



## Original Article

# Safety of a Multiperforated Catheter Implanted in the Surgical Wound for the Continuous Infusion of Local Anaesthetics in Post-Operative Analgesia<sup>☆</sup>

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## A B S T R A C T

**Objective:** To evaluate the incidence of infection at the surgical site in patients who have a multiperforated catheter implant for continuous infusion of a local anaesthetic as a local analgesic.

**Patients and method:** An observational, descriptive and prospective study, of one-month duration. It included 50 patients subjected to selective laparotomy in whom a multiperforated pre-peritoneal catheter was implanted for analgesia purposes (Painfusor<sup>®</sup>, Baxter). Patients with a surgical incision of less than 15 cm and/or ASA >III, were excluded from the study.

**Results:** The catheter was removed from all patients at 48 h. An infection at the surgical site was present in 6% of the patients who had the catheter implanted, which was similar to the incidence in clean-contaminated surgery (5.5%; 95% CI: 3.4%–8.7%). Colonisation of the catheter was observed in two patients, causing only one infection of the surgical site.

**Conclusions:** The use of an in situ pre-peritoneal catheter for post-surgical anaesthesia does not increase the risk of surgical site infection.

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## Seguridad de un catéter multiperforado implantado en la herida quirúrgica para la infusión continua de anestésicos locales en la analgesia post-operatoria

## R E S U M E N

**Objetivos:** Evaluar la incidencia de infección del sitio quirúrgico en pacientes en los que se implanta un catéter multiperforado para infusión continua de un anestésico local a este nivel con intención analgésica.

**Pacientes y método:** Estudio observacional, descriptivo, y prospectivo, de un mes de duración. Se incluyeron 50 pacientes sometidos a laparotomía programada en los que se implantó el

## Palabras clave:

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catéter pre-peritoneal multiperforado con intención analgésica (Painfusor<sup>®</sup>. Baxter). Se excluyeron del estudio los pacientes con una incisión quirúrgica inferior a 15 cm y/o ASA > III.

**Resultados:** El catéter se retiró en todos los pacientes a las 48 horas. El 6% de los pacientes a los que se les implantó el catéter presentó una infección del sitio quirúrgico, con una incidencia similar a la del centro para cirugías limpias-contaminadas (5,5%; IC95%: 3,4-8,7%). En dos pacientes se observó colonización del catéter, presentado sólo uno infección del sitio quirúrgico.

**Conclusiones:** La utilización del catéter en posición pre-peritoneal para analgesia post-quirúrgica no incrementa el riesgo de infección del sitio quirúrgico.

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## Introduction

The management of postoperative pain is essential for improving the quality of life for patients and for an adequate clinical response, and sometimes leads to a reduction in hospital stay.<sup>1,2</sup> In recent years, the administration of local anaesthetic agents into the surgical wound has been evaluated as an effective method for the control of postoperative pain. A multiperforated catheter is inserted into the surgical site and continuously delivers local anaesthetic agents at this level.<sup>1-3</sup> A meta-analysis by Liu et al.<sup>1</sup> analysed 44 controlled clinical trials with a total of 2141 patients treated mainly with bupivacaine (n=34) and ropivacaine (n=9). It was concluded that continuous local infiltration of anaesthetic agents by inserting a multiperforated catheter into the surgical site was effective in controlling postoperative pain, reducing opioid use, and reducing the length of hospital stay. Forastiere et al. found that the administration of ropivacaine into the surgical site improved patient analgesia and accelerated recovery.<sup>4</sup> In addition, a meta-analysis by Karthikesalingam et al.<sup>5</sup> on the effect of continuous infusion of local anaesthetic agents into the surgical wound after colorectal surgery, showed better control of analgesia for the patient.

However, one of the concerns limiting the use of this technique is the increased risk of surgical site infection (SSI) by implantation of the catheter into the surgical wound, as well as the possible impact on wound healing associated with placing a foreign body in it.

All things considered, it was suggested conducting a study with the main objective of assessing the risk of SSI in patients with a catheter implanted into the surgical wound with analgesic intent.

## Material and Methods

An observational, descriptive and prospective study was performed in a university general hospital with 850 beds. The target population of the study was patients admitted on a scheduled basis to the general surgery department. The patients were older than 18 years, undergoing laparotomy surgery with a multiperforated catheter implanted with analgesic intent and gave their written consent to participate in the study. Patients who had a surgical incision less than

15 cm, an ASA classification >III and emergency operations were excluded.

## Study Variables

The main variable was the presence of SSI in patients within 30 days of surgery, which affected the skin and subcutaneous tissue (superficial incisional SSI), deep soft tissues from the incision (deep incisional SSI), and/or organ or space handled during surgery (SSI of organs and spaces). SSI was diagnosed if there was a positive culture of purulent discharge or by clinical criteria, diagnostic or surgical procedures, and/or when the surgeon deliberately opened the wound and considered that it was infected.<sup>6</sup>

## Other Variables Studied

**Patient:** age, sex, anaesthetic-surgical risk index (ASA), weight, height, diagnosis, comorbidity (e.g., diabetes, HIV) and chronic treatments that increase the risk of infection (e.g., anti-neoplastics, immunosuppressants or corticosteroids).

**Process:** degree of contamination of the surgical wound (clean, clean-contaminated, contaminated and dirty), duration of surgery (h), size of the incision (cm), type of anaesthesia (general or spinal), surgical site preparation (type of antiseptic and pre-surgery time), antibiotic prophylaxis (antibiotic, pre-surgery time, and any need for additional intraoperative doses), type of procedure, and intraoperative complications. The NNIS index, which classifies patients according to the degree of wound contamination, the ASA value, and duration of the intervention were used to assess the risk of infection.<sup>7</sup>

**Catheter placement:** number of insertion attempts, anatomical position of the catheter, catheter dwell time, and catheter-related incidents (e.g., obstruction).

**Post-operation:** analgesia used, rescue analgesia, postoperative complications (e.g., sepsis or adverse effects of analgesics used), length of stay, and wound healing (e.g., healing properly, by secondary intention, etc.).

## Method

Since it was an initial study to evaluate the safety of using this novel analgesic technique in the hospital, it was decided to include the first few patients undergoing this analgesic

catheter technique in the study, with a time limit of 1 month. The data for each patient were obtained prospectively from the patient's medical history and the operating room record.

In addition to the post-surgical analgesia commonly used in the hospital (a intravenous mixture of 200 mg dexketo-profen, 400 mg tramadol, and 4 mg ondansetron in continuous intravenous infusion for 48 h), patients implanted with the catheter for analgesic intent received a bolus of 5 ml of 0.2% ropivacaine in the surgical wound (on inserting the catheter), followed by a continuous infusion in the surgical wound of ropivacaine (240 ml of 0.2% ropivacaine at an infusion rate of 5 ml/h).<sup>8,9</sup> All parenteral mixtures were prepared in the pharmacy department following standard safety measures for parenteral treatment preparation (with a vertical laminar flow cabinet).

The catheter was withdrawn by a standard procedure to prevent its contamination, and a sample taken in a sterile container was sent to the microbiology department for culture analysis. The culture media used for the microbiological analysis were those commonly used in the hospital (aerobic and anaerobic blood agar at 37 °C, Chapman medium for *Staphylococcus* spp., and Sabouraud-chloramphenicol-agar for fungi growth). A colony count at 24, 48, and 72 h was performed for the microbiological study, with each sample processed in duplicate. The microorganism in any positive growth was identified according to standard techniques used at the hospital.

The degree of surgical wound healing and any SSI after hospital discharge was determined up to 30 days after the intervention. Some 30 days after the intervention patient information from the surgery outpatient medical records was collected, and/or contact was made with the surgeon who performed the procedure.

### Statistical Analysis

The qualitative variables were studied according to their absolute and relative frequency of occurrence and quantitative variables according to the central tendency and dispersion measures. The normality of each variable was examined using the goodness-of-fit test (Kolmogorov-Smirnov). To compare the studied variables, homogeneity tests were applied using the z-test statistic and Student's t-test (or non-parametric tests), considering a Pearson value of .05 for P and calculating the 95% confidence interval in all cases.

### Results

A total of 50 patients were included during the study period (Table 1). All studied variables followed a normal distribution.

The main diagnoses of the patients included in the study were colorectal neoplasia (52.0%), liver metastases from colorectal cancer (12.0%), adenomatous polyposis (10.0%) and hernia (8.0%). Considering these diagnoses, the surgical procedures most frequently performed were partial removal of the large intestine (transverse colon resection: 24.0%; right hemicolectomy: 26.0%; sigmoidectomy: 5.0%) and metastasectomy (12.0%).

**Table 1 – Baseline Characteristics of Patients Included in the Study.**

Age, years <sup>a</sup>	62.5 (58.49–66.55)
Sex, % female	22 (44.0)
Weight, kg <sup>a</sup>	71.4 (69.26–73.58)
Height, m <sup>a</sup>	1.69 (1.68–1.71)
Obesity (BMI>30 kg/m <sup>2</sup> )	5 (10.0)
Incision, cm <sup>a</sup>	22.70 (21.42–24.02)
Duration of surgery, min <sup>a</sup>	132.5 (122.55–142.57)
Contaminated surgery <sup>b</sup>	34 (68.0)
NNIS score	
0	16 (32.0)
1	30 (60.0)
2–3	4 (8.0)

n (%).

<sup>a</sup> Mean and 95% confidence interval.

<sup>b</sup> Grouping of surgery as contaminated or dirty. Student's t-test and the Levene test were applied for homogeneity of variances.

The risk of SSI according to the NNSI score was 1 for the majority of patients (n=30/50), i.e., a medium-high risk of SSI, with only 8% of cases with high risk. All patients received prophylactic antibiotics correctly and underwent successful surgical field preparation via the standard hospital procedure.

All catheters were implanted at the first attempt. There were no complications related to the catheter or infusion of local anaesthetic agent in the patients. The catheter was removed after 48 h in all cases, after delivering the local anaesthetic agent, and no premature withdrawal of the catheter was recorded.

Some 30 days after the operation, the evaluation of patients showed that the surgical wound healing was correct in 90.0% of patients (n=45/50).

SSI was found in 3 patients (6% cumulative incidence), although only 2 gave a positive culture from the catheter tip. The microorganisms identified were *Staphylococcus hominis* and *Escherichia coli* (*E. coli*). However, only the patient with *E. coli*, which is a microorganism common in SSI in clean-contaminated wounds, was diagnosed with SSI.

Of these 3 patients, only 1 required the incision to be opened and cleaned. The remaining cases were resolved with antibiotic treatment, as they were considered superficial infections of the surgical wound. Patients who had SSI had similar features to those who did not in terms of mean age (70.33 vs 62.02; P=.052) and BMI (24.63 kg/m<sup>2</sup> vs 25.61 kg/m<sup>2</sup>; P=.807). All patients with SSI were males. The average duration of surgery was also similar between groups (135.00 min vs 132.40 min; P=.906). In only 1 of the 3 SSI cases was the surgery classified as contaminated.

### Discussion

Surgical site infection (SSI) is the 3rd most common nosocomial infection.<sup>10</sup> It accounts for 15%–20% of nosocomial infections, and 40% of nosocomial infections acquired by patients admitted to the surgery department, according to data from the study of prevalence of nosocomial infections in Spain (EPINE).<sup>11</sup> Results obtained in the HELICS project on nosocomial infection in Europe show that the incidence of SSI

is 6.0% in Spain (95% CI: 5.3%–6.6%). According to data from the Spanish Association of Surgeons,<sup>12</sup> SSI in contaminated surgery may reach figures of up to 21.1% and may exceed 33.0% for dirty surgery. In the centre where the study took place, data from EPINE 2010 showed that SSI accounted for 20.0% of nosocomial infections, with a cumulative incidence of 8.1% (95% CI: 7%–9.4%).<sup>13</sup> The patients included in our study underwent abdominal surgery, especially colorectal, with the wound in most cases being classified as contaminated, posing a greater risk of SSI. For patients with clean-contaminated surgery, the centre's own data showed a cumulative incidence of 5.5% (95% CI: 3.4%–8.7%). Thus, SSI data obtained in this study were consistent with the HELICS data and the incidence of infection observed in the centre. As such, inserting a catheter into the surgical wound did not increase the incidence of SSI.

Although the use of a multiperforated catheter with analgesic intent is being used with increasing frequency in abdominal and other surgery, such as Caesarean sections, the published studies focus on the effectiveness of the technique. However, a study by Loro Represa et al.<sup>14</sup> showed that the use of a catheter in thoracic and abdominal surgery was effective in controlling post-surgical pain and did not increase the incidence of SSI.

Nor were there any changes observed in the degree of wound healing, which showed that catheter placement did not interfere with this process. This may be due to the infusion of the local anaesthetic agent into the surgical wound, reducing the inflammatory response to damage, reducing neutrophil adhesion to the endothelium and oedema in this area,<sup>15,16</sup> and thereby improving surgical wound healing.

The microbiological analysis results for the catheters implanted in the patients showed that the risk of colonisation is low, with only 2 cases of bacterial growth being observed. This may be because the implantation was performed in the operating room before the surgical wound closure, following a procedure that prevents mishandling of the device. Also, the fact that the catheter was in place for only 48 h reduced the risk of postoperative contamination.

The small sample size was one of the study limitations. However, as this was an initial study, the results provided some data on the safety of this postoperative analgesia technique in terms of SSI risk and the effect on surgical wound healing, which was not available before. Studies with a larger sample size are needed to confirm these results and to demonstrate the safety of this mode of analgesia.

In conclusion, considering the study limitations and potential bias of its design, the results obtained show that implantation of a catheter in the pre-peritoneal space for continuous infiltration of local anaesthetic agents into the surgical wound did not increase the risk of SSI.

## Conflicts of Interest

This research was conducted with support from Baxter SL., with no type of legal commitment or influence to/over the results. Dr Juan Fco Marquez received fees from Baxter SL. for

his consultancy services. The other authors have no conflicts of interest to declare.

## REFERENCES

1. Liu S, Richman J, Thirlby R, Wu C. Efficacy of continuous wound catheter delivering local anesthetic for postoperative analgesia: a quantitative and qualitative systematic review of randomized controlled trials. *J Am Coll Surg*. 2006;203:914–32.
2. Baig MK, Zmora O, Derdemezi J, Weiss EG, Nogueras JJ, Wexner SD. Use of the ON-Q pain management system is associated with decreased postoperative analgesic requirement: double blind randomized placebo pilot study. *J Am Coll Surg*. 2006;202:297–305.
3. Gómez Ríos MA, Vázquez Barreiro L, Nieto Serradilla L, Diz Gómez JC, López Alvarez S. Eficacia analgésica de la infiltración continua de la herida quirúrgica en el postoperatorio de la histerectomía abdominal. *Rev Esp Anestesiol Reanim*. 2009;56:417–24.
4. Forastiere E, Sofra M, Giannarelli D, Fabrizi L, Simone G. Effectiveness of continuous wound infusion of 0.5% ropivacaine by On-Q pain relief system for postoperative pain management after open nephrectomy. *Br J Anaesth*. 2008;101:841–7.
5. Karthikesalingam A, Walsh SR, Markar SR, Sadat U, Tang TY, Malata CM. Continuous wound infusion of local anaesthetic agents following colorectal surgery: systematic review and meta-analysis. *World J Gastroenterol*. 2008;14:5301–5.
6. Horan TC, Gaynes RP, Martone WJ, Jarvis WR, Emori TG. CDC definitions of nosocomial surgical site infections, 1992. A modification of CDC definitions of surgical wound infections. *Infect Control Hosp Epidemiol*. 1992; 13:606–8.
7. Culver DH, Horan TC, Gaynes RP, Martone WJ, Emori TG, Banerjee SN, et al. Surgical wound infection rates by wound class, operative procedure, and patient risk index, National Nosocomial Infections Surveillance System. *Am J Med*. 1991;91:152–7.
8. Bianconi M, Ferraro L, Ricci R, Zanolli G, Antonelli T, Giulia B, et al. The pharmacokinetics and efficacy of ropivacaine continuous wound instillation after spine fusion surgery. *Anesth Analg*. 2004;98:166–72.
9. Ansaloni L, Agnoletti V, Bettini D, Caira A, Calli M, Catena F, et al. The analgesic efficacy of continuous elastomeric pump ropivacaine wound instillation after appendectomy. *J Clin Anesth*. 2007;19:256–63.
10. Emori TG, Gaynes RP. An overview of nosocomial infections, including the role of the microbiology laboratory. *Clin Microbiol Rev*. 1993;6:428–42.
11. Estudio de Prevalencia de Infección Nosocomial en España (EPINE). Sociedad Española de Medicina Preventiva. Salud Pública e Higiene; 2009.
12. Cainzos M. Infección de la herida quirúrgica. In: Parrilla P, Landa JL, editors. *Cirugía AEC. Manual de la Asociación Española de Cirujanos*. Madrid: Panamericana; 2010; p. 181–6.
13. Camargo R, Cama J. Caso de infección de localización quirúrgica. Situación actual de este centro. Hospital General Universitario de Alicante. Available from: [www.dep19.san.gva.es/.../sesiones%20generales/23-03-11Medicina%20Preventiva%20Dr.%20Camargo.pdf](http://www.dep19.san.gva.es/.../sesiones%20generales/23-03-11Medicina%20Preventiva%20Dr.%20Camargo.pdf) [accessed: April 2011].
14. Loro Represa JM, Tur Alonso A, Aparicio Chagoyen R, Castro Villor F, Matoses Jaén S, Peláez Vielba MS, et al. Experiencia

- en el uso de catéteres incisionales multiperforados para analgesia post-operatoria en cirugía torácica y abdominal mayor. Abstract No. 162. VIII Congreso de la Sociedad Española del Dolor-IX Reunión Iberoamericana. Madrid; 2010.
15. Hahnenkamp K, Theilmeier G, Van Aken HK, Hoenemann CW. The effects of local anesthetics on perioperative coagulation, inflammation, and microcirculation. *Anesth Analg*. 2002;94:1441-7.
16. Beaussier M, El'Ayoubi H, Schiffer E, Rollin M, Parc Y, Mazoit JX, et al. Continuous preperitoneal infusion of ropivacaine provides effective analgesia and accelerates recovery after colorectal surgery: a randomized, double-blind, placebo-controlled study. *Anesthesiology*. 2007;107:461-8.