



# Incidence and risk factors of parastomal hernia after radical cystectomy and ileal conduit diversion: a systematic review and meta-analysis

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**Background:** Our aim is to report the incidence and risk factors of parastomal hernia (PH) after radical cystectomy (RC) and ileal conduit (IC) diversion with a cumulative analysis.

**Methods:** Various databases, including PubMed, the Cochrane Library, Embase and Web of Science, were retrieved electronically and manually to identify eligible studies from inception to August 20, 2020. Two reviewers independently searched the above databases and selected the studies using prespecified standardized criteria. The Newcastle-Ottawa Scale (NOS) was used to assess the risk of bias in the included studies, and the data was completed by STATA version 14.2.

**Results:** Fifteen studies were included in the final analysis. A pooled analysis of eight studies representing 1,878 patients reported the incidence of overall radiographic PH was 23% (95% CI: 17–29%). The 1-year PH incidence rate and 2-year incidence rate of RC and IC were 14% (95% CI: 6–22%) and 26% (95% CI: 14–38%), respectively. A pooled analysis of nine studies reported the incidence of clinically evident PH was 15% (95% CI: 10–19%). PH-related symptoms were reported in six studies, and the pooled result was 29% (95% CI: 24–33%), and a pooled analysis of ten studies showed that 20% (95% CI: 11–28%) of patients required surgical repair. However, it's noteworthy that among symptomatic PH patients undergoing surgical repair, the pooled analysis of five studies showed that up to 26% (95% CI: 16–36%) of patients suffered PH recurrence. The most frequent risk factor was body mass index (BMI). Patients with BMI  $\geq 22.9$  kg/m<sup>2</sup> experienced 2.92-fold higher risk of PH than their counterparts [hazard ratio (HR): 2.92; 95% CI: 1.65–5.19].

**Conclusions:** Our findings indicated that the PH incidence rate after RC and IC was significantly higher in radiographic evaluation than that of clinical examination, and the recurrence of repairment is considerable for patients requiring reconstruction.

**Keywords:** Parastomal hernia (PH); ileal conduit diversion (IC diversion); radical cystectomy (RC); bladder cancer

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## Introduction

Bladder cancer is one of the most pernicious urologic cancers globally, with an estimated 549,000 new cases and 200,000 deaths each year (1). It is universally acknowledged that BC not only poses a great threat on patients' existence and quality of life, but also increases drastically the economic burden of the national health care system (2). Radical cystectomy (RC) and ileal conduit (IC) diversion has currently been regarded as the mainstream treatment of muscle-invasive and high-risk non-muscle-invasive bladder cancer (3). However, this approach is usually associated with noteworthy complications and higher mortality concerning the complexity of the operation involving urinary and intestinal systems (4).

It is conceivable that the urinary diversion (UD) contributes to great risk of postoperative morbidity and complications other than cystectomy itself (4,5). Among the long-term complications reported, parastomal hernia (PH) is a frequent sequela resulting in cosmetic and functional concerns, and surgical repair is required in some cases, such as intestinal incarceration and strangulation (6,7). Concerning the incongruous incidence and risk factors, and deficiency of effective treatments, we determine to report the findings of this review with a cumulative analysis of incidence and risk factors of PH in patients undergoing RC and IC, and explore the potentially effective treatments for this medical problem. We present the following article in accordance with the PRISMA reporting checklist (available at <http://dx.doi.org/10.21037/tcr-20-3349>).

## Methods

### Study selection

In accordance with the Preferred Reporting Items for Systematic Review and Meta-analyses guidelines (8), various databases including PubMed, the Cochrane Library, Embase and Web of Science were systematically searched through electronic retrieval from inception to August 20, 2020 without language limitations. The Medical Subject Heading (MeSH) terms related to this article included "Hernia" and "Cystectomy", and the search strategy used in PubMed was as follows: ((Cystectomy[Title/Abstract]) OR (Cystectomies[Title/Abstract])) AND (((Hernia[Title/Abstract]) OR (Hernias[Title/Abstract])) OR (Enterocoele[Title/Abstract])). The specific search strategy is shown in [Appendix 1](#). We also artificially retrieved the reference lists of relevant reviews and articles

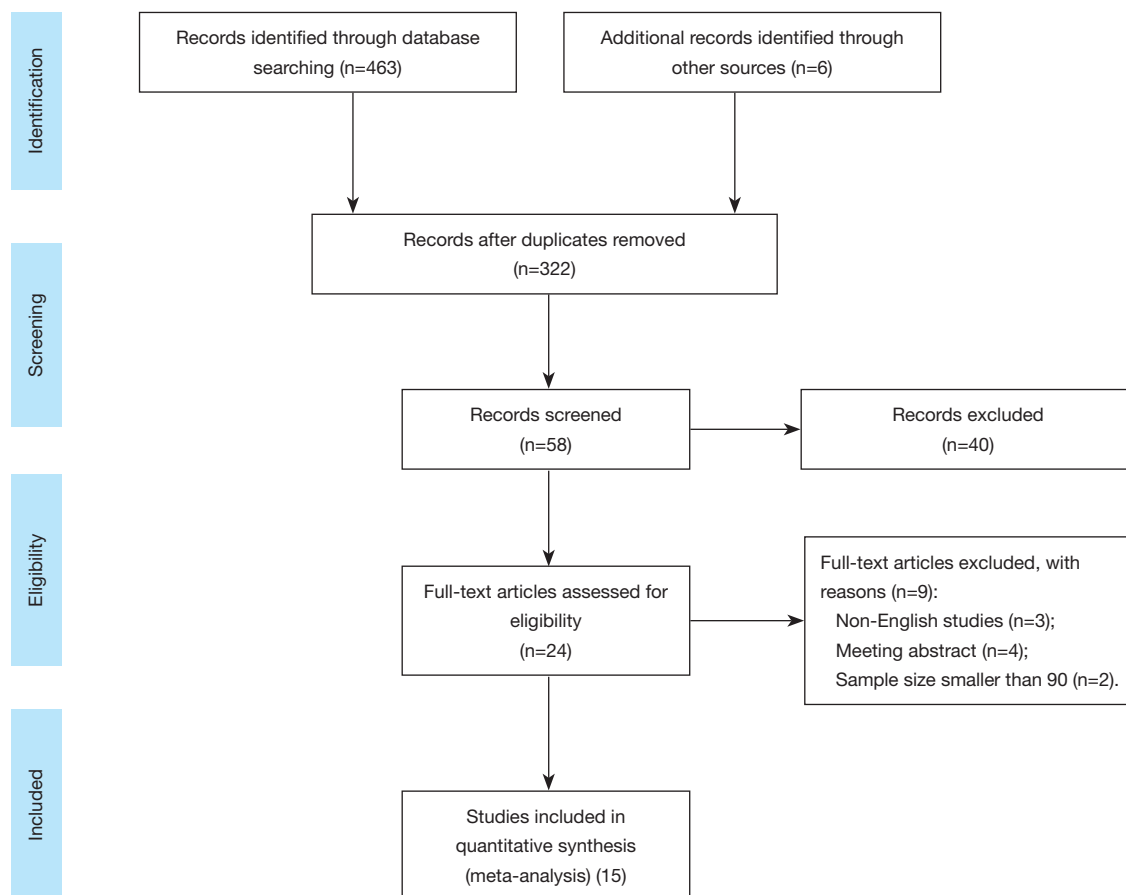
to expand the search. Two independent authors identified the potential studies for full-text evaluation based on screening titles and abstracts. Subsequently, articles that met the inclusion criteria were included in the final analysis. Data were extracted by two independent authors, and any disagreement was resolved by consensus or a third party. By formulating a table previously, we extracted the following data: (I) the first author name and publication year; (II) details of the study design; (III) the characteristics of the included patients, and (IV) data associated with outcomes of interest.

### Selection criteria

We used the following PICOS method to identify the qualification of included studies: (I) patients (P): patients undergoing RC and IC; sample size greater than 90; radiographically, PH was defined as evidence of the protrusion of abdominal contents through the abdominal wall defect created by forming the stoma. When present, PH grade was recorded using a previously published classification system of type 1-hernia sac that contains the prolapsed bowel loop forming the stoma, type 2-contains abdominal fat or omentum herniating through the abdominal wall defect created by the stoma and type 3-contains herniated loops of bowel other than that forming the stoma (9). Clinically, PH is defined as any protrusion in the vicinity of the urostoma with the patient straining in a supine and an erect position; (II) intervention (I): patients without any precaution for PH formation; (III) comparison; not applicable; (IV); outcomes (O): any study reporting incidence or risk factors of PH after RC and IC was collected. The main outcomes were the PH incidence rates of overall radiographic imaging and clinical examination; The secondary outcomes were the PH incidence of overall symptom, surgical repair and recurrence of reconstruction, and risk factors associated with PH. (V) Study design (S): full-text studies published with English. For articles with potentially overlapping population, only the largest report was included, unless they reported different outcomes of interest. Besides, exclusion criteria were as follows: (I) any study which did not satisfy the inclusion criteria; (II) single-case report, meeting abstracts, review or meta-analysis; (III) data not available. *Figure 1* sketches the PRISMA flowchart of this meta-analysis.

### Quality assessment

The methodological quality of included studies was assessed



**Figure 1** The PRISMA flowchart.

by two independent reviewers using the Newcastle-Ottawa Scale (NOS) (10). The NOS applied a ‘star system’ to evaluate the quality of study from three perspectives: the selection of the studies, the comparability of studies, and the assessment of outcome. If seven or more stars were received, the study was considered as to be high-quality. Furthermore, two reviewers independently rated the level of evidence of the included articles through the Oxford Centre for Evidence-Based Medicine criteria (11). This scale graded studies from strongest (level 1) to weakest (level 5) strength of evidence according to study design and data quality.

### Statistical analysis

The  $Q$  and  $I^2$  tests were calculated to assess the heterogeneity among studies. Pooled rates (PRs) or hazard ratio (HR) and corresponding 95% CIs were calculated through random-effect model unless the between-study

heterogeneity was endurable ( $P > 0.1$  or  $I^2 \leq 50\%$ ). We quantified the asymmetry of funnel plots through the Egger’s test and Begg’s test to evaluate the underlying publication bias. A  $P$  value of less than 0.1 was regarded as significant. In addition, we conducted a sensitivity analysis through single factor analysis to evaluate the robustness of the pooled effects. For all statistical analyses, two-sided  $P < 0.05$  was considered statistically significant. Data from each study were pooled where possible, otherwise narrative review was conducted. This meta-analysis was accomplished through STATA version 14.2.

## Results

### Literature search results

After removing duplicates, screening titles and abstracts, and evaluating full texts, 15 (9,12-25) of 469 studies containing 4,252 patients were included to evaluate the incidence of

PH after RC and IC. The studied population came from USA (9,12,14,15,18,20,24,25), China (22), Switzerland (23), Denmark (13), Japan (16,17), Spain (19), and Sweden (21). The vast majority of articles were reported retrospectively, and the span of median time to diagnosis of PH was from 11 to 28.8 months. *Table 1* showed the characteristics of included studies in this meta-analysis.

### Incidence

A total of eight studies (9,12,15,16,18-21) representing 1,878 patients reported the incidence of overall radiographic PH, and the rates ranged from 10% to 35%. As integrated, PH developed in 23% (95% CI: 17–29%; *Figure 2*) of patients who underwent RC and IC. The between-study heterogeneity was obvious ( $P < 0.001$ ,  $I^2 = 90.8\%$ ; *Figure 2*). A pooled analysis of three studies (9,18,21) showed that the PH incidence rate of open RC (ORC) and IC was 27% (95% CI: 19–36%; *Figure 2*). The 1-year PH incidence rate and 2-year incidence rate of RC and IC were 14% (95% CI: 6–22%; *Figure 2*) and 26% (95% CI: 14–38%; *Figure 2*), respectively. Similarly, patients undergoing ORC and IC had a higher risk of 2-year radiographic PH (PR: 37%; 95% CI: 14–59%; *Figure 2*). The incidence of clinically evident PH after RC and IC was provided in nine studies including 2,433 patients (9,13,14,17,21-25), and the synthesized result was 15% (95% CI: 10–19%; *Figure 2*). The heterogeneity among studies was also detected ( $P < 0.001$ ,  $I^2 = 90.2\%$ ; *Figure 2*). Only two studies (9,12) reported the incidence of type 1 PH and type 2 PH, and the corresponding PRs were 1% (95% CI: 0–2%; *Figure 2*) and 16% (95% CI: 4–29%; *Figure 2*), respectively. A total of three studies (9,12,21) provided the incidence of type 3 PH, and the pooled result was 10% (95% CI: 8–12%; *Figure 2*). Only Donahue *et al.* (9) reported the results of progression to a higher type of hernia. They observed that 80% (1/5) of initial type 1 hernias progressed to type 3 while 33% (30/90) of initial type 2 hernias progressed to type 3. In addition, Hussein *et al.* (12) reported that 32% patients developed PH after robot-assisted RC (RARC) and IC at 3 years.

PH-related symptoms, such as pain, bowel incarceration, appliance difficulties, discomfort, or PH-induced leakage, were reported in six studies (9,12,14,16,19,20), and the incidence rate ranged from 15% to 44%. The pooled results indicated that 29% (95% CI: 24–33%; *Figure 3*) of PH patients were at risk of presenting symptoms without significant between-study heterogeneity

( $P = 0.302$ ,  $I^2 = 17.2\%$ ; *Figure 3*). A pooled analysis of ten studies (9,12,14-21) including 455 symptomatic patients showed that 20% (95% CI: 11–28%; *Figure 3*) of patients who underwent RC and IC required surgical repair with significant heterogeneity among studies ( $P < 0.001$ ,  $I^2 = 82.8\%$ ; *Figure 3*). Besides, the surgical repair rate of symptomatic patients after ORC and IC was provided in three studies (9,18,21), and the synthesized result was 7% (95% CI: 3–11%; *Figure 3*). We did not observe an evident between-study heterogeneity ( $P = 0.163$ ,  $I^2 = 44.9\%$ ; *Figure 3*). However, it's noteworthy that among symptomatic PH patients undergoing surgical repair, the pooled analysis of five studies (9,12,14,15,19) showed that up to 26% (95% CI: 16–36%; *Figure 3*) of patients suffered PH recurrence.

### Risk factors

A wide array of independent risk factors was reported. A pooled analysis of two studies (12,16) showed that patients with fascial defect size 24 mm or greater experienced 6.80-fold higher risk of PH than their counterparts (HR: 6.80; 95% CI: 3.54–13.06; *Figure 3*). A pooled analysis of two studies (9,21) showed that per increased unit of body mass index (BMI) was associated with the increasing risk of PH (HR: 1.05; 92% CI: 1.05–1.11). Furthermore, patients with  $BMI \geq 22.9 \text{ kg/m}^2$  had 2.17 times higher risk of PH than their counterparts (HR: 2.17; 95% CI: 0.81–5.80) (16). Other significantly reported risk factors included female (HR: 2.25; 95% CI 1.58–3.21) (9), preoperative albumin (HR: 0.43; 95% CI: 0.25–0.75) (9), longer operative time [odds ratio (OR): 1.25; 95% CI: 1.06–1.46] (12), postoperative eGFR less than 60 mL per minute (OR: 2.17, 95% CI: 1.23–3.90) (12), prior exploratory laparotomy (HR: 1.98; 95% CI: 1.97–3.36) (15), prior tobacco use (OR: 0.23; 95% CI: 0.09–0.63) (20), anterior fixation (OR: 2.3; 95% CI: 1.03–5.14) (24), prophylactic mesh (OR: 0.49; 95% CI: 0.26–0.95) (21) and surgery in one of the hospitals (OR: 3.34; 95% CI: 1.39–8.06) (21).

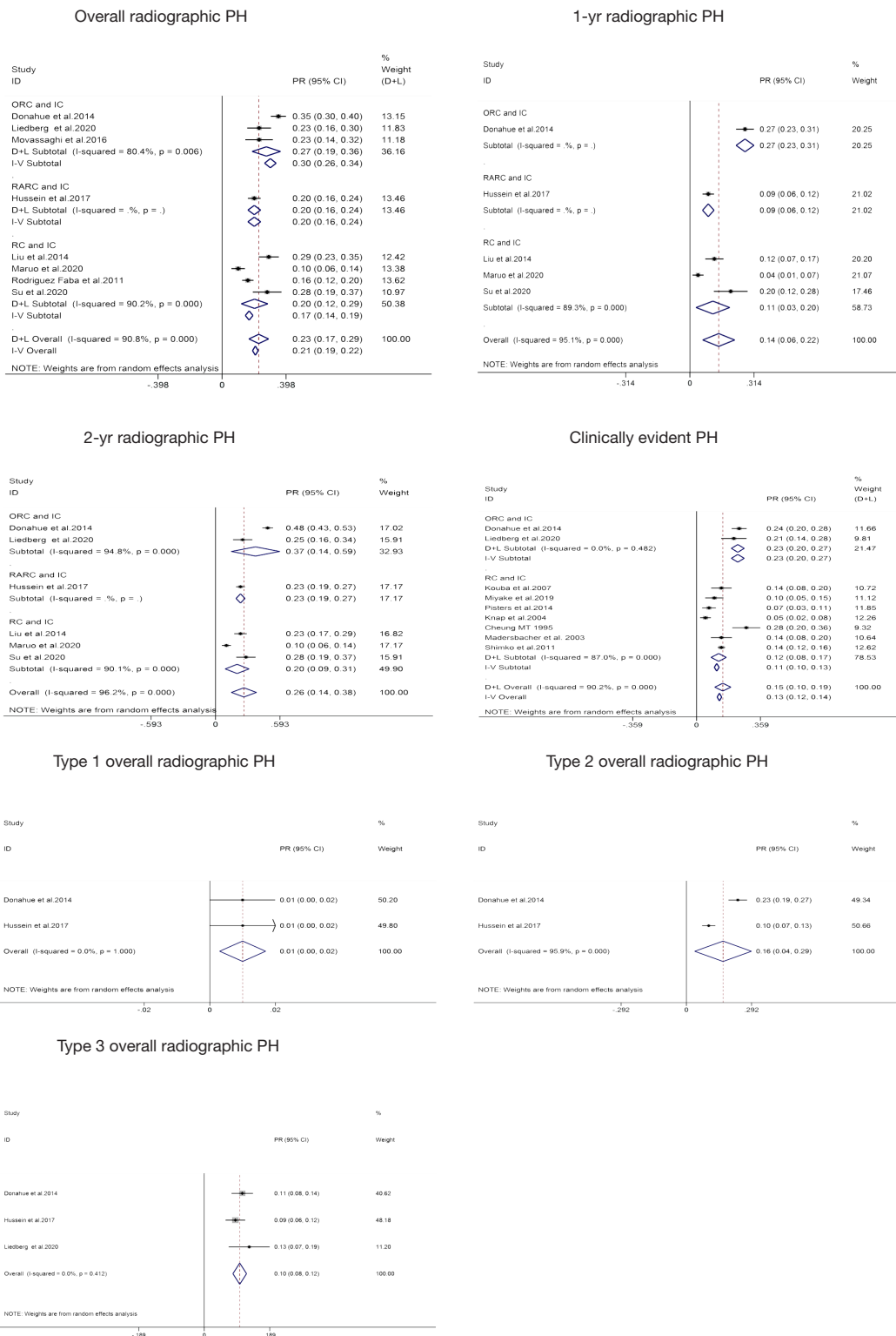
### Publication bias and sensitivity analysis

We employed the Egger's test and Begg's test to quantify the asymmetry of funnel plots, and P value greater than 0.1 meant no obvious publication bias. The results of Egger's test and Begg's test related to the main outcomes were provided in *Table S1*. Generally speaking, we did not detect noticeable publication bias. We evaluated the impact of a single study on the combined effect size through

**Table 1** The basic characteristics of included studies in this meta-analysis

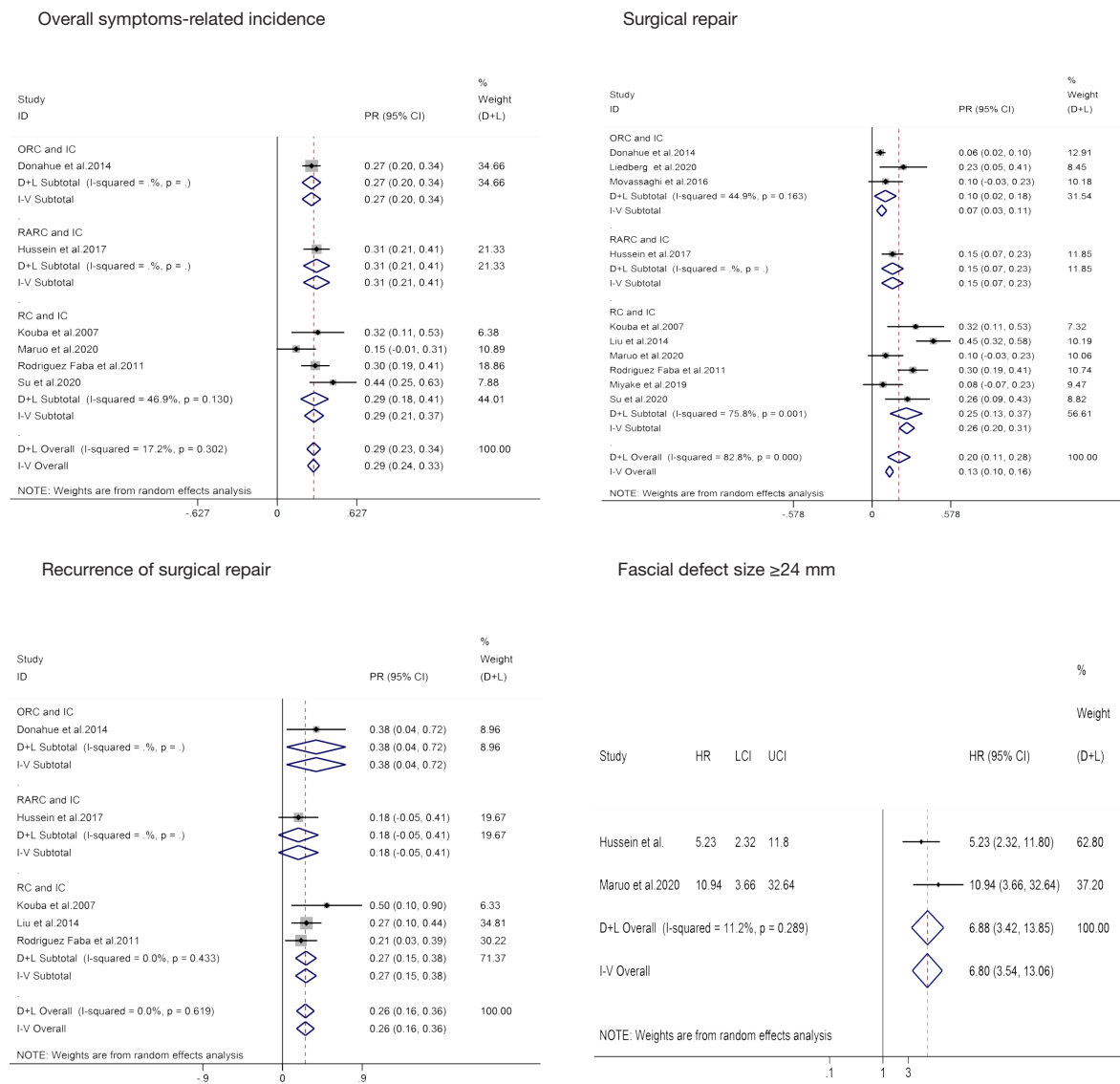
Study	Year	Country	Study type	Samples	Duration	Time to PH	Surgical type	Overall incidence (%)	Risk factors	NOS*	LoE
Donahue <i>et al.</i>	2014	USA	Retrospective	386	2006.1 to 2010.10	Median: 1 year	ORC and IC	35.4	Female, BMI, preoperative albumin	9	2b
Hussein <i>et al.</i>	2017	USA	Retrospective	383	2005 to 2016	Median: 13 months (IQR, 9–22)	RARC and IC	19.5	Operative time, postoperative eGFR less than 60 mL per minute, fascial defect size 30 mm or greater	9	2b
Knap <i>et al.</i>	2004	Denmark	Retrospective	195	1992.1 to 1998.12	NR	RC and IC	5.1	NR	7	4
Kouba <i>et al.</i>	2007	USA	Retrospective	137	2001 to 2005	Mean: 8.4 months (range, 6–30)	RC and IC	13.9	NR	8	4
Liu <i>et al.</i>	2014	USA	Retrospective	199	2001 to 2011	Median: 14 months (range, 1–105)	RC and IC	29.1	BMI, prior exploratory laparotomy	9	4
Maruo <i>et al.</i>	2020	Japan	Retrospective	194	2005 to 2016	Median: 25.5 months	RC and IC	10.3	BMI, DPRAM	8	4
Rodriguez Faba <i>et al.</i>	2011	Spain	Retrospective	405	2000 to 2006	NR	RC and IC	15.6	NR	7	2b
Miyake <i>et al.</i>	2019	Japan	Retrospective	129	2000 to 2017	Median: 11 months	RC and IC	10.1	NR	7	4
Movassaghi <i>et al.</i>	2016	USA	Prospective	92	2003 to 2013	Median: 11.5 months (range, 1–37.2)	ORC and IC	22.8	NR	8	4
Su <i>et al.</i>	2020	USA	Retrospective	96	2011 to 2016	NR	RC and IC	28.1	BMI, prior tobacco use	8	4
Pisters <i>et al.</i>	2014	USA	Retrospective	496	1994.7 to 2010.8	NR	RC and IC	7.3	Anterior fixation	8	2b
Cheung MT	1955	China	Retrospective	123	NR	NR	RC and IC	27.6	NR	7	2b
Madersbacher <i>et al.</i>	2003	Switzerland	Retrospective	131	1971.3 to 1995.9	NR	RC and IC	13.7	NR	9	4
Shimko <i>et al.</i>	2011	USA	Retrospective	1,045	1980 to 1998	Median: 2.4 years (range, 0.2–18.3)	RC and IC	14.1	NR	8	2b
Liedberg <i>et al.</i>	2020	Sweden	RCT	241	2012.8 to 2017.5	NR	ORC and IC	22.8	BMI, prophylactic mesh, surgery in one of the hospitals	-	1b

\*, The methodological quality of Liedberg *et al.* (21) was low, high, low, low, low, low, and unclear risk in turn according to the Cochrane Collaborator's RoB tool in Review Manager software (<https://community.cochrane.org/help/tools-and-software/revman-5>). NR, not reported; PH, parastomal hernia; IQR, interquartile range; RC, radical cystectomy; RARC, robot-assisted RC; ORC, open RC; IC, ileal conduit; BMI, body mass index; DPRAM, diameter of the passage through the rectus abdominis muscle for the IC; NOS, Newcastle-Ottawa Scale; LoE, level of evidence; RoB, risk of bias.



**Figure 2** The pooled results of the primary outcomes in this study. PH, parastomal hernia; PR, pooled rate; RC, radical cystectomy; ORC, open RC; RARC, robot-assisted RC; IC, ileal conduit.





**Figure 3** The pooled results of the secondary outcomes in this study. PR, pooled rate; RC, radical cystectomy; ORC, open RC; RARC, robot-assisted RC; IC, ileal conduit.

excluding each study in sequence, and the results of the sensitivity analysis indicated that the pooled effects were robust (Figure S1).

**Discussion**

Perioperative outcomes and complications are the primary two aspects that patients are most concerned about. Postoperative complications are inevitable for complex procedures such as RC. As is known to all, ORC with extended pelvic lymph node dissection has been gold

standard for patients with muscle-invasive and high-risk non-muscle-invasive bladder cancer for decades (3). However, conspicuous complications and higher mortality leave much to be desired (4). Although our previous studies indicated that minimally invasive approaches, scilicet RARC and laparoscopic RC (LRC), presented improved perioperative outcomes and comparable pathological and oncologic outcomes at the cost of longer operative time when compared to ORC (26,27), on no account can we ignore the fact that many of the perioperative complications following RC might derive from the reconstructive part

of the procedure, and overwhelming majority of studies included in our meta-analysis were insufficient information of stomal-related complication, such as PH whose incidence was not low (PR: 23%; 95% CI: 17–29%).

RC is generally accompanied by the UD, which is closely related to the patient's long-term quality of life. Since it was introduced by Seiffert and popularized by Bricker (23), the IC has been the gold standard for those with incontinent UD and has still been the primary choice for patients with contraindications to continent UD for over seven decades due to its simplicity and practicability (16,17). Extensively used as IC is, stoma-related complications are rarely reported in spite of relatively high incidence of 25% to 60% (14). PH is a relatively common complication with specific to IC. In our study, the synthesized rate was 23%, and the PH incidence seemed to be associated with length of follow up. The PH incidence rate at 1 and 2 years were 14% and 26%, respectively. Besides, the detection rate of radiographic evaluation is higher than that of clinical examination (23% *vs.* 15%). The reason was that clinical evaluation is enslaved to variation in terms of whether it is patient reported *vs.* documented on physical examination, and whether examination was performed with the patient supine or upright and with or without the Valsalva maneuver (6,12). On the other hand, radiological images are more objective, less prone to variation due to body habitus and not subject to bias while it also enables consideration of other aspects, including rectus muscle defects and abdominal wall thickness, which may contribute to PH (6,12).

In most cases, PH is symptomless and incidentally diagnosed during cancer surveillance. In our cumulative analysis, a total of 29% of PH patients suffered from symptoms. Symptoms related to PH included pain, discomfort, bowel incarceration. Moreover, if the hernia increases in size, distortion of the abdominal wall might obstruct the application of the stoma bag, leading to urine leakage. Additionally, our study indicated that a total of 20% of symptomatic patients with PH required surgical correction, but the recurrence of surgical repair was as great as 26%. There are currently conflicting results of risk factors associated with PH. Obesity is the most frequently reported factor among them. Based on our clinical experience, diameter of the passage through the rectus abdominis muscle for the IC (DPRAM), prophylactic mesh, and surgery in one of the hospitals are the most potential factors in addition to obesity. Several corrective techniques have been reported to repair PH, including

translocation of the stoma (19), anterior fixation (24), and mesh usage (7,21,28–30). Prophylactic mesh placement has been demonstrated safe and effective in reducing PH rate for patients undergoing elective colorectal operation (31). However, there is a paucity of data alluding to the use of mesh in prevention or repairment of PH. Considering that a PH constitutes a significant clinical problem for the individual patient, it pays to be further investigated the role of a prophylactic mesh.

Our study did have the following limitations. First of all, there were inherent limitations in the included studies of this meta-analysis. The retrospective study may lead to selection bias, such as Berkson bias and Neyman bias. Secondly, the broad heterogeneity in study populations, designs and definitions of outcome measures. Finally, different follow-up duration detected among the included studies also affected the incidence rates, and we were unable to evaluate the long-term incidence rate of PH.

## Conclusions

Our findings indicated that the PH incidence rate of radiographic evaluation and clinical examination were 23% and 15%, respectively. A total of 29% of PH patients suffered from symptoms, and a total of 20% of symptomatic patients with PH required surgical correction. However, the recurrence of surgical repair was as great as 26%. Given that a PH constitutes a noticeable clinical problem for the individual patient, it pays to be further investigated the PH-related risk factors and the role of a prophylactic mesh.

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## Footnote

*Reporting Checklist:* The authors have completed the PRISMA reporting checklist. Available at <http://dx.doi.org/10.21037/tcr-20-3349>

*Conflicts of Interest:* All authors have completed the ICMJE uniform disclosure form (available at <http://dx.doi.org/10.21037/tcr-20-3349>). The authors have no conflicts of interest to declare.



**Ethical Statement:** The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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