Tramadol or fentanyl analgesia for ambulatory knee arthroscopy

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Summary

In a double-blind, randomized, controlled study, 61 patients who received a standardized anaesthetic for day case arthroscopic knee surgery were studied. Group T (n=31) received tramadol 1.5 mg kg\(^{-1}\), and group F (n=30) received fentanyl 1.5 l g kg\(^{-1}\) at the induction of anaesthesia. All patients also received 20 mL of intra-articular bupivacaine 0.5% at the end of surgery. Assessments were made of pain at rest and on movement, analgesic requirements and side-effects at hourly intervals up to 6 h and by means of a postal questionnaire at 24 h and 48 h post-operatively. Group F had higher pain scores than group T at 4 h only [VAS 3.3 (1.6–5.5) vs. 2.4 (1–4), \(P=0.039\), respectively; median (interquartile range)]. There were no other significant differences between the groups in terms of pain scores, supplemental analgesic requirements or incidence of side-effects. We conclude that tramadol offers little benefit clinically compared with fentanyl when used at induction of anaesthesia for day case arthroscopic knee surgery. Further studies are indicated in patients with more severe pain to determine the role of tramadol in post-operative analgesia.

Keywords: analgesics; tramadol, fentanyl; anaesthesia, ambulatory; surgery, arthroscopy; complications, pain.

Introduction

The growth of ambulatory surgery over the past decade, after which patients are discharged home within hours of anaesthesia and surgery, requires both a rapid return to street fitness and the provision of analgesia appropriate to the nature of the surgery undertaken. Balanced analgesia in ambulatory surgery commonly involves intra-operative administration of short-acting opioids such as fentanyl (elimination half-life 3–6 h; analgesic duration 35–55 min), supplemented in the post-operative period by an oral, non-opioid analgesia with a profile of efficacy, safety and potential suitability for patients undergoing ambulatory surgery. Tramadol is a relatively new analgesic with opioid and non-opioid actions which is reputed to produce less opioid side-effects than morphine [1,8].

Our objective, therefore, was to compare tramadol and fentanyl, given at induction of anaesthesia, in terms of the post-operative analgesic outcome in ambulatory patients.

Methods

Sixty-five patients (ASA I and II) undergoing day case arthroscopic surgery of the knee joint were studied. All the patients provided written informed consent to take part in the study, which had been approved by the hospital ethics committee. Patients were excluded if there was a history of recent ingestion of centrally acting analgesic drugs, epilepsy or known adverse reaction to the study drugs. Before surgery, patients were instructed in the use of a 100-mm visual analogue score (VAS) and were told of the availability of post-operative oral analgesia. They were then requested to complete a 48-h questionnaire—‘pain diary’ detailing their pain scores on movement of the knee, analgesic requirements, any side-effects of analgesic therapy and their overall level of satisfaction with their pain control.

After a baseline assessment of pain at rest and on movement recorded using the VAS, patients were...
randomized to receive either tramadol 1.5 mg kg\(^{-1}\) or fentanyl 1.5 \(\mu g\) kg\(^{-1}\) at induction of anaesthesia. We chose these doses because, in a previous study using post-operative, patient-controlled analgesia (PCA), tramadol 1.5 mg kg\(^{-1}\) was comparable with morphine 0.143 mg kg\(^{-1}\). Therefore, using an accepted potency ratio of fentanyl–morphine of 1:100, we took tramadol 1.5 mg kg\(^{-1}\) to be equianalgesic with 1.5 \(\mu g\) kg\(^{-1}\) fentanyl. A non-investigator was responsible for randomization (using a sealed envelope technique) and syringe identification, using freshly pre-prepared, coded, 2-mL syringes. Patients and investigators were unaware which drug was used. All the anaesthetics were administered by one of two specified anaesthetists.

Anaesthesia was induced with 2.0–2.5 mg kg\(^{-1}\) intravenous propofol (depending on the dose necessary to lose verbal communication with the patient) and the study drug was given. A laryngeal mask airway (LMA) was placed, and patients were allowed to breathe spontaneously with nitrous oxide 66% in oxygen and isoflurane 0.5–2%. Additional analgesia, the same as the study drug given at induction, was administered as indicated on clinical grounds by the anaesthetist looking after the patient. As is the clinical practice in our day case unit, 20 mL of bupivacaine 0.5% was injected into the knee joint by the surgeon at the end of the operation. All patients were prescribed Co-codamol (codeine 60 mg/paracetamol 1 g) after surgery according to standardized instructions. Co-codamol was given to take home if further analgesia was required.

Records were kept of the type of operation (arthroscopy only or arthroscopy with further arthroscopic surgery), tourniquet time and additional analgesics given intra-operatively. The level of sedation was assessed for up to 3 h after surgery using a scale from zero to three (0, patient alert; 1, easy to arouse; 2, drowsy; 3, somnolent). Pain at rest and on movement of the knee joint, presence of nausea, analgesic and anti-emetic requirements and time to first recall of name and address after surgery were recorded on emergence from anaesthesia and thereafter at hourly intervals up to 6 h after surgery. These parameters were recorded again at 24 h and 48 h post-operatively. An independent observer was available to help with the first three or four assessments before discharge of the patient, and later assessments were recorded by the patient in a pain diary, which was returned in a prepaid envelope. Patients were telephoned 3 days after surgery to encourage the return of the diary. Previous studies have indicated that the VAS of patients undergoing arthroscopy may have a standard deviation of the order of 1.6 cm.

We decided that a VAS reduction of < 3 cm would not be clinically significant, hence \(n = 32\) patients would be required in each group taking a type I error = 0.05 and type II error = 0.1, i.e. for a power of 90% to demonstrate these differences. Data were analysed using Arcus pro-stat 3.25. Patient characteristics were compared using Student’s t-test and non-parametric tests as indicated. VAS, patient level of satisfaction and time to first requirement of co-codamol analgesia were analysed using Mann–Whitney tests for non-parametric data. The incidence of nausea and other side-effects were compared using Fisher’s exact test. Results are shown as median (interquartile range). \(P < 0.05\) was considered to be statistically significant.

### Results

Sixty-five patients were recruited into the study. Three did not return the postal questionnaire, and one patient was excluded because of non-adherence to the study protocol. The remaining 61 patients were \(n = 30\) in group F (fentanyl) and \(n = 31\) in group T (tramadol). There was no significant difference between the groups with respect to age, weight, sex, tourniquet time, operation type or expectation of nausea and pain after surgery (Table 1). Although patients in group F had higher pain scores than those in group T from 1 h post-operatively, the difference became statistically significant only at 4 h after surgery (VAS 3.3 (1.6–5.5))

<table>
<thead>
<tr>
<th>Table 1. Patient characteristics</th>
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<tr>
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<tr>
<td>Age (years)</td>
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<tr>
<td>Weight (kg)</td>
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<tr>
<td>Male/female</td>
</tr>
<tr>
<td>Tourniquet time (min)</td>
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</tbody>
</table>

Values expressed as mean (range) or number (%).
Table 2. Visual analogue scores (VAS)

<table>
<thead>
<tr>
<th>Time (h)</th>
<th>Fentanyl (n=30)</th>
<th>Tramadol (n=31)</th>
</tr>
</thead>
<tbody>
<tr>
<td>T zero baseline</td>
<td>0 (0–1)</td>
<td>0 (0–1)</td>
</tr>
<tr>
<td>T 1</td>
<td>4.0 (1.2–7.1)</td>
<td>3.0 (1.4–5.0)</td>
</tr>
<tr>
<td>T 2</td>
<td>5.1 (1.5–7.5)</td>
<td>3.5 (2.2–7.5)</td>
</tr>
<tr>
<td>T 3</td>
<td>4.1 (1.8–6.2)</td>
<td>2.7 (2.0–5.8)</td>
</tr>
<tr>
<td>T 4*</td>
<td>*3.3 (1.6–5.5)</td>
<td>2.4 (1.0–4.0)</td>
</tr>
<tr>
<td>T 5</td>
<td>2.8 (1.2–4.1)</td>
<td>2.2 (0.8–3.0)</td>
</tr>
<tr>
<td>T 6</td>
<td>2.6 (1.0–3.5)</td>
<td>2.0 (0.5–2.7)</td>
</tr>
<tr>
<td>T 24</td>
<td>2.5 (1.0–3.2)</td>
<td>2.0 (0.8–2.8)</td>
</tr>
<tr>
<td>T 48</td>
<td>1.3 (0–3.0)</td>
<td>1.0 (0–3.0)</td>
</tr>
</tbody>
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Values expressed as median (interquartile range); *P=0.039.

Table 3. Side-effects

<table>
<thead>
<tr>
<th></th>
<th>Fentanyl (n=30)</th>
<th>Tramadol (n=31)</th>
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</thead>
<tbody>
<tr>
<td>Nausea</td>
<td>9</td>
<td>14</td>
</tr>
<tr>
<td>Constipation</td>
<td>10</td>
<td>11</td>
</tr>
<tr>
<td>Dizziness</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Feeling drowsy</td>
<td>6</td>
<td>8</td>
</tr>
<tr>
<td>Headache</td>
<td>18</td>
<td>19</td>
</tr>
<tr>
<td>Intraoperative recall</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Values expressed as number of the group.

Discussion

The success of day case surgery depends to a large extent on both effective control of post-operative pain and minimization of side-effects such as sedation, nausea and vomiting. Analgesic potency should be proportional to the severity of pain, which is usually greater in the first 24 h after surgery. Pain levels after arthroscopic knee surgery may be considered, in general, to be mild to moderate. In this study, median VAS and VRS were low during the study period, representing good levels of analgesia in both groups but, on account of this, the power of the study to detect a true difference in pain scores is reduced to approximately 75%, rather than 90% as we had projected. This is based on an assumption of a standard deviation in VAS and VRS of the order of 1.6. The small, isolated difference in pain scores at 4 h is clinically unimportant. It may be argued that the administration of intra-articular bupivacaine to all patients may have masked any small differences in analgesic efficacy. However, we did not feel it would have been ethically acceptable to have a local anaesthetic-free control group, given current trends to compare new treatments with broadly accepted alternatives, rather than a purely inert placebo. Moreover, in a study comparing 30 mL of 0.5% bupivacaine with saline, no differences in pain scores were noted, despite earlier ambulation and less opioid requirement in the bupivacaine group [3].

The nature of the procedure performed during arthroscopy of the knee might be expected to be a major determinant of post-operative pain. However, Laurent and colleagues [4] showed that mean post-operative pain scores were similar in three groups of patients studied (diagnostic arthroscopy, additional biopsy or debridement and additional partial meniscectomy). Tourniquet time was measured, as it has been shown that the duration of arthroscopic surgery may influence post-operative pain [2]. However, no such difference was seen in our study.

The incidence of side-effects was similar in both groups, with nausea in the tramadol group at 45% and 30% in the fentanyl group, results which are similar to those quoted in previous studies [1, 7]. This may have been influenced by the use of co-codamol in the follow-up period in this study. There has been some concern about the possibility of awareness with the intraoperative use of tramadol [6]. No patient in our study complained of intraoperative recall when asked immediately after surgery and again in the post-operative questionnaire.

In summary, in this randomized, double-blind study of patients undergoing ambulatory arthroscopy and...
followed up for 48 h, pre-induction tramadol was sim-
ilar to fentanyl in terms of post-operative pain man-
agement and incidence of side-effects. Further studies
are indicated to determine whether patients with more
severe post-operative pain may derive greater benefit
from the use of tramadol both intraoperatively and
continued into the post-operative period.

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