Continuous local anesthetic wound infusion: Impact on pain score and opioid use in patients undergoing elective mastectomy

ABSTRACT
Introduction: Opioids are commonly used to control acute postoperative pain but their usage is associated with significant complications and the potential of addiction. This study was designed to assess the effect of a Continuous Local Anesthetic Wound Infusion Catheter (CLAWIC) on pain score and as an opioid-sparing agent in patients undergoing elective mastectomy.

Method: The search was done using all patients' record from February 2013 to February 2018. The data were collected through the acute pain service database, operation room lists, surgical site infection database, acute pain service sheet, and anesthesia sheet. The patients inclusion criteria were adults who underwent elective mastectomy surgery at King Fahad Specialist Hospital. Patient age, sex, weight, and height were also recorded.

Result: The opioid use intraoperatively and postoperatively was significantly lower in the CLAWIC than in the control group. Also, accumulative opioid use was significantly lower in the CLAWIC group. From transfer to the PACU until 48 hours postoperatively, the percentage of patients requiring opioids was significantly lower in the CLAWIC group. After 48 hours, there was no difference in opioid use between the two groups. Visual Analog Scale (VAS) pain scores were significantly lower in the CLAWIC than in the control group.

Conclusion: CLWIC showed opioid-sparing effects following mastectomy, as shown by a significantly lower mean opioid dose and a lower percentage of subjects needing opioid analgesia. The procedure is easy to perform and relatively safe. CLWIC could reduce opioid consumption while maintaining good postoperative pain control.

Key words: Anesthetic, cancer, mastectomy, opioids, pain score, wound infusion

Introduction

Patients undergoing mastectomy have significant acute postsurgical pain and require analgesia for several days.11 Different modalities are available for controlling the postsurgical pain. Although opioids are widely used to control pain, they result in potential side effects. Moreover, opioids may increase the risk of malignancy recurrence.2,3

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Alternatives to opioids as part of multimodal analgesia are needed to control pain after mastectomy, such as CLAWIC. The present study assessed the impact of CLAWIC on pain control after mastectomy and its opioid-sparing effects.

**Setting and Methods**

The study was approved by the Institutional Review Board (IRB) of King Fahad Specialist Hospital, Dammam, Saudi Arabia, which waived the requirement for written informed consent because of the retrospective nature of this study (date of approval 23-02-2016). The records of all patients who underwent mastectomy surgery at King Fahad Specialist Hospital from February 2013 to February 2018 were reviewed. Patients who received nerve block, experienced chronic pain, or had a psychiatric disorder were excluded. The data were collected through the acute pain service database, operation room lists, surgical site infection database, acute pain service sheet, and anesthesia sheet. Patients’ age, sex, weight, and height were also recorded.

Patients who underwent mastectomy were divided into two groups: the CLAWIC group and the control group. Patients in the CLAWIC group underwent direct implantation of a catheter into the wound at the end of mastectomy. The catheter was attached to a pump that dispensed a pre-set amount of bupivacaine (0.125% per hour) directly into the wound. Patients in the control group were not treated with CLAWIC. Both groups were allowed to receive opioids as needed for pain management.

Data were collected on axillary node biopsy, local anesthetic concentration and infusion rate, presence of drain, intraoperative opioid consumptions, postoperative opioid consumption, and visual analog scale (VAS) pain scores at 0, 12, 24, 36, 48, 60, and 72 h. Time to the return of bowel motion, length of hospital stay, and occurrence of wound infection were also recorded. All opioid doses were reported as morphine-equivalent doses (MED), with 1 mg of intravenous (IV) morphine being equivalent to 0.01 mg of IV fentanyl, 25 mg per os (PO) of tramadol, or 15 mg PO of codeine. The drug of choice for pain management in both groups was morphine 5 mg every 6–8 h as needed, whereas the adjuvant for both groups was paracetamol IV every 4–6 h in patients dissatisfied with morphine as first-line treatment. The second-line treatment for pain management was tramadol 50 mg IV every 12 h. Patients who had positive sentinel lymph node biopsy underwent axillary dissection at the time of mastectomy, whereas patients with negative biopsy results did not.

**Catheter placement and removal**

In the CLAWIC group, a 15-cm-long fenestrated catheter (Baxter PAINfusor® catheter 15; Baxter Healthcare S.A., Zurich, Switzerland) was placed subcutaneously over the muscle layers. The fenestration was distributed through the wound, and the catheter exited from the axillary folds. The catheter was connected aseptically to a portable elastomeric infusion system (INFUSOR; Baxter Healthcare Corporation, Deerfield, IL, USA). Before hospital discharge, the catheter was removed aseptically at the bedside.

**Infusion system and management**

The elastomeric infusion system is managed by the acute pain service within the Department of Anesthesia. Most patients underwent CLAWIC removal on the second postoperative day. The infusion rate was adjusted to 5, 7, 10, or 12 mL/h by the acute pain service based on each patient’s pain score.

**Statistical analysis**

All quantitative variables were presented as mean ± standard deviation (SD) and compared by two-tailed unpaired t tests or Mann–Whitney U-tests, as appropriate. All qualitative variables were reported as number (percentage) and compared by the Pearson Chi-square test or Fisher’s exact test, as appropriate. Predictive variables include the duration of surgery, axillary lymph node biopsy (positive/negative), body mass index (BMI), and intraoperative opioids. All statistical analyses were performed using IBM SPSS Statistics software (Statistical Package for the Social Sciences version 24.0). A two-sided P < 0.05 was considered statistically significant.

**Results**

**Patients**

During the study period, a total of 266 patients underwent modified radical mastectomy. Of these, 135 (50.8%) underwent CLAWIC implantation, allowing infusion of a pre-set amount of bupivacaine 0.125% into the wound. The CLAWIC was placed over the muscle layers and exited from the axillary folds. The remaining 131 patients (49.2%) did not undergo CLAWIC implantation. Baseline characteristics did not differ significantly in these two groups [Table 1]. Surgical drains were placed in 133 patients (98.5%) in the CLAWIC group and 118 (90.1%) in the control group (P = 0.003). The surgical site infection (SSI) rate was similar in the two groups.

**Intervention**

Patients in the CLAWIC group were infused with local anesthetic for different lengths of time and rates, with differences in amounts of bupivacaine infused and times to catheter removal. Catheters in 85 patients (69.6%) remained

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**Table 1**

The present study assessed the impact of CLAWIC on pain control after mastectomy and its opioid-sparing effects. The study was approved by the Institutional Review Board (IRB) of King Fahad Specialist Hospital, Dammam, Saudi Arabia, which waived the requirement for written informed consent because of the retrospective nature of this study (date of approval 23-02-2016). The records of all patients who underwent mastectomy surgery at King Fahad Specialist Hospital from February 2013 to February 2018 were reviewed. Patients who received nerve block, experienced chronic pain, or had a psychiatric disorder were excluded. The data were collected through the acute pain service database, operation room lists, surgical site infection database, acute pain service sheet, and anesthesia sheet. Patients’ age, sex, weight, and height were also recorded.

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**Intervention**

Patients in the CLAWIC group were infused with local anesthetic for different lengths of time and rates, with differences in amounts of bupivacaine infused and times to catheter removal. Catheters in 85 patients (69.6%) remained
in situ for ≤48 h. The mean overall duration of catheter implantation was 49.2 ± 13.6 h, the median infusion rate was 7 mL/h (range: 5–12 mL/h), and the mean volume of local anesthetic infused was 395 ± 150 mL.

Opioid use
Opioid use intraoperatively and for the first 36 h postoperatively was significantly lower in the CLAWIC than in the control group [Table 2]. In addition, accumulative opioid use was significantly lower in CLAWIC than in the control group (4.9 ± 17.2 mg MED vs. 11.0 ± 13.9 mg MED, P = 0.001). From transfer to the PACU until 48 h postoperatively, the percentage of patients requiring opioids was significantly lower in the CLAWIC than in the control group [Table 3]. After 48 h, there was no difference in opioid use between the two groups, likely because catheters were removed from 85 patients (69.9%) in the CLAWIC group within 48 h. The wide standard deviations in opioid doses were due to the large number of patients who did not need opioid. The CLAWIC in 20 patients (14.7%) remained in situ for 72 h, which can be attributed to an underlying etiology, such as axillary lymph node dissection (ALND) or the presence of a surgical drain, which caused more pain.

Pain score
VAS pain scores were significantly lower in the CLAWIC than in the control group at 36 and 48 h, which can be attributed to disconnecting of the CLAWIC in most patients in this group. VAS pain scores in the PACU were higher in the CLAWIC group but were lower from 12 to 72 h [Table 4].

Discussion
Unilateral single paravertebral block (PVB) is regarded as the treatment of choice for postoperative pain following mastectomy; however, a recent meta-analysis showed no differences in pain score when compared with continuous local anesthesia infusion via a wound catheter. Moreover, CLAWIC is much faster, less invasive, easier, and safer than PVB, suggesting that CLAWIC may have advantages in the treatment of postoperative pain following mastectomy.

This large retrospective study showed that CLAWIC had a significant opioid-sparing effect in patients who underwent elective simple or modified radical mastectomy, despite the equivalent pain scores in the CLAWIC and control groups. However, the two groups differed significantly in two important demographic characteristics: a higher percentage of patients in the CLAWIC group underwent axillary dissection, and the intraoperative opioid dose was lower in the CLAWIC group.

The recent trend toward opioid-free anesthesia (OFA) highlights the awareness of risks associated with opioids. The current opioid crisis is due in large part to patients being prescribed massive doses of opioids, especially for chronic pain. Patients who undergo modified radical mastectomy are at risk of developing chronic pain if acute pain is not managed properly. CLAWIC provides adequate analgesia while having an opioid-sparing effect. A randomized controlled trial compared opioids with OFA in 66 patients who underwent modified radical mastectomy, with their comfort being the primary outcome. Patients in the OFA group were treated with clonidine, ketamine, lidocaine, acetaminophen, dicyclofenac, and piritramide, which is a synthetic opioid. Postoperatively, both groups received IV patient-controlled analgesia (PCA) with piritramide. Postoperative sedation scores were higher, possibly
Table 3: Numbers of patients not administered opioids

| Interval | Intervention group (%) | Control group (%) | P       |
|----------|------------------------|-------------------|---------|
| PACU     | 115 (85.2)             | 53 (40.5)         | <0.001  |
| 0-12 h   | 125 (92.6)             | 62 (47.3)         | <0.001  |
| 12-24 h  | 122 (90.4)             | 88 (67.2)         | <0.001  |
| 24-36 h  | 119 (88.1)             | 98 (74.8)         | 0.002   |
| 36-48 h  | 119 (88.1)             | 105 (80.2)        | 0.026   |
| 48-60 h  | 121 (89.6)             | 116 (88.5)        | 0.233   |
| 60-72 h  | 129 (95.6)             | 121 (92.4)        | 0.101   |

Table 4: Median (range) VAS pain scores over time

| Time     | Intervention group | Control group | P       |
|----------|-------------------|---------------|---------|
| PACU     | 3 (0-9)           | 3 (0-8)       | 0.457   |
| 12 h     | 1 (0-7)           | 0 (0-8)       | 0.069   |
| 24 h     | 0 (0-5)           | 0 (0-8)       | 0.024   |
| 36 h     | 0 (0-9)           | 0 (0-10)      | <0.001  |
| 48 h     | 0 (0-6)           | 0 (0-8)       | 0.116   |
| 60 h     | 0 (0-8)           | 0 (0-9)       | 0.361   |
| 72 h     | 0 (0-4)           | 0 (0-8)       | 0.661   |

due to clonidine, and postoperative opioid use was lower in the OFA group. CLAWIC may mitigate sedation and opioid consumption in this cohort. Moreover, morphine stimulates endothelial cell proliferation, survival, and cell cycle progression and angiogenesis both in vitro and in vivo, suggesting that opioid use can lead to higher tumor recurrence rates.[12]

Peripheral nerve block is an important aspect of multimodal analgesia for mastectomy patients, but it is limited by operator experience. Although PVB is considered the technique of choice for modified radical mastectomy, it shows no clear advantage when compared with CLAWIC.[7]

The length of hospital stay was similar in the study groups, which can be attributed to the set discharge time in our surgical unit regardless of other parameters. A randomized controlled trial comparing CLAWIC and PCA with epidural analgesia in patients undergoing liver resection found that length of stay was shorter for the CLAWIC group, with the discharge criteria adhering to those of the Enhanced Recovery After Surgery (ERAS) program.[13]

Pain scores assessed by nurses at fixed intervals were judged unreliable, which may have been due to their lack of adequate education. In addition, pain assessment is a complex process when related to the patient’s activity.[6] A randomized prospective study comparing CLAWIC and PVB in 48 patients after mastectomy assessed VAS, shoulder movement, and morphine consumption. Because CLAWIC establishment of sufficient analgesia requires approximately 16 h, pain scores and shoulder movements were equivalent in the two groups.[7]

There was no correlation between the infused volume of anesthetic and outcome parameters. CLAWIC may have increased the volume of fluid draining from the wound through drain catheters, but this did delay drain removal. A study of the effect of wound instillation through surgical drains in which ropivacaine 0.2% (0.5 mL/kg) was injected through axillary and chest drains followed by clamping for 10 min reduced opioid use in patients who underwent modified radical mastectomy. Clamping the drain may have enhanced the opioid-sparing effects of CLAWIC.[14]

**Limitation**

This study had several limitations associated with retrospective design. One of the limitations was the inconsistency of catheter location. The ideal location for catheter placement is unclear. For example, CLAWIC placement into the intra-articular space in patients undergoing total knee replacement surgery minimized highly intense pain and improved mobilization.[15] Opioid use was obtained from the electronic healthcare system (EHS), which records every opioid prescribed and given to patients. In addition, pain scores were assessed by attending nurses every 12 h. Moreover, patients were not followed up after discharge because catheters were removed, and the acute pain service does not follow up discharged patients. As our center is the only tertiary center in the province, many patients come from remote and rural areas. Therefore, the hospital protocol is to discharge patients without complications after 3 days to avoid complications such as seroma and infection that can arise if catheters were removed by others. Another limitation of our study was the extended duration of recruitment, from 2013 to 2018, which resulted in changes in surgeons and anesthesiologists.

**Conclusion**

CLAWIC showed opioid-sparing effects following mastectomy by significantly lowering the mean opioid dose and the percentage of subjects needing opioid analgesia. The procedure is easy to perform and relatively safe. CLAWIC can reduce opioid consumption while maintaining good postoperative pain control. However, double-blinded randomized controlled studies are needed to assess its efficacy and safety.

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Nil.

**Conflicts of interest**

There are no conflicts of interest.

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