Intraoperative continuous intestinal loop warming technique A prospective randomised trial



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Intraoperative continuous intestinal loop warming technique. A prospective randomised trial

AIM: The aim of this study is to evaluate if the Intraoperative Continuous Intestinal Loop Warming (ICLW) is a valid trick to decrease the postoperative paralytic ileus.

METHODS: The subjects were patients who underwent emergency open abdominal surgery for either benign or malignant diseases. Patients were divided into two groups; group A patients who was secluded for ICLW, and a control group B who was not secluded for ICLW. The primary outcomes were the time of recovery of bowel movement, 30 days postoperative mortality and morbidity, morbidity was graded by the Clavien-Dindo classification of surgical complications. Secondary outcomes were operative time, and length of hospital stay.

RESULTS: A total numbers of 100 patients were randomly assigned in this prospective study. The mean time of bowel function recovery in the group A was 41.52 hours, whereas for group B was 67.20 hours, these differences were statistically significant with a P value < 0.05. In group B the bowel function recovery for 64% of the patients took between 72-96 hours furthermore, the longest time for peristaltic recovery was 96 hours which was only observed in patients of group B. There were no intra-operative complication in both groups. There is no difference in the two groups in term of 30 day postoperative morbidity.

CONCLUSIONS: Intra-operative continuous intestinal loop warming technique is a simple, safe and low cost technique. It seems that intra-operative continuous intestinal loop warming technique maintain tissues hydration and conserve the body temperature limiting the stress response and help in decreasing the incidence of postoperative paralytic ileus.

KEY WORDS: Paralytic Ileus, Postoperative Care, Warming

Introduction

Recently, new perioperative treatment strategies have been adapted; "Fast track surgery" or Enhanced Recovery After Surgery (ERAS) to facilitate early recovery with a reduction of postoperative morbidity and mortality by reducing the body's stress response and limiting the organ dysfunction to a minimum. A focus on optimal pain management, minimally invasive surgery, and aggressive postoperative rehabilitation, together with early oral feeding mobilization^{1,2}.

A suggestion for a shift to include patients undergoing more complex surgical procedures, reduction in postoperative complications, length of hospital stay, and time to recovery with extension to include end points of cost reduction, safety preservation, and patient satisfaction³.

To the best of our knowledge this is the first study to evaluate the effect of intraoperative heating of the intestinal loop during emergency intestinal surgery as a component of ERAS program.

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Methods

Study Design and Participants

The subjects were patients who underwent emergency open abdominal surgery for either benign or malignant diseases. Patients who were younger than 18 years, pregnant female, or those on opioid more than 3 doses within one week of surgery were excluded. Laparoscopic surgery was an exclusion character except conversion was occurred.

Patients were divided into two groups; group A patients who was secluded for ICLW, and a control group B that was not secluded for ICLW. Both groups were manually matched for age, sex, ASA score, and type of pathology and intervention. Patients on odd dates were treated with ICLW and patients on even dates had a normal perioperative care (rinsed with physiologic water when needed and at the end of surgery).

Pre-operative evaluation

All patients were evaluated preoperatively by expert anesthesiologists for comorbidities with quantification using the ASA score. Antibiotic prophylaxis was given at the induction of anesthesia inform of 1 gm cephalosporin with a second dose for operation more than four hours. Adequate thromboembolic prophylaxis was given inform of low-molecular-weight heparin (4000 IU/day) 8 hours before elective procedure or 8 hours after urgent procedure.

Technique

Intraoperative continuous intestinal loop warming technique included intraoperative wash with physiological saline (0.9% Sodium Chloride solution) at about 35°-38° Celsius every 10 to 15 minutes during surgical interventions.

Intra-operative care

The maintenance of intraoperative normo-thermia was secured by a hot air blower. The operating room temperature was also increased to 22°C. In order to shorten the recovery time of intestinal peristalsis, there were no epidural anesthesia nor postoperative usage of opioids, the type of anesthesia agents used were intra venous. Also in order to shorten the recovery time of intestinal peristalsis oro-gastric tube was aspirated and removed at the end of the intervention.

Variables

Basic demographic data were recorded including age and sex of patients as well as ASA, type of pathology, type of intervention, operative duration, time of bowel function recovery, postoperative hospital stay, 30 days morbidity and mortality. Morbidity was graduated according to the Clavien-Dindo classification⁴ of surgical complications.

Outcomes

We aim to add "Intraoperative Continuous Intestinal Loop Warming technique" to be a part of ERAS in emergency colorectal surgery. The primary outcomes were the time of recovery of bowel movement, 30 days postoperative mortality and morbidity. Postoperative complications were graded by the Clavien-Dindo classification of surgical complications. Secondary outcomes were operative time, and length of hospital stay.

Ethical consideration

All patients signed written informed consent including the possibility of future publication according to the Italian bioethics laws. There was no specific consent asked for the usage of ICLW method, as it consists of normal physiological saline. Institutional Review Board (IRB) approval has been obtained from the Ethical Committee of the Policlinico Tor Vergata Hospital in compliance with the Principals of Helsinki Declaration.

Statistical analysis

We compared the differences in patient characteristics and postoperative outcomes in two groups; group A treated with ICLW and group B without. Analysis was performed with SPSS® software (Windows version 19.0; SPSS Inc., Chicago, IL). Continuous variables were analyzed with ANOVA-test, a Pearson Chi Square (χ^2) test for ordinal variables, the independent T Test was used when appropriate. We run different test to determine if the proportion of the variables between the two groups like males and females, age, pathology, infections, fistulas, surgical treatment and ASA classification were similar. Data were expressed as median and range or mean \pm standard deviation. P \leq 0.05 was considered to be statistically significant.

Results

PATIENT CHARACTERISTICS

A total number of 100 patients were randomly assigned in this prospective study. Fifty patients in each group with mean age of 54.86 \pm 11.52, and 57.50 \pm 11.84 years for group A, and B respectively. There were 24 (48%) men, and 26 (52%) women in group A, and 26 (52%) men, and 24 (48%) women in group B (Table I).

TABLE I - Patient's demographic

Variable	Group A	Group B	P value
Number of patients	50	50	
Age (mean ± SD)	54.86 ±11.52	57.5 ±11.84	NS
Male (no, %)	24 (48%)	26 (52%)	NS
Female (no, %)	26 (52%)	24 (48%)	NS

Variable	Group A	Group B	P value
I ASA	7 (14%)	4 (8%)	NS
II ASA	40 (80%)	39 (78%)	NS
III ASA	3 (6%)	7 (14%)	NS

TABLE II - American society of anesthesiologist's classification

TABLE III - Disease type

Variable	Group A	Group B	P value
	r	r -	
Volvulus	4 (8%)	2 (4%)	NS
Ventral hernia	16 (32%)	14 (28%)	NS
Diverticular disease	18 (36%)	20 (40%)	NS
Malignancies	12 (24%)	14 (28%)	NS

TABLE IV - Surgical approach

Variable	Group A	Group B	P value	
Untwisting	2 (4%)	1 (2%)	NS	
Resection	5 (10%)	8 (16%)	NS	
Adhesolysis	15 (30%)	11 (22%)	NS	
Resection and anastomosis	7 (14%)	6 (12%)	NS	
Hartman resection	18 (36%)	20 (40%)	NS	
Protection resection	3 (6%)	4 (8%)	NS	

Both groups A and B, have similar characteristics in the proportion of age, sex, and ASA (Table II) score, pathology (Table III), and type of surgery (Table IV) with no statistically significant differences. Pathology for which patients underwent surgery and types of surgical intervention were similar in both groups.

BOWEL FUNCTION RECOVERY

The mean time of bowel function recovery in the group A was 41.52 hours, whereas for group B was 67.20 hours, these differences were statistically significant with a P value of 0.000. In group B the bowel function recovery for 64% of the patients took between 72-96 hours furthermore, the longest time for peristaltic recovery was 96 hours which was only observed in patients of group B (Table V).

OPERATIVE TIME

The mean operative time was 148.44 ± 52.97 , and 158.00 ± 57.23 for group A and B respectively. These data were with no significant differences (Table VI).

MORBIDITY AND MORTALITY

We did not record any intra-operative complication in both groups. There is no difference between the groups in term of 30 day postoperative morbidity and this would suggest that intra-operative continuous intestinal

TABLE V - Recovery of peristalsis in hours

Variable	Group A	Group B	P value
Recovery of peristalsis (mean ± SD)	41.52 ±16.12	67.20 ±19.39	0.000
Recovery of peristalsis in 24 hours	17 (34%)	2 (4%)	
Recovery of peristalsis in 36 hours	7 (14%)	0 (0%)	
Recovery of peristalsis in 48 hours	19 (38%)	16 (32%)	
Recovery of peristalsis in 72 hours	7 (14%)	22 (44%)	
Recovery of peristalsis in 96 hours	0 (0%)	10 (20%)	

TABLE VI - Operative time in minutes

Variable	Group A	Group B	P value
Operative time (mean ± SD)	148.44 ±52.97	158.00 ±57.23	NS

TABLE VII - Complications after surgery; fistula or infection with Clavien-Dindo classification

Variable	Group A	Group B	P value	Clavien-Dindo classification
Total	8 (6%)	6 (2%)	NS	
Fistula Infection	3 (6%) 5 (10%)	1 (2%) 5 (10%)	NS NS	IIIB I

loop warming does not reduce infections or fistulas after surgery (Table VII). According to the Clavien-Dindo classification of surgical complications, were 3 patients with Grade I complications in group A and 1 patient with Grade I complications in group B. There was no mortality in either group.

Discussion

Over the years, lavage was widely used by surgeons in the treatment of peritonitis due to perforated viscus or from acute abdomen but with number of opponents who were afraid from possibility of infection spread ⁵.

Peritoneal lavage in the treatment of peritonitis combined with adequate surgery and the use of systemic antibiotics offers a better chance for recovery ⁶. With a little evidence, the concept of removal peritoneal contamination not considered debatable, but more aggressive form of peritoneal lavage may be harmful to the peritoneal mesothelial cells ⁵.

On the other side, Breborowicz and Oreopoulos in review about rinsing the peritoneal cavity with normal saline concluded that it may be harmful to the peritoneal mesothelial cells, and may impair their fibrinolytic activity ⁷. Intraoperative saline irrigation at cesarean delivery did not significantly decrease infections, intra-operative, or postoperative complications, furthermore, it was associated with increased intra-operative and postoperative nausea and concurrent use of anti-emetics. These new evidence was highlighted in clinical trials and metaanalysis ⁸⁻¹⁰. Eke et al, in their meta-analysis suggested that the difference in surgical techniques can also influence the outcomes ¹⁰.

The lethal triad of hypothermia, acidosis and coagulopathy has been recognized as a significant cause of death in patients with traumatic injuries or in emergency situation ¹¹. Intraoperative hypothermia less than 35°C can alter physiological mechanisms, associated with increased morbidity with the cardiac complications being the main type, which can be reversed by maintenance of normal temperature ¹². Also, it is a risk factor for surgical site infection in elective colorectal procedures¹³. The risk of perioperative hypothermia shows wide variation from 1.5% to 20% ¹⁴.

There is a number of interventions used to maintain body temperature, one of these is active warming systems which aimed at transferring heat to the patient including infrared lights, blankets, whether electric or with warm water circulation, convective air warming transfer, use of warm intravenous or irrigation fluids, and warm and humidified anesthetic air ¹⁴.

Adherence to ERAS have shown low complications rate and decrease of length of hospital stay, with a dependence on number of ERAS components pathway ^{15,16}. There is little information on ERAS in emergency sitting, specially colorectal emergency, with erase earlier outcomes in shorter hospital stay and lower postoperative complications ¹⁷⁻¹⁹.

Despite our efforts to minimize bias, our study still has certain limitations that must be discussed. First, the number of patients was low. Second, the work is a result of single institution experience. Third, paralytic ileus has multifactorial etiology, our study mainly focused on hypothermia theory. A future multicenter study is important, with higher number of patients and more focus on other causes of paralytic ileus especially on biological level.

Conclusions

Intra-operative continuous intestinal loop warming technique, is a simple, safe, and low cost technique. It seems that intra-operative continuous intestinal loop warming technique maintain tissues hydration and conserve the body temperature limiting the stress response and help in decreasing the incidence of postoperative paralytic ileus.

Riassunto

Lo scopo di questo studio è di valutare se il riscaldamento intraoperatorio continuo delle anse intestinali è un approccio valido per ridurre la durata dell'ileo paralitico postoperatorio.

I soggetti erano pazienti sottoposti a chirurgia addominale d'urgenza sia per malattie intestinali benigne che maligne. Sono stati suddivisi in due gruppi; gruppo A: pazienti operati con ICLW, e un gruppo di controllo B. Gli end point erano: il tempo di ripresa della peristalsi, mortalità e morbilità postoperatoria. Quest'ultima classificata secondo Clavien-Dindo. Gli end point secondari erano: durata dell'intervento, durata della degenza ospedaliera.

Un totale di 100 pazienti sono stati randomizzati in questo studio prospettico. Il tempo medio di recupero della funzionalità intestinale nel gruppo A è stato di 41.52 ore, mentre per il gruppo B di 67.20 ore. Queste differenze sono risultate statisticamente significative (P< 0,05). Nel gruppo B il recupero della funzione intestinale per il 64% dei pazienti è stato di 72-96 ore. In entrambi i gruppi non sono state registrate complicanze post-operatorie. La tecnica del riscaldamento intraoperatorio continuo delle anse intestinali è semplice, sicura, e a basso costo. Il suo ruolo specifico è il mantenimento di una corretta idratazione e normotermia che limiterebbero la risposta allo stress con evidente riduzione dei tempi di recupero della peristalsi.

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