

# Mechanical Bowel Preparation for Elective Colorectal Surgery

## A Meta-analysis

Pascal Bucher, MD; Bernadette Mermillod, BS; Pascal Gervaz, MD; Philippe Morel, MD

**Hypothesis:** There is little scientific evidence to support the routine practice of mechanical bowel preparation (MBP) before elective colorectal surgery in order to minimize the risk of postoperative septic complications.

**Data Sources:** Trials were retrieved using a MEDLINE search followed by a manual search of the bibliographic information in select articles. Languages were restricted to English, French, Spanish, Italian, and German. There was no date restriction.

**Study Selection:** Only prospective randomized clinical trials (RCTs) evaluating MBP vs no MBP before elective colorectal surgery were included.

**Data Extraction:** Outcomes evaluated were anastomotic leakage, intra-abdominal infection, wound infection, reoperation, and general and extra-abdominal morbidity and mortality rates. Data were extracted by 2 independent observers.

**Data Synthesis:** Seven RCTs were retrieved. The total number of patients in these RCTs was 1297 (642 who had received MBP and 655 who had not). Among all the RCTs reviewed, anastomotic leak was significantly more frequent in the MBP group, 5.6% (36/642), compared with the no-MBP group, 2.8% (18/655) (odds ratio, 1.84;  $P = .03$ ). Intra-abdominal infection (3.7% for the MBP group vs 2.0% for the no-MBP group), wound infection (7.5% for the MBP group vs 5.5% for the no-MBP group), and reoperation (5.2% for the MBP group vs 2.2% for the no-MBP group) rates were nonstatistically significantly higher in the MBP group. General morbidity and mortality rates were slightly higher in the MBP group.

**Conclusions:** There is no evidence to support the use of MBP in patients undergoing elective colorectal surgery. Available data tend to suggest that MBP could be harmful with respect to the incidence of anastomotic leak and does not reduce the incidence of septic complications.

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**M**ECHANICAL BOWEL preparation (MBP) is commonly used by surgeons before elective colorectal procedures.<sup>1-4</sup> In a survey among colorectal surgeons, Nichols et al<sup>5</sup> showed that 100% of the respondents used MBP and 87% used it in association with systemic antibiotic prophylaxis. Mechanical bowel preparation is currently considered to decrease the rate of postoperative infectious complications.

Mechanical bowel preparation in patients undergoing colorectal surgery has many potential attractions. It enables surgeons to work with a clean bowel and may decrease intraoperative bacterial contamination load of the peritoneal cavity. Proponents of MBP believe that it prevents anastomotic disruption by the passage of hard feces. It may also decrease the operative time by improving bowel han-

dling during anastomotic confection. Finally, MBP is generally well tolerated by the patient.<sup>3,6</sup>

### See Invited Critique on page 1365

Since the acceptance of MBP as a surgical "dogma" during the 1970s, it has been demonstrated that systemic antibiotic prophylaxis is effective in decreasing septic complication in colorectal surgery.<sup>7,8</sup> Retrospective studies have analyzed the outcome of emergency colon surgery without MBP, showing low postoperative infectious complication rates.<sup>9,10</sup> Recently, prospective studies have demonstrated feasibility and safety of left colon and rectal surgery with avoidance of mechanical bowel cleaning.<sup>11,12</sup> Moreover, randomized prospective studies<sup>13-19</sup> on the role of MBP in preventing postoperative complication rates

**Author Affiliations:** Clinic of Visceral and Transplantation Surgery, Department of Surgery (Drs Bucher, Gervaz, and Morel) and Division of Medical Statistics (Ms Mermillod), Geneva University Hospital, Geneva, Switzerland.

**Table 1. Randomized Clinical Trials (RCTs) Evaluating Mechanical Bowel Preparation (MBP) in Elective Colorectal Surgery**

Variable	Brownson et al <sup>13</sup>	Burke et al <sup>19</sup>	Santos et al <sup>16</sup>	Fillmann et al <sup>15</sup>	Miettinen et al <sup>17</sup>	Zmora et al <sup>18</sup>	Bucher et al <sup>14</sup>
No. of patients included	179	186	157	60	279	415	93
No. of patients excluded	Not given	17	8	Not given	12	35	0
No. of patients (MBP and no MBP groups)	86 and 93	82 and 87	72 and 77	30 and 30	138 and 129	187 and 193	47 and 46
Age, y, mean (MBP and no MBP groups)	Not given	65 and 64	52 and 50	54 and 61	61 and 64	68 and 68	63 and 65
Patients with colon cancer (MBP and no MBP groups), %	Not given	85 and 72	49 and 43	Not given	46 and 55	78 and 78	36 and 35
Patients with left colon surgery with primary anastomosis (MBP and no MBP groups), %	100 and 100	100 and 100	92 and 90	55 and 47	80 and 74	68 and 72	100 and 100
Type of bowel preparation	Polyethylene glycol	Sodium picosulfate	Laxative, enema, and mannitol	Mannitol	Polyethylene glycol	Polyethylene glycol and enema when rectal surgery	Polyethylene glycol or phosphonate
Antibiotic prophylaxis	Yes	Yes	Yes	Yes	Yes	Yes	Yes

and review<sup>20</sup> have been published. However, none of them had sufficient power to conclude on the role of MBP and therefore may be unable to bring to the fore a difference of clinical importance. The aim of this meta-analysis was to evaluate the role of MBP in patients undergoing colorectal surgery with systemic antibiotic prophylaxis through a systematic review of these randomized prospective trials.

## METHODS

Inclusion criteria for this meta-analysis were published prospective clinical trials with random allocation of human subjects to MBP or no MBP before elective colorectal surgery. A computerized search (MEDLINE and Old MEDLINE) was performed using the terms *bowel cleaning*, *bowel preparation*, and *cathartics*. In addition, a manual search was done on the reference list in selected articles. Languages were restricted to English, French, Spanish, Italian, and German. There was no date restriction.

Included trials were reviewed and appraised for methodological quality using the method described by Hall et al.<sup>21</sup> Outcome measures analyzed were anastomotic leak rates, wound infection rates, intra-abdominal infection rates, relaparotomy rates, and general and extra-abdominal morbidity and mortality rates.

Seven randomized clinical trials (RCTs) were retrieved. The total number of patients included in these 7 RCTs<sup>13-19</sup> was 1297 (642 who had received MBP and 655 who had not). Two of these RCTs were only published as abstracts.<sup>13,14</sup> Inclusion of abstracts in a meta-analysis could add bias. While some authors will advocate exclusion of them, others will include them.<sup>22</sup> For this reason, we have performed analysis both with and without including the Brownson et al study.<sup>13</sup> With regard to the Bucher et al study,<sup>14</sup> all information was available to us, so we included it in our analysis. When excluding the Brownson et al study, the total number of patients among the remaining 6 trials<sup>14-19</sup> was 1118 (556 who had received MBP and 562 who had not). A meta-analysis was performed on 6 end points with the results available for each end point among these 7 RCTs. For all end points,

exclusion of the Brownson et al study did not influence the results significantly.

Statistical analysis was done according to the Fleiss approach.<sup>23</sup> Odds ratios (ORs), confidence intervals (CIs), and *P* values were calculated for each end point. The number needed to treat was derived to aid in clinical interpretation of the results. A positive OR was in favor of no MBP. A *P* value < .05 was considered statistically significant.

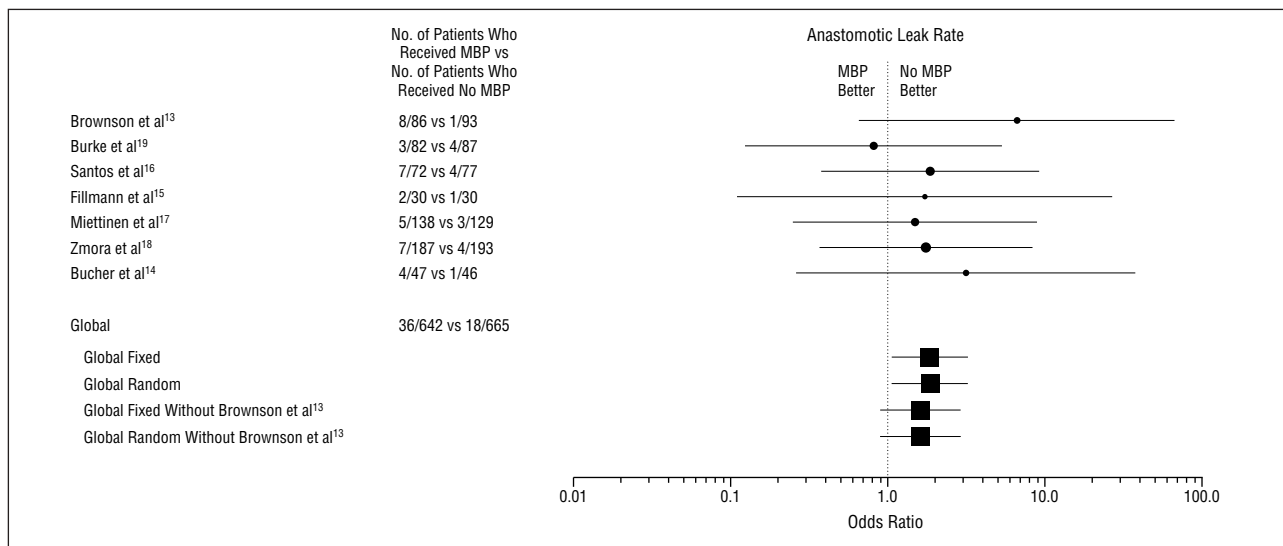
## RESULTS

Among 17 prospective trials published in the international literature, only 7 were RCTs evaluating MBP vs no MBP in patients undergoing elective colorectal surgery and were eligible for this meta-analysis<sup>13-19</sup> (**Table 1**). If these studies were all randomized with an adequate control group (no MBP), all of them failed to complete all of the items described by Hall et al<sup>21,24</sup> (**Table 2**). Of importance, none of these trials, except the Bucher et al study,<sup>14</sup> prospectively defined the sample size, which is critical in determining the power of the trial. However, the Bucher et al study has only been published as an intermediate analysis and is still ongoing. The methodological aspects of the 7 RCTs<sup>13-19</sup> reviewed are summarized in Table 1 and Table 2.

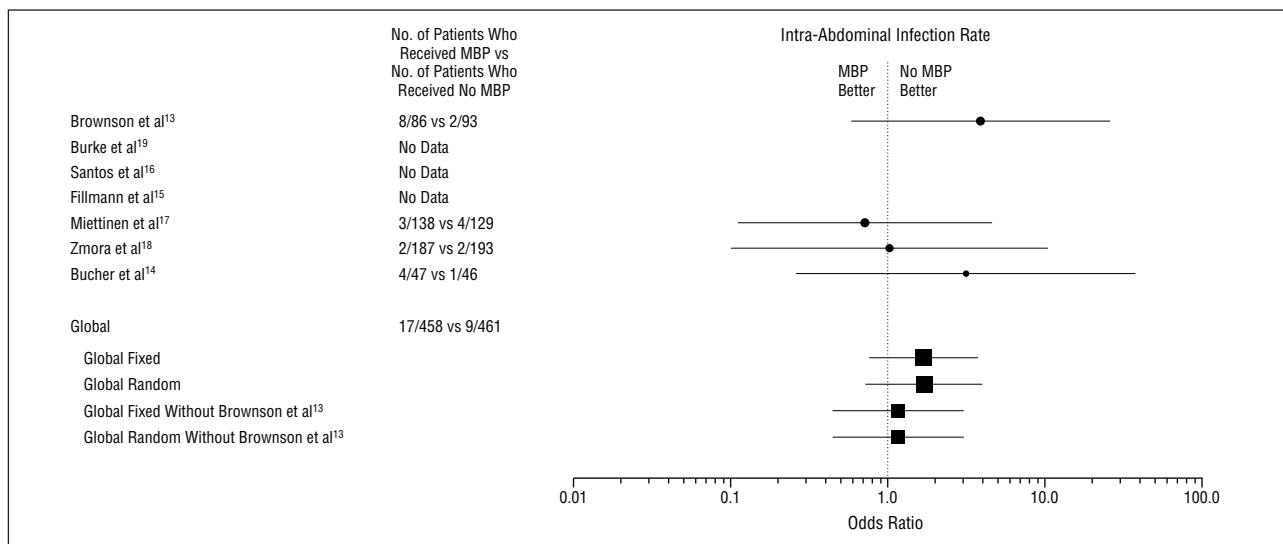
A meta-analysis of these 7 RCTs was performed. This meta-analysis revealed a higher incidence of anastomotic dehiscence in patients receiving MBP, 5.6% (36/642), vs no MBP, 2.8% (18/655) (*P* = .03; OR, 1.85 [95% CI, 1.06-3.22]) (**Figure 1**). While ORs or relative risks can be difficult to interpret, the number needed to treat was calculated to provide an absolute measure of risk. With an incidence of 5% of anastomotic leak, 32 patients (95% CI, 19-306) would have to be operated on without MBP to prevent 1 leak in a patient receiving MBP before surgery.

**Table 2. Assessment of the Randomized Trials Evaluating Mechanical Bowel Preparation**

Variable	Brownson et al <sup>13</sup>	Burke et al <sup>19</sup>	Santos et al <sup>16</sup>	Fillmann et al <sup>15</sup>	Miettinen et al <sup>17</sup>	Zmora et al <sup>18</sup>	Bucher et al <sup>14</sup>
Randomization	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Clearly stated aim	No	Yes	No	No	Yes	Yes	Yes
Adequate control group	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Account of the selection process	No	Yes	No	No	Yes	No	Yes
Prospective definition of the sample size	No	No	No	No	No	No	Yes
Description of the randomization technique	No	No	Yes	No	No	Yes	Yes
Demonstration of baseline equivalence between the study groups	No	Yes	Yes	No	Yes	Yes	Yes
Definition of the study end points	No	No	Yes	No	No	Yes	Yes
Unbiased assessment of study end points	No	No	No	No	No	No	No
Description of the intervention studied	Yes	Yes	Yes	No	Yes	Yes	Yes
Clear documentation of adverse events	Yes	Yes	Yes	No	Yes	Yes	Yes



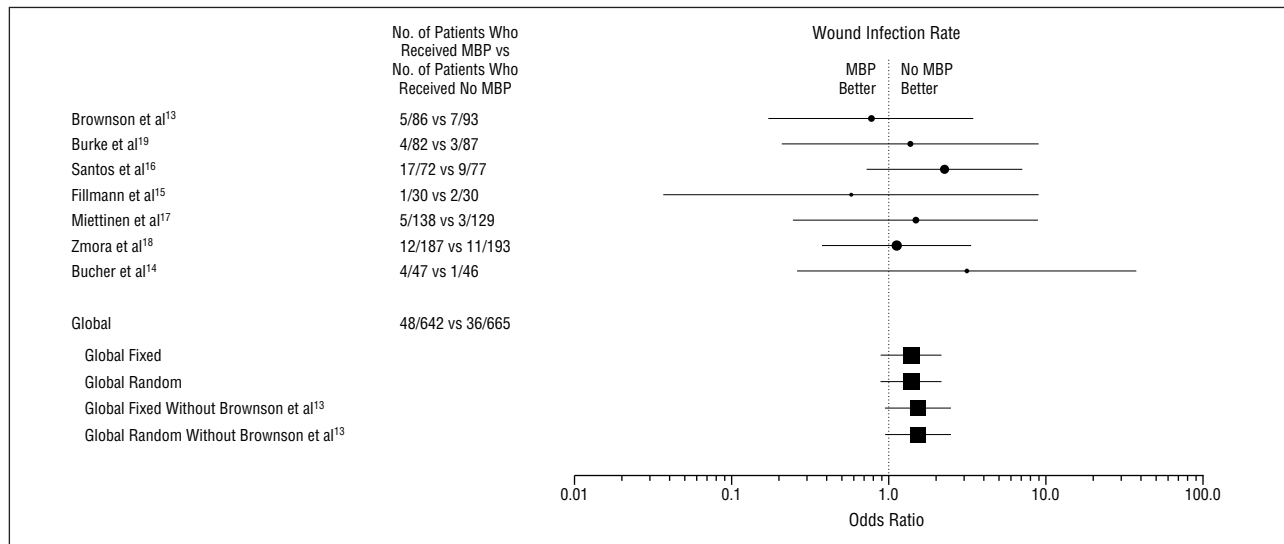
**Figure 1.** Anastomotic leak rates: mechanical bowel preparation (MBP) vs no MBP (an odds ratio >1 favors no MBP).



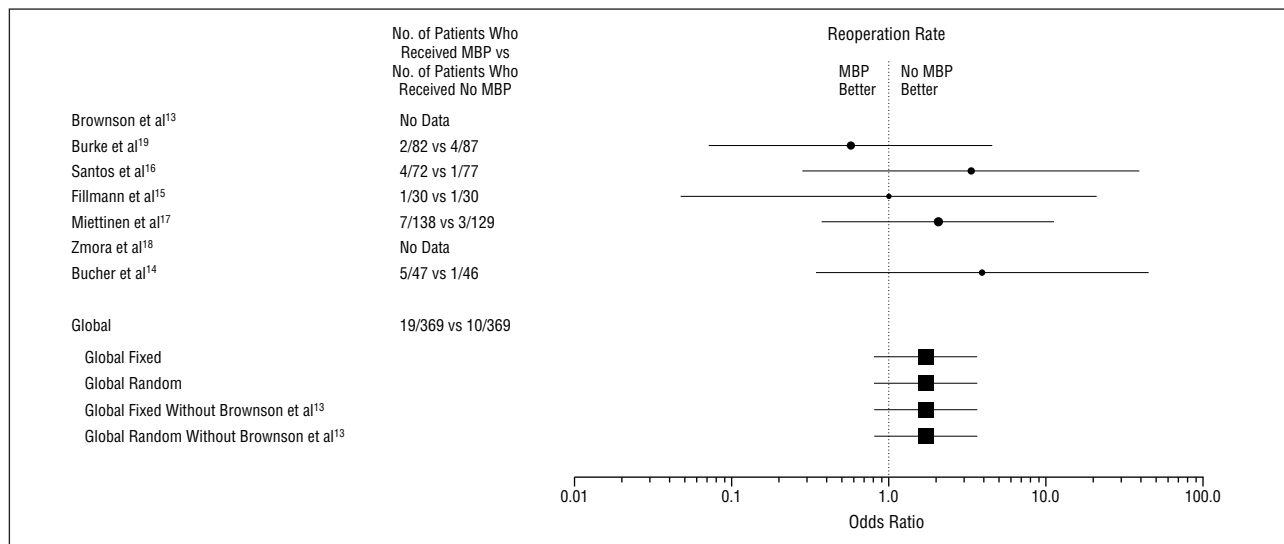
**Figure 2.** Intra-abdominal infection rates: mechanical bowel preparation (MBP) vs no MBP (an odds ratio >1 favors no MBP).

The rate of intra-abdominal infection (peritonitis or abscess) was similar in the MBP group, 3.7% (17/458), compared with the no-MBP group, 2.0% (9/461) (OR, 1.69 [95% CI, 0.76-3.75];  $P = .18$ ) (**Figure 2**).

The rate of wound infection was slightly higher in patients receiving MBP, 7.5% (48/642), vs no MBP, 5.5% (36/655) (OR, 1.38 [95% CI, 0.89-2.15];  $P = .15$ ) (**Figure 3**).



**Figure 3.** Wound infection rates: mechanical bowel preparation (MBP) vs no MBP (an odds ratio >1 favors no MBP).



**Figure 4.** Reoperation rates: mechanical bowel preparation (MBP) vs no MBP (an odds ratio >1 favors no MBP).

In accordance with the higher rates of anastomotic leak and of intra-abdominal infection in patients receiving MBP, the rate of reoperation was slightly higher in the MBP group, 5.2% (19/369), in comparison with the no-MBP group, 2.2% (10/369) (OR, 1.72 [95% CI, 0.81-3.65];  $P = .16$ ) (**Figure 4**). Reoperation ( $n = 21$ ) was performed mainly for anastomotic leaks (17 cases; 10 in the MBP group and 7 in the no-MBP group).

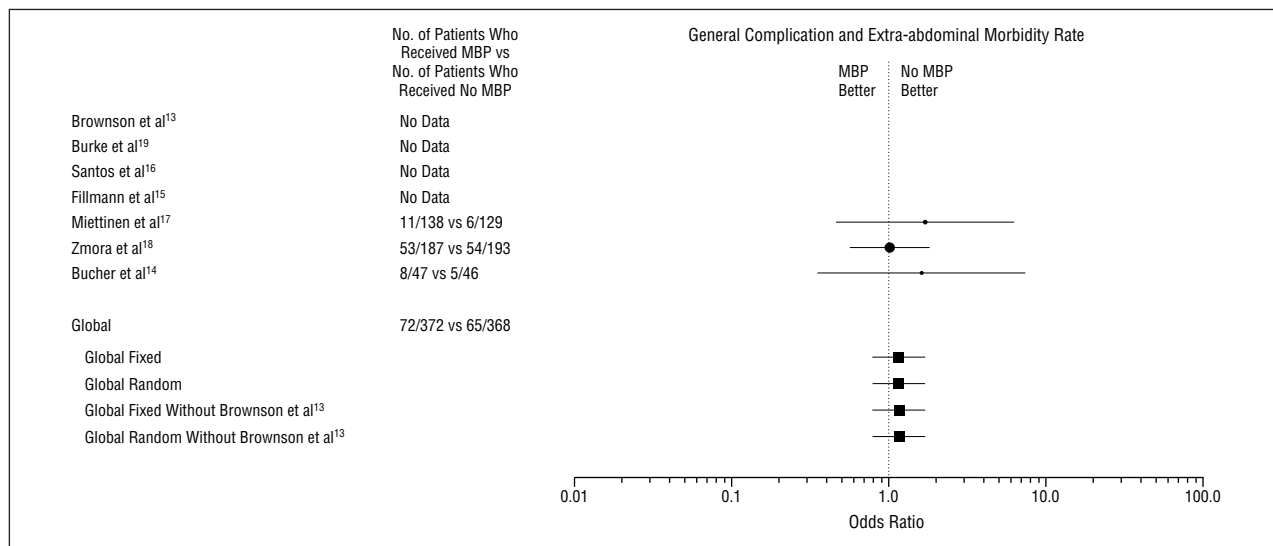
General complication and extra-abdominal morbidity rates are reported by Fillmann et al,<sup>15</sup> Miettinen et al,<sup>17</sup> Zmora et al,<sup>18</sup> and Bucher et al.<sup>14</sup> In these studies, general complication rates were similar between the 2 groups, which is further demonstrated in the meta-analysis (OR, 1.15 [95% CI, 0.79-1.70];  $P = .45$ ) (**Figure 5**). Mortality rates were reported in 5 studies (**Figure 6**),<sup>14,16-19</sup> postoperative deaths were recorded in only 2 studies,<sup>18,19</sup> and mortality rates were null in other studies. The meta-analysis would favor the avoidance of MBP in terms of mortality rates (OR, 1.42 [95% CI, 0.37-5.45];  $P = .60$ );

however, analysis should be taken with caution because of the low number of events for this outcome.

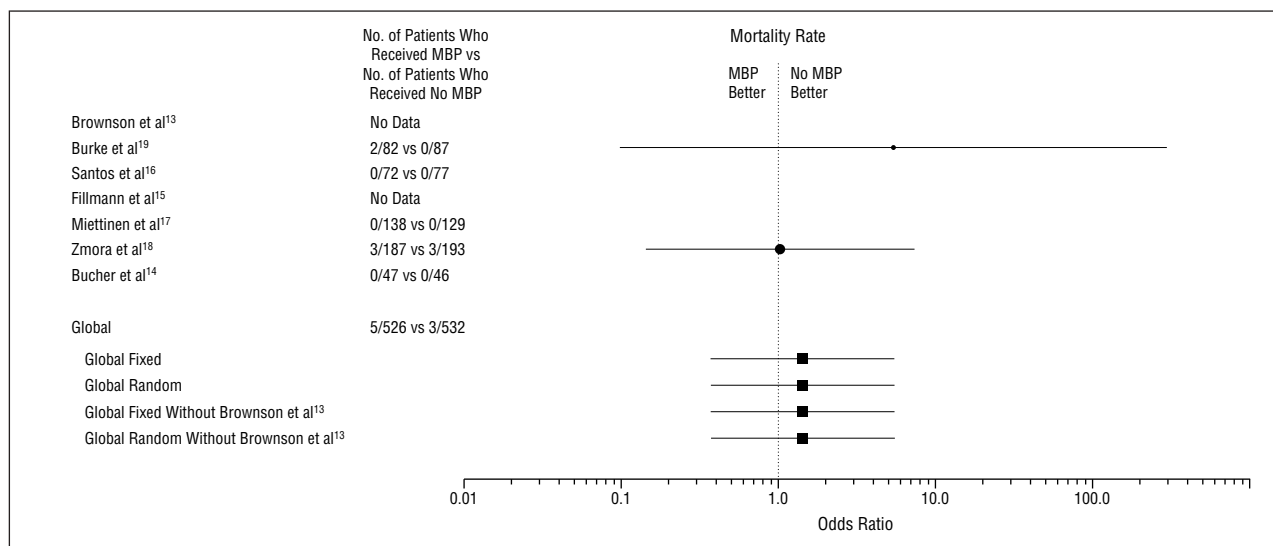
#### COMMENT

This meta-analysis reviews the role of MBP regarding morbidity in colorectal surgery. The results of this study suggest that MBP may be deleterious in terms of septic complications and anastomotic dehiscence after elective colorectal surgery with primary anastomosis.

Reduction of postoperative septic complication rates and especially of anastomotic dehiscence incidence have been concerns since the first attempts in bowel surgery,<sup>25</sup> and this meta-analysis still considers the same questions more than 100 years later. The concept of bowel antisepsis was introduced in the 1940s.<sup>26</sup> Garlock et al championed bowel asepsis by the mean bowel preparation in 1939.<sup>26</sup> In 1966, Plumley<sup>27</sup> developed a new regimen for bowel prepara-



**Figure 5.** General complication and extra-abdominal morbidity rates: mechanical bowel preparation (MBP) vs no MBP (an odds ratio >1 favors no MBP).



**Figure 6.** Mortality rates: mechanical bowel preparation (MBP) vs no MBP (an odds ratio >1 favors no MBP).

tion and claimed that MBP should be performed in patients undergoing colorectal surgery, arguing that the “usefulness of bowel cleaning has been recognized by second world war surgeons.”<sup>27(p413)</sup> In 1971 and 1969, respectively, Barker et al<sup>28</sup> and Everett et al<sup>29</sup> claimed that MBP should be performed in patients before surgery because gross fecal loading of the bowel was associated with an increased incidence of wound infection. In the 1970s, MBP was then nearly uniformly accepted as a dogma.<sup>30</sup>

However, while major improvements in patient care have been achieved to facilitate the postoperative course, the routine use of MBP has recently been under unprecedented scrutiny. One of the first to question the routine use of MBP was Hughes<sup>31</sup> in 1972. Since then, several RCTs evaluating MBP have been published. However, it is difficult to have faith in conclusions that are drawn from published RCTs that contain flawed methods. As mentioned, all of them failed to complete the items described by Hall et al.<sup>21,24</sup> Between 5% and 10% of the se-

lected patients were excluded in the different studies. Such deficiencies weaken the conclusions made in these 7 RCTs.

Meta-analyses are not devoid of methodological problems, most notably the risk of publication bias. Of note, 2 of these 7 RCTs were published only as abstracts, and not all end points were reported among all studies. However, the funnel plot (a homogeneity test) is not asymmetrical, which indicates that no serious publication bias is present. Another concern when evaluating these studies is that right colectomies were included in all of them, excluding the Burke et al<sup>19</sup> and Bucher et al<sup>14</sup> trials, whereas MBP is alleged to be mandatory for ileocolic anastomosis.<sup>32</sup>

A minimal sample size for an RCT on MBP with a power of 80% ( $\alpha = .05\%$ ) would be 950 patients (assuming a variation in end-point incidence of 5%). It is difficult for 1 institution to accrue such a large number of patients. Multicentric studies expedite patient accrual; however, this may compromise the treatment homoge-

neity and may increase the reproducibility of the results. According to the results of the present meta-analysis, we have started a randomized multicentric trial evaluating MBP for elective colorectal surgery. The preliminary results were presented at the Digestive Disease Week in 2003 and favor the avoidance of MBP before elective left colorectal surgery.<sup>14</sup>

Meanwhile, the current common practice of MBP is based mainly on historical, noncontrolled, small sample studies published before the routine introduction of antibiotic prophylaxis and on a small number of animal studies, as well as surgical tradition.<sup>33</sup>

## CONCLUSION

Bowel cleaning by means of MBP has never been demonstrated to reduce postoperative septic complication rates in controlled trials. Furthermore, RCTs evaluating MBP in elective colorectal surgery either show no benefit or a deleterious effect of mechanical bowel cleaning. Yet, none of these trials are sufficiently reliable to detect advantage or disadvantage for mechanical bowel cleaning. This meta-analysis shows that MBP may be deleterious in terms of postoperative anastomotic and septic complications. The current popular practice of MBP before elective colorectal surgery is based mainly on surgical dogma than on scientific evidence. As we have done in our center, avoidance of MBP for elective colon and rectal surgery should be considered.

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Correspondence: Pascal Bucher, MD, Department of Surgery, Geneva University Hospital, 24, Rue Micheli-du-Crest, 1211, Geneva 14, Switzerland (pascal.bucher@hcuge.ch).

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