26 (4, 19–36) Control: 25 (4, 18–38)	–
Mala [47]	2008	R	2b	6	72	56	65 (39–89)	–	–
Mishra [48]	2014	R	2b	6	Lap: 289 Open: 768	Lap: 50.2 Open: 59.4	Lap: 68.2 (23.3) Open: 68.5 (38.8)	–	–
Oriel [4]	2017	R	2b	6	114	Hernia: 100 No hernia: 96.1	–	Hernia: 29.9 (5.9) No hernia: 27.5 (4.9)	Hernia: 54.6 No hernia: 35.9
Rosen [49]	2005	R	2b	6	22	45.5	54 (33–73)	26 (19–34)	–
Rutegard [50]	1987	R	2b	6	56	LC: 57.1 LI: 51.6	LC: 72 (38–94) LI: 67 (26–89)	–	–
Saeed [51]	2012	P	2b	6	179	71.2	66 (29–79)	–	–
Saha [3]	2009	R	2b	6	325	53	59 (16–90)	–	–
Schreinemacher [52]	2011	P	2b	8	111	50.5	62 (18–84)	< 25 (40.5); 25–29.9 (39.6); > 30 (19.8)	–
Seo [53]	2013	R	2b	6	836	66.7	56 (11)	–	–
Vermeulen [54]	2009	R	2b	6	HP: 139 PA: 19	HP: 55.6 PA: 84	HP: 61 (23–85) PA: 63 (38–82)	–	–
Welten [55]	1991	R	2b	6	30	63.3	64.6 (56–84)	–	–

Continuous data are median (interquartile range), mean (standard deviation) or mean (standard deviation, range).

A, delayed closure group; B, early closure group; BMI, body mass index; C, clinical diagnosis; CM, case matched; CT, computed tomography diagnosis; d, days; HP, Hartmann's procedure; Lap, laparoscopic; LC, loop colostomy; LI, loop ileostomy; LOE, level of evidence; m, months; MRI, magnetic resonance imaging; NOS, Newcastle–Ottawa scale; NSSE, nonstoma site extraction; P, prospective; PA, primary anastomosis with diverting ileostomy; R, retrospective; RCT, randomized controlled trial; SSI, surgical site infection; SSIH, stoma site incisional hernia; SSE, stoma site extraction; US, ultrasound; y, years.

*Data on risk of bias are given in Figure S1.

Chemo (%)	Follow-up details			Method of closure	Method of SSIH detection
	Total duration	Time to closure	Time since closure		
–	–	24 w (2–124)	72 w (1–219)	–	–
–	–	–	10 m (3–48)	–	C, CT or MRI
18.7	–	6 m (0.36)	20.5 m (0–69)	Primary	C, US, CT
–	26 m (3–118)	5.7 m (1–14)	–	Secondary	C, US
–	–	66 d (25–356)	2.56 y (1.62)	–	CT
–	34 m (1.9–64.2)	18.2 w (11.3–35.0)	–	Primary	–
–	–	LC: 73 d (28–141)	36 m (6–48)	Primary	–
–	–	LI: 62 d (17–120)	–	–	–
–	95w (1–242)	18 w (8–137)	–	Primary	–
–	44.1 m (23.5–58.8)	9.8 m (6.9–11.9)	–	Primary	–
–	–	9.1 m (18.6)	18.9 m (5.2)	Primary	–
–	–	106d (69–174)	> 2 m	Primary	–
–	–	–	28 m (2–87)	Primary	–
–	34 m (16–47)	4 m	–	Primary	C
–	1331 d (34–2906)	272 d (55–1142)	–	–	–
64.2	26 m (18–36)	10.4 d (8–14)	–	Primary	–
–	–	A: 12 w (7–33)	A: 27 m (4–50)	Primary	–
–	–	B: 12 d (10–14)	B: 24 m (3–49)	–	–
–	–	9 w (5–53)	0.5–2 y	Primary	–
2.7	SSE: 23.2 m (14.7–36.2)	SSE: 4.7 m (3.0–9.0)	SSE: 16.4 m (7.7–30.6)	–	–
–	NSSE: 32.7 m (18.5–48.6)	NSSE: 5.4 (3.1–7.4)	NSSE: 25.6 m (12.3–41.8)	–	–
–	No SSI: 32 m (1–71)	No SSI: 10 m (7.0)	–	No SSI: 49 open; 20 closed; 13 loose	C, CT
Mesh: 51.1 Control: 30.6	SSI: 30 m (2–73) 18.2 m (11.7–30.8)	SSI: 10 m (6.0) Mesh: 9.2 m (4.1–15.0)	– Control: 8.6 m (4.1–15.1)	SSI: 19 open; 20 closed; 7 loose Mesh: onlay, skin defect open Control: Skin defect open or closed	C, CT
–	–	–	30d	–	–
–	Mesh: 16.8 m (3.3, 11.4–23.9)	Mesh: 11 w (5, 5–26)	Mesh: 16.8 m (3.3, 11.4–23.9)	Mesh: sublay, primary	CT
–	Control: 39.2 m (16.9, 14.9–79.7)	Control: 11 w (5, 2–27)	Control: 39.2 m (16.9, 14.9–79.7)	Control: primary	–
–	–	4 m (1–11)	36 m (2–118)	–	–
–	44 m (9–72)	9 m (3–33)	–	–	C, CT
–	5.7 y (0.5–14)	Hernia: 245.1d (218.5)	5.7 y (0.5–14)	–	–
–	14.7 m	No hernia: 359.6d (707.4)	14.7 m	–	–
–	36–60 m	168d (69–385)	–	–	–
–	3 y	6 m (2–22)	1 y (n = 43), 2 y (n = 28), 3 y (n = 12)	–	CT
15.7	67 m (12–96)	34 w (19–57)	67 m (12–96)	–	–
–	35 m (5–77)	6 m (1–48)	35 m (5–77)	Primary = 99Se condary = 12	C, US
–	54 m (6–146)	7 m (3)	–	–	C, US, CT
–	18–150 m	–	–	–	C
–	25 m (6–52)	3.5 m (1–7)	–	–	–

Table 2 Stoma characteristics.

Author	Year	Stomas formed	Stomas closed	Indications for stoma formation				
				CRC	DIV	IBD	Trauma	Other
Bakx [29]	2004	69	60	36	12	12	0	9
Bhangu [30]	2012	59	59	–	–	–	–	–
Brook [5]	2016	193	193	102	20	47	0	24
Cingi [31]	2008	31	31	23	4	–	–	–
De Keersmaecker [32]	2016	153	153	153	0	0	0	0
D'Hacninc [33]	2011	197	197	138	0	41	0	18
Edwards [34]	2001	70	63	70	0	0	0	0
El-Hussuna [35]	2012	159	158	159	0	0	0	0
Fiscon [36]	2014	20	20	3	12	0	0	5
Garcia-Botello [6]	2004	127	109	72	5	32	1	17
Giannakopoulos [7]	2009	119	119	49	10	33	2	25
Guzman-Valdivia [37]	2008	70	70	12	43	0	3	12
Hasegawa [38]	2000	13	13	0	0	0	0	13
Holmgren [39]	2017	273	229	273	0	0	0	0
Köhler [40]	2014	14	14	10	4	0	0	0
Krand [41]	2008	50	50	46	0	2	0	2
Lewis [42]	1990	50	40	0	0	50	0	0
Li [43]	2017	SSE: 139 NSSE: 599	SSE: 139 NSSE: 597	SSE: 23 NSSE: 119	0	SSE: 106 NSSE: 449	0	SSE: 10 NSSE: 31
Liang [44]	2013	No SSI: 82 SSI: 46	No SSI: 63 SSI: 40	–	–	–	–	–
Liu [45]	2013	Mesh: 47 Control: 36	Mesh: 47 Control: 36	63	6	9	0	5
Luglio [8]	2011	944	944	279	64	507	0	94
Maggiori [46]	2015	Mesh: 30 Control: 64	Mesh: 30 Control: 64	Mesh: 30 Control: 64	0	0	0	0
Mala [47]	2008	72	62	72	0	0	0	0
Mishra [48]	2014	Lap: 35 Open: 282	Lap: 12 Open: 68	Lap: 35 Open: 282	0	0	0	0
Oriel [4]	2017	114	114	Hernia: 2 No hernia: 33	Hernia: 6 No hernia: 37	Hernia: 0 No hernia: 8	0	Hernia: 3 No hernia: 25
Rosen [49]	2005	22	22	2	15	0	1	4
Rutegard [50]	1987	61	23	19	15	3	0	19
Saced [51]	2012	179	59	–	–	–	–	–
Saha [3]	2009	325	325	160	25	118	0	22
Schreinemacher [52]	2011	111	111	53	0	33	0	25
Seo [53]	2013	246	245	246	0	0	0	0
Vermeulen [54]	2009	HP: 139 PA: 19	HP: 63 PA: 14	0	HP: 139 PA: 19	0	0	0
Welten [55]	1991	30	23	–	–	–	–	–

C, colostomy; CRC, colorectal carcinoma; DIV, diverticular disease; EC, end colostomy; EI, end ileostomy; IBD, inflammatory bowel disease; HP, Hartmann's procedure; Lap, laparoscopic; LC, loop colostomy; LI, loop ileostomy; NSSE, nonstoma site extraction; PA, primary anastomosis with diverting ileostomy; SSI, surgical site infection; SSE, stoma site extraction.

Hernia rates

Table 3 provides data on the number of closures, SSIH, SSI and SSIH repairs in individual studies for different stoma types. The rate of SSI after stoma closure ranged from 0% to 18.3% [median follow-up 28 (21.08–36) months]. SSIH rates per stoma type are given in Table 4. The total SSIH rate was 6.5%, with a range from 0% to 38.5% [median follow-up 27.5 (17.54–36) months]. Eleven studies assessed SSIH rate as the primary outcome, whereas the other studies recorded SSIH as a secondary outcome. The SSIH rate of all 11 studies with SSIH rate as the primary outcome was 17.7% [172/970; range 1.7%–36.1%, median follow-up 28

(15.25–51.70) months]. Of these studies, nine used imaging to detect hernias, also leading to a 17.7% rate (139/786; range 1.7%–36.1%). From the 22 studies which did not have SSIH as the primary outcome, an overall rate of 3.6% [129/3622; range 0%–38.5%, median follow-up 27 (16.56–36) months] was found. As calculated from 11 studies (11/33) that used imaging to detect hernias, the SSIH rate was 15.3% [173/1134; range 1.2%–36.1%, median follow-up 28 (15.25–51.7) months]. In contrast, an incidence rate of 3.7% for SSIH [128/3458; range 0%–38.5%, median follow-up 27 (16.56–36) months] was derived from all studies (22/31) that did not use or did not mention the use of imaging for detection of SSIH.

Primary surgery				Stoma types					
Acute	Elective	Lap	Open	LC	LI	EC	EI	C (total)	I (total)
–	–	–	–	0	69	0	0	0	69
–	–	–	–	0	49	10	0	10	49
23	169	50	139	0	193	0	0	0	193
–	–	0	31	8	4	16	3	24	7
0	153	53	100	0	153	0	0	0	153
–	–	–	–	0	197	0	0	0	197
–	70	–	–	36	34	0	0	36	34
0	159	0	159	0	158	0	0	0	158
–	–	3	17	0	0	20	0	20	0
–	118	–	–	0	127	0	0	0	127
–	–	–	23	0	119	0	0	0	119
–	–	–	–	–	–	–	–	65	5
–	–	–	–	12	1	0	0	12	1
–	–	–	–	38	235	0	0	38	235
–	–	4	10	0	14	0	0	0	14
0	50	–	–	0	50	0	0	0	50
0	50	–	–	0	50	0	0	0	50
–	–	–	–	0	SSE: 51	0	SSE: 88	0	SSE: 139
–	–	–	–	–	NSSE: 286	–	NSSE: 313	–	NSSE: 599
No SSI: 45	No SSI: 37	No SSI: 19	No SSI: 63	No SSI: 7	No SSI: 41	No SSI: 18	No SSI: 16	No SSI: 25	No SSI: 57
SSI: 34	SSI: 12	SSI: 16	SSI: 30	SSI: 5	SSI: 13	SSI: 21	SSI: 7	SSI: 26	SSI: 20
–	–	46	37	0	Mesh: 47	0	0	0	Mesh: 47
–	–	–	–	–	Control: 36	–	–	–	Control: 36
–	944	–	–	0	944	0	0	0	944
0	Mesh: 30	Mesh: 30	0	0	Mesh: 30	0	0	0	Mesh: 30
–	Control: 64	Control: 64	–	–	Control: 64	–	–	–	Control: 64
–	–	–	–	10	61	0	1	10	62
–	–	289	768	–	–	–	–	Lap: 16	Lap: 19
–	–	–	–	–	–	–	–	Open: 135	Open: 147
Hernia: 0	Hernia: 11	–	–	–	–	–	–	Hernia: 5	Hernia: 6
No hernia: 2	No hernia: 101	–	–	–	–	–	–	No hernia: 47	No hernia: 56
–	–	20	2	0	0	22	0	22	0
40	21	–	–	29	32	0	0	29	32
–	–	–	–	0	92	0	87	0	179
55	270	–	–	0	325	0	0	0	325
–	–	–	–	64	47	0	0	64	47
0	836	–	–	0	246	0	0	246	0
HP: 139	0	–	–	0	19	139	0	139	19
PA: 19	–	–	–	–	–	–	–	–	–
24	6	–	–	0	30	0	0	30	0

Figure 2 shows a forest plot of seven studies from which data could be used to compare SSIH rates after ileostomy and colostomy reversal. No difference in SSIH risk was found (OR 0.82, 95%CI 0.40–1.69, I^2 0%). Publication bias seemed unlikely, because the study distribution was justifiably symmetrical in an additional funnel plot (Fig. 3). In addition, no differences were found in cumulative meta-analysis (cumulative OR 0.87, 95%CI 0.44–1.75), as shown in Figure S2.

SSIH operation rates

SSIH operation data are shown in Table S1. No data on SSIH operations were available for LC and EI. Of

all patients undergoing stoma closure, 6.1% (0%–38.4%) needed an operation for SSIH. Of the patients with SSIH, 51.4% (0%–100%) were operated. In the total ileostomy group, these percentages were 5.6% (0%–12.5%) and 56.4% (0%–100%), respectively, as derived from 10 studies.

Risk factors

Eight studies reported on risk factors for development of SSIH (Table S2) [3–5,30–32,45,52]. In univariate analysis, Brook *et al.* [5] found a significantly higher BMI in patients who developed SSIH compared with patients without SSIH (mean 28.4 kg/m² vs 24.7 kg/m²).

Table 3 Hernia rates (subdivided per study).

Author	Year	All stomas		SSIH per stoma type				
		Number of stoma closures	Number of SSIH (%)	Number of SSI (%)	LC		LI	
					Closed	SSIH (%)	Closed	SSIH (%)
Bakx [29]	2004	60	5 (8.3)	4 (6.7)	0	0	60	5 (8.3)
Bhangu [30]	2012	59	20 (33.9)	–	0	0	49	16 (32.7)
Brook [5]	2016	193	26 (13.8)	–	0	0	193	26 (13.8)
Cingi [31]	2008	31	10 (32.3)	4 (12.9)	8	3 (37.5)	4	2 (50)
De Keersmaecker [32]	2016	153	17 (11.1)	–	0	0	153	17 (11.1)
D'Haenincq [33]	2011	197	7 (3.6)	9 (4.6)	0	0	197	7 (3.6)
Edwards [34]	2001	63	5 (7.9)	LC: 2 (6.5) LI: 1 (3.1)	31	5 (16.1)	32	0
El-Hussuna [35]	2012	158	8 (5.1)	8 (5.1)	0	0	158	8 (5.1)
Fiscon [36]	2014	20	3 (15)	0	0	0	0	0
Garcia-Botello [6]	2004	109	13 (11.9)	20 (18.3)	0	0	109	13 (11.9)
Giannakopoulos [7]	2009	119	2 (1.7)	12 (10.1)	0	0	119	2 (1.7)
Guzman-Valdivia [37]	2008	70	22 (31.4)	3 (4.3)	–	–	–	–
Hasegawa [38]	2000	13	5 (38.5)	1 (7.6)	12	–	1	–
Holmgren [39]	2017	229	1 (0.4)	–	34	–	195	–
Köhler [40]	2014	14	4 (28.6)	0	0	0	14	4 (28.6)
Krand [41]	2008	50	1 (2)	4 (8)	0	0	50	1 (2)
Lewis [42]	1990	40	0	1 (2.5)	0	0	40	0
Li [43]	2017	SSE: 139 NSSE: 597	SSE: 2 (1.4) NSSE: 11 (1.8)	SSE: 4 (2.8) NSSE: 20 (3.4)	0	0	SSE: 51 NSSE: 286	–
Liang [44]	2013	No SSI: 63* SSI: 40*	No SSI: 15 (23.8) SSI: 16 (40)	46	No SSI: 7 SSI: 5	–	No SSI: 41 SSI: 13	–
Liu [45]	2013	Mesh: 47 Control: 36	Mesh: 3 (6.4) Control: 13 (36.1)	Mesh: 2 (4.3) Control: 1 (2.8)	0	0	Mesh: 47 Control: 36	Mesh: 3 (6.4) Control: 13 (36.1)
Luglio [8]	2011	944	1 (0.1)	44 (4.7)	0	0	944	1 (0.1)
Maggiore [46]	2015	Mesh: 30 Control: 64	Mesh: 1 (3.3) Control: 12 (18.8)	Mesh: 2 (6.7) Control: 1 (1.6)	0	0	Mesh: 30 Control: 64	Mesh: 1 (3.3) Control: 12 (18.8)
Mala [47]	2008	62	5 (8.1)	2 (3.2)	–	–	–	–
Mishra [48]	2014	Lap: 12 Open: 68	Lap: 1 (8.3) Open: 3 (4.4)	–	–	–	–	–
Oriel [4]	2017	114	11 (9.7)	–	–	–	–	–
Rosen [49]	2005	22	1 (4.5)	3 (13.6)	0	0	0	0
Rutegard [50]	1987	23	1 (4.3)	–	15	1 (6.7)	8	0
Saeed [51]	2012	59	1 (1.7)	–	0	0	92	–
Saha [3]	2009	325	18 (5.5)	24 (7.4)	0	0	325	18 (5.5)
Schreinemacher [52]	2011	111	36 (32.4)	12 (10.8)	64	–	47	–
Seo [53]	2013	245	3 (1.2)	0	0	0	245	3 (1.2)
Vermeulen [54]	2009	HP: 63 PA: 14	HP: 0 PA: 1 (7.1)	HP: 7 (11.1) PA: 1 (7.1)	0	0	14	1 (7.1)
Welten [55]	1991	23	1 (4.3)	2 (8.7)	0	0	23	1 (4.3)

C, colostomy; EC, end colostomy; EI, end ileostomy; HP, Hartmann's procedure; Lap, laparoscopic; LC, loop colostomy; LI, loop ileostomy; NSSE, nonstoma site extraction; PA, primary anastomosis with diverting ileostomy; SSI, surgical site infection; SSIH, stoma site incisional hernia; SSE, stoma site extraction.

*Late outcomes of stoma closures were available in 63 of 92 no SSI patients and 40 out of 46 SSI patients.

Moreover, they found a significantly higher percentage of clinically obese patients ($BMI \geq 30 \text{ kg/m}^2$) in the SSIH group (42.3% vs 15%, $P < 0.001$). From a logistic regression model, an OR of 1.2 was found for BMI. Furthermore, from a nonparametric correlation test of Stage 1 hypertension ($\geq 140/90 \text{ mmHg}$), a Spearman's rho of 0.183 was found ($P = 0.01$). In addition, malignant

disease was found to be associated with a higher likelihood of hernia in logistic regression analysis (OR 18, $P = 0.009$) and, albeit in univariate analysis, postoperative complication rates were higher in patients with SSIH (27% vs 22%, $P < 0.001$).

Liu *et al.* [45] investigated the influence of PMR versus no mesh in ileostomy closures and assessed

EC		EI		C (total)		I (total)		SSIH repair
Closed	SSIH (%)	Closed	SSIH (%)	Closed	SSIH (%)	Closed	SSIH (%)	
0	0	0	0	0	0	60	5 (8.3)	–
10	4 (40)	0	0	10	4 (40)	49	16 (32.7)	4
0	0	0	0	0	0	193	26 (13.8)	19
16	5 (31.3)	3	0	24	8 (33.3)	7	2 (28.6)	3
0	0	0	0	0	0	153	17 (11.1)	6
0	0	0	0	0	0	197	7 (3.6)	7
0	0	0	0	31	5 (16.1)	32	0	–
0	0	0	0	0	0	158	8 (5.1)	–
20	3 (15)	0	0	20	3 (15)	0	0	3
0	0	0	0	0	0	109	13 (11.9)	8
0	0	0	0	0	0	119	2 (1.7)	–
–	–	–	–	65	21 (32.3)	5	1 (20)	–
0	0	0	0	12	–	1	–	5
0	0	0	0	34	–	195	–	–
0	0	0	0	0	0	14	4 (28.6)	–
0	0	0	0	0	0	50	1 (2)	0
0	0	0	0	0	0	40	0	0
0	0	SSE: 88	–	0	0	SSE: 139	SSE: 2 (1.4)	–
		NSSE: 313	–			NSSE: 597	NSSE: 11 (1.8)	–
No SSI: 18	–	No SSI: 16	–	No SSI: 25	–	No SSI: 57	–	–
SSI: 21	–	SSI: 7	–	SSI: 26	–	SSI: 20	–	–
0	0	0	0	0	0	Mesh: 47	Mesh: 3 (6.4)	Mesh: 0
						Control: 36	Control: 13 (36.1)	Control: 3
0	0	0	0	0	0	944	1 (0.1)	–
0	0	0	0	0	0	Mesh: 30	Mesh: 1 (3.3)	Mesh: 0
						Control: 64	Control: 12 (18.8)	Control 8
–	–	–	–	–	1	–	4	3
–	–	–	–	–	–	Lap: 12	1	Lap: 1
–	–	–	–	–	–	Open: 68	3	Open: 1
–	–	–	–	52	5 (9.6)	56	6 (10.7)	–
22	1 (4.5)	0	0	22	1 (4.5)	0	0	0
0	0	0	0	15	1 (6.7)	8	0	–
0	0	–	–	0	0	59	1 (1.7)	–
0	0	0	0	0	0	325	18 (5.5)	–
0	0	0	0	64	–	47	–	–
0	0	0	0	0	0	245	3 (1.2)	–
63	0	0	0	63	0	14	1 (7.1)	–
0	0	0	0	0	0	23	1 (4.3)	0

potential risk factors. From univariate analyses, the following significant factors were found: age > 60 years, malignant disease, diabetes, hypertension, chronic steroid usage and chronic kidney injury. A multivariate analysis was performed and showed malignancy (OR 21.93, 95% CI 1.58–303.95, $P = 0.02$) and diabetes (OR 20.98, 95% CI 3.23–136.31, $P = 0.001$) to be independent risk factors for SSIH.

Bhangu *et al.* [30] found no significant differences in age or gender for patients with SSIH versus no SSIH. Moreover, no difference in MIH between patients with and without SSIH was found (50% *vs* 41%, $P = 0.51$). Age, SSI, stoma type, gender, BMI and time to closure did not significantly increase the risk of SSIH in the study by Cingi *et al.* [31]. However, patients with a MIH had an increased risk (OR 4.4) of SSIH.

De Keersmaecker *et al.* [32] assessed a number of potential patient- and surgery-related risk factors but did not find any significant differences in univariate analysis.

Oriel *et al.* [4] showed that myofascial release was performed more often in the SSIH group (18.2% *vs* 2.9%, $P = 0.02$) and more SSIH patients had superficial incisional SSI (27.3% *vs* 5.8%, $P = 0.01$).

From univariate analyses, Saha *et al.* [3] found the development of SSIH to be significantly associated with reoperation after LI reversal (3% *vs* 25%, $P < 0.001$) and emergency surgery (4% *vs* 13%, $P = 0.01$).

Lastly, Schreinemacher *et al.* [52] performed a multivariate analysis for risk factors, which only showed that BMI (≥ 30 kg/m² *vs* < 25 kg/m²) was a significant risk factor (OR 5.53, 95% CI 1.72–17.80), whereas a time to closure of < 6 months did not appear as risk factor (OR 2.38, 95% CI 0.96–5.99, $P = 0.06$).

Prophylactic mesh reinforcement

Four studies provided data on PMR outcomes, of which details are given in Table 5. Bhangu *et al.* [56] used biological mesh (StratticeTM) and intraperitoneal onlay mesh (IPOM) placement in a case series of seven patients. During 30-day follow-up, only one adverse event was seen (a SSI with subsequent superficial wound breakdown) while the mesh was still *in situ* (on US).

In the case series by Van Barneveld *et al.* [57], 10 patients received a Parietex Composite Parastomal® mesh during creation of a temporary stoma for parastomal hernia prophylaxis (IPOM placement). At stoma reversal, mesh continuity was restored to serve as SSIH prophylaxis. No serious mesh-related or other serious

complications were observed during 12 month' follow-up. After a median follow-up of 26 months [interquartile range (IQR) 14–29], no SSIH was found during physical and US examination in nine patients.

Two other studies, by Liu *et al.* and Maggiori *et al.*, were comparative cohort studies, including 83 and 94 patients, respectively [45,46]. In the retrospective study by Liu *et al.* [45], consecutive patients undergoing ileostomy closure were included, of whom 47 (56.6%) had PMR with polypropylene mesh (Ultrapro, Ethicon Inc.) placed in an onlay position by the same surgeon in all patients. During median follow-up of 18.2 months (IQR 11.7–30.8), three SSIHs (6.4%) were detected in mesh patients, whereas 13 SSIHs (36.1%) were found in control patients (OR 8.29, 95% CI 2.14–32.08, $P = 0.001$). SSIH in the mesh group was small and asymptomatic, and did not require repair, compared with 23% SSIH repairs in control patients. In the matched case-control study by Maggiori *et al.* [46], 30 consecutive patients were individually matched to patients from a prospective database. In these patients, a biological mesh (noncross-linked collagen, porcine dermal matrix; Meccellis BioTech, France) was placed in a retromuscular position. At 1-year CT follow-up, SSIH incidence was lower in mesh patients than the control group (3% *vs* 19%, $P = 0.04$), while postoperative morbidity was similar in both groups (17% *vs* 11%, $P = 0.51$). SSIH repair was needed in eight control patients (13% *vs* 0%, $P = 0.05$).

Discussion

This study shows an overall incidence of SSIH of 6.5% [range 0%–38.5%, median follow-up 27.5 (17.54–36) months], which is in accordance with the review by

Table 4 Hernia rates (subdivided by stoma type).

Stoma group	Studies	Number of stomas closed	Number of SSIH detected	Percentage SSIH detected (%)	Range (%)*	Median follow-up (IQR)†
Loop colostomy	3	54	9	16.7	6.7–37.5	36 (36–36)
Loop ileostomy	21	2837	150	5.3	0–50	23.75 (14.92–43.75)
End colostomy	4	131	13	9.9	0–40	12.35 (10–12.35)
End ileostomy	1	3	0	0	–	–
Colostomy	9	302	48	15.9	0–40	28 (12.35–52.20)
Ileostomy	26	3776	175	4.6	0–36.1	27 (18.53–51.50)
Total	33	4602	301	6.5	0–38.5	27.5 (17.54–36)

Only control patients were included, patients with prophylactic mesh placement were excluded.

SSIH, stoma site incisional hernia; IQR, interquartile range.

*Range of SSIH percentages reported in studies.

†Median (IQR) of available information on reported median study follow-up since closure (months).

Bhangu *et al.* [58], who reported an overall hernia rate of 7% (range 0%–48%, median follow-up 36 months). However, this study was based on a smaller number of patients ($n = 2698$) than the present study ($n = 4602$). Both previous studies, by Bhangu *et al.* and Nguyen *et al.*, reported on significant heterogeneity between studies and difficulties in interpretation and combining study results [58,59]. To reduce this heterogeneity, several inclusion and exclusion criteria were used during our systematic literature search (Fig. 1). Most importantly, to be included, studies had to mention follow-up duration, since hernia rates increase over time and might vary between different durations. Furthermore, studies with > 10% of patients with abdominal trauma were excluded, as earlier reports showed these patients to be more prone to hernia development [60,61].

To compare the SSIH rate between ileostomy and colostomy reversal, seven studies were eligible for analysis. Whereas the previous review of Bhangu *et al.* [58] showed a significantly different lower SSIH rate after ileostomy (OR 0.28, 95% CI 0.12–0.65), this review found no significant difference in the risk of SSIH between ileostomy and colostomy (OR 0.82, 95% CI 0.40–1.69), which was also not found in an additional cumulative meta-analysis (cumulative OR 0.87, 95% CI 0.44–1.75).

In this study, only one-third (11/33) of included studies assessed SSIH incidence as the primary outcome. Twenty studies did not mention detection methods and, therefore, it seems likely to assume that imaging was not used in these studies. To investigate potential underestimation, the overall incidence of SSIH from the 11 studies with SSIH as the primary outcome was calculated (17.7%, range 1.7%–36.1%) [4,5,30–32,37,45,46,48,51,52]. These rates indeed support the hypothesis that the overall incidence of hernia from all included studies (6.5%), as from those only reporting on SSIH as a secondary outcome (3.6%), is an underestimation. The potential risk of underestimation by not

using imaging for detection of SSIH is further supported by the higher incidence in studies that used imaging, compared with studies that did not use, or did not mention the use of imaging as a detection method (15.3% vs 3.7%, respectively). Indeed, from the literature on incisional hernias it is known that prevalence rates vary substantially, through differences in diagnostic modalities, observer, definition and diagnostic protocol [62]. The use of imaging, which led to higher SSIH rates, might have identified asymptomatic or occult hernias. Therefore, the overall SSIH rate of 6.5% seems to be lower but more clinically relevant, and thus it remains debatable if PMR might even be necessary at all. Hence, it is important to identify high-risk patients, in whom PMR might still be of added value and if in these patients its risks outweigh its benefits.

Eight studies were identified that reported on potential risk factors for development of SSIH. Three studies [5,45,52] performed a multivariate analysis, from which BMI, primary surgery for malignant disease and diabetes mellitus were identified as potential risk factors. BMI is known to affect midline incisional and parastomal hernia rates [16,63–66], which might be explained by higher intra-abdominal pressure and consequent higher

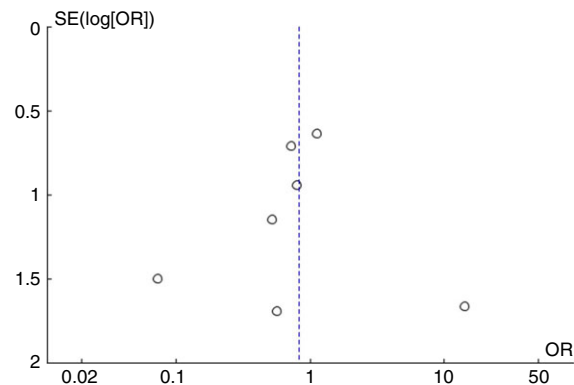


Figure 3 Funnel plot of the included studies

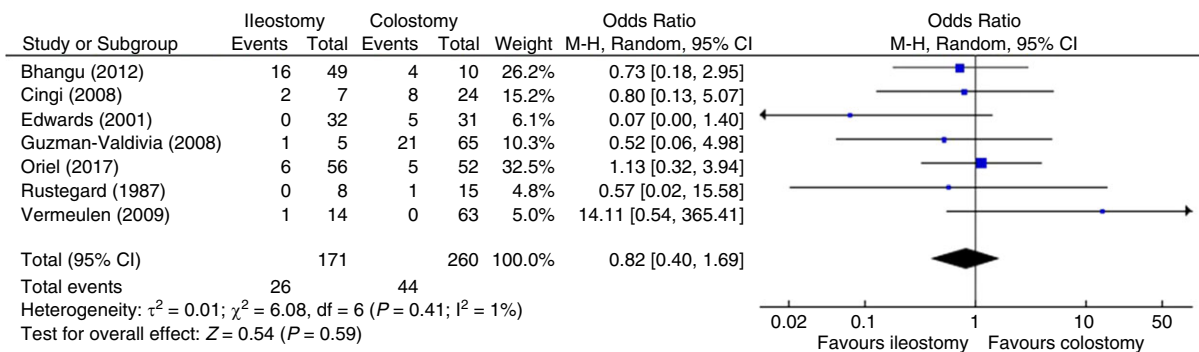


Figure 2 Forest plot of SSIH rates. M-H, random, Mantel–Haenszel random-effects model; df, degrees of freedom.

Table 5 Overview of studies reporting on prophylactic mesh placement for the prevention of SSIH.

Author	Year	Design	Method of closure		Mesh placement	Control group	Outcome measure	SSIH detection method
			Mesh or control	Mesh type				
Bhangu [56]	2014	CS	Mesh	Biological (Strattice™)	IPOM	None	30-day outcomes	–
Liu [45]	2013	R	Mesh	Polypropylene (Ethicon Ultrapro®)	Onlay	–	Rate of SSIH	C and/or CT
			Control	–	–	Skin defect open	–	–
Maggiori [46]	2015	CM	Mesh	Bioprosthetic, noncross-linked collagen, porcine dermal matrix (Meccellis, Biotech)	Sublay, retromuscular	–	1-year rate of SSIH	CT
			Control	–	–	Primary closure	–	–
van Barneveld [57]	2013	CS	Mesh	Parietex™ Composite Parastomal mesh + AbsorbaTack™ (Covidien/Medtronic)	IPOM	None	SSIH and mesh complications	C and US

Continuous data are mean (standard deviation), mean (standard deviation, range), or median (interquartile range). C, clinical diagnosis; CT, computed tomography diagnosis; CS, case series; EI, end ileostomy; LC, loop colostomy; LI, loop ileostomy; m, months; R, retrospective; CM, case matched; IPOM, intraperitoneal onlay mesh; SSI, surgical site infection; SSIH, stoma site incisional hernia; US, ultrasound.

abdominal wall tension [16,67]. Additionally, obesity and diabetes are associated with wound healing complications due to local hypoxia, caused by a decreased vascularization of adipose tissue and other microvascular changes, impairing collagen synthesis and having a negative effect on the overall healing process [16,68]. Smoking has a comparable negative effect on wound healing and is considered a risk factor for incisional hernia [69]. However, none of the included studies has shown a significant effect on occurrence of SSIH. Moreover, with regard to primary surgery for malignant disease, factors as malnutrition, poor general health and immunosuppressive effects of chemotherapy are thought to negatively affect the normal healing process [45,68,70]. Wound infections are known to increase the risk of hernia formation [63,71]; however, in the present literature review SSIs were not found to be independently associated with an increased risk of SSIH. Overall, the study by Oriol *et al.* [4] was the only study to identify superficial SSI as a factor contributing to future SSIH formation. The data on risk factors in this review might help with the selection of high-risk patients and therefore help guide clinical decision-making, potentially involving PMR. Moreover, since factors

such as obesity and smoking can potentially be minimized, it might be of interest to focus not only on PMR but also on lifestyle interventions such as preoperative weight loss, smoking cessation and nutritional optimization for the prevention of SSIHs. However, to date no evidence is available on the efficacy or effectiveness of these lifestyle interventions with regard to incidence of SSIH.

Four studies reported on PMR for SSIH prevention [45,46,56,57]. These studies had several methodological limitations that made it difficult to draw conclusions about the potential added value of PMR. Two of the studies reported on a very limited number of patients ($n < 10$), decreasing their generalizability [56,57]. Furthermore, these studies had no control (nonmesh) group. Two other studies on PMR were of better quality because they included larger numbers of patients and as well as control patients [45,46]. Liu *et al.* [45] stated that mesh placement significantly reduced the incidence of SSIH following ileostomy closure, without an increase in complications. Maggiori *et al.* [46] reported a significant difference in SSIH on 1-year follow-up CT in favour of PMR. Nevertheless, all four studies recognized the need for RCTs to further evaluate the beneficial

Patients				Follow-up details						
Number	Male gender (%)	Age	BMI (kg/m ²)	Total	Time to closure	Time since closure	Number of stomas closed	Type of stomas	Number of SSIH (%)	Number of SSI (%)
7	–	–	–	30 days	–	30 days	7	LI, EI	0	1 (14.3)
47	63.8	69.6 (57.9–76.0)	> 30, <i>n</i> = 9	18.2 m (11.7–30.8)	9.2 m (4.1–15.0)	–	47	LI	3 (6.4)	2 (4.3)
36	58.3	65.0 (57.8–70.5)	> 30, <i>n</i> = 12	18.2 m (11.7–30.8)	8.6 m (4.1–15.1)	–	36	LI	13 (36.1)	1 (2.8)
30	60	61 (13, 25–79)	26 (4, 19–36)	16.8 m (3.3, 11.4–23.9)	11 weeks (5, 5–26)	–	30	LI	1 (3.3)	2 (6.7)
64	62	61 (13, 28–84)	25 (4, 18–38)	39.2 m (16.9, 14.9–79.7)	11 weeks (5, 2–27)	–	64	LI	12 (18.8)	1 (1.5)
10	40	66 (58–77)	25 (20–28)	–	6 m (2–15)	–	10	LI, LC	0	1 (10)

effects, safety and (cost-) effectiveness of PMR. Efforts have already been made by several research groups, and further trial results are awaited. A feasibility study by the Reinforcement of Closure of Stoma Site (ROCCS) Collaborative has recently been published and reported their study protocol to be feasible, without early safety concerns [72]. Based on their data, progression towards their ROCCS trial (ClinicalTrials.gov identifier NCT02238964) has continued [72,73]. Several other trials have been initiated, such as the MEMBO trial (NCT02576184), the ILEOCLOSE trial (NCT02226887) and the LISTO-trial (NCT02669992). Next to ileostomy closure, only the ROCCS trial also includes patients undergoing colostomy closure, and none of these trials focuses on a specific risk group, such as obese patients. However, since obesity seems to increase the risk of SSIH after stoma closure, this group of patients might potentially benefit more from PMR, although, paradoxically, these patients, especially in case of diabetes, might at the same time also be at higher risk of developing mesh-related complications [74,75]. Therefore, it would be interesting to see the results of PMR in these patients specifically. With regard to the efficacy and (cost-)

effectiveness of PMR, it is still debatable as to what would be a clinically significant reduction in SSIH rates. In the case of the ROCCS trial, sample size calculation of the full Phase III study was based on a 40% reduction (25% to 15%) in the 2-year clinical hernia rate [72]. In the study by Maggiori *et al.* [46], a 16% difference was found (19% vs 3%, $P = 0.043$), which might have been used for the sample size calculation of the MEMBO trial. However, further data on sample size calculations and risk reduction were not available. Unfortunately, robust conclusions cannot yet be drawn on its risks and benefits from the available literature on PMR. If PMR is proven to be beneficial in these studies, further implications for practice should be made sufficiently clear (e.g. patient selection) in order to overcome the barriers of implementing these findings [76].

The low level of evidence and the vast heterogeneity of the included studies are two important limitations of this study. Nevertheless, inclusion of these studies was still deemed necessary as they allowed a more comprehensive overview of potential risk factors, as well as more detailed analyses of SSIH and repair rates. The

lack of a predefined time period from which studies could be included might also have been a limitation of this review, because important changes in operative and perioperative care of patients have been introduced in recent decades (e.g. laparoscopy). However, this effect is presumably largely negligible since the majority of included studies were published in the previous decade (Table 1).

In conclusion, this review shows an overall incidence of SSIH of 6.5% (range 0%–38.5%), as well as an incidence of 17.7% (range 1.7%–36.1%) from 11 studies assessing SSIH as the primary outcome. Furthermore, potential risk factors have been identified, of which BMI, malignant disease and diabetes were considered to be the most important. Lastly, early results from four studies on PMR were identified, but no robust conclusions could be drawn. Results of ongoing trials are awaited.

Acknowledgements

The authors thank Wichor Bramer, biomedical information specialist at the Erasmus Medical Center, for his assistance with the search strategy and syntax.

Conflict of interests

None to disclose.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Figure S1. Risk of bias assessment.

Figure S2. Cumulative meta-analysis of studies reporting on SSIH rates of ileostomies and colostomies.

Table S1. SSIH repair rates (subdivided by stoma type).

Table S2. Risk factors for SSIH.

Appendix S1. Details of the search strategy.