Use of elastomeric pumps for continuous intravenous analgesia administration in ambulatory surgery pain management

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Abstract

Aim: To evaluate the feasibility and security of the use of elastomeric infusion pumps for the administration of continuous intravenous analgesia during the post-operative period of potentially painful surgical operations performed in the context of ambulatory surgery. Material and methods: Prospective study with 40 patients scheduled for inguinal hernia repair, haemorrhoidectomy, knee arthroscopy and foot orthopedic surgery. At the end of surgery a LV-5 of 5 ml/h Baxter® elastomeric infusor was connected. Intravenous ketorolac, tramadol and ondansetron were supplied for 55 h. Daily out-patient controls were performed by the nurses of the post-operative out-patient care unit. Pain intensity by means of a plain oral scale, the need for supplemental oral analgesics and the level of patient satisfaction were evaluated daily. Results: 92.5% of the patients reported absence or slight pain 48 h after the surgical operation, and 7.5% referred to moderate pain. No severe pain was reported by the patients in the first 72 h of the post-operative period. 7.5% of the patients felt nauseated, 15% vomited and 10% had discomfort at the venous puncture point. No patient required re-admission after discharge. 87.5% of the patients revealed satisfaction with the analgesic treatment. Conclusion: The use of invasive out-patient analgesic techniques could have viability in some procedures in which oral analgesics are unable to control the post-operative pain. Comparative studies would be needed in order to elucidate the procedures that could benefit from these techniques in our context.

Keywords: Elastomeric pumps; Pain management; Ambulatory surgery

1. Introduction

Persistent post-operative pain can lead to problems in the flow of patients in day surgery units (DSUs) by delaying discharges, impeding the application of fast-track programmes in recovery rooms, increasing the contact of the patients with medical staff after discharge and increasing re-admission rates [1].

In the majority of procedures performed in DSUs, post-operative pain can be managed by means of analgesic techniques based on the administration of oral analgesia. However, there are some surgical procedures that can cause moderate to severe pain and where the use of oral analgesics can be ineffective [2]. Rawal et al. [3] published an epidemiological study with 1035 patients submitted to a variety of out-patient procedures in which they observed that around 30% of the patients referred to moderate to severe pain in the first 48 h of the post-operative period despite the analgesic drugs supplied. Twenty percent of the patients displayed sleep problems on the first post-operative night because of severe pain. Surgical operations such as foot surgery, knee or shoulder reconstruction, haemorrhoidectomy, inguinal hernia repair or varicose vein surgery can frequently produce severe post-operative pain [4,5] and subsequent failure of conventional post-operative analgesia. In these cases, it would be useful to dispose of invasive out-patient analgesic techniques such as the
maintenance of intravenous lines for continuous infu-
sion systems or PCA, the use of the subcutaneous access
or even catheters for continuous regional techniques.

The aim of this study is to evaluate the feasibility and
security of the use of elastomeric perfusion pumps for
the administration of continuous intravenous analgesia
during the post-operative period of potentially painful
surgical procedures performed in the context of day
surgery. The analgesic quality achieved with the two
type of drugs used in this study will be evaluated.

2. Material and methods

Prospective study with 40 ASA I–III patients sched-
uled for ambulatory haemorrhoidectomy, foot surgery,
lateral inguinal hernia repair and knee arthroscopy
with meniscectomy. Informed consent was obtained.
Exclusion criteria were patients younger than 18 years, a
body weight less than 50 kg or greater than 90 kg, any
contra-indication to the use of non-steroidal anti-
flammatory drugs, allergy or hypersensitivity to trama-
dol, important psychic disturbances and an unwilling-
ess to participate in the study.

Pre-operatively an intravenous catheter was placed in
the non-dominant superior extremity (preferably in the
forearm or in the back of the hand avoiding the
antecubital flexure). An Abbocath® equal or less than
18 G in size was used. The Abbocath® was fixed with
MEFIX® adhesive strips shaped as a lace overlaid
with transparent TEGADERM®. A three-way tap
between the Abbocath® and the intravenous equip-
ment was allowed at this stage for intra-operative use. Once
the intravenous catheter was placed, sedative and
antiemetic drugs were given according to departmental
procedure.

The anaesthetic technique consisted of spinal blocks
with hyperbaric mepivacaine at a dose according to the
criteria of the anaesthetist in charge. Ten minutes before
the end of the surgery, 30 mg of ketorolac and 50 mg of
tramadol were administered intravenously.

Post-operatively the three-way tap was removed and
the patient admitted to the post-anesthesia care unit
(PACU-1). There a 275 ml infusor Baxter® LV-5 system
was connected to the intravenous catheter. The infusor
system had been previously charged with one of two
different analgesic solutions according to the following:

- **Analgesic solution A**: for haemorrhoidectomy and
  foot orthopedic surgery: ketorolac 180 mg, tramadol
  500 mg and ondansetron 16 mg diluted with saline.

- **Analgesic solution B**: for knee arthroscopy and
  inguinal hernia repair: ketorolac 180 mg, tramadol
  200 mg and ondansetron 16 mg diluted with saline.

In the PACU-2 phase, the nursing staff familiarized
the patients and their relatives with the infusor system.
They detected potential ‘problem-patients’ who might
be non-collaborative for the removal of the infusor
system and excluded these from the study. At this stage
the patients met the out-patient care staff.

At discharge, a last revision of the infusor system was
performed. A normal oral drug pack was also given to
the patients to be used if the infusor system be removed
early either unintentionally or according to out-patient
care staff criteria. They were also given rescue analgesic,
which consisted of tramadol (50 mg) one tablet per day.

The out-patient follow-up by the Out-patient Care
Unit consisted of three visits. One during the evening/night
on the day of surgery, the second during the
evening/night of the day after and the third during the
morning of the third post-surgical day.

At these visits the following was undertaken:

- Review of the infusor system and intravenous cathe-
ter integrity.
- Detection of potential undesirable effects that could
  be attributed to the analgesic drugs supplied (nausea,
  vomiting, dizziness) and detection of patients’ pro-
  blems with the infusor system (discomfort in the
  venous puncture zone or with the reservoir).
- Early removal of the system when deemed necessary
  by the out-patient care staff criteria and transfer to
  oral analgesics.
- Removal of the system at the end of the study at the
  third out-patient visit.
- Filling in the data collection paper.

The data evaluated in the study were:

- Out-patient evaluation of pain by means of a Plain
  Oral Scale (no pain, slight pain, moderate pain,
  severe pain).
- Out-patient evaluation of the degree of patient
  satisfaction with the infusor system (satisfied, some
  discomfort, uncomfortable).
- The need for rescue analgesic tablets.
- Collection of incidences that could be attributed
either to the drugs used or to the infusor system.

3. Results

Forty patients (20 men and 20 women, aged 18–65
years) were studied. The distribution according to
procedure was five hallux valgus operations, 19 haemor-
rhoidectomies, seven knee arthroscopies and nine bilat-
eral inguinal hernia repairs. In the distribution of the
pain intensity per day (Table 1) no patients had severe
pain. Slight or absence of pain occurred in 80% of
patients on the first day, in 92.5% during the second day.
and in 94.9% the third day. Twenty percent of the patients had moderate pain on the first day, 7.5% on the second day and 5.1% on the third day.

The distribution of pain intensity per day according to the procedure revealed that 100% of the patients operated on for hallux valgus (Table 2) had no pain on the third post-operative day. Among the patients who underwent haemorrhoidectomy (Table 3), 31.6% had no pain on the first post-operative day, 42.1% referred to slight pain and 26.3% had moderate pain. 84.2% had no pain on the third day, 10.5% slight pain and 5.3% moderate pain. Following knee arthroscopy (Table 4), there were no patients with moderate pain, 83.3% of the patients had no pain on the third post-operative day and 16.7% had slight pain. The greatest percentage of either slight pain (37.5%) or moderate pain (12.5%) on the third post-operative day was observed in the group who had had bilateral inguinal hernia repair (Table 5).

Five patients on the second post-operative day (12.5%) and six patients on the third day (15%) required analgesic rescue with tramadol tablets (Table 6). Bilateral inguinal hernia repair was the procedure in which the most rescues were needed.

Side effects were observed in 11 patients (27.5%) attributed to the analgesic drugs. 7.5% of the patients had nausea, 15% vomited and 5% had dizziness. Analgesic A solution had been given to 8 out of these 11 patients.

Regarding problems with the infusor system, 10% of patients referred to discomfort at the venous puncture point and 12.5% had discomfort with the infusor system reservoir. The system was removed before the end of the study in only two patients (5%). In both cases the cause was pain at the venous puncture point. No other problems due to the system were recorded and no patient required re-admission to the hospital after discharge.

The degree of patient satisfaction was as follows: 87.5% were very satisfied, 7.5% had some discomfort and 5% were uncomfortable.

### Table 1
Pain intensity distribution per day

<table>
<thead>
<tr>
<th></th>
<th>First day</th>
<th>Second day</th>
<th>Third day</th>
</tr>
</thead>
<tbody>
<tr>
<td>No pain</td>
<td>42.5% (17)</td>
<td>62.5% (25)</td>
<td>80% (32)</td>
</tr>
<tr>
<td>Slight</td>
<td>37.5% (15)</td>
<td>30% (12)</td>
<td>15% (6)</td>
</tr>
<tr>
<td>Moderate</td>
<td>20% (1)</td>
<td>7.5% (3)</td>
<td>5% (2)</td>
</tr>
<tr>
<td>Severe</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
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</table>

### Table 2
Pain intensity in foot orthopedic surgery

<table>
<thead>
<tr>
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<th>First day</th>
<th>Second day</th>
<th>Third day</th>
</tr>
</thead>
<tbody>
<tr>
<td>No pain</td>
<td>60% (3)</td>
<td>80% (4)</td>
<td>100% (5)</td>
</tr>
<tr>
<td>Slight</td>
<td>20% (1)</td>
<td>20% (1)</td>
<td>0%</td>
</tr>
<tr>
<td>Moderate</td>
<td>20% (1)</td>
<td>0%</td>
<td>0%</td>
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</table>

### Table 3
Pain intensity in haemorrhoidectomy

<table>
<thead>
<tr>
<th></th>
<th>First day</th>
<th>Second day</th>
<th>Third day</th>
</tr>
</thead>
<tbody>
<tr>
<td>No pain</td>
<td>31.6% (6)</td>
<td>62.2% (12)</td>
<td>84.2% (16)</td>
</tr>
<tr>
<td>Slight</td>
<td>42.1% (8)</td>
<td>31.6% (6)</td>
<td>10.5% (2)</td>
</tr>
<tr>
<td>Moderate</td>
<td>26.3% (5)</td>
<td>5.3% (1)</td>
<td>5.3% (1)</td>
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</table>

### Table 4
Pain intensity in knee-arthroscopy

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<thead>
<tr>
<th></th>
<th>First day</th>
<th>Second day</th>
<th>Third day</th>
</tr>
</thead>
<tbody>
<tr>
<td>No pain</td>
<td>71.4% (5)</td>
<td>71.4% (5)</td>
<td>83.3% (5)</td>
</tr>
<tr>
<td>Slight</td>
<td>28.6% (2)</td>
<td>28.6% (2)</td>
<td>16.7% (1)</td>
</tr>
<tr>
<td>Moderate</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
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</table>

### Table 5
Pain intensity in inguinal hernia repair

<table>
<thead>
<tr>
<th></th>
<th>First day</th>
<th>Second day</th>
<th>Third day</th>
</tr>
</thead>
<tbody>
<tr>
<td>No pain</td>
<td>33.4% (3)</td>
<td>44.4% (4)</td>
<td>50% (4)</td>
</tr>
<tr>
<td>Slight</td>
<td>44.4% (4)</td>
<td>33.4% (3)</td>
<td>37.5% (3)</td>
</tr>
<tr>
<td>Moderate</td>
<td>22.2% (2)</td>
<td>22.2% (2)</td>
<td>12.5% (1)</td>
</tr>
</tbody>
</table>

### Table 6
Analgesic rescue need with oral tramadol (50 mg)

<table>
<thead>
<tr>
<th>Procedures</th>
<th>First day</th>
<th>Second day</th>
<th>Third day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hallux valgus</td>
<td>0</td>
<td>1 (20%)</td>
<td>0</td>
</tr>
<tr>
<td>Haemorrhoidectomy</td>
<td>0</td>
<td>3 (15.8%)</td>
<td>2 (10.5%)</td>
</tr>
<tr>
<td>Knee arthroscopy</td>
<td>0</td>
<td>0</td>
<td>1 (14.3%)</td>
</tr>
<tr>
<td>Inguinal hernia repair</td>
<td>0</td>
<td>1 (11.1%)</td>
<td>3 (33.5%)</td>
</tr>
<tr>
<td>Total</td>
<td>0</td>
<td>5 (12.5%)</td>
<td>6 (15%)</td>
</tr>
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### 4. Discussion

Analgesic techniques in ambulatory surgery have to be effective with minimal side effects, secure and easy to manage for the patient [6]. In the majority of ambulatory procedures post-operative pain can be managed with analgesic techniques based on the administration of tablets. However, they can be ineffective in some surgical procedures [2]. The use of invasive analgesic techniques on an out-patient basis with the support of Out-patient Care Units makes the total control of intense post-operative pain possible. This facilitates early discharge, reduces re-admission, decreases mor-
bidity and decreases the cost of surgical procedures. It also potentially increases the range of surgical procedures that be performed on an out-patient basis [7].

The use of out-patient continuous regional techniques with the administration of local anaesthetic in out-patient procedures has been well documented. Rawal et al. published two series of 70 and 149 patients [2,8], undergoing a variety of day surgery procedures, in which an elastomeric infusion system PCA-like was used connected to a peridural multiperforated catheter inserted into different places—subcutaneous in the surgical wound, in the brachial plexus sheath or intra-articular. The patients self administered boluses of local anaesthetic at different concentrations and volume depending on the type of surgery and the catheter localization. They were even trained for the out-patient removal of the catheter. Checks were performed daily by specialized staff and by phone. In both series the analgesic control was good or excellent in more than 85% of the patients and there was high satisfaction with the system. There were no problems detected either technical or infection. Klein et al. [9] published two cases of patients undergoing major ankle surgery with continuous sciatic nerve block and they were discharged with a continuous infusion of 0.2% ropivacain for 27 h through a disposable elastomeric pump with which they successfully extended the analgesic blockade effect. In both cases patients and relatives were instructed in detecting any side effects due to the local anaesthetic and to clamp down on the infusor if such occurred. They were also instructed on the removal of the catheter, which was successfully performed. Each patient was given a phone number of the medical staff to be used if problems occurred. The authors expressed the need for choosing collaborative, serious and participatory patients in these kind of analgesic techniques. Chelly et al. [10], with regard to the two cases described above, considered it inadequate to transfer the responsibility for the care of continuous analgesic blockade catheters to the patients and that out-patient monitoring by specialized staff was necessary. The same authors defended the use of electronic PCA pumps which allow the rate of continuous infusion of local anaesthetic to be reduced. Ganapathy et al. [11] used continuous regional blockades and elastomeric PCA pumps in seven out-patient cases. Patients were instructed both orally and with written material in the use of the infusor, bolus administration, side effect detection and catheter removal. Daily checks by medical staff were made by phone. Two disconnections of the infusor system occurred in two patients all the content of the pump reservoir was emptied in a few minutes and in another case the catheter detached on the way home. Analgesic quality was documented as excellent and there were no problems with the removal of the catheter or with the bolus administration; however, the authors considered the infusor system as imprecise and they doubted its security when used in continuous perineural blockades. Goldstein et al. [5] used an out-patient electronic conventional PCA infusion pump to give subcutaneous morphine as post-operative analgesia in 41 out-patients who underwent haemorrhoidectomy. In this case, nurses of an out-patient support unit undertook daily checks. The results were satisfactory achieving a good control of the pain and a high degree of acceptance by the patients, without increasing either the side effects or the re-admission rate.

There are no references to out-patient continuous endovenous infusion through elastomeric infusors in the context of out-patient surgery. In view of the lack of previous experience, our study was designed with the support of the out-patient care unit which allowed the patients to be monitored daily. There were no observed important technical problems or problems due to the intravenous catheter or the infusor system. The two cases of early elastomeric pump removal were due to pain at the venepuncture site, but in both cases the puncture had been made in the wrist. The venepuncture place of choice might be in the forearm. All the beginning of the study five patients reported discomfort in motion with the reservoir of the infusor system, which was not been observed again when an elastic net for fastening the reservoir to the forearm was given to the patients (Fig. 1). Regarding pain control, satisfactory values of pain intensity were achieved but in the haemorrhoidectomy and in foot surgery cases, a high incidence of side effects associated with the use of the analgesic solution with the higher tramadol concentration were registered. The most difficult procedure for pain control and the one which required the most analgesic rescues was bilateral inguinal hernia repair. Here good pain control with the infusor system at rest was observed by the out-patient care staff, but when patients moved, the whole evaluation of pain intensity

Fig. 1. Elastic net for fastening the reservoir to the forearm.
increased. Our study did not reflect the differences in pain intensity at rest and in motion. In these cases it would be better to use PCA systems.

We think that our study demonstrates the feasibility and security of the use of out-patient intravenous analgesic solutions in achieving an acceptable control of post-operative pain. Further work is needed in order to establish the optimum analgesic solutions per procedure and to reduce the incidence of side effects. Also needed are comparative studies with traditional analgesic techniques for determining the procedures that could benefit from these invasive techniques in order to be included in out-patient programmes.

References