

The effects of incisional bupivacaine infusions on postoperative opioid consumption and pain scores after total abdominal hysterectomy

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Abstract

Background: The aim of this study was to determine opioid requirements and pain intensity scores in patients after a total abdominal hysterectomy (TAH) administered with a bupivacaine infusion for a 30-hour period, and then to compare the data with that of a control group.

Method: This was a prospective, parallel, single-blinded randomised trial which took place at the Rahima Moosa Mother and Child Hospital, Johannesburg. Thirty-six consenting patients, who underwent a TAH, were randomised to either having a 0.39% bupivacaine infusion in the incisional site or not. Morphine was administered via a patient-controlled analgesia pump (PCA) for rescue analgesia. Dynamic, static and worst pain scores were assessed one, six and 30 hours after surgery by using a visual analogue scale (VAS). Morphine consumption was recorded at set intervals.

Results: There were statistically significant differences between the two groups' dynamic VAS scores in the first hour and at 24 hours and 30 hours; in the static VAS score in the first hour; and in the VAS scores for the worst pain experienced since the patients were last seen in the first hour and six hours after the operation. There was no statistical difference between the two groups' opioid consumption at all set observation points.

Conclusion: The opioid requirements of the two groups were comparable, although participants who had the bupivacaine infusion experienced reduced pain intensity which lasted until six hours postoperatively, and also had reduced pain intensity when moving around 30 hours after the operation.

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Introduction

Pain is rated as a highly undesirable postoperative outcome. Postoperative pain, especially when poorly controlled, results in acute adverse physiological responses and chronic effects.¹ The two modalities of pain relief are systemic (opioid and non-opioid) analgesia and regional analgesia.

Local analgesia is a well-recognised component in multimodal analgesia. It is inexpensive and relatively safe and simple to use. Infusing local anaesthetics through catheters is a new and evolving area of postoperative pain management.^{2,3}

In the international arena of postoperative pain control, many pain control protocols are available for total abdominal hysterectomy (TAH). The Procedure-Specific Postoperative Pain Management (PROSPECT) website contains recommendations of several postoperative pain protocols for patients undergoing TAH.⁴ This committee has made recommendations based on evidence collected from randomised controlled trials. The committee suggests

that after TAH, patients should be given "strong" opioids via an intravenous patient-controlled analgesia pump (PCA), or by fixed intravenous dosing titrated to pain intensity. Continuous wound infiltration with a local anaesthetic after closure is not recommended, as there is limited procedure-specific evidence that is currently available.⁵

Pain relief provided by a local anaesthetic that is continuously infused in the incisional site has not yet been tried out in a public hospital. This technique of acute pain management has also not been studied in a healthcare setting in a developing country such as South Africa. This was evident from a PubMed medical subject headings (MESH) search, in October 2008, for the following terms: "South Africa", "local anaesthetic infusions" and "postoperative pain management in South Africa".⁶ The aim of this study was to determine whether there is a reduction in patients' opioid requirements after TAH, and a decrease in the patients' pain intensity as a result of a bupivacaine infusion into the incisional site.

Method

Approval to conduct the study at the Rahima Moosa Mother and Child Hospital in Johannesburg was obtained from the ethics committee of the University of the Witwatersrand, the postgraduate committee of the University of the Witwatersrand, and the hospital superintendent. Thirty-six patients enrolled for the study, which was a contextual, prospective, parallel and single-blinded randomised trial.

The selected participants were patients with an American Society of Anesthesiologists (ASA) physical status of one or two, scheduled for an elective TAH that required a Pfannenstiel incision. The following patients were excluded from the clinical trial: those who had a contraindication to general anaesthesia, an allergy to any of the study medications, a history of alcohol/drug abuse, a major medical disease such as cardiovascular, pulmonary, metabolic, renal, neurological or psychiatric disease, and patients with a clinically significant bacterial infection. Patients scheduled for a TAH were assessed preoperatively by the investigator. If the inclusion criteria were met, informed consent to participate in the trial was obtained. Patients who consented to participate in this clinical study were randomly assigned to receive either a bupivacaine infusion into their incisional sites and a morphine PCA pump, or a morphine PCA pump only. A consecutive convenience sampling method was used, and the control device was inserted into alternate patients.

The patients were assessed the day before the operation, required to fast, and given no analgesic premedication. Intraoperatively, the study participants were given a uniform general anaesthesia with opioid analgesia only. All patients were subjected to standard monitoring (noninvasive arterial blood pressure, heart rate, peripheral oxygen saturation, end-tidal gas monitoring and an electrocardiogram). After intravenous cannulation, anaesthesia was induced with opioids (either fentanyl, alfentanil or morphine) and propofol until loss of consciousness was established. The doses were titrated to effect on the patient and varied accordingly. Tracheal intubation was performed after muscle relaxation with a non-depolarising muscle relaxant of the anaesthetists' choice. Anaesthesia was maintained with air and oxygen. The inhalational anaesthetic was either isoflurane or sevoflurane. Mechanical ventilation was used in a low-flow system to maintain end-tidal CO₂ of 35-45 mmHg. Doses were titrated according to the patients' body mass and effect. At the end of the operation, muscle relaxation was reversed with glycopyrrolate and neostigmine in adequate doses, and the inhalational anaesthetic was turned off. After satisfactory spontaneous ventilation and awakening, the patients were extubated and transferred to the recovery area. Standard postoperative observations took place, and face mask oxygen was supplied via Venturi masks. Once the recovery sisters were satisfied with the patients' condition, they discharged the patients to the ward, where further standard postoperative observations were performed by the nursing staff.

Surgery was performed in a standardised manner using a Pfannenstiel incision of approximately 10-15 cm,

depending on the patients' body habitus. None of the participants experienced extensive blood loss requiring blood transfusion.

The device group participants had On-Q PainBuster Soaker™ 6.5 pain relief system [270 ml volume, 4 ml/hour; I-Flow Corporation, USA (all within their expiry dates)] devices inserted. This was accomplished at wound closure, when a multi-holed catheter was inserted by the gynaecologist along the length of the incisional site under the abdominal fascia. The placement method was as per the manufacturer's instructions, using the Z-track method. The fascial layer was closed with sutures over the catheter. After closure of the fascia, the second catheter was inserted in a similar manner as the subfascial catheter, but from the opposite side, and above the subfascial catheter. Once the skin was closed, a 5 ml bolus of 0.5% bupivacaine was injected through each catheter, infiltrating the incision. The catheters were secured to the skin by coiling the catheter with tape. Using an aseptic technique, these catheters were then connected to a 270 ml elastomeric disposable balloon pump with 0.39% bupivacaine solution. Opening the clamps on the catheter started the drug infusion. The drug was infused at 4 ml/hour (15.6 mg/hour) for 30 hours.

The control participants had a sterile bandage placed over the wound site and a catheter (positioned on top of the bandage that was coiled) connected to apparatus similar to that of the trial group. The catheter was taped and covered by another bandage. The catheter neither penetrated the wound site, nor infused any substance. Both groups had the pump apparatus concealed in a black bag. After surgery, all the patients were connected to a morphine CADD-Legacy® PCA Pump Model 6300s (Smith Medical). The PCA protocol was 1 mg morphine bolus dose, with a lockout of six minutes for breakthrough pain. The maximum dose of morphine was 10 mg/hour. This PCA pump was set up to manage breakthrough pain. Before surgery, the patients were given instructions on how to use it. No other pain analgesia was prescribed. If the patients complained of nausea or vomiting, prochlorperazine 12.5 mg was administered intramuscularly. Promethazine 25 mg intramuscularly (eight hourly) was prescribed for patients with itchiness. After 30 hours, the catheter was withdrawn and the intravenous line was taken down, along with the morphine PCA pump. Regular diclofenac suppositories (100 mg every 18 hours) and paracetamol (1 g orally every six hours) were prescribed for analgesia. The surgical team then discharged the patients.

Data collection was performed by two assessors at one, six, 24 and 30 hours postoperatively. With regard to the measurement taking, the time at which the infusion of the study drug was started was considered to be Time 0. Parameters assessed were visual analogue scale (VAS) scores for the worst pain experienced since the last observation, static pain intensity at the time of observation, and dynamic pain intensity at the time of observation. Total morphine consumption was recorded for the periods 0-1 hour, 1-6 hours, 6-24 hours and 24-30 hours postoperatively. In addition, opioid adverse effects, namely nausea, vomiting and itchiness, were recorded. The day of

discharge and any perioperative complications were noted. Data was collected by the investigator and compiled on a Microsoft Excel (2003) data table.

Results

Data analysis was conducted in consultation with the biostatistician. Testing was carried out at the 0.05 level of significance.

The opioid consumption and the VAS scores of the two groups for the set observation periods were verified with the two sample t-tests with unequal variances, and two sample Wilcoxon rank-sum (Mann-Whitney) tests. The non-continuous variables, namely the adverse effects of the opioids (nausea, vomiting and itchiness) were tested with the Fischer exact test.

An analysis of the demographic information, namely the study participants' age, body mass index, type of operation and racial group, and a comparison of the two groups using parametric and non-parametric testing, indicated that there were no statistical differences between these two groups.

There was no statistical difference between the two groups regarding opioid consumption. The mean opioid consumption in the device group was 3.35 mg, 10.83 mg, 25.11 mg and 5.78 mg in the first, second, third and fourth periods respectively. This can be compared to the mean opioid consumption in the control group, which was 4.89 mg, 8.22 mg, 24.67 mg and 8.33 mg in the respective observation periods. The following p-values are obtained when equal variance is assumed and tested again for unequal variance. The p-values at the first set period were 0.134 and 0.145. The p-values at the second set period were 0.302 and 0.369. At the third set period, the p-values were 0.922 and 0.544, and for the last set period, the p-values were 0.094 and 0.090 respectively. Figure 1 is a line graph illustrating the opioid consumption of the participants at the set observation periods.

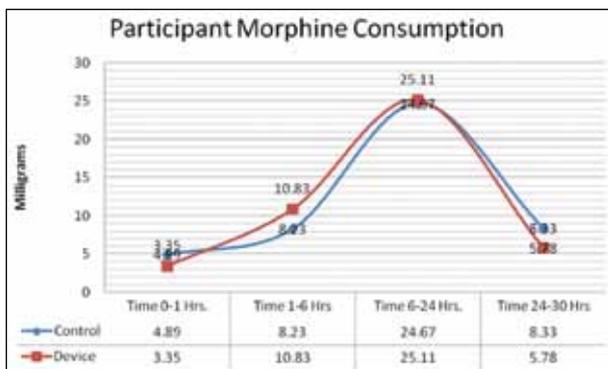


Figure 1: Comparison of morphine consumption between the groups

Opioid adverse effects in the control and device groups were analysed with the Fischer's exact test and showed no statistical difference between the groups for the incidence of nausea, vomiting and itchiness.

The mean dynamic VAS scores of the device group in the first, third and fourth periods were 39.42, 39.17 and 35.36 respectively. This is in comparison with the mean dynamic VAS scores of the control group in the first, third and fourth periods, which were 67.17, 60.88 and 54.31 respectively. The p-values were 0.013, 0.019 and 0.023 respectively. This is illustrated in Figure 2. The significant p-values are asterisked.

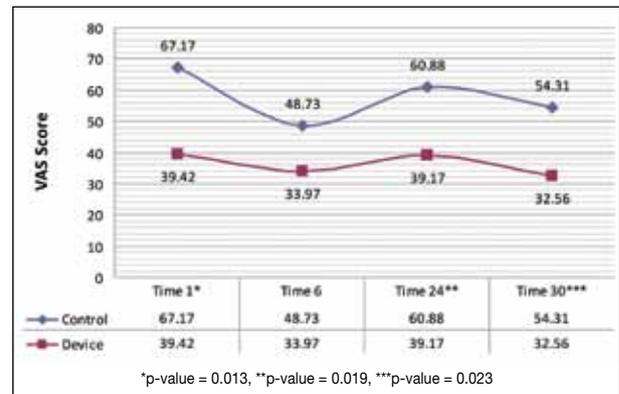


Figure 2: Dynamic VAS scores for the two groups

The mean static VAS score of the device group in the first period was 34.89, compared to the mean static VAS score of the control group of 59.25. This resulted in a statistically significant p-value of 0.038.

The p-values for the second set period were 0.887 and 0.596 respectively. At the third set period, the p-values were 0.405 and 0.921 respectively, while the p-values for the last set period were 0.339 and 0.231 respectively. These data are depicted in Figure 3.

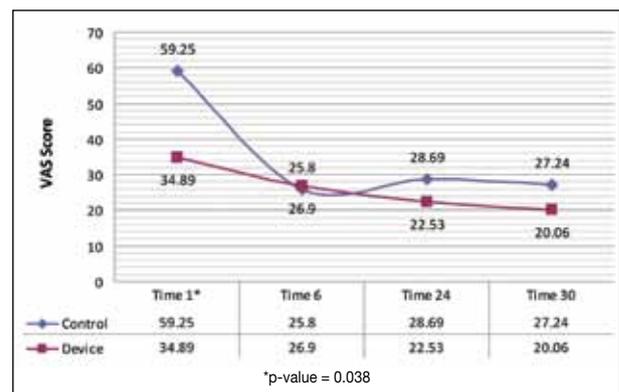


Figure 3: Static VAS scores of the control and device groups

The VAS scores of the control group, in the first and second observation period, for the worst pain experienced since the patients were last seen, were 72.45 and 60.43 respectively. The mean VAS scores of the device group, for the same periods, for the worst pain experienced since the patients were last seen were 46.89 and 35.86 respectively. The p-values were 0.008 and 0.023 respectively. At the third set period, the p-value value was 0.704, while it was 0.711 in the last set period. These data are illustrated in Figure 4.

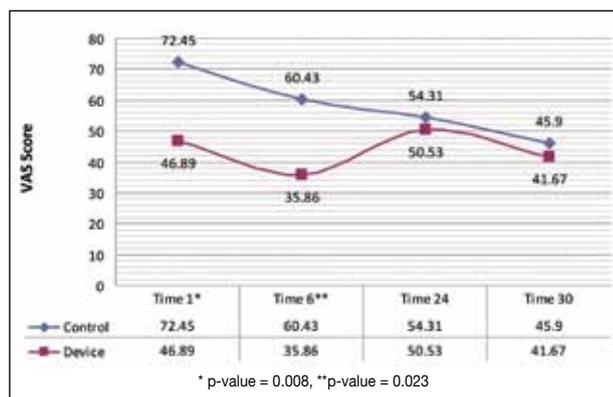


Figure 4: VAS in the device and control groups, for the worst pain experienced since the patients were last seen

Discussion

The two clinical study groups shared a similar demographic profile, to ensure the validity of the measured study findings.

Statistical differences were seen between the dynamic VAS scores in the first (one hour postoperatively), third (24 hours postoperatively) and fourth (30 hours postoperatively) observation periods. There was also a statistical difference in the static VAS score in the first observation period. There was a statistical difference in the VAS scores for the worst pain experienced since the patients were last seen in the first and second observation periods. Movement by a patient elicits somatic pain, rather than visceral pain. The decrease in dynamic VAS scores could be an indication that the bupivacaine infusion decreased the somatic pain at the incisional site. By contrast, from six hours postoperatively, the static VAS scores were not different, as the bupivacaine infusion did not provide any pain relief from the visceral component originating mainly from the peritoneum. The reason for the difference in VAS scores, but similarity in opioid consumption, is not clear. One could speculate that the bupivacaine infusion helped relieve somatic pain at the incisional site, but not the visceral component of pain after the operation, which needed morphine boluses to be eased. Psychological factors, beliefs and expectations were not tested in this trial. The VAS scores did not correlate with the participants' opioid consumption and require further evaluation.

Limitations and logistical issues

The study population was not representative of the group of women undergoing TAH in South Africa as a whole. However, the study sample addressed a clinical setting at a public hospital in central Johannesburg, which is relevant locally.

The clinical setting of the study resulted in single-blinded conditions while the evaluations were being performed. The patients did not know whether or not they were receiving a bupivacaine infusion in their incisional sites, as all participants had the same external apparatus. The researchers and surgeon knew this. Scientific guidelines advocated the placement of a subfascial catheter in all the

participants, whereas evident ethical reasons restrained us in applying this method. Bias may have occurred as the design of the trial was not double-blinded.

The application of the subfascial catheter prolonged the anaesthetic time minimally, and the surgeons found the technique of inserting the catheters to be simple. The time required for the insertion of these catheters was less than five minutes. There was one complication with the subfascial catheter, when the surgeon transected the first catheter with a scalpel on insertion. It was noted immediately and the catheter parts were removed and replaced with a complete catheter, with no further problems. The participants reported no adverse effects or hindrances as a result of the elastomeric pumps. The nursing staff in the recovery holding area and wards required only basic education and training in the use of these pumps. They were highly satisfied with the ease of use of the elastomeric pumps and required minimal re-education. Overall, the nurses felt that the participants had received an increased standard of patient care, and that there was no extra nursing burden with regard to care of the elastomeric pumps and their application. Generally, the surgical teams were pleased with the level of patient postoperative pain control.

Conclusion

Continuous bupivacaine infusion into the incisional site increases options for postoperative pain relief. In this study, it was noted that participants who received the bupivacaine infusion experienced decreased pain intensity in the first hour postoperatively. They also experienced a decreased level of dynamic pain intensity in three of the four time periods, and decreased worst pain intensity up to six hours postoperatively. This pain relief option could provide better analgesia, although we did not show that it helps to reduce patients' opioid consumption.

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