Infusional therapy: an alternative for post-laparoscopy shoulder pain

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Abstract

Introduction: Neuraxial anesthesia in upper abdominal laparoscopic surgery decreases perioperative morbidity and mortality; however, shoulder pain is common and difficult to control. Major opioids (e.g., fentanyl) for the control of this event may depress respiratory function. We believe that a safe and effective therapeutic control of this pain is a multimodal analgesic scheme that we refer to as infusional therapy. We undertook this study to compare various schemes for controlling shoulder pain secondary to pneumoperitoneum.

Methods: We conducted a nonrandomized clinical trial with 56 patients (ASA I-II) divided into four groups undergoing laparoscopic cholecystectomy. Group I (n = 15) was managed with ketorolac (1 mg/kg), group II (n = 12) ketoprofen 100 mg, group III (n = 14) ketoprofen 50 mg + 50 mg tramadol, and group IV (n = 15) ketoprofen 100 mg + 100 mg tramadol. Variables analyzed were presence and intensity of pain, analgesia rescue and operative time.

Results: Group I had more shoulder pain events compared to other groups (p = 0.002) in the same manner that group IV required less rescue analgesia (p = 0.034).

Conclusions: Preemptive analgesia with infusional therapy with ketoprofen–tramadol at doses of 100 mg each is safe for use in laparoscopic surgery.

Key words: laparoscopic surgery, neuraxial anesthesia, infusional therapy.

Introduction

The International Association for the Study and Treatment of Pain (IASP) defines pain as an unpleasant emotional and sensory experience associated with actual or potential tissue damage or described in terms of such damage and, if it persists without available treatment to alter its cause or manifestations, it is a disease by itself.1 This leads us to believe that pain is an experience, i.e., having felt, lived or witnessed something related with the senses and emotions. Pain, in addition to the biological processes that transmit it, also has repercussions on our feelings and world view.

General anesthesia facilitates the complete control of the airway, breathing and circulation but its cost is greater and requires complex care.2 Neuraxial anesthesia is easy to administer, has a low cost, less risks to the airway,3 and decreases postoperative pain, nausea, and vomiting and days of hospital stay.4,5 In laparoscopic surgery, neuraxial anesthesia is given only to patients who are not candidates for general anesthesia.6,7 In 80% of patients, pain referred to the shoulder could be an intraoperative problem8,9 or secondary to diaphragmatic irritation of the phrenic nerve10 caused by insufflation of carbon dioxide.11 In our study, thoracic epidural anesthesia was used because it is less invasive than spinal anesthesia.12-14 Some reports point out that for decreasing pain it is recommended to use low pressures of carbon dioxide in the pneumoperitoneum15 and, for analgesic treatment of shoulder pain, specific and multimodal regional anesthesia should be used,16 i.e., it should be based on the administration of more than one drug with different mechanisms of action.17-19

The first step on the analgesic ladder proposed by the WHO is the application of a nonsteroidal anti-inflammatory drug (NSAID) and, if that is not sufficient, a combination of opioids is indicated.20 Nonopioid analgesics are the drugs...
of choice for patients with postoperative pain in ambulatory surgery.\textsuperscript{21} Ketoprofen is the most potent enantiomer whose action begins at 5 min and has a half-life of 2 h. It stimulates the synthesis and activity of neuroactive substances and is able to specifically block N-methyl-D-aspartate receptors.\textsuperscript{22} Infusion of 12.5 mg/h, after a loading dose of 100 mg, decreases pain to a mild level.\textsuperscript{23} In various studies it has been given IV with advantages of reducing opioids.\textsuperscript{24} Analgesia control with a pump infusion of tramadol is an option used from 1970 according to Lehman.\textsuperscript{25} Tramadol is a weak morphine agonist in which the enantiomer (+) inhibits capture of serotonin and the enantiomer (-) inhibits capture of noradrenaline and stimulates \(\alpha-2\) adrenergic receptors.\textsuperscript{26} Good results have been reported with a tramadol infusion at a dose of 12 mg/24 h after a bolus of 100 mg.\textsuperscript{27} To obtain an effective and safe analgesia with mild nausea, it is recommended that tramadol be given in an infusion at a dose of 7 mg/kg/24 h and bolus dose of 2 mg/kg.\textsuperscript{28} According to Tuncer et al.,\textsuperscript{29} during the postoperative pain of gynecological surgery an additive effect is obtained when ketoprofen is administered (100 mg bolus) and tramadol (20 mg). At the beginning of the 20th century, Cirile\textsuperscript{30} proposed the term “preventive analgesia” with regional blocks combined with general anesthesia to reduce postoperative pain. Analgesic drug therapy, administered by any route, is preventive and generates neuroplasticity with stable modification of the neurotransmitters and of the pain sensation.\textsuperscript{31,32} In this study, multimodal analgesia with thoracic epidural anesthesia was used. The scheme of preventive analgesia was started 60 min for surgery, with infusion therapy of ketoprofen–tramadol at a dose of 100 mg of ketoprofen, 100 mg of tramadol in 100 mL of physiological solution followed by an infusion of 0.2 mg/kg/h of tramadol and 2 mg/kg/24 h of ketoprofen in 1000 mL physiological solution. Infusion pump therapy achieves analgesia without peaks of pain. Precision is achieved in the product supply and reflected in the nociceptive system with better pain control.\textsuperscript{17}

### General Objective

The general objective of this study was to compare the analgesic efficacy of ketoprofen–tramadol in infusion therapy vs. conventional analgesic therapy in different modalities of laparoscopic surgery, specifically for the control of shoulder pain in patients treated with regional anesthesia.

### Specifics

1. Analyze the analgesic efficacy of ketorolac for control of shoulder pain in postoperative patients with laparoscopic surgery under regional anesthesia.

2. Analyze the analgesic efficacy of ketoprofen for control of shoulder pain in postoperative patients with laparoscopic surgery with regional anesthesia.

3. Analyze the analgesic efficacy of tramadol plus ketoprofen for control of shoulder pain in postoperative patients with laparoscopic surgery with regional anesthesia.

4. Identify the adverse effects of the drugs in this study.

### Hypothesis

The hypothesis was the administration 60 min prior to the procedure of 100 mg tramadol and equal doses of IV ketoprofen, continuing with infusional therapy of tramadol (0.2 mg/kg/h–ketoprofen 2 mg/kg/24 h) reaching analgesic efficacy in patients with painful shoulder syndrome during the intraoperative period in laparoscopic surgery with regional anesthesia.

### Null Hypothesis

Null hypothesis was the administration of tramadol (100 mg)–ketoprofen (100 mg IV) 60 min before the procedure and continuing with infusion therapy of tramadol (0.2 mg/kg/h–ketoprofen 2 mg/kg/24 h) does not reach the expected analgesic efficacy in painful shoulder syndrome during the intraoperative period in laparoscopic surgery under regional anesthesia.

### Methods

We carried out a nonrandomized, clinical trial that included patients of either gender, >18 years and <70 years of age with ASA anesthetic risk classification I-II. Patients were undergoing laparoscopic cholecystectomy at the Hospital General de Cerralvo, Nuevo Leon, with thoracic epidural neuraxial anesthesia. We excluded patients with contraindications to neuraxial anesthesia, history of allergic reaction to any of the drugs used in this study, under treatment with oral or parenteral anticoagulants, antidepressants, psychiatric patients, or with septic or hematologic disease. Sample size calculation was based on proportions and yielded a sample of 60 patients who were divided into four groups.

### Measurement of Key Variables

Measured variables were age, gender, pain, rescue analgesia, surgical time, exhaled carbon dioxide (EtCO\(_2\)), nausea, vomiting, sweating, diaphoresis, dizziness or sleepiness.
Patients were assigned for convenience to one of four treatment groups. All were given a preload of 500 mL Hartmann solution with fluid balance in accordance with the requirements of each patient. Prior to the procedure of neuroaxial epidural anesthesia, the patients were administered ranitidine (50 mg) and ondansetron (4 mg). Sedation was done with a loading dose of propofol (0.25–0.50 mg/kg) with maintenance dose of 0.025 mg/kg/min (1.50 mg/kg/h), according to Ramsay 2 scale. Continuous thoracic epidural maintenance dose of 0.025 mg/kg/min (1.50 mg/kg/h), ac with a loading dose of propofol (0.25–0.50 mg/kg) with
didine (50 mg) and ondansetron (4 mg). Sedation was done
with a loading dose of propofol (0.25–0.50 mg/kg) with
maintenance dose of 0.025 mg/kg/min (1.50 mg/kg/h), according to Ramsay 2 scale. Continuous thoracic epidural
maintenance dose of 0.025 mg/kg/min (1.50 mg/kg/h), ac
didine (50 mg) and ondansetron (4 mg). Sedation was done
with a loading dose of propofol (0.25–0.50 mg/kg) with
maintenance dose of 0.025 mg/kg/min (1.50 mg/kg/h), according to Ramsay 2 scale. Continuous thoracic epidural
maintenance dose of 0.025 mg/kg/min (1.50 mg/kg/h), ac

Group I received analgesia at the start of the anesthesia. Groups II, III and IV received therapy with infusion pump (Terfusion TE 171, Terumo Corporation (Tokyo Japan) 60 min prior to the surgery (in a preventive manner). The dose was individualized according to the weight of the patient with the following distribution: group I (conventional)—15 patients treated with ketorolac (1 mg/kg in 100 mL in a 0.9% physiological solution), maximum dose for the ideal weight of the patient; group II—12 patients were given ketoprofen (100 mg in 100 mL physiological solution 60 min prior to surgery) and also infusion with ketoprofen (2 mg/kg/24 h in 1000 mL at 0.9% physiological solution). For group III, 14 patients received tramadol (50 mg)—ketoprofen (50 mg) in 100 mL physiological solution as well as infusion with tramadol (0.1% in 24 h)–ketoprofen (1 mg/kg/24 h) in 1000 mL 0.9% physiological solution. The 15 patients in group IV received the suggested ideal regimen, ketoprofen (100 mg)—tramadol (100 mg) in 100 mL physiological solution, infusion with tramadol (0.2 mg/kg/h–ketoprofen 2 mg/kg/24 h in 1000 mL 0.9% physiological solution). All patients remained with noninvasive monitoring with EKG, heart rate, mean blood pressure, hemoglobin saturation (SpO2), temperature, respiratory frequency and capnography (expired carbon dioxide, captured on the oxygen mask 3-6 l/min), every 5 min until the end of the procedure.

Ethical Aspects

This project was approved by the Research and Education Committee of the Ministry of Health in the State of Nuevo Leon, after signed informed consent was obtained from all the participants.

Record sheets were designed specifically for the study. The general characteristics of the population are presented in measures of central tendency and dispersion, with frequencies and ranges for qualitative variables and mean and standard deviation for quantitative variables. To determine whether there was a statistically significant difference between groups, the Kruskal-Wallis test was used for more than two unpaired groups; p <0.05 was considered statistically significant.

Results

The study included 56 patients: 87.5% (49 patients) were female and 12.5% (seven patients) were male. There was no difference in age between groups. The population was distributed into one of four groups as follows: group I: 15 patients (27%), group II: 12 patients (21%), group III: 14 patients (25%), and group IV: 15 patients (27%). The physical condition of the patients according to the classification of the American Society of Anesthesiology was ASA I: 42 patients (75%) and ASA II: 14 patients (25%).

The incidence of shoulder pain was 84%. Group I had 42 episodes of pain with a predominance of severe pain in 37 surgical events (88%), moderate in four surgical events (9.5%), and mild in one event (2.3%). Group II experienced severe pain in 13 surgical events (68.4%) and moderate pain in six surgical events (31.5%). Group III experienced severe pain in 16 surgical events (61.5%) and moderate pain in 10 (38.4%) events. Group IV experienced severe pain in two events (13%) and moderate pain in 14 (88%) (Table 1).

Group I had the most events of severe pain (88%). In one patient, mild pain persisted even with the use of fentanyl, unlike group IV, which recorded fewer events of pain and with a lower intensity. It replaced a moderate category in 88% of pain events (Table 2) (Figure 1). On evaluation of the second criteria of analgesia efficacy, it was believed that the administration of rescue doses of fentanyl reduces the slope of the curve response to carbon dioxide with decrease in minute ventilation (Table 3) (Figures 2 and 3).

The requirement of rescue fentanyl in group I was 100% of patients, in group II 92% required rescue and only one patient did not receive rescue, 93% in group III required administration of rescue analgesia (some patients required more than one rescue for pain control). In group IV, only 67% required rescue analgesia, a statistically significant difference (Tables 4 and 5).
Table 1. Surgical time and presence and intensity of pain in the study groups

<table>
<thead>
<tr>
<th>Group</th>
<th>Average surgical time (95% CI)</th>
<th>Pain events</th>
<th>No pain</th>
<th>Light</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>87.3 (79.2 - 95.4)</td>
<td>42</td>
<td>0</td>
<td>1</td>
<td>4</td>
<td>37</td>
</tr>
<tr>
<td>II</td>
<td>80.4 (73.0 - 87.8)</td>
<td>19</td>
<td>1</td>
<td>0</td>
<td>6</td>
<td>13</td>
</tr>
<tr>
<td>III</td>
<td>81.4 (72.2 - 90.6)</td>
<td>26</td>
<td>1</td>
<td>0</td>
<td>10</td>
<td>16</td>
</tr>
<tr>
<td>IV</td>
<td>82.6 (72.2 - 90.6)</td>
<td>16</td>
<td>5</td>
<td>0</td>
<td>14</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>82.9 (75.0 - 90.8)</td>
<td>103</td>
<td>7</td>
<td>1</td>
<td>34</td>
<td>68</td>
</tr>
</tbody>
</table>

VAS, Visual Analog Scale.

Table 2. Pain events and VAS in study groups

<table>
<thead>
<tr>
<th>Group</th>
<th>Pain events</th>
<th>No pain</th>
<th>VAS 0–3</th>
<th>VAS 4–6</th>
<th>VAS 7–10</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>%</td>
<td>No.</td>
<td>%</td>
<td>No.</td>
</tr>
<tr>
<td>I</td>
<td>42</td>
<td>1</td>
<td>2.3</td>
<td>9.5</td>
<td>37</td>
</tr>
<tr>
<td>II</td>
<td>19</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>6</td>
</tr>
<tr>
<td>III</td>
<td>26</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>IV</td>
<td>16</td>
<td>5</td>
<td>0</td>
<td>0</td>
<td>14</td>
</tr>
<tr>
<td>Total</td>
<td>103</td>
<td>7</td>
<td>0</td>
<td>0</td>
<td>34</td>
</tr>
</tbody>
</table>

VAS, Visual Analog Scale.

Figure 1. Average intraoperative pain in the study groups. Pain category scale (0-3) in minutes (time).
Upon application of carbon dioxide (14–15 mmHg abdominal pressure maneuvers) during the pneumoperitoneum, no procedures that would alter the pain characteristics were performed in order to control potential biases that skew the results. However, in group IV, 100% of patients retained automatic ventilation during the procedure and a compensatory increase in respiratory rate 18–24/min was observed. Also expired carbon dioxide remained more stable with a mean of 31.8 ± 1.3 mmHg as opposed to group I, which had a tendency to ventilatory depression with a mean of 26.6 ± 4.1 mmHg. Four patients required ventilatory support with 100% oxygen with positive pressure mask. Groups II and III showed no statistically significant differences (Figure 4). Blood pressure remained stable in all four groups (Figure 5).

Intraoperatively, 48.21% (27) of the patients had bradycardia, two with heart rate <50 beats/min. All reacted favorably to the IV application of 0.5 mg of atropine. The temperature that started low in the groups increased. In group I (conventional), one patient had nausea and vomiting at the end of surgery, and two patients suffered anxiety when the shoulder pain began at the initiation of the pneumoperitoneum (Table 6).

### Discussion

In Mexico, laparoscopic surgical procedures are performed with general anesthesia, with spinal anesthesia in T2–T4 or epidural anesthesia at T4-T6 as administered.
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To the patients studied. Despite the anesthetic procedures, shoulder pain continues when a pneumoperitoneum is performed with pressure applications of CO₂ at 14-15 mmHg or even at low pressures (8-10 mmHg) due to peritoneal cell death caused by the combination of low gas temperatures (21°C) and its drying effects (0.0002%). This is prevented with spinal anesthesia in T2–T4 or epidural anesthesia at T4–T6. The latter was given to the patients studied. For proper anesthetic treatment, strict early monitoring is required of adequate expired carbon dioxide (EtCO₂) for early detection of gas embolism and to apply multimodal analgesia to more definitively control the pain caused by painful shoulder syndrome during the intraoperative period of laparoscopic surgery. This reduces the application of supplemental narcotic analgesics and preserves automatic ventilation, minimize shoulder pain and avoid complications.

For the analgesic treatment of shoulder pain with regional anesthesia, different medications have been used, among them a local anesthetic with a narcotic (fentanyl, 0.02 mg) combined with IV opioid analgesics during spinal anesthesia. Sinha et al. administered preventive analgesia for shoulder pain to 2996 patients. Of these, 571 (12.29%) patients manifested discomfort and anxiety and 10 patients required conversion from regional anesthesia to general anesthesia. Bessa et al. studied a group of 30 patients who were given lumbar spinal anesthesia (diclofenac 75 mg plus fentanyl 20 μg subarachnoid) as a preventive treatment. Nine patients (30%) had shoulder pain during laparoscopic cholecystectomy, two of them (6.7%) with mild pain, 23% moderate, two (6.7%) experienced headache and three had urinary retention.

To prevent shoulder pain during laparoscopic cholecystectomy, Tzovaras et al. administered the following to a group of patients with body mass index (BMI) of 30: lumbar spinal anesthesia plus 0.25 mg morphine and 0.02 mg fentanyl. The result was that 43% of 50 patients with severe pain required the addition of fentanyl and 6% also had urinary retention.

Van Zundert et al. studied 20 patients with BMI of 32 who were given spinal thoracic anesthesia and fentanyl (50-100 mg); five patients suffered shoulder pain and six had discomfort. This demonstrated that with spinal anesthesia, adequate analgesia is not achieved in all patients. There are also secondary effects such as spinal cord puncture, postpuncture headache, urinary retention and hypotension.

Lee et al. provided epidural fentanyl (50 μg and 2 mg/kg IV) to 12 patients treated with thoracic epidural anesthesia. Of the total group, 11 patients had shoulder pain, six had severe pain requiring 50 mg of fentanyl, five required additional doses of fentanyl (difficult-to-treat shoulder pain requiring several injections of fentanyl without reporting how many). Due to the pain, one patient required conversion to general anesthesia and mask ventilatory support; eight patients had hypotension and one had urinary retention. In laparoscopic surgery, thoracic epidural anesthesia offers great advantages; however, limited advances in eliminating pain exclude their election. Yi et al. reported a slow insufflation with Veress needle (2 mm) prevents stimulation of the vagus nerve. Lee et al. reported low bradycardia (in the 50s) in two patients. A 10-mm trocar was used at initia-

### Table 4. Total intraoperative rescue dose of fentanyl

<table>
<thead>
<tr>
<th>Group</th>
<th>I</th>
<th>II</th>
<th>III</th>
<th>IV</th>
<th>Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Without rescue</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>5</td>
<td>7</td>
</tr>
<tr>
<td>0.05 mg total dose</td>
<td>0</td>
<td>2</td>
<td>1</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>0.1 mg total dose</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>11</td>
</tr>
<tr>
<td>0.15 mg total dose</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td>0.2 mg total dose</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>0.3 mg total dose</td>
<td>6</td>
<td>1</td>
<td>3</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>0.4 mg total dose</td>
<td>3</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>total</td>
<td>15</td>
<td>12</td>
<td>14</td>
<td>15</td>
<td>56</td>
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</table>

### Table 5. Frequency and rescue dose of fentanyl in each study group

<table>
<thead>
<tr>
<th>Group</th>
<th>Fentanyl 0.05 mg dose</th>
<th>Fentanyl 0.1 mg dose</th>
<th>Fentanyl μg/kg used in each group</th>
<th>Fentanyl μg/kg highest patient dose</th>
<th>Patients</th>
<th>Patient with ventilatory support</th>
</tr>
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<tbody>
<tr>
<td>I</td>
<td>5</td>
<td>37</td>
<td>56.79</td>
<td>7.27</td>
<td>0</td>
<td>4</td>
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<tr>
<td>II</td>
<td>6</td>
<td>13</td>
<td>22.05</td>
<td>4.61</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>III</td>
<td>10</td>
<td>16</td>
<td>31.88</td>
<td>4.61</td>
<td>1</td>
<td>1</td>
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<tr>
<td>IV</td>
<td>14</td>
<td>2</td>
<td>12.3</td>
<td>2.7</td>
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</tr>
<tr>
<td>total</td>
<td>33</td>
<td>69</td>
<td>123.02</td>
<td>19.19</td>
<td>7</td>
<td>6</td>
</tr>
</tbody>
</table>
Infusional therapy in painful shoulder

Figure 4. Average expired carbon dioxide (etCO₂) in the study groups (mmHg in minutes) (time).

Figure 5. Average mean arterial pressure in the study groups (mmHg in minutes) (time).

tion. In our study, with the use of an 11-mm trocar there was a decrease of heart rate with similar results.

Oberhofer et al.,39 when evaluating the efficacy and safety of 100 mg of ketoprofen administered as a 30-min ketoprofen (100 mg/9 h) infusion and tramadol (200 mg plus metamizole) (5 g/24 h infusion) with 25 mg tramadol rescue in major abdominal surgery, reported that ketoprofen decreases the pain scale by 30% with reduction of rescue with tramadol.

Tuncer et al.,39 reported an additive effect of ketoprofen with tramadol; 25 patients received a 100-mg bolus of ketoprofen at the conclusion of the surgery and analgesia with infusion pump (20 mg of tramadol/10 min for 24 h) in gynecological cancer surgery, reporting a lower consumption of tramadol, but without significant differences with the placebo group.

In conclusion, our study showed that, during laparoscopic surgery, the incidence of shoulder pain is high in patients
treated with regional anesthesia. The effective and analgesic treatment with few side effects is the combination of tramadol plus ketoprofen. This scheme of infusional therapy decreases the likelihood of respiratory depression with the consequent reduction of risk of aspiration and problems related to the manipulation of the airway. This scheme of analgesia is recommended for populations similar to ours.

**References**

26. Elia N, Lysakowski C, Tramér MR. Does multimodal analgesia with acetaminophen, nonsteroidal antiinflammatory drugs, or selective

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Table 6. Intraoperative events

<table>
<thead>
<tr>
<th>Group</th>
<th>Bradycardia</th>
<th>Nausea and vomiting</th>
<th>Anxiety</th>
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<tbody>
<tr>
<td></td>
<td>Frequency %</td>
<td>Frequency %</td>
<td>Frequency %</td>
</tr>
<tr>
<td>I</td>
<td>4</td>
<td>26.6</td>
<td>1</td>
</tr>
<tr>
<td>II</td>
<td>9</td>
<td>75</td>
<td>0</td>
</tr>
<tr>
<td>III</td>
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</tr>
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<td>8</td>
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</tr>
<tr>
<td>total</td>
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<td>48.21</td>
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