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REVIEW

Parastomal hernia following cystectomy and ileal conduit urinary diversion: a systematic review

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Abstract
Purpose The natural history of development of Parastomal hernia (PH) following cystectomy and ileal conduit diversion is poorly understood. The aim of this study was to systematically review the frequency and risk factors of PH following ileal conduit diversion.
Methods A systematic review of literature was performed and the Cochrane, EMBASE and PubMed databases were searched from 1st January 1985 to 30th April 2016. All articles reporting occurrence of PH following cystectomy and ileal conduit diversion were analysed. The primary outcome measure was the frequency of development of PH. Secondary outcome measures were risk factors for PH development, complications of PH, frequency of PH repair and recurrence of PH.
Results Twelve articles of the 63 originally identified were analysed. Sample sizes ranged from 36 to 1057 patients with a pooled total of 3170 undergoing ileal conduit surgery. Age at the time of surgery ranged from 31 to 92 years. Of the 3170 patients who underwent ileal conduit surgery, 529 patients (17.1%) developed a PH based on either clinical examination or cross sectional imaging. Female gender, high BMI, low preoperative albumin and previous laparotomy were significantly associated with the development of PH in two studies. Repair of PH was offered to 8–75% of patients. The rate of recurrence following repair of PH was reported to range from 27 to 50%.
Conclusion A PH is frequent following cystectomy and ileal conduit urinary diversion. The diagnosis of a PH depends upon duration of clinical follow-up and the use of cross-sectional imaging. The recurrence rates following the repair of a PH remain substantial.

Keywords Urinary diversion · Ileal conduit · Morbidity · Parastomal hernia · Cystectomy

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Introduction

Since its introduction in the 1940s, an ileal conduit remains the commonest form of external urinary diversion following cystectomy [1, 2] despite orthotopic bladder substitution growing in popularity in recent years [3, 4]. A parastomal hernia (PH) is defined as an incisional hernia that develops in the vicinity of a colostomy, ileostomy or

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urostomy [5]. Korenkov defined PH as an abdominal wall gap with or without a bulge in the area of a postoperative scar perceptible by clinical examination or imaging [6]. The incidence of PH varies widely and depends on the definition used, length of follow-up and whether the diagnosis is made on clinical examination or imaging [7]. Repair of PH may be necessary for symptoms such as discomfort, pain, poor fit of appliance and rarely due to bowel obstruction and strangulation [8]. Factors including malnutrition, smoking, obesity, steroids, chronic cough, radiation exposure and advanced age have been implicated in the development of parastomal herniae [9–13]. Technical factors including location of stoma (trans-rectus or lateral to rectus) on the abdominal wall may also contribute to the development of PH [14].

There is a paucity of data alluding to the natural history of PH development. The knowledge base for development of PH has been adapted from patients undergoing formation of colostomy or ileostomy. It is unclear if this information can be applied to a urostomy. The frequency of, and risk factors for, the development of PH have been inconsistently reported in the literature. Therefore, the aim of this study was to systematically review the frequency and risk factors reported in the literature according to predefined standardized criteria.

Materials and methods

Search strategy

A systematic review of all English language literature relevant to the development of PH following cystectomy and ileal conduit urinary diversion published between 1 January 1985 and 30 April 2016 was carried out using MEDLINE (PubMed and Ovid), EMBASE (Ovid) and the Cochrane Library of Systematic Reviews/Controlled Trials for relevant literature. Searches were performed using a combination of medical subject headings (MeSH) terms and text words 'parastomal hernia', 'cystectomy', 'morbidity', 'urinary diversion', 'ileal conduit', 'urostomy' and 'hernia', All randomised/nonrandomised, controlled/non-controlled clinical trials, prospective observational studies, clinical registry data and retrospective case series that reported development of PH in ileal conduit urinary diversion following cystectomy for benign or malignant pathology were included for analysis. Conference abstracts, letters, technical notes and commentaries were excluded. In addition, bibliographies from the papers requested were manually checked to identify additional relevant papers.

Study selection

Titles and abstracts of the identified studies were screened by the main reviewer SKN and independently checked by NNA. Studies that were irrelevant were rejected. The full texts of identified papers were independently assessed by two reviewers (SKN and NNA) to determine whether they met the predetermined inclusion/exclusion criteria. Disagreements were resolved by discussion or adjudication by the senior author.

Inclusion criteria

All Studies should have been published in print or electronic format between 1st January 1985 and 30th April 2016. Only adult patients undergoing cystectomy for benign or malignant pathology having cystectomy and urinary diversion with ileal conduit formation were included in the review. Cystectomy may have been performed as an open procedure, laparoscopic, hand-assisted or robot-assisted.

Exclusion criteria

Studies on the paediatric population or using techniques such as jejunal or colonic conduit, orthotropic neobladder reconstruction and ureterostomy/ureterosigmoidostomy for urinary diversion were excluded from this review. Diagnosis of PH established on the basis of patient-reported symptoms of PH or telephone or postal follow-up were excluded from the review. Recent studies using prophylactic mesh placement were excluded as they would confound the outcome of the systematic review.

Outcomes

The primary outcome measure of the systematic review was to assess the frequency of parastomal hernia following cystectomy and ileal conduit external urinary diversion. Other factors such as time interval to development of PH and diagnostic definition of PH (clinical, cross-sectional imaging, patient-reported or telephone interview) were also noted.

The secondary outcome measures recorded were the following:

1. Risk factors for development of PH– patient-related factors, intra-operative factors and post-operative factors.
2. Frequency of repair of PH, operative technique of repair, success rate of repair and complications following repair.

3. Medical and surgical complication rates in patients with PH who were managed conservatively such as persistent pain, poor fit of appliance, skin excoriation, psychosocial issues, bowel obstruction and stomal stenosis.
4. Patient-reported outcome measures or quality of life scores.

Definitions

Clinically, PH is defined as a palpable bulge at the base of the ileal conduit associated with protrusion of intra-abdominal viscera through the defect in the abdominal wall fascia and musculature. Radiographic PH is defined as evidence on cross-sectional imaging of protrusion of intra-abdominal contents through the abdominal wall defect created by forming the ileal conduit.

Risk of bias (quality) assessment

The revised and validated version of the methodological index for non-randomised studies (MINORS) criteria were used to assess study quality including risk of bias by two separate investigators SKN and NNA to produce an average score [15]. A quality score was assigned to each study by summing up the score for each criterion with 0 (not reported), 1 (reported but inadequate) or 2 (reported and adequate).

Data extraction (selection and coding)

Data on the study type, number of patients treated, length of follow-up, cross-sectional imaging and symptoms from PH were extracted from the included studies by the reviewers. The data were extracted separately by reviewers (SKN and NNA) to guard against reviewer bias. All data and results of statistical tests were extracted from the papers and entered into an electronic data sheet (Microsoft Excel). No assumptions were made regarding the missing data.

Statistical analysis

There was significant heterogeneity in the included studies in the study design, intervention design, study cohorts and outcome measures. A weighted analysis of variables for risk factors for PH development was not possible because of the lack of both uniformity and the quantity of the data reported. For this reason a meta-analysis of the data could not be undertaken; therefore, primary and secondary outcome measure parameters have been expressed as a range.

Results

Study selection

A total of 68 articles were identified from the initial literature search. After removal of duplicate articles 63 articles remained (Fig. 1). Two articles in French and one article in Japanese were excluded. Using the inclusion criteria described above, 38 articles were eliminated on title and abstract review. Full text articles were obtained for 22 articles out of which 10 articles were rejected, as they did not meet the inclusion criteria. Twelve articles were included for final analysis and all were retrospective studies evaluating patients undergoing cystectomy and ileal conduit urinary diversion.

Study characteristics

Table 1 depicts the various characteristics of the included studies. All included studies ($n = 12$) were retrospective observational studies of variable methodological quality. The quality assessment of the included studies is presented in Table 2. The level of evidence based on the Oxford centre for evidence-based medicine (March 2009) was 4 at best. Some studies had clearly defined inclusion and exclusion criteria. One study selected patients older than 75 years only [16] and long-term survivors (at least 5 years post-operative) only were included in two studies [4, 17]. The primary and secondary outcome measures are described in Tables 3 and 4 respectively.

Primary outcome measure: frequency of PH

There were a total of 4733 study participants with sample sizes ranging from 36 to 1057 patients in the included studies. A cumulative total of 3170 subjects underwent cystectomy and ileal conduit external urinary diversion for benign or malignant pathology. Other methods of urinary diversion were utilized for the remaining 1563 patients and were, therefore, not included in the review. The largest series published was from a single centre retrospective study presenting 1054 patients over a 19 years [18]. Age at the time of surgery ranged from 31 to 92 years. Only one study documented preoperative radiotherapy and chemotherapy given to patients prior to radical cystectomy [19].

Follow-up periods were variable: however, patients undergoing surgery for cancer were followed up for longer and this ranged from 1 to 354 months. One study followed up patients for at least 12 months before including them in the study [20].

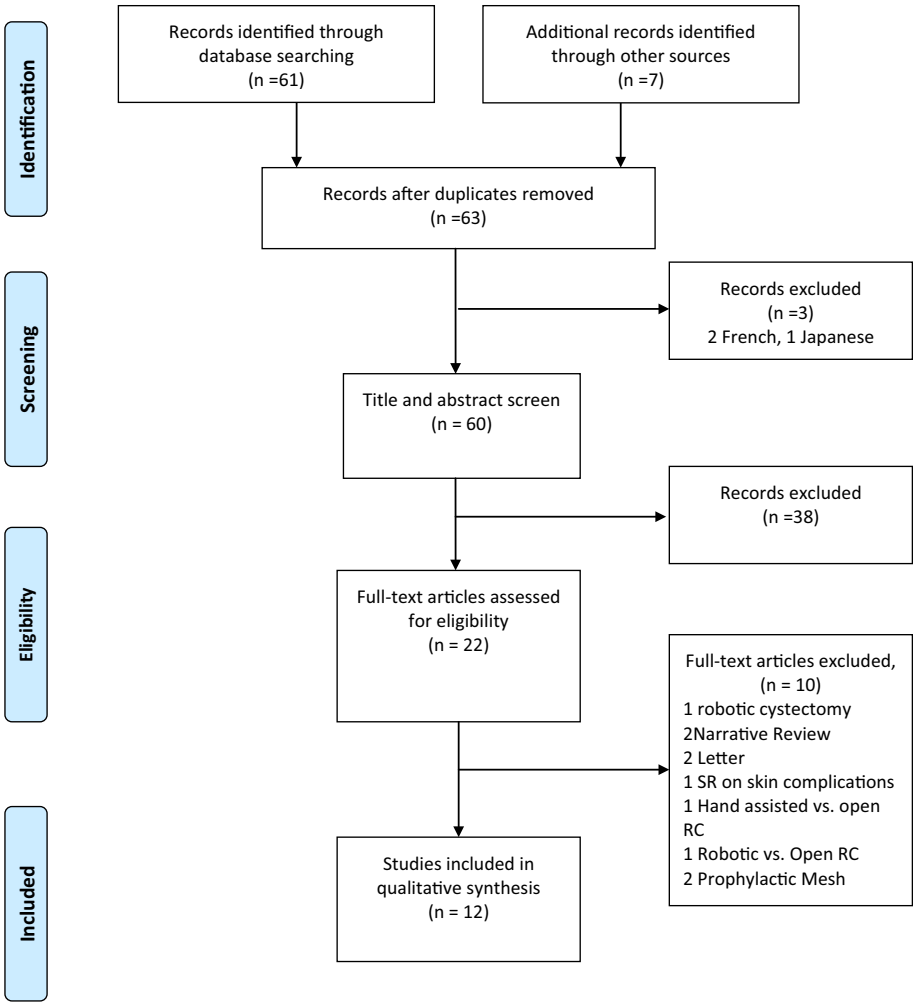

Fig. 1 PRISMA flow diagram outlining study selection

Table 1 Table of papers describing study characteristics

Author	Country	Year of publication	Study type	Level of evidence*
Klein et al.	USA	1989	Retrospective case series	4
Cheung et al.	HK, China	1995	Retrospective case series	4
Soulie et al.	France and Germany	2002	Retrospective case series (Multicenter)	4
Madersbacher et al.	Switzerland	2003	Retrospective case series	4
Knap et al.	Denmark	2004	Retrospective case series	4
Kouba et al.	USA	2007	Retrospective case series	4
Khalil et al.	Egypt	2010	Retrospective case series	4
Shimko et al.	USA	2011	Retrospective case series	4
Pisters et al.	USA	2014	Retrospective case series	4
Donahue et al.	USA	2014	Retrospective case series	4
Liu et al.	USA	2014	Retrospective case series	4
Movassaghi et al.	USA	2016	Retrospective case series	4

* Oxford centre for evidence-based medicine—levels of evidence (March 2009)

Table 2 MINORS Criterion for risk of bias assessment

Study name	Q1 Aim	Q2 Consec patients	Q3 Prospective data	Q4 Appropriate endpoints	Q5 Unbiased assessment of endpoints	Q6 Sufficient follow-up period	Q7 Loss to FU	Q8 Prospective calculation of study size	Q9 Adequate control group	Q10 Contemporary groups	Q11 Baseline equivalence	Q12 Adequate statistical analysis	Total
Klein et al.	1	1	0	2	1	1	0	0	0	0	0	0	6
Cheung et al.	1	1	0	1	1	1	0	0	0	0	0	0	5
Soulie et al.	1	1	0	1	1	1	0	0	0	0	0	0	5
Madersbacher et al.	2	2	0	2	1	1	2	0	0	0	0	0	10
Knap et al.	2	2	0	1	1	1	1	0	0	0	0	0	8
Kouba et al.	2	1	0	1	1	1	0	0	0	0	0	0	6
Khalil et al.	1	0	0	1	1	1	0	0	0	0	0	0	4
Shimko et al.	2	1	0	1	1	2	1	0	0	0	0	0	8
Pisters et al.	2	1	0	2	1	1	1	0	0	0	0	0	8
Donahue et al.	2	1	0	2	1	1	0	0	0	0	0	0	7
Liu et al.	2	1	0	2	1	1	0	0	0	0	0	0	7
Movassaghi et al.	2	1	1	1	1	1	0	0	0	0	0	0	7

The revised and validated version of **MINORS** Methodological items for non-randomized studies

Q1. *A clearly stated aim* the question addressed should be precise and relevant in the light of available literature

Q2. *Inclusion of consecutive patients* all patients potentially fit for inclusion (satisfying the criteria for inclusion) have been included in the study during the study period (no exclusion or details about the reasons for exclusion)

Q3. *Prospective collection of data* data were collected according to a protocol established before the beginning of the study

Q4. *Endpoints appropriate* to the aim of the study: unambiguous explanation of the criteria used to evaluate the main outcome which should be in accordance with the question addressed by the study. Also, the endpoints should be assessed on an intention-to-treat basis

Q5. *Unbiased assessment of the study endpoint* blind evaluation of objective endpoints and double-blind evaluation of subjective endpoints. Otherwise the reasons for not blinding should be stated

Q6. *Follow-up period* appropriate to the aim of the study: the follow-up should be sufficiently long to allow the assessment of the main endpoint and possible adverse events

Q7. *Loss to follow-up* less than 5%: all patients should be included in the follow-up. Otherwise, the proportion lost to follow-up should not exceed the proportion experiencing the major endpoint

Q8. *Prospective calculation* of the study size: information of the size of detectable difference of interest with a calculation of 95% confidence interval, according to the expected incidence of the outcome event, and information about the level for statistical significance and estimates of power when comparing the outcomes

Additional criteria in the case of comparative study:

Q9. *An adequate control group* having a gold standard diagnostic test or therapeutic intervention recognized as the optimal intervention according to the available published data

Q10. *Contemporary groups* control and studied group should be managed during the same time period (no historical comparison)

Q11. *Baseline equivalence of groups* the groups should be similar regarding the criteria other than the studied endpoints. Absence of confounding factors that could bias the interpretation of the results

Q12. *Adequate statistical analyses* whether the statistics were in accordance with the type of study with calculation of confidence intervals or relative risk

† The items are scored

0 (not reported), *1* (reported but inadequate) or *2* (reported and adequate). The global ideal score being **16 for non-comparative studies** and **24 for comparative studies**

Table 3 Primary Outcome measures

Author	No of patients in the study	No of IC included in the study	Age (range)	Follow-up months (range)	No of PH (%)	Interval to diagnosis of PH (months)	Diagnostic criteria
Klein et al.	319	291	Mean 52 years	Median 35 (1–152)	12 (4.1%)	Mean 44	NR
Cheung et al.	316	123	Median 66 years	Median 38	34 (27.6%)	Mean 22.4	NR
Soulie et al.	73 (older than 75 years)	39	Median 79.3 years (75–89)	Median 14.4 (6–74)	3 (7.69%)	NR	NR
Madersbacher et al.	412	131 (long term survivors >5 years post op)	Median 62 years (15–82)	Median 98 (60–354)	18 (13.74%)	NR	NR
Knap et al.	268	195	Median 65 years	Median 2.6 years (0–9.5 years)	15 (7.69%)	NR	NR
Kouba et al.	137	137	Mean 71.5 years	Mean 29	19 (13.8%)	Mean 8.4 (6–30)	Clinical. Imaging requested only for clinical suspicion of PH
Khalil et al.	36	36 (long term survivors > 5 years)	Median 61 years (48–72)	Median 82 (61–118)	4 (11.11%)	NR	NR
Shimko et al.	1057	1045	Median 69 years (31–92)	Median 6.3 (0.1–29.1)	147 (14.06%)	Median 2.4 years (0.2–18.3)	NR
Pisters et al.	496	496	Mean	Median 16 (1–189)	61 (12.29%)	NR	Clinical examination
			Ant fixation 71.3 years (41–93)		Ant fascial fixation (43/281, 15.3%)		
			Post fixation 74.6 years (41–91)		Post fascial reinforcement (6/51, 11.7%)		
			No fixation 70.0 years (42–87)		No fascial fixation (12/164, 7.3%)		
Donahue et al.	433	386	Median 74 years (68–79)	NR	137 on radiology (35.4%)	27% (95% CI 22–33%) at 1 year	CT/MRI 137
					93 clinical exam (24.09%)	48% (95% CI 42–55%) at 2 years	Type 1, 5 (4%),
							Type 2, 90 (66%)
							Type 3, 41 (30%)
							Clinical diagnosis 93

Table 3 continued

Author	No of patients in the study	No of IC included in the study	Age (range)	Follow-up months (range)	No of PH (%)	Interval to diagnosis of PH (months)	Diagnostic criteria
Liu et al.	516 RC and IC	199 (FU for at least 1 yr)	Median No PH 72 years (66.1–76.6) PH 70.2 years (60.5–77.6)	27 median (12–125)	58/199 (29%)	Median 14	CT only 12 Examination only 5 CT + Examination 41
Movassaghi et al.	670	92	76.5 years (±8.7 years	Median 34 months (range 5–67)	21/92 (22.8%)	11.5 months median (1–37.2 months)	Clinical and radiological
Total	4733	3170			529 (17.18%)		

In most studies, the diagnosis of PH was based on the clinical examination finding of a protuberant swelling in the vicinity of the stoma; however, four studies utilized cross-sectional imaging in addition to physical examination [7, 20, 21, 22]. Of the 3170 patients who underwent ileal conduit surgery, 529 patients (17.1%) developed a PH based on either clinical examination or cross-sectional imaging. The rate of diagnosis of PH based on clinical examination alone ranged from 4.1 to 27.6%. One study reported utilizing CT scanning only if there was any diagnostic doubt on clinical examination [21]. Three studies used clearly defined radiological criteria to detect development of PH on cross-sectional imaging during routine follow-up after oncologic resection [7, 20, 21]. In these studies, the radiological diagnostic rate of PH was reported to be as high as 35.4% [7]. There was an attempt to qualify the type of PH visible on cross-sectional imaging using the classification of Moreno Matias et al. and it was reported that 80% of Type 1 and 30% of Type 2 hernias eventually progressed to Type 3 hernias [7, 23]. It was also reported that up to 40% of patients had symptoms from their PH in the form of discomfort, pain, obstruction or poor fit of appliance [7]. Six studies clearly reported the mean length of time period between the formation of ileal conduit and establishing diagnosis of PH and this ranged from 8.4 to 44 months [18, 20, 21, 22, 24, 25].

Secondary outcome measures

Patient-related factors and technical factors contributing to the development of PH were analysed in five studies [7, 20, 21, 22, 26]. Table 5 depicts the various risk factors assessed in different studies. BMI over 30, female gender, low albumin, previous laparotomy and longer operative times were reported to be a significant risk factor for PH. Age, smoking status, alcohol consumption, neo adjuvant chemotherapy or radiation therapy, diabetes mellitus type 1 and 2, chronic obstructive pulmonary disease, steroid use, estimated blood loss, post-operative pneumonia and wound dehiscence were not found to have a statistically significant association with development of PH.

Intraoperative technique was evaluated in two studies [20, 26]. One study assessed the role of fixation of ileal conduit to the anterior or posterior rectus sheath in preventing development of PH. This reported that anterior fascial fixation was an independent predictor of the development of PH (odds ratio, 2.3; 95% confidence interval, 1.03–5.14; $p < 0.04$) [26]. Another study reported that 4 quadrant fixation sutures did not prevent PH formation [20].

Symptoms and complications resulting from PH were reported in 1 study that showed that 3% of PH was asymptomatic although there was no documentation of symptoms in 57% patients [7].

Table 4 Secondary outcome measures

Author	Complications of PH (medical/surgical)	Risk factors for development of PH	Repair of PH
Klein et al.	Peristomal dermatitis 6	NR	9/12 (75%)
	Bleeding 6		
	Appliance difficulty 4		
	Stenosis 2		
	Ulceration 3		
Cheung et al.	Stenosis 7.3%	NR	6/34 (17.6%)
	Prolapse 4.1%		
	Peristomal Excoriation 20.3%		
	Peristomal dermatitis 17.9%		
Soulie et al.	Ureteral anastomosis stenosis 4	NR	NR
Madersba	Stoma-related complications in 32 (24%)	NR	15/18 patients needed
cher et al.	PH 18		19 surgical procedures
	Stenosis 8		
	Bleeding/skin irritation 6		
Knap et al.			8/15 repaired (53.3%)
Kouba et al.	Stomal stenosis 1 (0.7%)	BMI > 30 was associated with stomal complications.	6/19 (31.57%) repair (5 Laparoscopic/1 Open) for abdominal discomfort or appliance difficulty
	Stomal prolapse 1 with a parastomal hernia (0.7%) 13/19 Asymptomatic PH	Gender, age, race, smoking, alcohol,preoperative laboratory values or history of abdominal/pelvic radiation therapy had no bearing	Repair fashioned using mesh
			3/6 had recurrent PH (50%)
Khalil et al.	Stenosis 2 (1 repaired)	NR	3/4 repaired (75%)
	Prolapse and skin irritation 1 (repaired)		
Shimko et al.	NR	NR	12 (8.2%) repair or resiting of their stoma
			Stomal stenosis occurred in 22 patients (2.1%) at a median of 9.2 years (range 0.2 to 23.4)
			Two patients (9.1%) required revision of their stoma to correct the stenosis
Pisters et al.	NR	Anterior fascial fixation was an independent predictor of the development of parastomal hernia (odds ratio, 2.3; 95% confidence interval, 1.03–5.14; $p < 0.04$)	NR
		Previous abdominal surgery, post op pneumonia, High BMI, Age, COPD, Steroid, CT, RT wound dehiscence were not predictors of PH	

Table 4 continued

Author	Complications of PH (medical/surgical)	Risk factors for development of PH	Repair of PH
Donahue et al.	80% of Type 1 and 30% of Type 2 hernias eventually progressed to Type 3 hernias	Female gender, Higher BMI, Lower preoperative albumin was a risk factor for PH	93/137 radiographic PH had clinical PH
	Appliance Issues (poor fit, leakage) 15 (16%)	Age, DM, Smoking history, COPD, EBL, prior abdominal surgery, prior hernia repair, preop RT, neoadjuvant CT and stoma type have no statistical significance association with development of PH	37/93 (40%) of clinical PH were symptomatic
	Self-reported bother due to PH 10 (10%)		3/93 were asymptomatic
	Pain and discomfort associated with PH 8 (9%)		53/93 no documentation of symptoms
	Incarceration of PH 5 (5%)		75/93 prescribed hernia belt
	Asymptomatic 3 (3%)		16 referred for surgery
	No documentation of symptoms 53 (57%)		8/16 (50%) with Clinical PH had repair (2 emergency repairs for incarceration)
			3/8 repairs developed recurrence (37.5%)
Liu et al.	The cumulative risk of parastomal hernia formation at 1 and 2 years after cystectomy was 12.2% and 22.5%, respectively	Previous Laparotomy, Longer operative time and Severe Obesity	45% had repair
		(BMI > 40)were predictive of PH	Indications for surgical repair included
		Low Hb, DM type 1 and 2, Smoking, serum total protein and albumin levels, neoadjuvant chemotherapy and radiation therapy, EBL were not predictive of PH	15 (58%) cases of abdominal discomfort or poorly fitting ostomy appliance from a bulging hernia
		4 quadrant fascial fixation sutures did not prevent PH formation	4 (15%) with acute intestinal strangulation/ incarceration requiring urgent exploration.
			4 (15%) with partial small bowel obstructions
			3 (12%) elected for repair while undergoing another abdominal procedure
			Technique of repair
			Twenty patients (77%) had hernia repair with mesh,
			3 (12%) had relocation of the urostomy without mesh
			4 (15%) underwent laparoscopic repair
			Recurrence
			7 patients (27%) who had PH recurrence
			4 (57%) underwent at least a second surgical repair
Movassaghi et al.	Bulge and pain in 59%	Age, Gender, BMI or pre op albumin levels were not associated with the development of PH	2 patients underwent repair

Table 5 Assessment of risk factors associated with the development of PH

	Kouba et al.	Pisters et al.	Donahue et al.	Liu et al.	Movassaghi
Patient-related risk factors					
Age	NS	NS	NS	NA	NS
Female Gender	NS	NS	HR 2.25, 95% CI 1.58, 3.21; $p < 0.0001$	NA	NS
BMI	Patients in whom complications developed had a significantly higher mean BMI compared to those without complications (30.8 vs. 26.5 kg/m^2, respectively, $p < 0.012$)	NS	HR 1.08, 95% CI 1.05–1.12; $p < 0.0001$	BMI > 40 Adjusted HR 4.26, 95% CI 1.52–11.93, $p = 0.006$	NS
Smoking	NS	NA	NS	NS	NR
COPD	NA	NS	NS	NA	NR
DM	NA	NA	NS	NS	NR
Anaemia	NA	NA	NA	NS	NR
Previous Laparotomy	NA	NS	NS	adjusted HR 1.98, 95% CI 1.97–3.36, $p = 0.011$	NR
Hypoalbuminemia	NS	NA	HR 0.43, 95% CI 0.25–0.75, $p < 0.003$	NS	NS
CT/RT	NS	NS	NS	NS	NR
Technique-related risk factors					**NR**
Operative time	NA	NS	NS	NA	NR
EBL	NA	NA	NS	NS	NR
Fascial fixation	NA	Anterior fascial fixation was an independent predictor of the development of PH (OR, 2.3; 95% CI, 1.03–5.14; $p = 0.04$	NA	4 quadrant fixation did not prevent development of PH	NR
Type of stoma	NA	NA	NS	NA	Turnbull stoma
Post op wound dehiscence	NS	NA	NA	NA	NR

NA Not assessed, *NS* not significant, *BMI* body mass index, *COPD* chronic obstructive pulmonary disease, *DM* diabetes mellitus, *CT/RT* neoadjuvant/adjuvant chemotherapy, *EBL* estimated blood loss, *fascial fixation* anterior/posterior/none, *Type of stoma* end or Turnbull

Between 8.2 and 75% with a PH were offered a repair depending upon the severity of the symptoms and stage of the malignancy; however, none of the studies had a clearly defined selection criterion for offering a repair. A variety of surgical techniques were used to repair PH including tissue repair, synthetic mesh, and biologic mesh and relocating the stoma. One study reported using mesh repair with laparoscopic approach [21]. The rate of recurrence following repair of PH was reported in three studies ranging from 27 to 50% [7, 20, 21].

None of the studies in our review used patient-reported outcome measures (PROMS) or quality of life indices for assessment of symptoms of PH. Complications in patients who were offered non-operative management were not reported in any of the included studies.

Discussion

In this systematic review, we describe the frequency and risk factors associated with the development of PH in patients undergoing cystectomy and ileal conduit urinary diversion. All the studies in this review were limited by being retrospective in nature. Data obtained from review of clinic notes, may not include PH observation and, therefore, they provide Level IV evidence. Most studies have a

heterogeneous group of patients with short- and long-term follow-up.

Due to the lack of standard criteria regarding reporting of morbidity, comparison with other studies was not undertaken. There has been an attempt to classify the complications of surgical procedures in order to rank and compare complications objectively. The Clavien–Dindo classification system has gained widespread acceptance, however, none of the included studies in this review attempted to grade the complications resulting from PH repair. The core outcome measures in effectiveness trials (COMET) initiative proposes the development and application of agreed standardised sets of outcomes, known as *'core outcome sets'* [27]. The development of core outcome datasets usually requires a broad range of stakeholder groups and Delphi methodology. These sets represent the minimum that should be measured and reported in all clinical trials of a specific condition. It may be most appropriate to develop such core outcome datasets under auspices of appropriate surgical specialty organisations such as the European Hernia Society. Widespread uptake of core outcome sets will bring uniformity in data collection and enable a meaningful conclusion to be drawn from comparison of studies with different designs.

There was a significant variation in the protocol to follow up patients following an oncological resection. The length of follow-up of patients following their surgery has an impact on the diagnosis of PH as patients who are followed up closely for a longer duration tend to have higher rates of detection of PH, especially if there is regular cross-sectional imaging following a cancer resection.

In the studies that utilized cross-sectional imaging for diagnosis of PH, the radiological follow-up focused on looking for local or distant recurrence of the disease rather than PH. Radiographic diagnosis is more sensitive compared to clinical examination and tends to pick up clinically asymptomatic hernia [7]. It is objective and reproducible and can be used to assess the progression of PH. There is evidence from studies of gastrointestinal stomas that cross-sectional imaging in prone position is superior to supine position at identifying PH [28]. In none of the studies included in this review on parastomal hernias around an ileal conduit were patients assessed radiologically in the prone position to evaluate the size of the defect and tissues involved [28, 29]. There are some new radiographic classification systems that are yet to be used widely and may have some role in the objective assessment of progression of PH over the follow-up period [29].

Patient related risk factors were analysed in four included studies. BMI greater than 30, previous laparotomy and longer operative time were found to be significantly predictive of PH. Age, race, smoking status, alcohol consumption, neoadjuvant radiation therapy, chemotherapy, COPD, steroid therapy, Diabetes mellitus, excessive blood loss and type of stoma had no significant association. Donahue et al. reported that female gender and lower preoperative albumin level were independent risk factors but this was not observed in the study by Kouba et al. [21]. A statistically significant association of female gender, high BMI and preoperative albumin levels with the development of PH was reported in one study [7]. In this study, there was no statistically significant association between the development PH and age, diabetes, smoking history, COPD, estimated blood loss, prior abdominal surgery, prior hernia repair, preoperative radiation therapy, neoadjuvant chemotherapy, and stoma type (end vs. Turnbull loop stoma).

The role of technical factors and position of stoma during construction of the conduit in relation to the rectus abdominis muscle was not well reported in the included studies.

It appears that a substantial number of PH remain asymptomatic and are never detected unless cross sectional imaging has been used for oncologic follow-up. There are no prospective studies that have directly compared parastomal hernia detection rates between physical examination and cross sectional imaging for parastomal hernia around an ileal conduit. There is considerable debate within the hernia literature regarding exactly what constitutes the reference standard for a parastomal hernia in general. Presence or absence of a histologically proven hernia sac at surgery or autopsy may well be the definitive reference standard but is unachievable in clinical practice. Patient reported outcome measures for parastomal hernia development have not yet been adequately described or validated. With regard to parastomal hernia around an ileal conduit, retrospective series such as Donahue et al. have given insufficient data to allow direct comparison of the two techniques of clinical examination and cross sectional imaging. Extrapolating from gastrointestinal stomas, cross sectional imaging in the prone position with an inflatable rubber ring around the stoma has a much higher detection rate for parastomal herniae as opposed to just the physical examination [28]. A pragmatic view may be that clinical examination forms the mainstay of quotidian practice and that cross-sectional imaging is reserved for cases of diagnostic uncertainty.

The surgical repair of a PH is often avoided due to the high morbidity rate, high recurrence rate and the technical difficulty of the operation. Moreover, some patients with recurrent or metastatic cancer may not be suitable candidates for surgery. None of the studies in our review reported on the outcome of patients who were managed conservatively with a hernia belt.

Surgical repair of PH is generally offered to patients who are either symptomatic or are facing significant

problems with the fit of the stoma appliance. Choice of repair was dependent upon the surgeon preference and it was not clear if there is an ideal repair technique. Approaches commonly used for PH repair include local repair, synthetic mesh, biological mesh or occasionally, relocating the stoma. Local repair using native tissues have high recurrence rates and relocating the stoma to another quadrant of the abdominal wall still requires closure of the original defect putting both the sites at risk of herniation [10]. There is currently no data available in the literature alluding to the *'gold standard'* technique for repair of PH due to a lack of standardisation and reporting either by classification (e.g. EHS or Moreno-Matias) or by stoma type. The outcomes of parastomal hernia repair are highly variable but have largely been reported by gastrointestinal stomata [29]. The applicability of the techniques described by Hansson et al. in their review to parastomal hernia repair around an ileal conduit is unknown since there is a paucity of published data. It is hypothesised that the approaches to repair of parastomal hernia repair around an ileal conduit hernia may differ from gastrointestinal stomas in that the ureteric attachment tethers the deep portion of the conduit to the posterior abdominal wall. Depending on the length of the conduit, the laparoscopic modified Sugarbaker technique of parastomal hernia repair favoured by many may not be feasible as the conduit may not be of sufficient length to allow lateralisation and peritonealisation by mesh placement.

Preventing development of PH may be the way forward and identifying those at greatest risk by meticulous preoperative assessment prior to cystectomy can help plan the operative technique. Bringing out the conduit through the rectus muscle may help reduce the risk of PH [30]. Several randomised controlled trials of prophylactic placement of mesh at the time of construction of the colostomy have demonstrated a reduction in the development of PH by up to 50% [31]. A recent publication by Israelsson's group studied the prophylactic use of lightweight mesh positioned in the sublay position at the time of construction of the ileal conduit in 114 patients [32]. They reported a PH rate of 14% which is similar to the overall rate that we have found in this systematic review and it is difficult to conclude if there is any merit in the use of a prophylactic mesh. Moreover, the rate of recurrence of PH following a repair is significantly high and there is paucity of data, which could influence the procedure of choice when dealing with recurrent PH. It is possible that development of PH is related to the intrinsic properties of abdominal wall fascia and amount of type 1 collagen deposition rather than surgical techniques [33].

Conclusion

This systematic review shows that the incidence of PH is high although the majority of herniae are asymptomatic. The reported incidence of PH depends on the duration of clinical follow-up and the use of cross sectional imaging in the follow-up after cancer resections. Of the symptomatic PH only a small subgroup of patients are deemed suitable for operative repair. The recurrence rates following repair of PH are high. Appropriate patient selection and meticulous surgical technique may be important in preventing the development of PH. Identifying those at greatest risk may permit use of prophylactic mesh in selected patients at the time of the initial surgery. The long-term benefit of this technical modification would require formal evaluation.

Compliance with ethical standards

Conflict of interest SKN, NNA, SP, NC and JM have no conflict of interest to declare. NJS and IRD declare conflict of interest not directly related to the submitted work.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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