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Original article

A prospective randomized multicenter study of Turkish Society of Urooncology comparing two different mechanical bowel preparation methods for radical cystectomy

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Abstract

Objective: To investigate the outcomes and complication rates of urinary diversion using mechanical bowel preparation (BP) with 3 day conventional and limited BP method through a standard perioperative care plan.

Materials and methods: This study was designed as a prospective randomized multicenter trial. All patients were randomized to 2 groups. Patients in standard 3-day BP protocol received diet restriction, oral antibiotics to bowel flora, oral laxatives, and saline enemas over a 3-day period, whereas limited the BP arm received liberal use of liquid diet, sodium phosphate laxative, and self administered enema the day before surgery. All patients received same perioperative treatment protocol. The endpoints for the assessment of outcome were anastomotic leakage, wound infection, wound dehiscence, intraperitoneal abscess, peritonitis, sepsis, ileus, reoperation, and mortality. Bowel function recovery, including time to first bowel movement, time to first oral intake, time to regular oral intake, and length of hospital stay were also assessed.

Results: Fifty-six patients in 3-day BP and 56 in limited BP arm were evaluable for the study end points. Postoperatively, 1 patient in limited BP and 2 patients in 3-day BP arm died. There was no statistical difference in any of the variables assessed throughout the study, however, a favorable return of bowel function and time to discharge as well as lower complication rate were observed in limited BP group.

Conclusions: Regarding all endpoints, including septic and nonseptic complications, current clinical research offers no evidence to show any advantage of 3-day BP over limited BP.

Keywords: Bladder cancer; Radical cystectomy; Mechanical bowel preparation; Urinary diversion

1. Introduction

Radical cystectomy represents the standard treatment for muscle-invasive and non-muscle-invasive bladder cancer not controlled by conventional treatment options [1,2]. Modern surgical techniques and improved perioperative care have significantly lowered the morbidity and mortality rate. Infectious complications, however, still are a major concern of morbidity leading to increased cost, prolonged hospital stay, and even mortality. Bowel preparation (BP) and perioperative care are key issues in decreasing morbidity and mortality as much as surgical technique and anesthetic procedures. Mechanical BP is aimed at cleaning the

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bowel of fecal content, thereby reducing the rate of infectious complications following surgery. Traditionally, bowel cleansing was achieved using enemas in combination with oral laxatives over a period of diet restriction. Freiha described a 3-day mechanical BP method accompanied by oral antibiotic prophylaxis for urologic surgeries in 1977, and since then most institutions used similar regimens [3]. The disadvantages, including patient exhaustion, patient inconvenience, long hospitalization, and potential nutritional imbalance have encouraged surgeons to reconsider BP protocols. A substantial number of nonrandomized and randomized trials have shown no additional protective effect of mechanical BP in elective colorectal surgery, in the presence of an adequate systemic antibiotic prophylaxis [4]. All these factors have resulted in modifications of BP protocols, and conventional rigid BP protocols have nowadays been replaced by less uncomfortable methods of BP, mainly by the use of more efficient laxative solutions. Limited BP methods with fast track programs have been advocated, but these are not yet used in all institutions [5–9]. While few authors have suggested limited regimens, others have questioned the need for any BP for radical cystectomy [5–7,10–12]. Because evidence mainly based on the large existing data from colorectal surgery and lack of evidence from prospective randomized cystectomy series, this prospective randomized study sought to investigate the outcomes and complication rates of urinary diversion following radical cystectomy for bladder cancer using mechanical BP with 3-day conventional and limited BP method through a standard per operative care plan.

2. Methods

This is a multicenter, prospective, randomized, trial conducted by the Turkish Society of Urooncology between June 2008 and November 2010. The study was approved by the local Institutional Review Board and by the local ethical committees, and all patients provided written informed consent to participate in the study.

2.1. Inclusion criteria

Candidates for radical cystectomy for bladder cancer with curative intent and intestinal urinary reconstruction were enrolled in this study. Eligible patients for whom radical cystectomy was indicated were those with muscle-invasive bladder cancer or with high-risk non-muscle-invasive bladder cancer or recurrent bladder cancer failed to conservative treatment. Patients were excluded if they had history of inflammatory bowel disease, prior abdominal bowel surgery, abdominal radiation, neoadjuvant chemotherapy, or liver and renal dysfunction.

2.2. Study design

All patients were randomized to two groups: standard 3-day BP protocol and limited BP protocol. Randomization was performed using internet via official web site of the Turkish Urooncology Society. All study participants enter this web site with their own password given by this society and obtain study protocol over a secure server. There was an electronic randomization table specifically designed for this study, which consisted of numbers from 1 to 120 allocated to each protocol equally. The allocation of numbers was blind to study participants and configured by the administration. After enrollment and registration on the web-based system, the surgeon ticked a number in the electronic randomization table describing which BP protocol is going to be used. All chosen numbers are automatically sealed off in order to prevent repeat selection.

BP protocol for each group and perioperative care program is described in Table 1. Oral intake was stopped 8 h before surgery in both groups. All patients received intravenous prophylactic antibiotics administered 1 h before surgery and continued on postoperative day 3 in both groups. Prophylaxis for deep venous thrombosis was done using low molecular weight heparin, sequential compression devices and elastic stockings, which was continued postoperatively.

Physical examination, vital signs, and laboratory tests (complete blood count, kidney and liver function tests, electrolytes, blood gas analysis) to show any change in laboratory values including electrolyte abnormalities were obtained at baseline and on the morning of surgery. Any complication or adverse events related to BP method were also recorded until the morning before surgery using Common Terminology Criteria for Adverse Events, ver. 3.0.

Except for the BP method, all patients received the same perioperative treatments (Table 1). Combined general and epidural anesthesia was given. All procedures were done by open surgery and the urinary diversions performed included orthotopic neobladder or ileal conduit. All patients underwent standard (from the level of the bifurcation of the iliac vessels) or extended (from the level of inferior mesenteric artery) bilateral pelvic lymph node dissection to the node of Cloquet distally. In all patients, the bowel chosen for the urinary diversion was the distal ileum, sparing the terminal 15 to 20 cm. The bowel continuity was restored using a stapler or hand sewn suture dependent to the surgeon's discretion. The nasogastric tube was removed on postoperative day 1, and an oral diet was instituted the following day beginning with clear liquids irrespective of presence of flatus or bowel movement unless patient experiences nausea or emesis. Patients with normal renal function and no other specific contraindications received the non-narcotic analgesic for the first 48 hours postoperatively, in addition to a narcotic analgesic (usually morphine) as needed by way of a patient-controlled delivery system or by epidural catheter. Criteria for hospital discharge included tolerance of regular

Table 1
Bowel preparation (BP) and perioperative care plan

	3-day BP	Limited BP
Bowel preparation		
Day 1	Soft liquid diet Enema 1 × 1 Oral bisacodyl 15 mg at 6 PM	—
Day 2	Soft liquid diet Sennoside 250 ml (2 mg/ml) 10 AM and 18 PM. Saline enema 21 PM Oral erythromycin 1 g t.i.d Oral metronidazole 1 g t.i.d	—
Day 3	Clear liquid diet until 8 PM IV fluid as needed Sennoside 250 ml (2 mg/ml) 10 AM and 18PM Saline enema 21 PM Oral erythromycin 1 g t.i.d Oral metronidazole 1 g t.i.d	Clear liquid diet until midnight Fleets phospho soda (C.B. Fleet) 45 ml taken at 2 PM and 18 PM Fleet enema self administered (C.B. fleet) 21 PM
Perioperative care plan	Adequate control of fluid and electrolyte balance Antibiotics: Metranidazole 1 g 3rd generation cephalosporin 1 g, i.v., 1 hour before surgery along with 3 postoperative days b.i.d. DVT prophylaxis: Varix stockings Low mol weight heparin 0.6 cc the night before surgery until mobilization Postoperative: Gastrointestinal ulcer prophylaxis with an H2 blocking agent Supplemental pain management with CaP or by Epidural catheter Parenteral non-narcotic analgesics for 48 hours then convert to oral NSAID Early mobilization: Day 1 NG tube out, nill by mouth Day 2 clear liquids as tolerated Day 3 soft diet as tolerated Day 4 regular diet as tolerated	

diet, satisfactory pain control with oral agents alone, pelvic drains were removed, and complete understanding of urostomy care. Patients were followed up at 2 weeks, 1 and 3 months postoperatively, and continued every 6 months thereafter.

2.3. Outcome measures

The endpoints for the assessment of outcome were anastomotic leakage, wound infection, wound dehiscence, intraperitoneal abscess, peritonitis, sepsis, ileus, re-operation, and mortality. Wound infection was defined as the discharge of pus or the presence of a serous discharge that contained pathogens. Intra-abdominal abscess was defined as either visual evidence of a localized collection of pus at relaparotomy or the demonstration on imaging of a localized collection that on aspiration contained pathogens. Anastomotic leak was identified if demonstrated by imaging or documented in surgery, or if fecal drainage was evident through a peri-anastomotic drain. Postoperative ileus was defined as the persistent absence of flatus or stool on postoperative day 4. When the patient experienced nausea, emesis, or gas distension on abdominal X-ray film, the patient was considered to have ileus and his/her diet was stopped.

Also, length of hospital stay (recorded as postoperative day), and time to first bowel movement, time to first flatus, time to first oral intake, time to regular oral intake, were assessed. The complications were recorded including those occurring during hospitalization and during the first 30 days after discharge and including all readmissions.

2.4. Statistical analysis

Quantitative data are expressed as median (range) or mean as appropriate. Statistical analysis was done using the Statistical Package for Social Sciences software, ver. 13.0 (SPSS, Chicago, IL). Student's *t*-test was used for continuous parametric variables, and the χ^2 test was used for categorical variables. The Mann-Whitney test was used for nonparametric data. Statistical significance was set at a P value < 0.05.

3. Results

A total of 120 patients were enrolled to study from 9 centers. Two patients were excluded from the study because

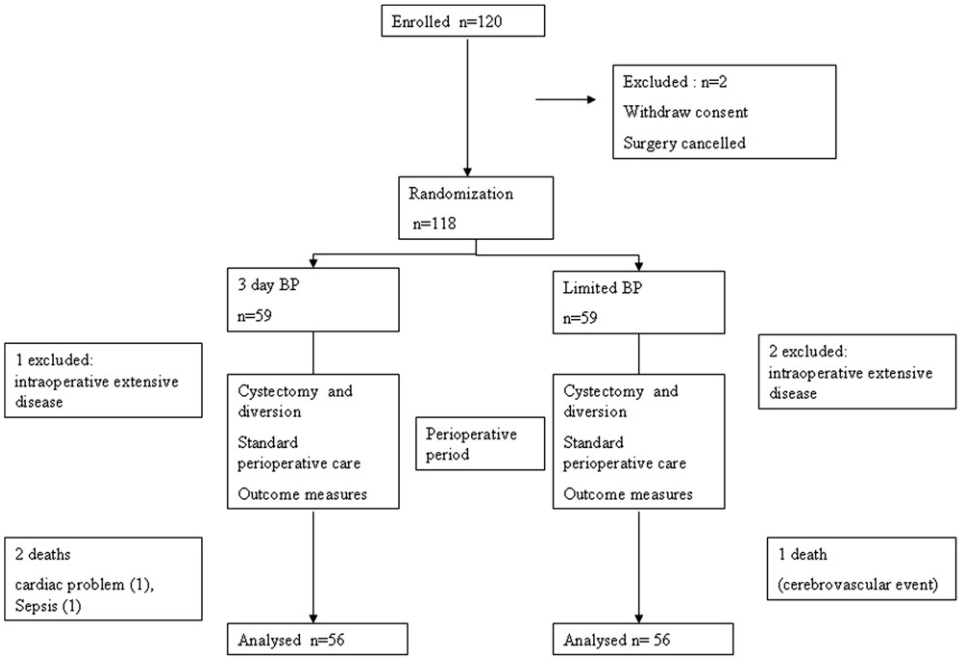

Fig. 1. CONSORT diagram. Enrollment and randomization scheme for patients.

their operations were cancelled either by themselves or the comorbid conditions that needed to be further treated before surgery.

Thus, 118 patients were equally randomized to either standard 3-day BP or limited BP protocol. At surgery, 2 patients in limited-BP arm and 1 in 3-day BP were found to have extensive disease (multiple positive paraortic lymph nodes determined by frozen section analysis, invasion to or fixated to rectum and anteriorly to pelvic side wall) and were thus excluded from the study. Postoperatively, 1 patient in limited BP and 2 patients in 3-day BP arm died. Thus, 56 in standard 3-day BP and 56 in limited BP arm were assessable for the study end points. The flow of participants is shown in Fig. 1.

The demographic and clinical characteristics and type of surgery did not significantly differ between the two groups (Table 2). BPs were generally well tolerated by the patients. Preparation related symptoms of cramping, bloating, nausea, and vomiting were generally mild and infrequent. No significant difference in incidence and type of side effects was seen between 3- day BP or limited BP before surgery. Patient discomfort due to diet restriction and hunger was significant in the 3-day protocol. No important changes occurred in the complete blood cell count, sodium, potassium, calcium, blood gas analysis, urea, or creatine in any patient from pre-preparation baseline through the morning before surgery. We did not observe any clinical manifestations related to electrolyte abnormalities, and no patient required specific treatment for these.

When assessing the main outcomes of this study, there was no significant difference in the rate of postoperative wound infections, ileus, clinical anastomotic leaks, or intra-abdominal abscesses between the 2 groups (Table 3). The overall complication rate was not significantly different between the 2 groups.

There was no significant difference in the time to recover bowel function between the 2 groups (Table 2). However the first bowel movement and time to flatus were considerably shorter in limited BP group. Time to institution of a clear liquid diet was similar in both groups but time to regular diet was 1 day earlier in limited group. The median length of hospital stay in 3-day BP and limited BP groups were 13 and 12 days, respectively.

There was no difference between the 3-day BP and limited BP groups with respect to the rate of wound infection and wound dehiscence (5.3% vs. 3.5%, $P = 0.54$ and 14.2% vs. 12.5%, $p = 0.78$ respectively). Postoperative ileus developed in 6 (10.7%) patients in 3-day BP and in 5 (8.9%) in limited BP arm. No patient needed surgical intervention for ileus and all episodes of ileus in both groups resolved with standard therapy. There was 1 anastomotic leak in each group that resulted in peritonitis and fever. They were reoperated within 8 days after cystectomy, and repeat enteroenterostomy were performed successfully. Fever was observed postoperatively in both groups (12.5% vs. 9%, $P = 0.64$). There was only 1 patient in 3-day protocol having ESBL + *E. coli* urinary tract infection. Urine leak was observed in 1 patient in each group, which ceased after insertion of percutaneous nephrostomy catheter, and recovered with no further intervention. Diarrhea in the early postoperative period was observed in 1 patient. Reoperations were limited to those with anastomotic leakage and wound repair.

Mortality occurred in 2 patients in 3-day BP group and 1

Table 2
Demographics and patient outcome

	3-Day BP	Limited BP	*P*
Mean age	61.5 ± 9.6	61.3 ± 8.7	0.89
Male	45	46	0.80
Female	11	10	
Diversion type			0.40
Conduit	47	50	
Neobladder	9	6	
Anastomosis technique			0.33
Stapler	26	21	
Primary suture	30	35	
Extended lymphadenectomy			0.59
Yes	41	39	
No	15	17	
Pathologic stage (AJCC2002)			0.85
Bladder confined (pT0-pTa-pT1-2.N0M0)	28	25	
Locally advanced (pT3-4a N0M0)	18	20	
Extravesical (pT4b-pN+ M0)	10	11	
Operation time (overall)			0.7
Mean	305.9 ± 91.9	312.8 ± 89.6	
Range	165–510	160–500	
Interval to flatus (hours)			0.66
Median	70	48	
Range	12–168	20–120	
Interval to bowel movement (hours)			0.34
Median	48	42	
Range	8–96	12–120	
Interval to clear liquid diet (hours)			0.48
Median	72	72	
Range	24–168	23–144	
Interval to regular diet (days)			0.17
Median	6	5	
Range	2–11	2–12	
Drains removed (days)			0.78
Median	9	9	
Range	3–21	2–15	
Hospital stay (days)			0.97
Median	13	12	
Range	5–61	5–52	

in limited BP group. One 78-year-old man in 3-day BP group died due to sepsis and septic shock. Although none of these patients underwent an autopsy, the other 2 deaths were not attributed to surgical infectious complications (1 cardiogenic shock due to ischemic heart disease, 1 cerebral vascular event of ischemic attack of brain). Two major complications occurred in 3-day BP group after surgery; 1 pulmonary embolism and 1 respiratory difficulty of a man with history of COPD. All these cases were treated accordingly and problems resolved with therapy.

4. Discussion

Our prospective randomized study has shown that there is no advantage to 3-day mechanical bowel preparation before surgery in patients undergoing radical cystectomy and urinary diversion. With reference to outcome parameters such as anastomotic leakage, wound infections, ileus, hospital stay, and bowel function recovery, no significant difference could be found between the 2 randomized groups. There was no statistical difference in any of the variables assessed throughout the study, however, a favorable return of bowel function and time to discharge as well as lower complication rate was observed in limited bowel preparation.

We have shown that oral antibiotics given during BP have no significant impact on surgical infectious complications such as wound infections, abscesses, and peritonitis. On the contrary, sepsis occurred in 1 patient resulting in his death where oral antibiotics were given as part of BP. Oral antibiotics change the intestinal flora, with the resultant emergence of resistant strains [13,14]. Postoperative diarrhea and pseudomembranous enterocolitis are other risks of antibiotic preparation [13,14]. Considering the infectious complications occurring in both groups to a similar extent, we can speculate that the nature of the bowel preparation did not appear to influence the septic complications in patients undergoing bowel surgery. This may be due to the broad use of prophylactic antibiotics in both groups. Current intravenous broad spectrum antibiotic prophylaxis is able to reduce postoperative septic complications. Thus, the use of preoperative oral antibiotics as a part of preoperative bowel preparation is hard to justify when small bowel surgery is performed.

In the present study, no significant incidence of adverse events, including nausea, vomiting, and bloating, was observed in each BP groups, however overall discomfort and low acceptability was higher in 3-day protocol. We have not determined any significant dehydration and electrolyte abnormalities, which are more likely to occur by sodium phosphates (NaP). It should be remembered that proper patient selection is critical whenever a bowel purgative is

Table 3
Complications due to surgery

Complications	3-Day BP	Limited BP	*P*
Anastomosis leakage	1	1	1
Mortality	2	1	0.55
Sepsis	1	0	0.31
İleus	6	5	0.75
Wound infection	3	2	0.54
Superficial wound dehiscence	8	7	0.78
Fever (postoperative)	7	5	0.64
Unknown origin	4	4	
Urinary tract infection	1	0	
Pulmonary and other reason	2	1	
Peritonitis	1	1	1
İntra-abdominal abscess	-	-	
Urine leak	1	1	1
Other			0.15
Pulmonary embolism	1	0	
Respiratory problem	1		
Diarrhea	1	0	0.31

prescribed. Patients with clinically significant impairment of renal function, congestive heart failure, and ascites should not receive NaP [15]. Our study excluded patients with contraindications to oral NaP.

We have used a multimodal perioperative care program reported previously describing fast track diet advancement regardless of bowel function [5]. Nasogastric tubes were removed overnight. We have not used pro-motility agents such as metoclopromide and erythromycin, as these have not been shown to be of benefit in randomized controlled trials [16]. Early institution of an oral diet is a key issue in these programs, and our experience demonstrates that it can be done in a safe manner. Our experience of implementing this perioperative care plan for the management of RC resulted in a significantly reduced hospital stay, with no effect on morbidity or mortality. Withholding diet until passage of flatus has been the standard approach to postoperative care after cystectomy. This approach has been questioned, and several trials have shown that early feeding may reduce the duration of postoperative ileus [14,17,18]. Several fast track programs have been reported and advocated for cystectomy [5,6,9,14]. With regard to perioperative care and management, our prospective randomized study further supports previously reported fast track program [5] to be safe and successful with high acceptability.

To our best knowledge, 3-day BP has not been compared with other BP methods in randomized controlled studies from cystectomy series. Most evidence comes from colorectal surgery favoring no bowel preparation before elective colorectal surgery [4,19]. A recent systematic review by Guenaga et al. [4] concluded that prophylactic mechanical bowel preparation prior to colorectal surgery had not been proven valuable and should be abandoned. Substantial data on colorectal surgery have resulted in several modifications of the BP protocols for cystectomy, and limited methods with more efficient laxative solutions have been advocated [5–7,20]. Few reports, of which only one is randomized, challenged no BP when ileum is to be used. Shafii et al. [11] reported the results of a retrospective comparison of BP (a standard 4-day protocol) vs. no BP in 86 patients who had undergone cystectomy and ileal conduit urinary diversion. The complication rates were not greater when no BP was used. Another recent study compared 3-day BP and no bowel BP in nonrandomized limited number of patient cohort [10]. They found no beneficial effect for BP. Similar results have been reported by a recent randomized study by Xu et al. [12]. Their study was limited to only ileal conduit diversion and no statistical difference in the frequency of complications, and recovery of patient was observed between the no BP and 2-day BP group. Morey et al. determined similar efficacy and tolerability of oral sodium phosphate and polyethylene glycol in their randomized study and reported sodium phosphate to have a slight advantage because of its convenience and economic advantage [20]. Comparative studies of different bowel preparations are limited to the studies above. Although there are several reviews and expert opinions recommending some form of limited BP methods, including magnesium citrate, NaP, single enema or two enemas, yet no randomized prospective study evaluates any form of these protocols [6,21–23]. Currently, there is a rising trend towards fast tract surgery and thus short form of BP or abandoning BP are highlighted in a few reports [8–12,14,21–26]. However, its acceptance seems to be low among urologists owing to the lack of randomized clinical trials to confirm a limited BP or rejecting BP. There is no uniformity in the literature for bowel preparation, and BP is not addressed in urology guidelines in detail. Although there is little data to advocate no BP at cystectomy when ileum is to be used, the current practice is in favor of some form of bowel preparation and even conventional 3-day BP methods are still being used in many developing countries. At this point, our study first compares the 3-day protocol with a short form of BP in a prospective randomized design. In our study, we have shown that limited BP protocol is as effective and safe as conventional diet restrictive method with lower incidence of complications and better bowel recovery. However, our aim is not to propose the limited BP protocol used herein as a new standard or ideal protocol. Our main aim is to provide scientific evidence in promoting abandonment of 3-day mechanical BP for radical cystectomy. We have clearly shown the rationale to change this medical practice, supported mostly by surgical tradition yet accepted as dogma.

This study had several strengths and limitations. Results were based on a randomized, prospective study with strict criteria for inclusion/exclusion and evaluability. In addition, standard perioperative care regimens were used in both randomization groups. Study designs assessing the role of mechanical bowel preparation separately from other measures used to reduce the rate of infectious and surgical complications are quite difficult. Ideally, all the measures, including the surgical technique, anesthesia, and analgesics should be maintained constant, while the variable component should be randomized into 2 groups. Assuming an infectious complications rate of 1%–5%, for a prospective study that will be able to detect a difference between two different BP protocols several hundreds of patients are required to be randomized. It seems impossible for 1 team to enroll such a number of patients into this kind of study in a reasonable period. Multicenter studies allow patient accrual but at the expense of heterogeneous operative and perioperative techniques, which may be important factors influencing the surgical outcome and study endpoints.

Our prospective results confirm that the fast tract program previously described by others applied, as liberal use of liquid diet and limited bowel prep the day before surgery and commencing early oral intake is safe with no significant morbidity and, thus, recommended as a perioperative care plan for cystectomy and urinary diversion. Antibacterial bowel preparation as a general recommendation before cystectomy did not add significant value in reducing the rate of infectious complications, and should be omitted. Regarding

all endpoints, including septic and nonseptic complications, current clinical research offers no evidence to show any advantage of 3-day BP over limited BP.

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