



Originals articles

A prospective, randomised, controlled study on the need to mechanically prepare the colon in scheduled colorectal surgery

Manuel Alcántara Moral,* Xavier Serra Aracil, Jordi Bombardó Juncá, Laura Mora López, Rubén Hernando Távira, Isidro Ayguavives Garnica, Oscar Aparicio Rodríguez, and Salvador Navarro Soto

Servicio de Cirugía General y Aparato Digestivo, Corporación Sanitaria Parc Taulí, Sabadell, Barcelona, Spain

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Introduction: Mechanical preparation of the colon (MPC) in colorectal surgery has been a dogma that has been questioned over the last few years. The objective of this study is to demonstrate that morbidity in scheduled colorectal surgery is the same or lower without MPC.

Material and method: Patients subjected to scheduled left colon and rectal surgery with primary anastomosis randomised into 2 groups. The "Preparation" group (MPC) received MPC and the "non-preparation" group (No-MPC) had only cleaning enemas. The variables collected were: demographic, oncological, nutritional, risk prediction models, and morbidity-mortality. **Results:** Of the 193 patients included: 69 received MPC and 71 did not; 89 patients with colocolic anastomosis (MPC, 38; no MPC, 51) and 50 colorectal (MPC, 31; no MPC, 19). Statistically significant differences were seen in the overall analysis in favour of "no preparation" as regards morbidity (43.55 % with MPC and 27% with No MPC) and nosocomial infection (27.5% and 11.4%). There was 11.6% wound infections in the MPC compared to 5.7% in the no MPC, which was not statistically significant. The only mortalities were in the MPC group 2/69 (2.9% of patients). As regards the location of the anastomosis, in the colocolics the differences were more pronounced, with statistically significant differences in the morbidity, anastomosis dehiscence, and nosocomial infection variables. The effect of no MPC was not so evident in colorectal anastomosis.

Conclusions: Our results suggest that there is no benefit in MPC before surgery in colocolic anastomosis. No-MPC is not associated with a higher morbidity in wound infection or anastomotic dehiscence. In colorectal anastomosis the differences are not so evident, therefore a much bigger series needs to be studied.

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*Author for correspondence.

E-mail address: malcantara@tauli.cat (M. Alcántara Moral).

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Preparación mecánica del colon

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Estudio prospectivo controlado y aleatorizado sobre la necesidad de la preparación mecánica de colon en la cirugía programada colorrectal**R E S U M E N**

Introducción: La preparación mecánica de colon (PMC) en la cirugía colorrectal es un dogma que se ha cuestionado en los últimos años. El objetivo de este estudio es demostrar que la morbilidad en cirugía programada colorrectal es igual o menor sin la PMC.

Material y método: Pacientes sometidos a cirugía programada de colon izquierdo y recto con anastomosis primaria fueron aleatorizados en dos grupos. Al grupo PMC se le practicó la preparación y al grupo sin PMC, sólo enemas de limpieza. Se recogieron variables demográficas, oncológicas, nutricionales y quirúrgicas, modelos de predicción de riesgo y morbi-mortalidad.

Resultados: Se incluyó a 193 pacientes, 69 con PMC y 71 sin ella; 89 pacientes con anastomosis colocolica (PMC, 38; sin PMC, 51) y 50 con anastomosis colorrectal (PMC, 31; sin PMC, 19). En el análisis general, se apreciaron diferencias estadísticamente significativas a favor de no preparar en cuanto a la morbilidad (el 43,5% en el PMC y el 27% en los sin PMC) e infección nosocomial (el 27,5 y el 11,4%). En la infección de herida, sin diferencias estadísticamente significativas, se obtuvo el 11,6% en el PMC, frente al 5,7% en el sin PMC. Las únicas muertes fueron 2/69 (2,9%) pacientes en el grupo PMC. Según localización de anastomosis, en las colocolicas las diferencias fueron más acusadas y estadísticamente significativas en las variables morbilidad, dehiscencia de anastomosis e infección nosocomial. en las anastomosis colorrectales no fue tan evidente el efecto de no preparar.

Conclusiones: Nuestros resultados indican que no existe un beneficio de la PMC en la cirugía ante anastomosis colocolicas. No preparar no tiene relación con más morbilidad en infección de herida ni dehiscencia anastomótica. En anastomosis colorrectales, las diferencias no tan evidentes hacen necesarias series más amplias.

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Introduction

We understand mechanical preparation of the colon (MPC) to be antegrade cleaning with administration of evacuating solutions such as phosphate sodium (Fosfosoda®) or polyethyleneglycol-based electrolyte solution (Bohm® solution). Generally, an oral antibiotic solution with neomycin (500 mg) and erythromycin (500 mg) is added.¹ However, MPC has been dogma among surgeons for more than a century (Halsted,² 1887; Thornton et al,³ 1997) in the prevention of infectious complications and anastomotic dehiscence. Nevertheless, it is not innocuous. It induces physiological changes, primarily dehydration, the correction of which requires fluid replacement.⁴ It is also associated with structural and inflammatory changes in the colon.⁵

However, in 1972, Hughes et al,⁶ in a randomised clinical trial, questioned its application and concluded that it was not necessary. Irving et al,⁷ in 1987, placed the need for preoperative and intraoperative MPC in doubt. However, it was strongly criticised by the journal's editor.⁸ In a randomised study with primary closure without MPC due to traumatic perforations, results that were similar to elective surgery with MPC were obtained.⁹

The first randomised controlled prospective studies¹⁰ on MPC were described in 1992, and they not only questioned its utility but also considered MPC to be detrimental. A recent joint review in this journal defends the need for this change.¹¹ Because of this, we offer the hypothesis that the rate of

complications in scheduled colorectal surgery was the same or less in patients who did not undergo MPC as in those who did. Therefore, not applying MPC avoids patient discomfort and hydro-electrolytic changes for the patient and reduces hospital stays prior to surgery. In our environment, there is no experience in controlled prospective studies and this pilot study was suggested with the goal of understanding if we are correct on preparing our patients for colorectal surgery.

Material and Method

Patients who underwent scheduled surgery of the left colon and rectum with primary anastomosis in the coloproctology unit were included. The exclusion criteria were: neoplasm of the colon less than 2 cm not previously seen on endoscopy, which avoided confusing faecal remnants when not applying MPC, abscessing of the neoplasm or acute diverticular disease in the surgery and when the patient refused to continue the study.

After inclusion and with informed consent, simple randomisation into groups was performed by sealed envelope. The MPC group was administered sodium phosphate monobasic monohydrate; sodium phosphate dibasic anhydrous (Fosfosoda®) evacuating solution or the polyethyleneglycol-based electrolyte solution (Bohm® solution) if there were cardiovascular or renal conditions, with admission 36 hours prior to surgery. In the non-MPC group, the patients were admitted 12 hours prior to surgery with a cleansing enema at 21:00 the day prior

to surgery and 2 hours prior surgery. In both groups, a liquid diet on the day prior to surgery, antithrombotic prophylaxis with 40 mg of subcutaneous low molecular weight heparin and single-dose antibiotic prophylaxis both oral (neomycin + metronidazole, 24 hours prior to surgery) and parenteral (ceftriaxone + metronidazole at the moment of anaesthesia induction) were used. In case of penicillin allergy, ceftriaxone was substituted with gentamicin. The group that underwent MPC was not administered replacement hydro-electrolytic treatment.

The patients with MPC were asked about the level of discomfort with MPC, mild, moderate, or intense. The surgeon was asked about the consistency of the faeces (soft, liquid) and the level of colon manipulation as a function of its content and dilation.

The anastomosis was defined as colorectal when the peritoneal flexure was included in the intestinal resection and colo-colic when it remained intact. In cases of low anterior resection with total excision of the mesorectum or a history of radiation-chemotherapy, a protective ileostomy was carried out.

Demographic variables (age, gender, type of disease), technical variables (location of the neoplasm, presence of distant metastases, surgical technique, radical or palliative surgery, nutritional parameters, POSSUM,¹² p-POSSUM,¹³ and CR-POSSUM¹⁴ prediction models, level of the anastomosis, tumour state) and 30-day morbidity and mortality data were collected.

Morbidity was divided into 3 groups: total nosocomial infection (surgical, catheter, respiratory, and urinary), surgical wound complications (evisceration, haematoma, seroma) or digestive tract bleeding and paralytic ileum, and non-surgical

complications (respiratory, cardiac, nephro-urological, and neurological). The main morbidity parameter studied was total nosocomial infection and from this, surgical infections, which encompasses infection of the surgical space (ISS) and anastomotic dehiscence (AD), which were the primary variables of the study. ISS was divided into incisional infection (wound infection) and organ-cavity infection of the surgical site.¹⁵ Dehiscence of the anastomosis was defined as that which was seen radiologically after clinical suspicion.

In the MPC group, electrolyte levels and renal function tests were recorded before and after MPC.

For calculation of the sample size, a 10% rate of ISS was assumed as the main variable which would allow differences of 5% and an alpha error = .05 to be found with a statistical power of 90%, so 770 patients per group were needed. Therefore, we consider this to be a pilot study with preliminary results in order to carry out a multisite study, which has still not been performed in our country.

The description of variables and the statistical analysis were performed using SPSS version 12. The quantitative variables were described using values of the median (standard deviation) whenever the distributions were normal. Otherwise, the median (range) was determined. The Student t test was used as a test of statistical significance when the criteria for its application were met, otherwise, the Mann-Whitney U test was used. For analysis of the paired data, the t test for paired data was used when the conditions for its application were met, otherwise the Wilcoxon test was used. For their part, the categorical variables are described in absolute numbers and percentages. The Pearson χ^2 test or the Yates correction was used to test statistical significance. The results of the test were given, whenever possible, with a 95% confidence interval (CI) and $P < .05$ was considered statistically significant.

This study was approved by our institution's ethics committee.

Table 1. Description of the Patients by Groups

	Patients, No.	MPC Group	Group Without MPC
Total	139	69	70
Colo-colic anastomosis	89	38	51
Colorectal anastomosis	50	31	19

Table 2. General Homogeneity of the Groups

Variable	MPC (n=69)	Without MPC (n=70)
Age, y	68	69.5
Gender, men/women	41/28	48/22
Cancer/benign disease	62/7	65/5
POSSUM-morbidity	34.8	26.1
POSSUM-mortality	6.7	4.83
P-POSSUM	1.7	1.2
CR-POSSUM	3.29	1.89
Albumin	41.95	41.85
Prealbumin	24.35	21.7
Transferrin	259.5	249
Non-significant differences ($P > .05$).		

Results

From May 2005 to August 2007, our unit has performed major colorectal surgery on 494 patients. Hundred thirty-nine patients met the inclusion criteria. Table 1 describes the patients distributed by different groups. In all, 69 patients underwent MPC and 70 did not. In the MPC group, 15 surgeries were laparoscopic (13 sigmoidectomies, 2 high anterior resections [HAR]). In the group without MPC, laparoscopy was used in 12 cases (9 sigmoidectomies and 3 HARs). Colo-colic anastomosis was performed in 89 patients (MPC, 38; without MPC, 51). Colorectal anastomosis was performed in 50 patients (MPC, 31; without MPC, 19), out of which 17 patients with MPC and 10 patients without MPC had protective ileostomies.

We see the homogeneity of the groups in Table 2. When they were analysed subdivided by colo-colic and colorectal anastomosis, we also see that they are homogenous.

The general analysis of the results (Table 3) highlights that MPC was not superior to no-MPC in any of the objective variables of the study. In addition, statistically significant

Table 3. General Results by Groups

Variable	MPC (n=69)	Without MPC (n=70)	P
Surgical time	120	130	.051
Hospital stay	10	8	.137
Total morbidity	30 (43.5%)	19 (27.1%)	.033
Nosocomial infection	19 (27.5%)	8 (11.4%)	.019
Wound infection	8 (11.6%)	4 (5.7%)	.243
Anastomotic dehiscence	5 (7.2%)	4 (5.7%)	.745
Non-surgical complication	6 (8.7%)	4 (5.7%)	.4
Mortality	2 (2.9%)	0	.245

Table 5. Result by Type of Colo-Rectal Anastomosis

Variable	MPC (n=31)	Without MPC (n=19)	P
Surgical time	142.5	140	.554
Hospital stay	10	10	.679
Total morbidity	11 (35.5%)	6 (31.6%)	.513
Nosocomial infection	6 (19.4%)	3 (15.8%)	.532
Wound infection	3 (9.7%)	0	.229
Anastomotic dehiscence	0	3 (15.8%)	.049
Non-surgical complication	3 (9.7%)	1 (5.3%)	.507
Mortality	0	0	1

differences were seen with regards to total morbidity and total nosocomial infection. Wound infection (incisional infection) was produced in 11.6% of the MPC group and in 5.7% of the group without MPC, and dehiscence of the anastomosis occurred more in the MPC group (5/69; 7.2%) than in the other group (4/69; 5.7%), without statistically significant differences in these 2 variables. It should be pointed out that organ-cavity infection of the surgical space coincided with the cases of anastomotic dehiscence, which is why they were recorded together in the results. In other words, there were no cases of organ-cavity infection that were not associated with anastomotic dehiscence.

Regarding non-surgical complications, there were poorer results in the MPC group but without statistical significance. The only deaths in the MPC group were associated with anastomotic dehiscence.

The patients were analysed according to the type of anastomosis. When comparing the groups in patients with colo-colic anastomosis (Table 4), the differences were more noticeable, with better results in the group without MPC. We observed statistically significant differences in the total morbidity variables, anastomosis dehiscence and total nosocomial infection. All of the patients with colo-colic anastomosis and anastomotic dehiscence required emergency surgery.

In the patients with colorectal anastomoses (Table 5), the protective effect on morbidity by not performing MPC was not as evident, perhaps due to the small sample size. We even find a statistically significant difference in favour of MPC in anastomotic dehiscence. In the rest of the variables studied, the tendency towards better results was maintained in the group without MPC, though the differences were not statistically significant.

Table 4. Result by Type of Colo-Colic Anastomosis

Variable	MPC (n=38)	Without MPC (n=51)	P
Surgical time	130	115	.119
Hospital stay	9	7	.101
Total morbidity	19 (50%)	13 (25.5%)	.025
Nosocomial infection	13 (34.2%)	5 (9.8%)	.005
Wound infection	5 (13.2%)	4 (7.8%)	.488
Anastomotic dehiscence	5 (13.2%)	1 (2%)	.049
Non-surgical complication	3 (7.9%)	3 (5.9%)	.513
Mortality	2 (5.3%)	0	.180

Table 6. Results of Hydro-Electrolytic Changes and Renal Function Before and After MPO

Variable	Prior to MPC	After MPC	P
Urea	35 (13-112)	22 (10-310)	NS
Creatinine	0.8 (0.4-1.6)	0.8 (0.5-1.5)	NS
Na	143 (136-146)	140 (131-148)	NS
K	4.3 (3.3-5)	3.8 (2.6-5.4)	<.05

NS indicates differences not significant.

MPC was not innocuous with respect to hydro-electrolytic changes (Table 6). Though we do not see differences in renal function, we do see a statistically significant reduction in natraemia and kalaemia. When analysing potassium values before and after MPC (Figure), hypokalaemia <3mEq/L was found following preparation in 5 (7%) patients.

Regarding patient tolerance to mechanical preparation, 35% considered the discomfort to be intense; 55% moderate; and 10% mild. Regarding the consistency of the faeces in the MPC group, more or less liquid faeces were found in 58% of cases and total cleansing of the colon was found in 42%. In the group that did not undergo MPC, faeces were not seen in 30% of cases; there were soft faeces in 48% and liquid in 22%.

Discussion

There is no evidence that MPC significantly reduces morbidity in colorectal surgery. Nevertheless, it has been a dogma that is difficult to change. This theory has been questioned over the years. Mahajna et al,¹⁶ in a study on spillage of intestinal contents following MPC, observed that there is a greater percentage of liquid faeces after MPC than when preparation is not performed (56% vs 41%) and it increased the risk of ISS. Holte et al⁴ published a study on the hydro-electrolytic changes in 12 healthy subjects who underwent MPC. They observed an increase in plasma osmolarity, urea and phosphate, with a reduction in calcium, sodium and potassium, and dehydration. Our results continue on the path observed by these authors. We do not see such noticeable changes in renal function, though we do see a worrisome trend in hypokalaemia, given that 5 (7%) patients were <3 mEq/L. We did not opt for hydro-electrolytic replacement therapy in the MPC group because this would have modified

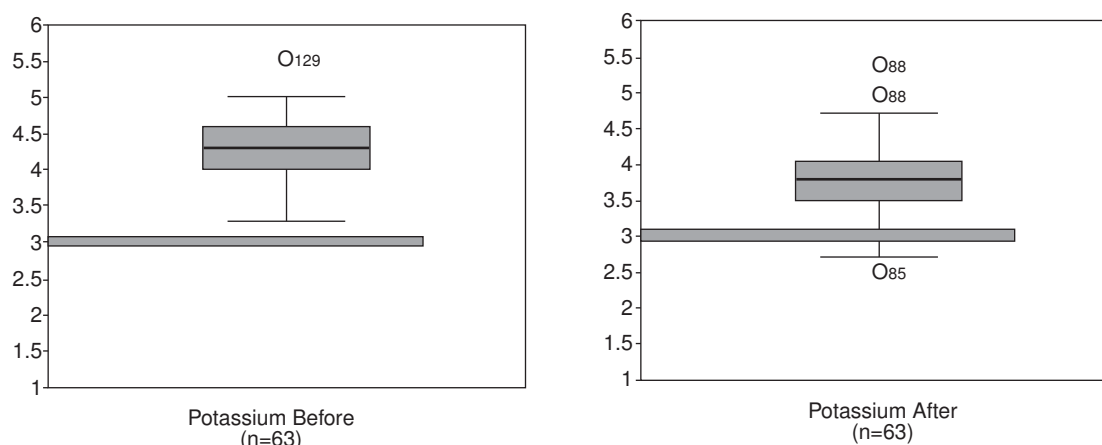


Figure – Hydro-electrolytic changes in potassium before and after mechanical preparation of the colon (Wilcoxon test, $P < .05$).

the total liquid supply to the patient during the perioperative period and may have been a source of bias for the MPC group. In reality, MPC appears to act as an additional surgical stress prior to the surgery with its own endocrine-metabolic reaction. These facts have led to the tendency to not perform MPC in recent years (Roig et al¹¹).

When we talk about the effect of MPC in prospective, controlled, randomised studies performed in recent years,¹¹ the results of on ISS and DA are better in the group without MPC. However, the sample has never been ideal. Because of this, a meta-analysis has been published with the same results.¹¹ Recently, Jung et al¹⁷ have published a multisite study with a sufficient sample to answer the question on the effect of MPC on cardiovascular complications and on ISS, and they did not obtain a better result than the group without MPC.

In our results, in general, we find that not performing MPC is not detrimental for the patient since the associated morbidity is the same or less, which confirms the initial hypothesis of the study. When we analyse the differences with respect to wound infection and AD, the difference still favour not performing MPC, but they were not statistically significant. This fact may be explained by the sample size. It deals with variables included in the total morbidity and nosocomial infection, whose differences continue to favour not performing preparation. Regarding the homogeneity of the groups, the relationships between malignant/benign diseases were practically equal. Regarding nutritional state and the risk prediction models between the patients with malignant disease and those with benign disease, no statistically significant differences were seen, which is why each of the study's source groups (MPC and without MPC) had oncology patients grouped together in the same group as patients with benign disease and they were all considered to be scheduled colorectal surgery.

When we analyse the results by type of anastomosis, the results are different. In the publications with colo-colic anastomoses,^{11,18,19} MPC did not offer any benefit in these

situations. Our results found the same tendency; including all of the variables studied, the differences were in favour of the group without MPC and with statistically significant differences in total morbidity, nosocomial infection and DA.

There are few publications on the impact of MPC in rectal surgery alone. It has been shown that ileostomy used to protect a low colorectal anastomosis leads to a reduction in symptomatic postoperative morbidity.²⁰ Common sense leads one to think that, in order to reduce septic complications following AD in a low colorectal anastomosis protected by an ileostomy, the rest of the colon should be as clean as possible. Nevertheless, the evidence does not point in this direction, probably due to the comments previously made by Mahajna et al¹⁶ on the effect of MPC and the presence of liquid faeces. In that regard, Wille-Jørgensen et al, in their published meta-analysis, list the complications of AD in anastomosis surgery of the rectum and they observe a rate of 9.8% (11 of 12 patients in the MPC group) in low anterior resection, compared to 7.5% (9 of 119 patients in the group without MPC), meaning that MPC did not provide any beneficial effect. Recently, Bretagnol et al,²¹ in a prospective and observational study that compared a retrospective homogenous series in sphincter-sparing rectal surgery, concluded that elective surgery for rectal cancer without MPC probably leads to a reduction in postoperative morbidity. In our results, we see an increase in AD in the group without MPC. These ADs were clinical and did not require reintervention. All were patients with protective ileostomies and they were treated conservatively.

Not ordering preparation means following a regular diet and applying simple cleansing enemas prior to surgical intervention in order to facilitate introduction of the circular mechanical stapler through the rectum. Simple enemas were chosen because the effect of a phosphate enema is not innocuous. Platell et al²² performed a randomised study with 294 patients and they observed that it produces histological and local endoscopic changes similar to those produced following ingestion of a laxative. In addition, the rectal

contents after the enema are liquid, with mucosal hypersecretion, which may also promote leaks. Despite being a completely subjective datum from the surgeon, this was also seen in our study, in which 58% of patients with MPC had faeces that were more or less liquid versus 22% of those who did not undergo MPC. One datum to point out is the level of discomfort for the patients with MPC that was intense or moderate in 90% and mild in 10%.

Our results indicate that patients who do not undergo MPC do not present more complications than those who do, but rather there are even worse results in this group. In colorectal anastomosis, wider samples for prospective, randomised controlled studies are needed with a representative sample that defines its usefulness given that, despite showing this tendency, the differences are not statistically significant. For this reason, we believe that it is important that we disseminate our results in our immediate setting since, as indicated by Roig et al,¹¹ "the weight of tradition" makes it difficult to change habits. Complications as serious as those produced by this surgery lead to fear of going against the logic transmitted since our training, and it makes it more difficult to impose scientific evidence.

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