# Pain Management, Local Infection, Satisfaction, Adverse Effects and Residual Pain after Major Open Abdominal Surgery: Epidural *versus* Continuous Wound Infusion (PAMA Trial)

# Controlo de Dor, Infeção Local, Satisfação, Efeitos Adversos e Dor Residual no Pós-Operatório de Cirurgia Abdominal *Major*: Epidural *versus* Infusão Contínua da Ferida Cirúrgica (PAMA *Trial*)

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## ABSTRACT

**Introduction:** The Management of postoperative pain after abdominal surgery is a major challenge to the anesthesiologist. The optimization of postoperative analgesia improves prognosis contributing also to patient satisfaction and reducing morbidity and mortality. The aim of this randomized control study is to perform the comparative analysis in terms of effectiveness of an unconventional and still poorly technique implemented, continuous wound infusion, and the currently most applied and gold standard technique, epidural analgesia, in the postoperative period after abdominal surgery.

**Material and Methods:** Fifty patients, previously subjected to abdominal surgery by median laparotomy with xifo-pubic incision were randomized to receive postoperative analgesia via epidural (n = 25) or via continuous wound infusion (n = 25) during 48 hours. The primary outcome was analysis of pain at rest (< 4/10 numerical pain scale) after 24 hours postoperatively. Scores of pain at six, 12 and 48 hours and three months after surgery were also evaluated, as well as the incidence of adverse effects 48 hours postoperatively.

**Results:** The proportion of patients with successful control of postoperative pain was 84% against 60% with epidural analgesia and continuous wound infusion, respectively. Within the continuous wound infusion group with uncontrolled pain, all patients rated the pain below 6/10 24 hours postoperatively. The incidence of nausea, vomiting, pruritus or íleus was lower in the continuous wound infusion group, with statistically significant results for recovery of intestinal function. There was one case of systemic local anesthetic toxicity with an episode of frequent ventricular extrasystoles without hemodynamic instability, which ceased after suspension of continuous epidural infusion of local anesthetic.

**Discussion:** This study suggests that continuous wound infusion is the technique with most efficacy and safety, being even better than epidural analgesia in postoperative pain control after major abdominal surgery. This technique is associated with better analgesia, lower incidence of side effects, high level of satisfaction and no residual pain, contributing to enhanced recovery.

**Conclusion:** Continuous wound infusion is an effective technique, which should be implemented for analgesia after major abdominal surgery, with advantages when compared with epidural analgesia, especially low incidence of adverse effects.

**Registration:** Trial not registered.

**Keywords:** Abdomen/surgery; Anesthesia, Epidural; Anesthetics, Local; Digestive System Surgical Procedures; Pain, Postoperative; Postoperative Complications; Postoperative Nausea and Vomiting

## RESUMO

**Introdução:** O controlo da dor no pós-operatório de cirurgia abdominal *major* é um desafio para o Anestesiologista. A otimização da analgesia no pós-operatório melhora o prognóstico e a evolução clínica contribuindo igualmente para a satisfação do doente e redução da morbimortalidade. O objetivo principal deste estudo randomizado é efetuar a análise comparativa em termos de eficácia de uma técnica pouco convencional e ainda pouco implementada, infusão contínua da ferida cirúrgica, e a técnica atualmente considerada *gold standard*, analgesia via epidural, no pós-operatório de cirurgia abdominal *major*.

**Material e Métodos:** Foram randomizados 50 doentes submetidos a cirurgia abdominal por laparotomia mediana com incisão xifo-púbica para receber analgesia pós-operatória por um esquema via epidural (n = 25) ou via infusão contínua da ferida cirúrgica (n = 25) durante 48 horas. Os critérios de eficácia foram baseados na análise da dor em repouso (escala numérica de dor < 4/10) às 24 horas de pós-operatório. Foram ainda avaliados os *scores* de dor às seis, 12 e 48 horas e aos três meses de pós-operatório, assim como a incidência de efeitos adversos às 48 horas de pós-operatório, grau de satisfação pessoal e dor residual após 3 meses.

**Resultados:** A proporção de doentes com controlo bem-sucedido da dor pós-operatória foi de 84% para infusão contínua da ferida cirúrgica e 60% para analgesia via epidural. No grupo infusão contínua da ferida cirúrgica com dor não controlada, todos os doentes classificaram a dor abaixo de 6/10 às 24 horas de pós-operatório. A incidência de náuseas, vómitos, prurido ou íleus foi menor no grupo infusão contínua da ferida cirúrgica, com resultado estatisticamente significativo para recuperação da função intestinal.

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Verificou-se um caso de toxicidade sistémica de anestésico local com um episódio de extrassístolia ventricular frequente sem repercussão hemodinâmica, que cessaram após suspensão da perfusão contínua de anestésico local por via epidural.
**Discussão:** A análise de eficácia sugere que a técnica de infusão contínua da ferida cirúrgica é uma técnica com eficácia e segurança, sendo até melhor que a analgesia via epidural no controlo da dor pós-operatória de cirurgia abdominal *major*. Esta técnica está associada a melhor controlo analgésico, com menor incidência de efeitos adversos, elevado grau de satisfação pessoal e ausência de dor residual, contribuindo para uma otimização da recuperação e alta precoce.
**Conclusão:** A infusão contínua da ferida cirúrgica é uma técnica eficaz, que deve ser implementada na analgesia de pós-operatório de cirurgia abdominal *major*, tendo vantagens quando comparada com a analgesia epidural, nomeadamente na menor incidência de efeitos adversos.
**Registo:** Ensaio clínico não registado.
**Palavras-chave:** Abdomen/cirurgia; Analgésicos Locais; Anestesia Epidural; Complicações Operatórias; Dor Pós-Operatória; Náusea e Vómito Pós-Operatório; Procedimentos Cirúrgicos do Sistema Digestivo

## INTRODUCTION

Laparotomy is associated with hard-to manage early postoperative pain.[1] Pain control optimisation can be challenging and different surgical factors should be considered (type of surgical procedure, approach and duration), as well as particular characteristics of the patient in response to pain and to surgery and the pharmacological approach to pain management.[2]

Postoperative pain has a relevant impact on personal satisfaction[3] and a negative effect on recovery, delaying patient's discharge from hospital, which is directly related not only to an adequate pain management as to the minimisation of drug's adverse effects.[4]

Apart from patient's comfort and personal satisfaction optimisation, improved recovery of functional capacity, reduced morbidity and the promotion of an early discharge are the major aims of postoperative pain management.[5]

Intravenous and epidural have been the two most frequently used routes in postoperative pain management. However, these have been increasingly challenged by the use of ultrasound-guided peripheral loco-regional anaesthesia as well as the use of other alternative techniques including continuous surgical wound infusion, with a mainly peripheral mechanism of action, through the blockade of nerve receptors in the skin, subcutaneous tissue and fasciae and some level of peritoneal absorption and subsequent systemic effect. Intravenous pain management has been frequently associated with some delay in postoperative recovery due to adverse effects including nausea and vomiting, prolonged postoperative ileus, sedation and lightheadedness.[6] Good outcomes in static and dynamic pain scores have been obtained with the use of epidural analgesia and this has been currently regarded as gold standard.[7] There are however some limitations such as absolute and relative contraindications, technique failures and the presence of adverse effects and complications found with a relevant prevalence.[8] Recent publications suggested that the benefits of epidural analgesia are not so significant as previously considered. Even though the analgesic efficacy has been established as well as benefits in high-risk patients undergoing major surgery regarding cardiovascular and respiratory morbidity and mortality, the use of this technique is in decline.[9] The reasons for this are related to the fact that there is scarce evidence that postoperative morbidity and mortality are actually reduced on the short as on medium and long-term. Improved surgical techniques have also reinforced this fact as many procedures previously performed in an in-patient unit are currently carried out as an outpatient or overnight surgery depending on early mobilisation programs. An increased evidence of unconventional analgesia techniques, sometimes with better outcomes than epidural[10] and the lack of evidence regarding cost-benefits are some of the limitations of the technique.[11]

Continuous surgical wound infusion of local anaesthetics is currently under research as an alternative technique for postoperative pain management with proven efficacy.[12] It has been increasingly used as part of a multimodal pain management regimen[13] with better outcomes than other single-shot alternative techniques (as for instance the TAP [transversus abdominis plane] block) as it allows for an over 24-hour continuous pain control. Comparative studies with intravenous PCA (patient-controlled analgesia) morphine have shown advantages in analgesia control, adverse effect and length of stay reduction.[14]

This study aimed at the comparative analysis between epidural analgesia (EDA) and continuous wound infusion (CWI) by using the following parameters: efficacy in postoperative pain control; incidence of adverse effects, level of satisfaction and risk of infection at the catheter insertion site.

## MATERIAL AND METHODS

This was a randomized prospective study carried out at the Department of General Surgery and the Department of Anaesthesiology of the *Hospital de Santa Maria* and was approved by the Ethics Committee of the Hospital. In total, 70 patients aged 21 to 89 were equally randomised to the EDA or CWI groups through an electronically generated list and transferred to individual envelopes. A written informed consent has been obtained from all the patients previous to the inclusion into the study. Patients having undergone upper or lower major open abdominal surgery (20-30 cm long xiphopubic midline incision) by the same surgical team, under general balanced anaesthesia, ASA ≤ 3 and keeping the catheter for a 48-hour period were included into the study. Exclusion criteria included the presence of significant preoperative abdominal pain, the use of opioids on the seven days previous to surgery, the inability to understand the pain scale used in the study and the presence of an absolute or relative contraindication for locoregional analgesia.

The type of anaesthesia has been standardized for all

the patients, including pre-induction with midazolam and induction with fentanyl, propofol and atracurium or rocuronium as selected by the anaesthetist responsible for the operation. Sevoflurane (0.6-1 MAC) and fentanyl were used in maintenance. Surgery was always carried out by the same team, through a xiphopubic midline incision. The use of intravenous morphine bolus was allowed during recovery from anaesthesia whenever necessary and within the first two postoperative hours.

In patients randomized for epidural analgesia (EDA group), this was performed before anaesthesia induction with a catheter inserted at upper lumbar (L1-L3) or thoracic (T10-T12) sites, according with the anaesthetist preference. The technique was performed with the patient placed into the sitting position, using a Portex®, Smiths Medical (Tuohy 18G needle) epidural pack. This was inserted 4 cm within the epidural space. A 3 ml test dose of 2% lidocaine was immediately administered and a 2 ml bolus of 0.2% ropivacaine per metameric block's level was subsequently used 30-40 minutes before the end of the surgery, associated to a morphine bolus according with the position of the catheter and the age of the patient, followed by a continuous perfusion as per the protocol in use (shown in Fig. 1), for a 48-hour period. Morphine boluses were repeated every 12 hours.

In the group of patients who underwent the continuous surgical wound infusion (CWI group), surgeons inserted a multiperforated catheter (PAINfusor® 30; Baxter Healthcare SA) within the surgical wound through a skin incision made 2 cm above the laparotomy and placed in a pre-peritoneal position underlying the aponeurosis (Fig. 2), during surgery and upon peritoneal closure with continuous suture. With the catheter in position and during closure of the abdominal wall, a 10 ml bolus of 0.2% ropivacaine was administered and a 10 ml/hour continuous infusion of 0.2% ropivacaine was immediately started (by using an infusion pump) for 48 hours (Fig. 3).

Basic analgesia regimen with every 6 hours intravenous 1g of paracetamol was followed in both groups, with an intravenous rescue analgesia with 30 mg of ketorolac. Nausea and vomiting were controlled with intravenous 4 mg of ondansetron.

Primary endpoint was pain at rest 24 h postoperatively by using a numeric rating scale (NRS). Secondary endpoints included (i) rest pain at 6, 12, 24, 48-hour and 3 months according with a NRS and (ii) incidence of adverse effects up to 48 h postoperatively (nausea and vomiting and the need for increased antiemetic therapy; pruritus; urinary retention [need for urinary catheter beyond 24 h postoperatively]; ileus [absent bowel sounds beyond 24 h postoperatively]; paresthesia). Other secondary endpoints included the level of satisfaction with the analgesia technique and the infection rate at the catheter insertion site up to three months postoperatively. Data on the latter were directly obtained by phone from the patient upon discharge from hospital by using a simple questionnaire. The following question ("Would you recommend the type of analgesia that was used to someone else?") was used for the assessment of patient's satisfaction. Three patients died before the three-month follow-up evaluation and therefore were excluded from the study. Whenever a patient described having been readmitted to hospital during this three-month period due to a surgical wound infection or to other reason, this was clarified by the analysis of the electronic medical record.

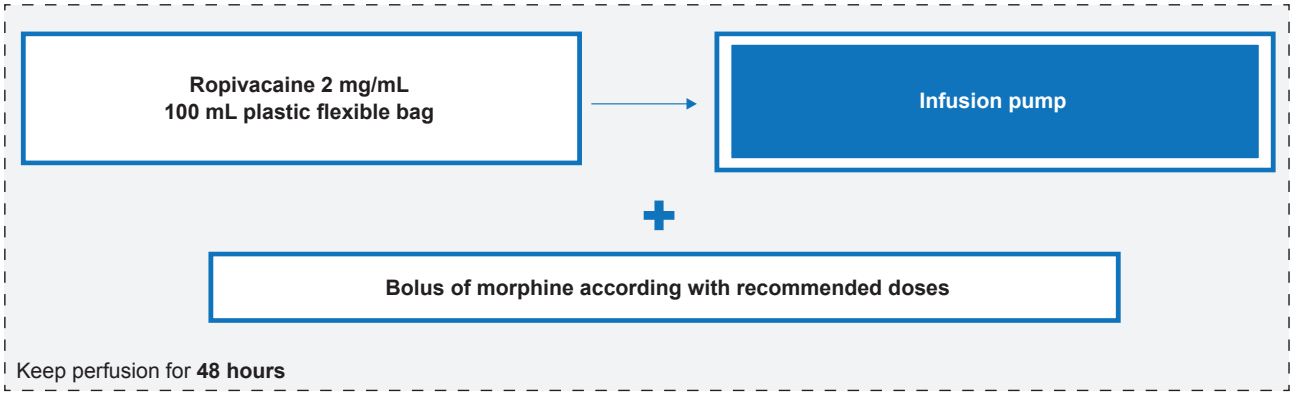


Figure 1 – Protocol for postoperative epidural analgesia

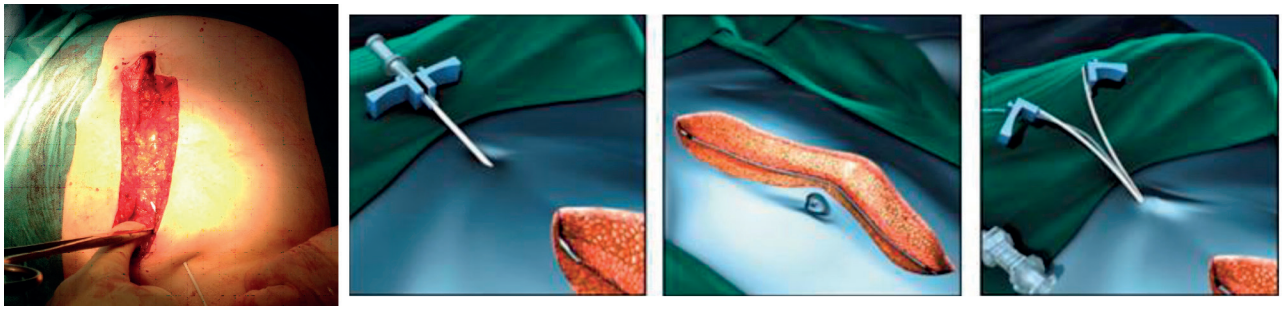

Figure 2 – Sub-aponeurotic / pre-peritoneal catheter placement

A 25-patient sample has been determined for each group, with a standard deviation of +/- 2 points in NRS score at 24 h postoperatively, with a normal distribution. The calculation was carried out with an 80% power and = 0.05. A total of 25 patients were selected for each group and a post hoc analysis has been made for the described variables, by using GraphPad Prism 6.00 (GraphPad Software, Inc. La Jolla, CA) software.

Student's t-test has been used for demographic analysis.

Primary endpoint and personal satisfaction were statistically analysed for a level of significance < 0.05 by using Mann-Whitney test. Fisher test has been used for the analysis of the incidence of adverse effects, with the same level of significance.

## RESULTS

A total of 70 patients were recruited and randomly selected to EDA (n = 25) or CWI (n = 25). Three deceased patients before three months postoperatively, five patients with incomplete medical records, one patient due to anatomically inadequate CWI placement, one patient in the EDA group due to catheter exteriorisation previous to the 24-hour postoperative period and two patients non-compliant with the analgesia regimen were excluded from the study and data regarding 50 patients were analysed (Fig. 4).

Patient's demographic characteristics are shown in Table 1.

An adequate randomisation has been found for both groups by the contingency analysis. Similar surgery duration has been found in both groups.

A CWI superiority vs. EDA has been found regarding pain at rest at 24 h postoperatively. Successful postoperative analgesia (NRS score < 4/10) has been found in 84% of the CWI patients (n = 21) and 60% (n = 15) of the EDA patients. All the patients in the CWI group with uncontrolled pain showed a pain score <6/10 at 24 h postoperatively.

The differences regarding median scores (shown in Fig. 5) are above the non-inferiority score defined for pain control at rest (score of 4), considering a 95% confidence interval of NRS of pain at rest at 24 h postoperatively.

A lower incidence of adverse effects has been found

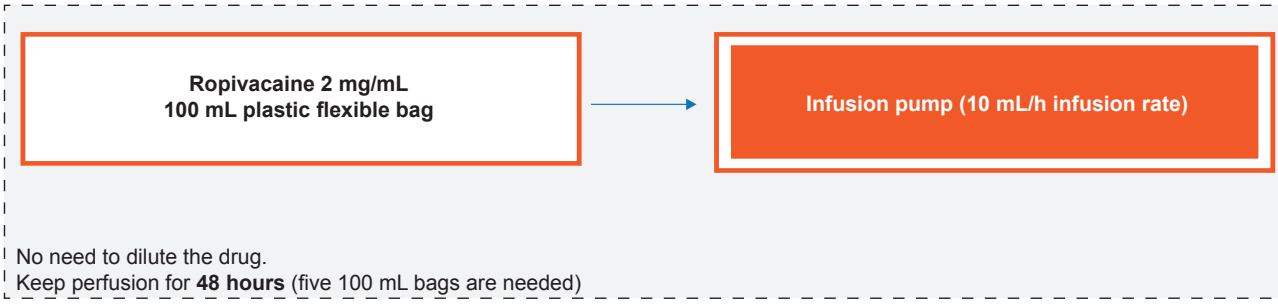


Figure 3 – Protocol for postoperative continuous surgical wound infusion

Table 1 - Demographic characteristics of our group of patients: age, body weight and height with reference to mean (standard deviation), gender, ASA physical status, level of catheter placement and types of surgery with reference to *n* (percentage)

| | EDA (n = 25) | CWI (n = 25) | *p*-value |
|---|---|---|---|
| **Age** (years) | **62 (18)** | **68 (12)** | **0.274** |
| **Weight** (kg) | **76 (18)** | **64 (12)** | **0.864** |
| **Height** (cm) | **162 (8)** | **164 (5)** | **0.688** |
| **Gender** (M / F) | **11 (44%) / 14 (56%)** | **9 (36%) / 16 (64%)** | |
| **ASA physical status** (1 / 2 / 3) | **1 (4%) / 10 (40%) / 13 (52%)** | **2 (8%) / 11 (44%) / 7 (28%)** | |
| **Level of catheter placement** (thoracic / lumbar) | **16 (64%) / 9 (36%)** | **-** | |
| **Type of surgery:** | | | |
| - Splenectomy | **1 (4%)** | **1 (4%)** | |
| - Right hemicolectomy | **2 (8%)** | **2 (8%)** | |
| - Left hemicolectomy | **5 (20%)** | **3 (12%)** | |
| - Total colectomy | **-** | **1 (4%)** | |
| - Partial gastrectomy | **7 (28%)** | **6 (24%)** | |
| - Total gastrectomy | **6 (24%)** | **9 (36%)** | |
| - Pheochromocytoma removal | **-** | **1 (4%)** | |
| - Sarcoma removal | **2 (8%)** | **2 (8%)** | |
| - Segmentectomy of the liver | **2 (8%)** | **-** | |
| **Surgery duration** | **301 (107)** | **306 (120)** | **< 0.001** |

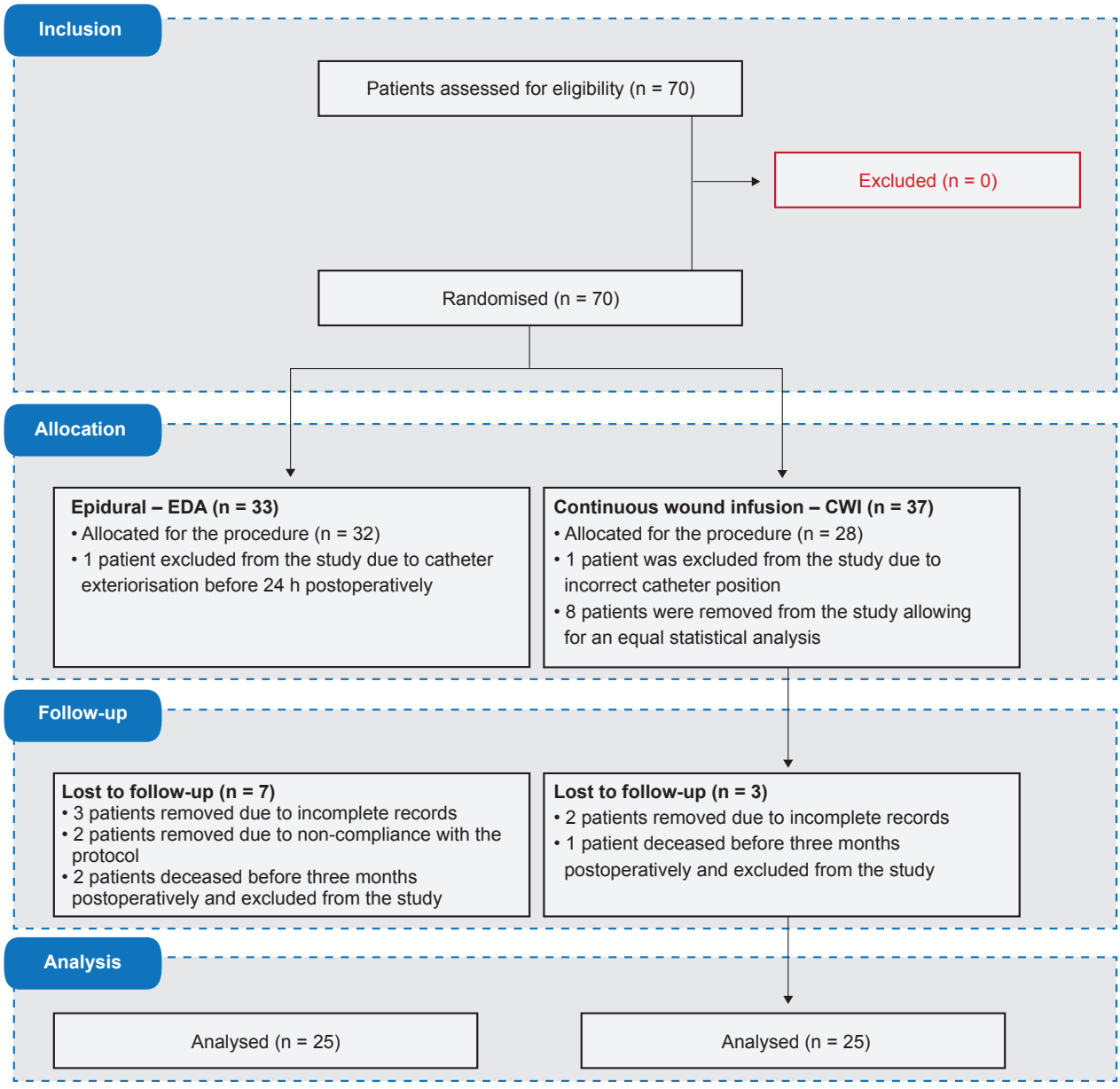


Figure 4 – CONSORT diagram

in the CWI group, with a statistically significant difference regarding postoperative ileus. The following number of patients in each group (CWI/EDA) having described the presence of adverse effects has been found: nausea/vomiting 7/2 ($p = 0.138$) ; pruritus 2/0 ($p = 0.49$); urinary retention 4/0 ($p = 0.11$); ileus 17/4 ($p = 0.0004$); local anaesthetic systemic toxicity 1/0 ($p = 1$); paresthesia 2/0 ($p = 0.483$); local infection 2/1 ($p = 1$).

One patient with local anaesthetic systemic toxicity has been found, presenting with an episode of frequent ventricular ectopy with no haemodynamic effects which has recovered upon removal of the continuous epidural perfusion.

A more efficient control regarding secondary endpoints has been found in the CWI group at 6 and at 12 hours postoperatively. A similar pain control has been found with any of techniques at the remaining follow-up periods.

A higher personal satisfaction has been found in the CWI group, with statistically significant differences found with Fisher's test. No differences have been found regarding the infection rate at the catheter insertion site. Two EDA patients with skin infection at the epidural catheter insertion site, self-limited upon removal of the catheter at 48 hours and one patient with an infection of the surgical wound has been found at one month upon surgery in the CWI group, having presented with no inflammatory signs at the catheter insertion site, which was removed at 48 hours and conservatively managed.

## DISCUSSION

Multimodal analgesia mainly based on systemic opioids is currently the most frequently used analgesia technique in the postoperative stage of major open abdominal surgery.

Standardized effects regarding the mechanisms of activity in the organism according with the region in which

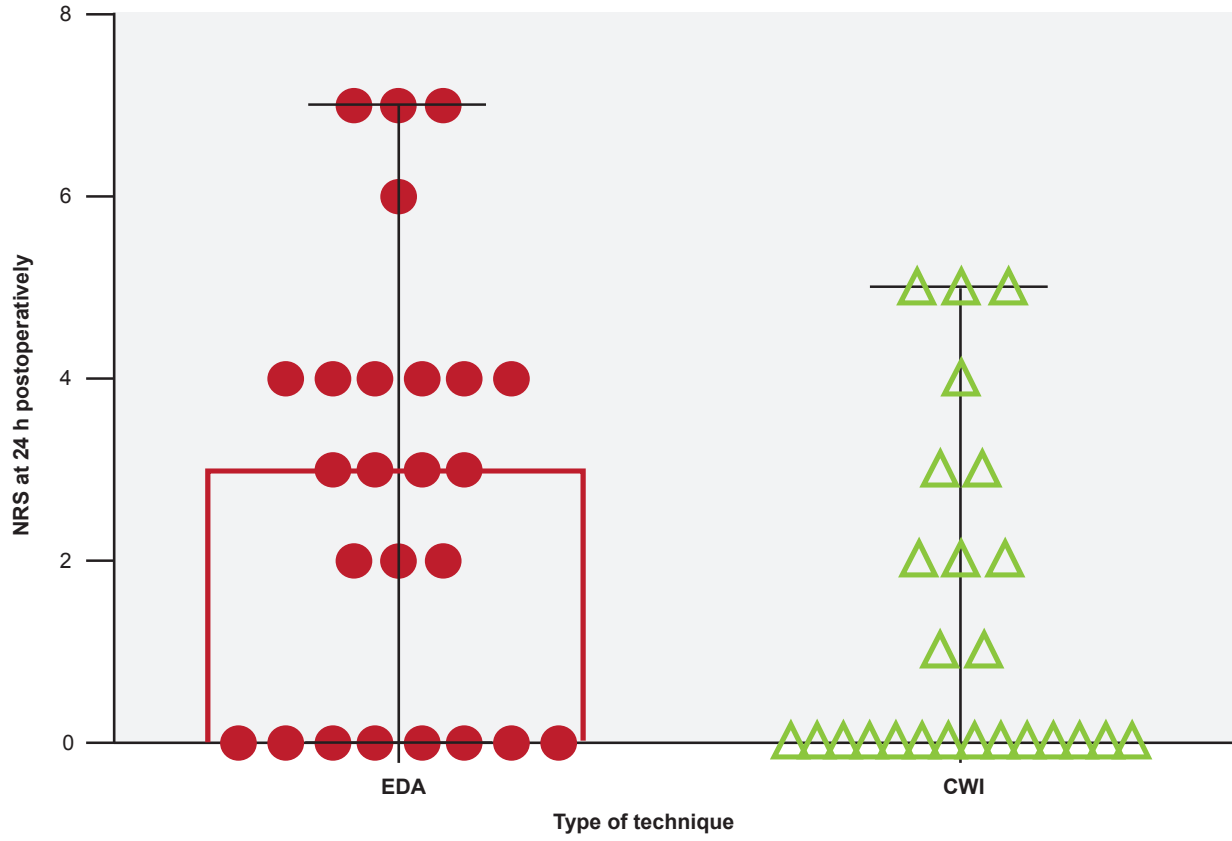


Figure 5 – NRS (numeric rating scale) for pain assessment at 24 h postoperatively. Results correspond to median with interquartile range. Showing statistical differences with Mann-Whitney test, $p = 0.032$.

opioid analgesics act have been found: (i) increasing the activity of the modulating system of the descending pathway, (ii) reducing the endocrine and metabolic response to surgical stress (limbic system and hypothalamus) and (iii) changing pain cognitive and emotional response (limbic system and cortex), at the central nervous system; (iv) modulating the information transmitted through C-fibres on second-order neurons, at the spinal cord and peripherally (v) reducing the concentration of inflammatory peptides and the oedema and hyperalgesia induced by prostaglandins.

Non-intravenous delivery of drugs to patients in order to reduce adverse effects and tolerance has long been studied. Epidural technique is currently considered as gold standard in the management of postoperative pain associated with major open abdominal surgery and is a well-tolerated, steep learning curve technique, with a rapidly consistent and predictable effect, allowing for patient mobilisation according with drug concentration and allowing for analgesia enhancement and rescue analgesia by using the same route.

This study aimed at the comparison of this well-established, gold standard technique with a more recent one preventing from the use of opioids and depending on the link between surgeons and anaesthetists for a successful analgesia.

The use of the CWI technique for postoperative analgesia in major open abdominal surgery was shown as adequate according with this randomized study, with a low level of toxicity and even with advantages in terms of immediate postoperative analgesia without the need for using opioids and subsequent minimisation of adverse effects, as well as with no described toxicity. Previous studies have shown similar results when applied to colorectal surgery, according with the meta-analysis by Karthikesalingam *et al.*[15] in addition to radical nephrectomy, C-section[16] and total hysterectomy, among others. Post-operative pain severity was always lower in the CWI group in all the evaluations regarding pain at rest. The use of a numeric pain scale allows for ranging pain from 0 (painless) to 10 (maximum pain) and has been shown as adequate in this study, as long as it is adequately understood by patients and assessed by the same group of evaluators.

This study allowed for the comparison between epidural analgesia and continuous wound infusion with a catheter placed into a pre-peritoneal position, allowing for the attenuation of nociceptive stimuli at the site where parietal pain develops, with a peripheral anti-nociceptive effect, i.e. at the peritoneum, aponeurosis and muscle, in addition to some systemic effect related to the absorption of the local anaesthetic, while epidural analgesia has a central effect associated with the opioid and a neuraxial blockade of the nociceptive stimuli related to visceral and parietal pain.

Statistically significant differences regarding pain at rest at 6, 12 and 24 hours postoperatively have been found in this study and globally lower pain scores have been found with the use of continuous surgical wound infusion *vs.*

epidural analgesia, possibly due to different factors. Continuous surgical wound infusion is aimed at reducing the somatic nociceptive stimuli transmitted through nerve endings affected by surgical incision, including C-fibre activity, with a subsequent reduction in peripheral and central sensitisation (medullary dorsal horn). In addition, the inflammatory response is also reduced by local anaesthetics, with a similar effect as locally-released diclofenac.[17] Local antibacterial[18] and antiseptic effect, very useful in preventing from postoperative complications, has also been described.

The fact that statistically significant differences were not found at 48 h postoperatively may be due to the efficacy of the opioids that were used in the EDA patients, with concomitant adverse effects impairing recovery from major open abdominal surgery, mainly ileus. The relative reduction in the incidence of nausea and vomiting found in the CWI group may have been related to a quicker bowel recovery and with the lack of use of opioids in this group. One patient presented with local anaesthetic systemic toxicity, with an episode of frequent ventricular ectopy with no haemodynamic effect, which has recovered upon removal of the continuous epidural perfusion. No toxicity has been found in the CWI group, even in patients in whom all the allowed rescue boluses have been administered, showing that pre-peritoneal placement is safe and well tolerated, in line with what has been found in other studies.[19,20]

Low incidence of catheter-related complications, namely local infection, has been found in both groups, showing that the presence of foreign bodies such as catheters within the surgical wound in CWI patients did not increase the risk of local infection, even though considering the abovementioned antiseptic and antibacterial effect of infusion of local anaesthetics.

The fact that three patients in the EDA group presented with residual pain (at three months upon surgery) is worth mentioning. These corresponded to dorsal pain at the insertion site, in line with some evidence found in literature.[21]

Finally, some limitations of the study should be mentioned: at first, many major abdominal surgeries are usually performed by laparoscopy, preventing from the use of CWI pre-peritoneal technique; in addition, drugs from different classes have been compared in this study, with different effects and therefore preventing from an adequate comparison of their adverse effects; another important limitation regards the fact that this has not been a double-blind study, which was not possible, considering the different protocols and involving medical bedside examination. This may have biased data collection and interpretation; the lack of use of PCA (patient-controlled analgesia) on both arms of the study is another limitation to the outcome accreditation; the number of patients within each arm is not very significant; the main limitation of the study, preventing from a routine implementation of CWI is the dependency from surgeons for an anatomically correct placement and the need for a separate closure of peritoneum and muscle-aponeurotic planes.

## CONCLUSION

In conclusion, even though opioid-based epidural analgesia is still the most frequently used technique in postoperative stage of major open abdominal surgery, this study showed that a peripheral approach, namely within the surgical wound may have a contribution to an adequate control of postoperative pain with minimal adverse effects and toxicity and no increase in local infection rate.

Based on the experience obtained with this study, continuous wound infusion has been shown as much simpler to use than epidural analgesia. This study has shown that pre-peritoneal continuous wound infusion upon an initial bolus of ropivacaine has produced better pain management than epidural continuous infusion with ropivacaine enhanced with an opioid, leading to lower adverse effects and lower residual pain.

## HUMAN AND ANIMAL PROTECTION

The authors declare that this prospective randomised and controlled study has been carried out at the *Hospital de Santa Maria* – Department of General Surgery and Anaesthesiology, with the approval by the Ethics and Clinical Research Committee and according to the Helsinki Declaration of the World Medical Association.

## DATA CONFIDENTIALITY

The authors declare that they have followed the protocols of their work centre on the publication of patient data.

## CONFLICTS OF INTEREST

The authors declare that there were no conflicts of interest in writing this manuscript.

## FINANCIAL SUPPORT

Pro bono supply of 30 PAINfusor® 30 catheters has been provided by Baxter. This equipment has been supplied to the Department of Anaesthesiology of the *Hospital de Santa Maria* as a sample, as it was not included into the hospital's stock. The catheters were used in the study without granting any power to the company in return.

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