The Role of Mechanical Bowel Preparation before Ileal Urinary Diversion: A Systematic Review and Meta-Analysis

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Key Words

Bowel preparation · Urethral reconstruction · Radical cystectomy

Abstract

Background: Although the use of mechanical bowel preparation (MBP) is still widely promoted as the dogma before patients undergo ileal urinary diversion, an increasing number of clinical trials have suggested that there is no benefit. Thus, we performed a meta-analysis to evaluate the efficacy of MBP in ileal urinary diversion surgery. **Methods:** A literature search was performed in electronic databases, including PubMed, Embase, Science Citation Index Expanded as well as the Cochrane Library and the Cochrane Clinical Trials Registry, from 1966 to January 1, 2013. Clinical trials comparing outcomes of MBP versus no MBP for ileal urinary diversion surgery were included in the meta-analysis. Pooled odds ratios with 95% confidence intervals were calculated using the fixed- or random-effects models. **Results:** In total, two randomized controlled trials and five cohort studies were included in this meta-analysis. The primary outcomes, such as bowel leak and bowel obstruction, showed no statistical difference between the two groups. Additionally, the overall mortality rate and death rate related to operation also manifested that MBP does not offer an advantage over the no MBP. **Conclusion:** This meta-analysis suggests that

MBP does not reduce the incidence of perioperative complications in urinary diversion compared with no MBP. However, large randomized controlled clinical trials are needed to confirm this finding.

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Introduction

Radical cystectomy (RC) and urinary diversion is the standard resection for muscle-infiltrating bladder tumors and recurrent, high-grade, superficial transitional cell carcinomas that are not controlled by other treatments [1, 2]. The second procedure in RC for bladder tumors and other serious bladder diseases is complex and associated with high risks and complications. In virtue of advances in surgical technical and perioperative medical care, its safety has improved significantly in many institutions around the world. Nevertheless, the surgical morbidity remains higher than in any other urologic procedure because of a series of serious complications [3, 4].

The key point in reconstructive surgeries on bowel segments is bacterial contamination. To reduce the re-

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lated incidence, the routine use of mechanical bowel preparation (MBP) prior to intestinal surgery was considered as a standard practice for many years without changes. However, this reasonable practice was called into question by colorectal surgeons. Through related research, they suggested that bowel preparation was dispensable [5, 6], and subsequent meta-analyses of randomized trials arrived at the same conclusion [7, 8].

For urinary diversion surgery, information regarding the dogma was scant. Recently, a meta-analysis by Yang et al. [9] comparing comprehensive MBP with limited bowel preparation suggested that there was no advantage to justify strict protocols before surgery. However, there were some limitations in their study. First, the sample size of this study was small because some important articles were not included [10–13]. In addition, limited BP was not really free preparation, but requested the patient to receive oral laxatives.

In order to achieve a more comprehensive conclusion, we designed this meta-analysis. The major objective was to pool the outcomes of ileal urinary diversion with or without MBP and to determine whether there is a difference between these measures.

Materials and Methods

Study Selection

A comprehensive literature search in Medline (PubMed), Embase, Science Citation Index Expanded as well as the Cochrane Library and the Cochrane Clinical Trials Registry, from 1966 to January 1, 2013, was performed to identify human trials published in the English language literature to compare MBP versus no MBP for ileal urinary diversion surgery.

The medical subject headings (MeSH) terms or equivalent free texts ‘bowel preparation’, ‘urinary diversion’ and ‘radical cystectomy’ were used in the search strategy. The full electronic search strategy for PubMed is provided in the online supplementary table (www.karger.com/doi/10.1159/000354326). Relevant papers were also identified from the bibliographies of papers obtained through the search. Besides, all relevant studies were identified by the experts in urology.

Inclusion and Exclusion Criteria

Two authors (S.D. and P.Z.) selected the eligible papers independently. For inclusion in this meta-analysis, a study had to fulfil the following criteria: (1) Patients (there were no restrictions concerning race, age, gender and duration of disease) who had bladder tumors or other serious bladder diseases and who underwent RC and urinary diversion were enrolled in the review. (2) The patients in the no MBP group received no oral laxatives or antibiotics preoperatively and were allowed oral intake before surgery; the patients in the MBP group received oral antibiotics and/or bowel preparation preoperatively. Other interventions were the same between the two groups. (3) At least one of the outcomes concerning

surgical complications was mentioned. (4) The papers were English language articles published in peer-reviewed journals; the following studies were not considered for meta-analysis: (a) abstracts, letters, editorials, expert opinions, reviews, and case reports; (b) no relevant result measure reported; (c) studies comparing different bowel preparation solutions rather than MBP versus no preparation; (d) studies comparing different bowel preparation pattern; (e) patients who received Indiana pouch diversion, previous intestinal surgery, previous radiation or chemotherapy, who had advanced liver or kidney disease and metastatic disease, or who received immunosuppression or antibiotic administration within 1 week before surgery.

Data Extraction and Quality Assessment

The first author (S.D.) extracted the data independently by using a pre-designed data extraction form including data source, eligibility, methods, participant characteristics, interventions and results. The other author (P.Z.) repeated the same procedures. Inconsistencies were resolved by discussion to achieve a final consensus. When this failed, another author (Q.D.) adjudicated. The Cochrane Collaboration Reviewers’ Handbook was used to assess the quality of the included randomized controlled trials (RCTs), including generation of randomization sequences, allocation concealment, blinding of outcome assessment, incomplete outcome data, selective reporting and other bias [14].

Outcome Measurements

Perioperative complications and related inpatient indicators were evaluated. We divided the complications into three classes: (1) infection-associated complications (*Clostridium difficile* colitis, urinary tract infection or urosepsis, non-urologic sepsis, abdominal abscess, peritonitis); (2) wound complications (wound infection, wound dehiscence, fascial dehiscence); (3) bowel function-associated complications (bowel obstruction, fistula, bowel leak, postoperative emesis). In addition, we examined the overall mortality rate and death rate related to operation. The primary outcomes were bowel leak, bowel obstruction and mortality; the other complications were all secondary outcomes.

Statistical Analysis

The Review Manager 5 software (The Cochrane Collaboration, Oxford, UK) was used to analyze the data. The χ^2 test was used to detect heterogeneity, with a p value <0.100 considered as statistical significance. The I^2 statistic was used for assessing the quantity of heterogeneity, and presence of heterogeneity was considered if I^2 was $>50\%$ [15]. At first, a fixed-effects model was applied. According to DerSimonian and Laird [16], if there was evidence of heterogeneity among the included studies, then the random-effects analysis was used. If these models came to the same conclusion, the results for the fixed-effects model were reported. Otherwise, the results of both the fixed-effects and the random-effects models were reported. For this reason, the results of the meta-analysis [odds ratio (OR) and corresponding 95% confidence interval (CI)] were presented as more conservative estimates compared with an analysis using a fixed-effects model in the absence of clinical heterogeneity [17]. Different definitions of outcome parameters, variability of interventions and perioperative management could account for the causes of heterogeneity. A subsequent sensitivity analysis was also performed to test the reliability of the results if remarkable heterogeneity existed.

Fig. 1. Flow diagram depicting the study selection process in accordance with the PRISMA guidelines.

Results

Trial Characteristics

Initially, 73 articles were identified. Through initial selection and screening, 62 articles were excluded. The remaining 11 articles were selected for further investigation. Of these, 1 study lacked a control group [18], 2 studies made an inappropriate comparison [19, 20], and 1 study focused on old people [21]; these studies were all excluded. In the end, 7 articles were identified for inclusion (two RCTs and five cohort studies) [10–13, 22–24]. The overall risk of bias was unclear in 2 RCTs. Figure 1 shows the selection process using the PRISMA criteria [25]. The study characteristics of the included studies are shown in table 1.

Patient Characteristics

Most of the patients recruited in the included studies were bladder tumor patients who underwent RC and urinary diversion treatment performed by ileal conduit or orthotopic neobladder. Only 19 cases were neurogenic bladder patients who received ileocystoplasty [22]. Considering that the subjects of this study were the patients who underwent urinary diversion surgery, we did not rule out this research.

Meta-Analysis Results

Infectious Complications. Complications were analyzed by subgroups: *Clostridium difficile* colitis, urinary tract infection or urosepsis, non-urolologic sepsis, peritonitis and abdominal abscess. The test for heterogeneity among studies was not statistically significant, so the fixed-effects model was used for all comparisons. Two studies reported *Clostridium difficile* colitis and the results did not favor MBP [10, 12] (OR 2.97; 95% CI 0.94–9.33; $p = 0.06$). Five studies described urinary tract infection or urosepsis and the pooled results did not favor MBP (OR 2.97; 95% CI 0.94–9.33; $p = 0.06$) [10–12, 23, 24]. Two studies reported non-urolologic sepsis and no difference was found in the incidence with MBP (OR 0.71; 95% CI 0.10–5.15; $p = 0.73$) [11, 12]. Abdominal abscess was described in four studies [10–12, 22]; no difference was found in the incidence with MBP (OR 0.53; 95% CI 0.15–1.87; $p = 0.32$). Two studies reported peritonitis and no difference was found in the incidence with MBP [11, 22] (OR 2.29; 95% CI 0.09–58.85; $p = 0.62$). The whole subgroup analysis is shown in figure 2.

Wound Complications. Complications were analyzed by three subgroups: wound infection, wound dehiscence and fascial dehiscence. The test for heterogeneity among

Fig. 2. Meta-analysis of infectious complications.

Table 1. Basic characteristics of included studies

Authors and country	Trial type	Year	Patients, n		Gender ratio (m/f)		Methods of MBP		Preparation time, days	No preparation	Follow-up, days
			MBP	no MBP	MBP	no MBP	MBP	no MBP			
Large et al. [10], USA	prospective study	2012	105	75	83/22	58/17	GoLYTELY		1	liquid diet	30
Hashad et al. [13], Egypt	RCTs	2012	20	20	18/2	17/3	day 3: liquid diet + oral bisacodyl; day 2: liquid diet + castor oil + normal saline enema; day 1: liquid diet + erythromycin + metronidazole + castor oil + normal saline enema + overnight fasting		3	not available	not available
Xu et al. [24], China	RCTs	2010	47	39	38/9	31/8	day 1: oral sodium phosphosoda + oral erythromycin t.i.d. + metronidazole; day 2: the same as day 1		2	fluid diet	not available
Raynor et al. [11], USA	retrospective study	2013	37	33	31/6	23/10	clear liquid diet + oral magnesium citrate solution		1	normal diet	30
Arumainayagam et al. [12], UK	retrospective study	2008	56	56	42/14	44/12	sodium picosulfate		1	normal breakfast, not clear fluids	available
Tabibi et al. [22], Iran	prospective study	2007	30	32	25/7	22/8	day 1: soft liquid diet + oral bisacodyl; day 2: soft liquid diet + castor oil + normal saline enema; day 3: soft liquid diet + castor oil + oral erythromycin + normal saline enema		3	soft diet	375
Shafii et al. [23], Ireland	retrospective study	2002	64	22	43/21	15/7	day 1: low-residue diet + castor oil; day 2: oral metronidazole + oral neomycin; day 3: clear fluids only + oral antibiotics + tap water enema; day 4: clear fluids only + oral antibiotics + rectal washouts		4	not available	not available

studies was not statistically significant, so the fixed-effects model was used for all comparisons. All trials reported the rate of wound infection [10–13, 22–24]. The pooled estimate indicated that the outcome measure was not affected by the use of MBP (OR 0.84; 95% CI 0.41–1.75; $p = 0.65$). Wound dehiscence was described in six studies [10–13, 22, 23]; the pooled results failed to support MBP (OR 2.16; 95% CI 0.92–5.08; $p = 0.08$). Two studies reported the number of patients who experienced fascial dehiscence postoperatively [10, 11]; the pooled estimate indicated that the outcome measure was not affected by the use of MBP (OR 1.02; 95% CI 0.22–4.65; $p = 0.098$). The whole subgroup analysis is shown in figure 3.

Bowel Function-Associated Complications. Complications were analyzed by the following subgroups: fistula, bowel leak, postoperative emesis and mortality rate. The test for heterogeneity among studies was not statistically significant, so the fixed-effects model was used for all comparisons. All trials reported the rate of bowel obstruction [10–13, 22–24]. The pooled estimate indicated that the outcome measure was not affected by the use of MBP (OR 1.36; 95% CI 0.60–3.07; $p = 0.46$). Fistula was described in five studies [10–12, 22, 23]. The pooled result showed no difference in the incidence with MBP (OR 0.61; 95% CI 0.23–1.61; $p = 0.32$). Five studies reported bowel leak and no difference was found in the incidence with MBP [10–12, 22, 24] (OR 1.11; 95% CI 0.34–3.64; $p = 0.87$). Postoperative emesis was described in two studies [11, 12]; the pooled results showed no difference with MBP (OR 1.71; 95% CI 0.36–8.25; $p = 0.50$). The whole subgroup analysis is shown in figure 4.

Mortality Rate. No difference was found in either peri-operative deaths (six trials [10–12, 22–24]) (OR 0.64; 95% CI 0.26–1.59; $p = 0.34$) or death related to operation (three trials [10, 23, 24]) (OR 0.89; 95% CI 0.18–4.52; $p = 0.89$). The whole subgroup analysis is shown in figures 5 and 6.

Sensitivity Analysis

A further sensitivity analysis was performed according to the publication type of the included studies. The results are presented in table 2. They were in line with the aforementioned results, indicating a comforting reliability.

Discussion

In the 1940s, the idea of bowel preparation emerged and was generally accepted by the 1970s [24]. The formation of this concept has much to do with the following

Fig. 3. Meta-analysis of wound complications.

reasons: (1) Bacteria, which were often considered the culprit of relative complications, can be reduced to a maximum [26]. (2) Without the impact by intraluminal hard feces, the anastomotic stoma is relative safer [27]. (3) Time can be saved by skipping the step of clearing feces in the operation, which is safer for the patient [28]. As bowel preparation gained popularity and became widely used in colorectal surgery, pioneers in urology attempted to use this method in urologic surgeries. In 1977, Freiha

[29] described a method of bowel preparation for urologic surgeries. After that, it was widely considered to be classic, almost all urologists followed this practice in RC from then on.

The concept seemed to logical, but was questioned by a series of data obtained by intestinal surgeries. Some clinical trials found no significant benefits obtained from preoperative bowel preparation [30–33], and the related meta-analyses also drew similar disappointed conclu-

Fig. 4. Meta-analysis of bowel function-associated complications.

Fig. 5. Meta-analysis of perioperative mortality rate.

Fig. 6. Meta-analysis of mortality rate related to operation.

sions [7, 8, 34]. In addition, some studies pointed out that this intervention can cause some adverse effects for patients, such as metabolic disturbances and intestinal mucosal architectural change, which both may adversely affect patients' rehabilitation after surgery [35, 36].

The emergence of similar reports inspired gastroenterologists and colorectal surgeons to abandon the code. Since there are only a few articles regarding this topic in urologic surgery, the data are limited. Can we abandon this long-standing practice? There is no definitive answer.

Nowadays, there is no clear unified decision-making advice on the efficacy, safety and advantage of that concept for MBP in urology, mostly due to a lack of evidence from large randomized clinical trials. Meanwhile, even when using this method, significant differences were encountered in the application of each method. Just examining the 7 articles included, the type of the enema and

the preparation periods were not all the same. Besides, some scholars recognized its inadequacy, but reluctantly abandoned it completely. They thought that limited bowel preparation was equivalent to traditional 3-day bowel preparation [20]. Despite the hundreds of urinary diversion surgeries which are performed in our hospital each year, we are still accustomed to the traditional bowel preparation. We could infer that heterogeneity in the practice patterns would be similar in most countries.

Recently, a meta-analysis by Yang et al. [9] examined comprehensive MBP versus limited bowel preparation and found that there is no advantage to justify strict protocols before surgery. Regrettably, there were some limitations in this study. First, the study sample size was small, just four articles were included. Second, the authors defined limited bowel preparation as no bowel preparation, or at the most a single enema administration before sur-

Table 2. Sensitivity analysis

Comparison item	RCTs				Observational studies			
	OR	95% CI	I ²	p	OR	95% CI	I ²	p
Infection-associated complications								
<i>Clostridium difficile</i> colitis					2.97	0.94, 9.33	0%	0.06
Urinary tract infection or urosepsis	2.55	0.10, 64.33		0.57	1.48	0.71, 3.11	0%	0.3
Non-urologic sepsis					0.71	0.10, 5.15		0.73
Abdominal abscess					0.53	0.15, 1.87	44%	0.32
Peritonitis					2.29	0.09, 58.85		0.62
Wound complications								
Wound infection	1.48	0.49, 4.44	0%	0.49	0.78	0.35, 1.73	0%	0.54
Wound dehiscence	3.15	0.12, 82.16		0.49	2.16	0.92, 5.08	25%	0.08
Fascial dehiscence					1.02	0.22, 4.65	0%	0.98
Bowel function-associated complications								
Bowel obstruction	0.91	0.18, 4.63	0%	0.91	1.61	0.66, 3.93	1%	0.29
Fistula					0.61	0.23, 1.61	14%	0.32
Bowel leak	0.83	0.05, 13.65		0.89	1.18	0.32, 4.41	0%	0.81
Postoperative emesis					1.71	0.36, 8.25	0%	0.5
Perioperative mortality rate	0.83	0.05, 13.65		0.89	0.62	0.24, 1.62	0%	0.33
Mortality rate related to operation	2.55	0.10, 64.33		0.57	0.62	0.10, 4.08	0%	0.62

gery. However, limited bowel preparation was not really free preparation; it also requested the patient to receive oral laxatives. Third, by examining the limited bowel preparation pattern in the four articles, we found that three studies used no bowel preparation, just one adopted one-day bowel preparation. Thus, the findings may be not accurate.

For the reasons given above, we designed this analysis to assess the value of preoperative MBP in ileal urinary reconstruction for muscle-invasive bladder cancer and other serious bladder diseases to a certain extent. It included the largest number of patients and showed the synthetically optimal result includes more information and contains all the virtues of multiple evaluation results. As mentioned above, we divided the complications into three classes: infectious complications, wound complications and bowel function-associated complications. None of the statistics confirm that the bowel preparation regimen is beneficial. All research reported the length of hospital stay, and two reports showed a short hospitalization time with bowel preparation [12, 23]. Due to the different health system models, the index was different. Besides, we failed to merge the data because of different statistical methods for the same reason as the other indexes – day of regular diet, operative time and time to bowel movement. Also, there was no difference in the death rate.

Although we achieved the similar conclusions to those of Yang et al. [9] that MBP did not reduce the incidence

of perioperative complications in urinary diversion compared with no preparation, this meta-analysis included more patients, and since the patients in the no MBP group received no oral intestinal lavage solution, the evidence was higher and more novel than that of Yang et al.

Although this review provides the best available evidence for comparison of MBP versus no MBP in urinary diversions to date, as always there are some limitations to this meta-analysis, particularly as a result of the nature of the primary data. To begin with, most of the articles were retrospective studies, and the strength of the evidences was not as powerful as that of RCTs. Second, most of the analyzed studies had different follow-up periods; some even did not report these data. Therefore, potential delayed complications remain uninvestigated, which may lead to an imprecise estimation of any long-term beneficial effects. Third, almost all patients included in this meta-analysis were bladder tumor patients, but this surgical option is not limited to specific populations in urology. Thus, the present findings do not sufficiently apply to urinary diversion surgery.

In conclusion, this meta-analysis suggests that MBP did not reduce the incidence of perioperative complications in urinary diversion compared with no MBP. Due to limited studies with poor quality, large randomized controlled clinical trials are needed to confirm this finding.

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Disclosure Statement

The authors declare no conflict of interest.

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