



Mechanical bowel preparation in elective colorectal surgery: a propensity score-matched analysis of the Italian colorectal anastomotic leakage (iCral) study group prospective cohorts

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Abstract

Retrospective evaluation of the effects of mechanical bowel preparation (MBP) on data derived from two prospective open-label observational multicenter studies in Italy regarding elective colorectal surgery. MBP for elective colorectal surgery remains a controversial issue with contrasting recommendations in current guidelines. The Italian ColoRectal Anastomotic Leakage (iCral) study group, therefore, decided to estimate the effects of no MBP (treatment variable) versus MBP for elective colorectal surgery. A total of 8359 patients who underwent colorectal resection with anastomosis were enrolled in two consecutive prospective studies in 78 surgical centers in Italy from January 2019 to September 2021. A retrospective PSMA was performed on 5455 (65.3%) cases after the application of explicit exclusion criteria to eliminate confounders. The primary endpoints were anastomotic leakage (AL) and surgical site infections (SSI) rates; the secondary endpoints included SSI subgroups, overall and major morbidity, reoperation, and mortality rates. Overall length of postoperative hospital stay (LOS) was also considered. Two well-balanced groups of 1125 patients each were generated: group A (No MBP, true population of interest), and group B (MBP, control population), performing a PSMA considering 21 covariates. Group A vs. group B resulted significantly associated with a lower risk of AL [42 (3.5%) vs. 73 (6.0%) events; OR 0.57; 95% CI 0.38–0.84; $p=0.005$]. No difference was recorded between the two groups for SSI [73 (6.0%) vs. 85 (7.0%) events; OR 0.88; 95% CI 0.63–1.22; $p=0.441$]. Regarding the secondary endpoints, no MBP resulted significantly associated with a lower risk of reoperation and LOS > 6 days. This study confirms that no MBP before elective colorectal surgery is significantly associated with a lower risk of AL, reoperation rate, and LOS < 6 days when compared with MBP.

Keywords Colorectal surgery · Mechanical bowel preparation · Anastomotic leakage · Surgical site infections · Morbidity

Introduction

The optimal bowel preparation before elective colorectal surgery remains controversial. Based on randomized trials [1, 2] and meta-analyses [3], the absence of a clear clinical benefit together with potential patient preoperative dehydration, electrolyte disturbance and discomfort [4], induced the Enhanced Recovery After Surgery (ERAS®) Society

[5] to recommend no mechanical bowel preparation (MBP). However, according to recent large surveys among North American [6] and German and Austrian surgeons [7], MBP is used before colorectal resections in about 70%–98% of cases. Moreover, numerous reviews and meta-analyses on various aspects of the topic of preoperative bowel preparation come to different conclusions. Toh et al. [8] associated MBP plus preoperative oral antibiotics (oAB) with the lowest risk of surgical site infections (SSI); Rollins et al. [9, 10] suggested a potentially significant role for oAB, either in combination with MBP or alone, in the prevention of postoperative complications in elective colorectal surgery; Nelson et al. [11] reported a statistically significant benefit

The members of the Study group coordinator and iCral study group co-investigators are listed in the Acknowledgments section.

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for combined oral and intravenous antibiotic administration, compared to oral prophylaxis alone for the rate of surgical wound infection (excluding organ space SSI). It must be considered that perioperative intravenous antibiotic prophylaxis (AP) may have a significant impact especially on the likelihood of SSI [12] with the consequence that studies without AP could confound the results of the meta-analyses [13]. To better understand the role of MBP, the Italian ColoRectal Anastomotic Leakage (iCraL) study group decided to estimate the effects of no MBP (treatment variable) versus MBP before elective colorectal surgery in patients treated with AP through a propensity score-matched analysis (PSMA) of data derived from two prospective open-label observational multicenter studies [14, 15].

Materials and methods

Study design

Retrospective PSMA of patients who had undergone colorectal surgery for malignant and benign diseases.

Patient population and data collection

A total of 8359 patients who underwent colorectal resection with anastomosis were enrolled in two consecutive studies upon explicit inclusion/exclusion criteria, in 78 surgical centers in Italy from January 2019 to September 2021: iCraL2 [14] and iCraL3 [15]. The inclusion criteria were American Society of Anesthesiologists (ASA) class I, II, or III; elective or delayed urgency setting (defined > 48 h from admission in iCraL2 and > 24 h from admission in iCraL3); patient's written informed consent for inclusion in the study and processing of sensitive data. The exclusion criteria were pregnancy; hyperthermic chemotherapy (HIPEC) for carcinomatosis; incomplete data. The iCraL2 study excluded patients with a protective stoma proximal to the anastomosis; conversely, these cases were included in iCraL3 study. Both studies were conducted in accordance with the Declaration of Helsinki and guidelines for good clinical practice E6 (R2). The study protocols were approved by the ethics committee of the coordinating center (Marche Regional Ethics Committee [CERM] 2018/334 released on 11/28/2018 for iCraL2 and 2020/192 released on 07/30/2020 for iCraL3) and registered at ClinicalTrials.gov (NCT03771456 for iCraL2 and NCT04397627 for iCraL3). Subsequently, all other centers were authorized to participate in their local ethics committees. Both studies followed the Strengthening the Reporting of Cohort Studies in Surgery (STROCSS) guidelines [16].

To control for data imbalance derived from several treatment confounders, the present PSMA study included 5455 patients (65.3%) out of 8359 in the parent studies, based on

explicit exclusion criteria. Delayed urgencies were excluded because this study only concerns elective colorectal resections; any anastomosis protected by a proximal stoma and patients treated with neo-adjuvant therapy, perioperative steroids or dialysis were excluded because these treatments were impacting only on subgroups of subjects; patients with missing data regarding bowel preparation were excluded to optimize the PSMA effectiveness; patients treated by no MBP with oAB were excluded because the treatment variable was no MBP alone; patients treated without AP were excluded in relation to the significant impact of this variable on the risk of SSI [12, 13]; patients treated by MBP with products different from polyethylene glycol and with oAB were excluded in relation to imbalance in the control population (Fig. 1). The variables and the outcomes considered in the original population of 5455 patients are shown in Table 1. To optimize the effectiveness of PSMA by reducing the number of unmatched cases, continuous variables were categorized according to their median values. The true population of interest, defined by the treatment variable named No MBP, included 3,872 patients (70.9%); the control population, defined by the variable named MBP, included 1,583 patients (29.1%). The overall adherence percentage to the ERAS recommendations was calculated on 19 items common to both parent studies. Patients in the MBP control population prepared their bowel by drinking products containing polyethylene glycol on the day before surgery. Adverse events after elective colorectal resections and their grading are reported in online supplementary material.

Outcomes

All the enrolled patients were followed up for at least 8 weeks after surgery, recording and grading any adverse event according to Clavien–Dindo [17] and the Japanese Clinical Oncology Group (JCOG) extended criteria [18] as well as any reoperation, readmission or death. Anastomotic leakage (AL) was defined according to the international consensus [19]. All the outcomes were calculated at 60 days after surgery.

The primary endpoints were AL and SSI [20] [defined as superficial and/or deep surgical site infections (s-d-SSI) and/or deep wound dehiscence and/or abdominal collection/abscess]. The secondary endpoints were: (1) superficial and/or deep surgical site infections (s-d-SSI), defined as drain-specific complications including purulent drainage from superficial incisions, positive culture of fluid or tissue from superficial incisions, pain or tenderness, localized swelling, redness, heat, and/or infections involving deep fascial and muscle layers without dehiscence [20]; (2) deep wound dehiscence; (3) abdominal collection/abscess defined as intraperitoneal postoperative collections that altered the normal postoperative course, requiring either

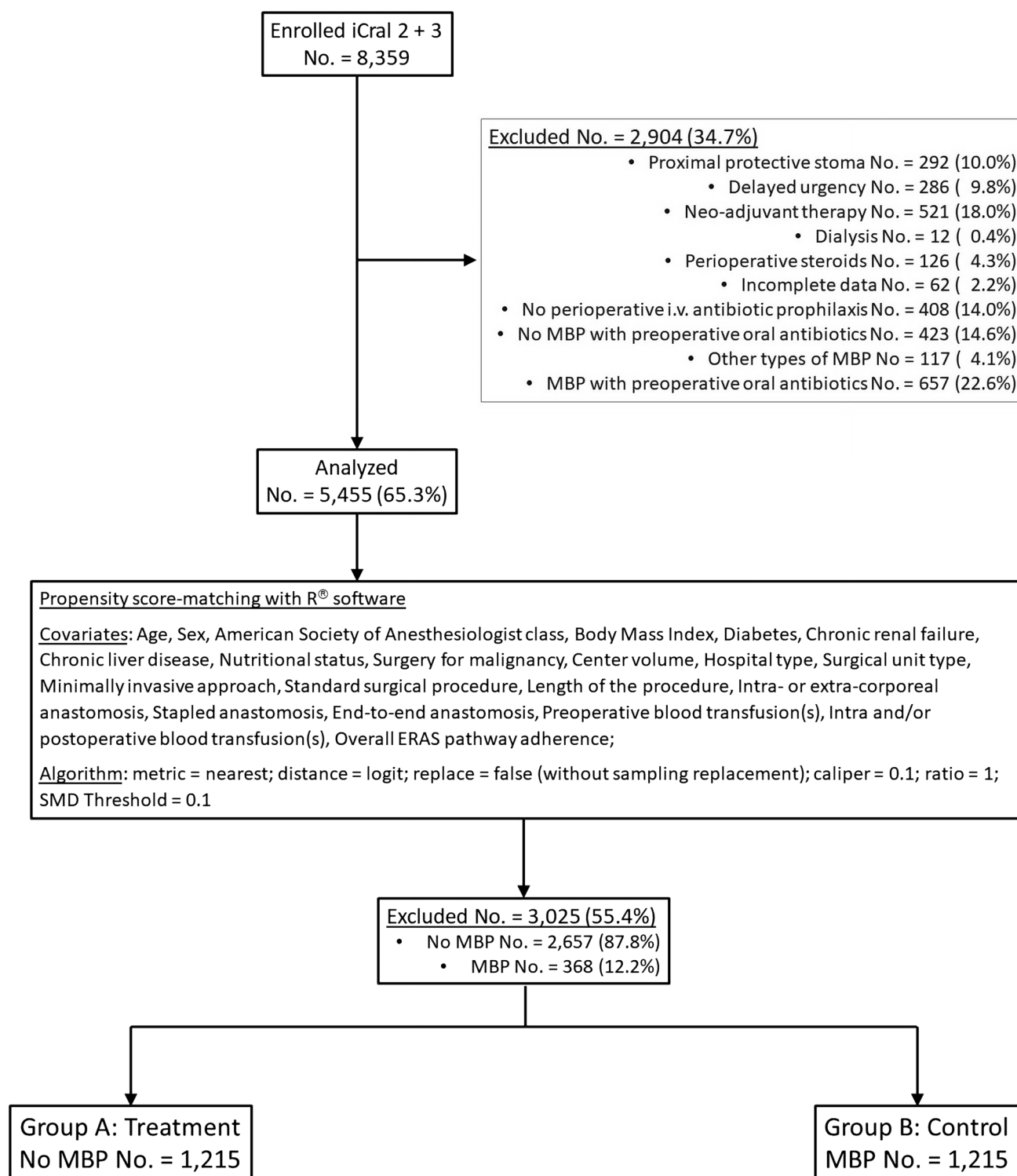


Fig. 1 Study flowchart according to the Strengthening the Reporting of Cohort Studies in Surgery (STROCSS) guidelines [16] and to the Reporting and Guidelines in Propensity Score Analysis [42];

iCral: Italian ColoRectal Anastomotic Leakage study group; ERAS: enhanced recovery after surgery0

medical, radiological, endoscopic, or surgical intervention [20]; (4) overall morbidity (any adverse event); (5) major morbidity (any adverse event grade > II); (6) reoperation

(any unplanned operation) rates; (7) mortality (any death) rates; and (8) the length of postoperative hospital stay (LOS, inclusive of any readmission).

Table 1 Descriptive analysis of the variables and outcomes in 5455 patients evaluated before PSMA

		Overall		No ^a MBP		^a MBP		
		No. 5455		No. 3872 (71.0%)		No. 1583 (29%)		
Part-A: Descriptive variables	Pattern	No	%	No	%	No	%	^b <i>p</i>
Age (years)	≤ 70	2873	52.7	1930	49.9	943	59.6	< 0.01
Sex	Male	2762	50.6	2026	52.3	736	46.5	< 0.01
^c ASA class	I–II	3552	65.1	2479	64.0	1073	67.8	0.01
Body mass index (Kg/ m ²)	≤ 25.26	2729	50.0	1903	49.2	826	52.2	0.04
Diabetes	Yes	795	14.6	586	15.1	209	13.2	0.07
Chronic renal failure	Yes	226	4.1	157	4.0	69	4.4	0.61
Chronic liver disease	Yes	57	1.0	42	1.1	15	1.0	0.65
^d MNA-SF	≤ 12	1509	27.7	1042	26.9	467	29.5	0.05
Surgery for malignancy	Yes	3911	71.7	2830	73.1	1081	68.3	< 0.01
Mini-invasive surgery	Yes	4729	86.7	3434	88.7	1295	81.8	< 0.01
^e Standard procedure	Yes	4693	86.0	3346	86.4	1347	85.1	0.20
Anastomosis 1	^f Intracorporeal	3656	67.0	2685	69.3	971	61.3	< 0.01
Anastomosis 2	Stapled	4929	90.4	3525	91.0	1404	88.7	0.01
Anastomosis 3	End-to-end	2601	47.7	1570	40.5	1031	65.1	< 0.01
Operation length (minutes)	≤ 180	3139	57.5	2325	60.1	814	51.4	< 0.01
Hospital type	^g Met./Ac	3123	57.2	2325	60.0	798	50.4	< 0.01
Unit type	^h Colorectal/Oncol	974	17.9	471	12.2	503	31.8	< 0.01
Center volume	< 4 cases/month	1372	25.2	917	23.7	455	28.7	< 0.01
Preoperative ⁱ BT(s)	Yes	309	5.7	242	6.2	67	4.2	< 0.01
Intra/postoperative ⁱ BT(s)	Yes	358	6.6	257	6.6	101	6.4	0.73
Overall ⁱ ERAS adherence (%)	> 73.68	3204	58.7	2691	69.5	513	32.4	< 0.01
Part-B: Outcomes		Overall		No ^a MBP		^a MBP		
	Pattern	No0	%	No0	%	No0	%	^m OR (95%CI)
Anastomotic leakage	Yes	225	4.1	134	3.5	91	5.7	00.59 (00.45–00.77) <i>p</i> < 0.01
ⁿ SSI	Yes	296	5.4	193	5.0	103	6.5	00.75 (00.59–00.96) <i>p</i> = 0.02
^o s-d-SSI	Yes	200	3.7	127	3.3	73	4.6	00.70 (00.52–00.94) <i>p</i> = 0.02
Deep wound dehiscence	Yes	13	0.2	8	0.2	5	0.3	00.65 (00.21–20.00) <i>p</i> = 0.45
Abdominal collection/abscess	Yes	94	1.7	66	1.7	28	1.8	00.96 (00.62–10.50) <i>p</i> = 0.87
Reoperation	Yes	278	5.1	179	4.6	99	6.2	00.73 (00.56–00.94) <i>p</i> = 0.01
^p LOS	> 6 days	2,002	36.7	1,186	30.6	816	51.5	00.42 (00.37–00.47) <i>p</i> < 0.01
Overall morbidity	Yes	1,501	27.5	1,043	26.9	458	28.9	00.91 (00.80–10.03) <i>p</i> = 0.13
Major morbidity	Yes	314	5.8	209	5.4	105	6.6	00.80 (00.63–10.02) <i>p</i> = 0.08
Mortality	Yes	49	0.9	34	0.9	15	0.9	00.93 (00.50–10.70) <i>p</i> = 0.81

^aMBP mechanical bowel preparation; ^bChi square independence test with one degree of freedom; ^cASA American Society of Anesthesiologists classes I–II versus III; ^dMNA-SF mini nutritional assessment—short form; ^eStandard procedures: Right colectomy, Left colectomy, Anterior resection versus Transverse colectomy, Splenic flexure colectomy, Hartmann reversal, (Sub) total colectomy, Other; ^fIntracorporeal: anastomosis performed under visual control through the scope in comparison to the Extracorporeal, performed under direct visual control through an open access; ^gMet./Ac.: Metropolitan/Academic versus Local/Regional hospitals; ^hColorectal/Oncol. units versus General Surgery units; ⁱBT blood transfusion(s); ^jERAS: Enhanced recovery after surgery items; ^munivariate ORs estimation with Wolf valuation of the confidence intervals (CIs); ⁿSSI Superficial surgical site infections (s-d-SSI plus deep wound dehiscence plus abdominal collection/abscess); ^os-d-SSI: superficial and/or deep surgical site infections; ^pLOS length of postoperative hospital stay

Statistical analysis

This was a retrospective PSMA of two prospective cohorts, with sample sizes calculated and reported in the respective core papers [14, 15]. Events per variable guideline were

followed [21]. There were no missing data in the database of 5455 patients. The target of estimands was represented by the average treatment effect in the true population of interest (ATT).

A propensity score-matching model [22, 23] was used for the analysis (Fig. 1). An adjusted logistic regression was used to estimate the propensity scores of the treatment and control groups. The exposure variable was a treatment that implied no MBP in elective colorectal surgery, and 21 covariates, potentially affecting the treatment [24], were selected: age, sex, American Society of Anesthesiologists (ASA) class, body mass index (BMI), diabetes, chronic renal failure, chronic liver disease, nutritional status measured through the Mini Nutritional Assessment—Short Form (MNA-SF) [25], surgery for malignancy, center volume, hospital type (academic/metropolitan versus local/regional), surgical unit type (general versus oncologic/colorectal), mini-invasive surgery, standard surgical procedure, operation length (minutes), intra- or extra-corporeal anastomosis, stapled versus hand-sewn anastomosis, end-to end anastomosis, preoperative blood transfusion(s), intra-and/or postoperative blood transfusion(s), and overall ERAS pathway adherence rates.

To ensure that the treatment groups were balanced [26], we performed PSMA using the software “R©” (Version 4.2.2, The R Foundation© for Statistical Computing, Vienna, Austria, 2022). We used a nearest neighbor approach with a logit distance metric and a caliper of 0.1 to minimize differences between the groups. We also used adjusted logistic regression to estimate the association between the treatment variable and outcomes.

Balance in the matched groups was assessed by calculating the standardized mean difference (SMD), using a threshold of 0.1 (a standardized mean difference less than 0.1 typically indicates a negligible difference between the means of the groups) and the general variance ratio (a variance ratio close to 1 indicates that variances are equal in the two groups). For outcome modeling, an adjusted logistic regression was performed based on a treatment variable represented by no MBP in elective colorectal surgery and on the same 21 covariates selected for the PSMA [27], presenting odds ratios (OR) and 95% confidence intervals (95%CI). The eventual effect of any unobserved confounder was tested through a sensitivity analysis [28], using the library “SensitivityR5” of the software R© (Version 4.2.2, The R Foundation© for Statistical Computing, Vienna, Austria, 2022) and presenting the Γ values (each 0.1 increment of Γ values representing a 10%-odds of differential assignment to treatment due to any unobserved variable).

Concerning significance, the Sidak-Bonferroni’s adjustment for multiple comparisons was applied, setting $\alpha = 0.025$, because the two primary outcomes were not independent and were selected based on literature evidence [12, 13, 29].

Results

The overall rate of no MBP before elective colorectal surgery was 71% (3872 out of 5455 patients). At univariate analysis, no MBP resulted significantly associated with a lower risk of the primary outcomes AL and SSI; regarding secondary outcomes, it was significantly associated with a lower risk of s-d-SSI, reoperation, and LOS (Table 1).

For the PSMA, 2430 patients were included and two groups of 1215 patients each were generated (Fig. 1): group A (No MBP, true population of interest), and group B (MBP, control population). This population of 2430 patients includes data deriving from 62 (79.5%) of the original 78 centers: group A included data deriving from 62 (100%) centers and group B from 62 (100%) centers. A good balance between the two groups was achieved (Fig. 2 and online supplementary material), with a model variance ratio of 1.058.

Regarding primary endpoints (Table 2), Group A (No MBP) vs. group B (MBP) resulted significantly associated to a lower risk of AL [42 (3.5%) vs. 73 (6.0%) events; OR 0.57; 95% CI 0.38–0.84; $p = 0.005$]. Sensitivity analysis calculated an AL Γ of 1.3 (p upper bound = 0.07). No difference was recorded between the two groups for SSI [73 (6.0%) vs. 85 (7.0%) events; OR 0.88; 95% CI 0.63–1.22; $p = 0.441$].

Regarding secondary endpoints, Group A vs. group B resulted significantly associated with a lower risk of reoperation [55 (4.5%) vs. 78 (6.4%) events; OR 0.69; 95% CI 0.48–1.00; $p = 0.050$]; sensitivity analysis calculated a reoperation Γ of 1.1 (p upper bound = 0.08). Group A vs. group B also resulted significantly associated to a lower risk of LOS > 6 days [480 (39.5%) vs. 612 (50.4%) events; OR 0.58; 95% CI 0.48–0.69; $p < 0.001$]; sensitivity analysis calculated a LOS Γ of 1.5 (p upper bound = 0.20). The mean $\pm$ standard deviation LOS was 7.2 ± 6.0 days in group A vs. 8.2 ± 6.8 days in group B ($p < 0.0001$; two-tailed Student t-test with unequal variances and with Satterthwaite’s correction).

No significant difference was recorded between the two groups for the other secondary endpoints (Table 2).

Discussion

To our best knowledge, this is the largest retrospective propensity score-matched analysis of a prospective multicenter database comparing no MBP versus MBP alone before elective colorectal surgery. This study involved 78 surgical centers, representing a snapshot of the real-life clinical practice in Italy.

Since the first guidelines published in 2005 [30], MBP has been not recommended by the ERAS Society

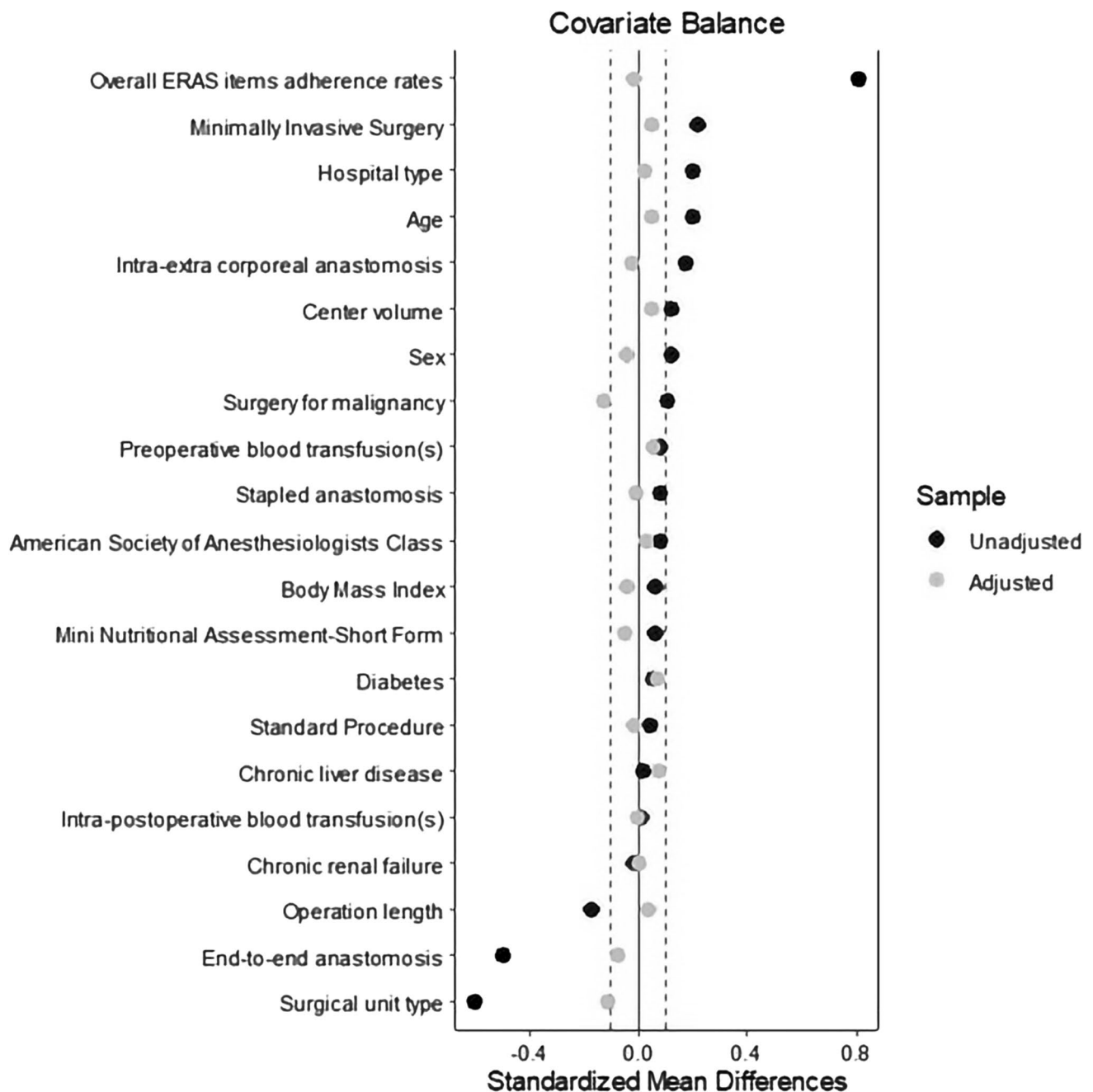


Fig. 2 Love plot of covariates' standardized mean differences between treatment and control groups before and after matching; the vertical lines represent the interval of ± 0.1 within which balance is considered acceptable; *ERAS* enhanced recovery after surgery

for nearly two decades [5] based on evidence from randomized trials [1, 31, 32] and later meta-analyses and reviews [34] indicating no benefit over no MBP in elective colon surgery. However, large surveys among USA and European surgeons [6, 7] revealed that MBP is used before colorectal resections in more than 70% of cases and recent meta-analyses of randomized controlled trials and observational studies [8–10], reported a potentially

significant superiority of MBP in combination to oAB in the prevention of postoperative complications in elective colorectal surgery.

In this study, we evaluated a population treated by elective colorectal surgery for benign and malignant disease in which all patients received perioperative intravenous antibiotic prophylaxis. We used a PSMA to compare patients in which the bowel preparation has excluded oAB and was

Table 2 Primary and secondary endpoints according to PSMA

Outcomes	Pattern	No ^a MBP		^a MBP		Propensity score-matched analysis OR (95%CI)
		No0	%	No0	%	
Anastomotic leakage	Yes	42	3.5	73	6.0	00.57 (00.38–00.84) $p=0.005$
SSI	Yes	73	6.0	85	7.0	00.88 (00.63–10.22) $p=0.441$
s-d-SSI	Yes	47	3.9	58	4.8	00.83 (00.55–10.24) $p=0.353$
Deep wound dehiscence	Yes	3	0.3	5	0.4	00.65 (00.15–20.89) $p=0.576$
Abdominal collection/abscess	Yes	27	2.2	25	2.1	10.16 (00.66–20.03) $p=0.609$
Reoperation	Yes	55	4.5	78	6.4	00.69 (00.48–10.00) $p=0.050$
LOS	> 6 days	480	39.5	612	50.4	00.58 (00.48–00.69) $p=0.001$
Overall morbidity	Yes	346	28.5	368	30.3	00.88 (00.73–10.06) $p=0.169$
Major morbidity	Yes	72	5.9	81	6.7	00.91 (00.65–10.28) $p=0.577$
Mortality	Yes	13	1.1	12	1.0	10.12 (00.49–20.56) $p=0.786$

MBP Mechanical bowel preparation

OR (95%CI)=odds ratios estimation with 95% confidence intervals; *SSI* superficial surgical site infections (s-d-SSI plus deep wound dehiscence plus abdominal collection/abscess); *s-d-SSI* superficial and/or deep surgical site infections; *LOS* length of postoperative hospital stay

of two types: no MBP (true population of interest) or MBP based on products containing polyethylene glycol (control population). The contemporary evaluation of patients in which the bowel preparation was also based on oAB alone or MBP plus oAB falls outside the aims of this PSMA and will possibly be evaluated through a multinomial propensity score analysis.

PSMA offers an alternative approach for estimating treatment effects with observational data when randomized trials are not feasible or unethical, or when researchers need to assess treatment effects based on real-life data, collected through the observation of systems as they operate in normal practice without any intervention implemented by randomized assignment rules.

After matching, the PSMA performed in the present study considered 2,430 total cases, and showed that no MBP before elective colorectal surgery was significantly associated with a lower risk of the primary endpoint AL. The sensitivity analysis showed $\Gamma=1.3$ for AL, which means that assuming that the probabilities of assignment to the two treatment groups could be different due to unknown and/or unmeasured confounding variables, 30% of patients should have been treated by MBP instead of no MBP to alter the significant association between no MBP and a lower risk of AL. Moreover, it has to be underlined that in the parent iCral 2 and 3 studies and consequently in the present study, all outcomes have been calculated at 60 days after surgery, minimizing the effect of tardive complications.

Regarding the secondary endpoints, no MBP resulted significantly associated with a lower risk of reoperation and LOS > 6 days. For reoperation, the sensitivity analysis showed $\Gamma=1.1$, which means that 10% of patients should have been treated by MBP instead of no MBP to alter the significant association between no MBP and lower risk

of reoperation. For LOS, the sensitivity analysis showed $\Gamma=1.5$, which means that 50% of patients should have been treated by MBP instead of no MBP to alter the significant association between no MBP and lower risk of LOS > 6 days.

Concerning the current ERAS Society recommendation to avoid MBP before elective colorectal surgery, our PSMA confirms that no MBP is significantly associated with a lower risk of AL, reoperation and LOS > 6 days. Conversely, MBP resulted associated with a higher risk of AL, being able to be considered a contributing cause favoring the occurrence of dehiscence, as well as other variables such as transfusions [34] or stapling devices [35], through a potential damage of the intestinal wall caused by bacterial translocation and electrolyte disturbance [36–38]. The protective effect of no MBP toward reoperation seems to be related to the causal link between AL and reoperation.

Regarding LOS, no MBP resulted associated with a lower risk of LOS > 6 days, while the mean difference with MBP was only 23 h. It is conceivable that MBP could be a contributing factor and/or cause of a delayed discharge concurring both to a prolonged time to first bowel movement and to a delayed time to realimentation [1]. In fact, MBP induces both dysbacteriosis in the gut [39] and loss of intestinal fluid via increased aldosterone secretion [40], determining hypokalemia [41] that favors periodic bowel paralysis and a prolonged time of first bowel movement. A prolonged time to first bowel movement is often associated to a delayed time to realimentation that negatively influences the balance of electrolytes and the composition of gut microbiota [41].

The main strength of this large sample size study is that it follows rigorous guidelines for applying PSMA [42, 43]. The PSMA used in the present study is based on the following items: (1) a rigorous patients' selection from the parent population, performed upon explicit criteria: to limit data

imbalance, several potential confounders related to the surgical procedure or exclusively impacting on a subgroup of patients (proximal protective stoma, delayed urgency, neo-adjuvant therapy, administration of perioperative steroids, patients treated by dialysis) were excluded; (2) a reasoned inclusion of 21 conditioning variables (covariates): hospital type, surgical unit type, and center volume to account for the potential imbalance of multicenter, clustered data; adherence to the ERAS pathway items to account for the potential imbalance of medical, anesthesiological and surgical perioperative management; resections for benign and malignant diseases, mini-invasive or open surgery, standard and non-standard procedures [14], intracorporeal (anastomosis performed under visual control through the scope) or extra-corporeal (anastomosis performed under direct visual control through an open access) anastomoses, stapled or hand-sewn anastomoses, end-to-end or different fashion anastomoses, and operation length, in relation to the imbalance of the surgical treatment; pre- and intra-postoperative blood transfusion(s) to account for transfusion-related morbidity [34]; age, sex, ASA class, body mass index, diabetes, chronic renal failure, chronic liver disease, and Mini Nutritional Assessment-Short Form, to account for patient's imbalance; (3) evaluation of the treatment effect through an adjusted multiple regression model including the same 21 covariates used for matching [27]; (4) a clear, sheer and restrictive balance algorithm (Fig. 1); and (5) a sensitivity analysis for unmeasured confounders.

Another strength of this study was the large number of enrolled patients in a well-defined time-lapse in a large number of centers, representing a very wide sample of surgical units performing colorectal resections in Italy. Although the multicenter nature of the considered data may be a definite source of clustering bias, it is undoubtedly representative of real-life data.

However, this study has several limitations, and its results should be interpreted with caution. First, single surgeon's experience [44] was not measured or recorded in the parent studies; second, some aspects of the preoperative preparation such as MBP and preoperative whole-body bathing or showering are entrusted to the patients; third, some aspects of the preoperative preparation of the surgical field such as hair removal and disinfection methods are inhomogeneous; fourth, although a sensitivity analysis to unmeasured confounders has been conducted, potential residual unknown factors and the inability to rule out potential measurement errors by the participating investigators, may have had an impact on the results.

Conclusions

This study confirms that no MBP before elective colorectal surgery is significantly associated with a lower risk of AL, reoperation rate and LOS < 6 days when compared with

MBP. The contemporary evaluation of patients in which the bowel preparation was also based on oAB alone or MBP plus oAB is outside the aim of this PSMA study and falls within the possibilities of a multinomial propensity score analysis.

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Declarations

Conflict of interest Dr. Catarci reports personal fees from Baxter Spa outside the submitted work. Dr. Guadagni, Ruffo, Viola, Borghi, Baldazzi, Pirozzi, Delrio, Garulli, Marini, Patriti, Campagnacci, Montemurro, Ciano, Benedetti, Guercioni, Sica, Caricato, and Scatizzi have no competing interests.

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