Preoperative oral naproxen for pain relief after day-case laparoscopic sterilization

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Summary

Analgesia with preoperative naproxen after laparoscopic sterilization was assessed in a prospective, double-blind, randomized study of 80 women: 42 women received oral naproxen 1 g, approximately 90 min before surgery, and 38 received placebo. Preoperative naproxen did not significantly influence postoperative pain scores, but was associated with a reduction in parenteral opioid administration ($P = 0.04$). (Br. J. Anaesth. 1995; 75: 12–14)

Key words


Laparoscopic sterilization is performed commonly on a day-case basis despite the high incidence of postoperative morbidity; 85% of women in one study [1] reported that pain, fatigue, or both, delayed recovery and it was almost 4 days before patients returned to normal activity. Effective analgesia is an outstanding problem and various regimens have been suggested, including opioids [2], local anaesthesia [3], non-steroidal analgesics [4–7], acupuncture [8] and posture [9], with no consistent success.

Fallopian tube trauma or ischaemia causes release of prostaglandins [6] and this may contribute to pain after surgery. Although non-steroidal anti-inflammatory drugs (NSAID), which inhibit prostaglandin release, have been used for pain after laparoscopic sterilization [4, 5, 7], the results have been disappointing. Late administration of the NSAID in these studies may have prevented adequate drug concentrations. We therefore chose to give oral naproxen approximately 90 min before laparoscopic sterilization so that therapeutic blood concentrations would be achieved at an appropriate time [10].

Patients and methods

Local Ethics Committee approval was obtained. We studied 80 women who were undergoing laparoscopic sterilization as day-cases. With 40 patients in each arm of the study, the study had an 80% power to detect a halving of the incidence of severe pain at the 5% level of significance. Written informed consent was obtained from all patients, who were ASA I or II. Patients who had a history of dyspepsia, allergy to aspirin or NSAID, renal disease or asthma, or were receiving concurrent analgesic medication, were excluded. A five-point verbal pain scoring system was explained by the recruiting anaesthetist (0 = no pain, 1 = mild pain, 2 = moderate pain, 3 = severe pain and 4 = unbearable pain). The patients were allocated randomly by computer-generated numbers to receive either naproxen 1 g as 2 × 500 mg non-enteric coated tablets of naproxen (Naprosyn, Syntex Pharmaceuticals Ltd) or placebo orally 90 min before surgery.

No premedication was given. The general anaesthetic was standardized. Anaesthesia was induced with propofol 2–3 mg kg$^{-1}$ followed by atropine 0.6 mg, diamorphine 0.05 mg kg$^{-1}$ and vecuronium 0.06–0.08 mg kg$^{-1}$. The trachea was intubated and the lungs ventilated mechanically with nitrous oxide and 1–2% enflurane in oxygen via a circle system. Monitoring included oxygen saturation, ECG, non-invasive arterial pressure and end-tidal carbon dioxide concentration. Neuromuscular block was antagonized with neostigmine and glycopyrronium.

All operations were performed by gynaecologists of registrar grade or above. Filshie clips were applied to the Fallopian tubes.

Pain was assessed by the patients themselves in the recovery room, and at 2 and 4 h after operation using the five-point verbal rating score described above. Assessments were made with the patients in bed, at rest. Rescue analgesia was administered by one of five experienced recovery and ward nursing staff according to a standardized regimen: mefenamic acid 500 mg orally if the pain was moderate and diamorphine 5 mg i.m. if the pain was considered severe. If the pain was “unbearable” and the patient distressed, diamorphine in 1 mg i.v. boluses was given until the patient was comfortable.

At the 2- and 4-h assessment, specific enquiry was made about the presence of nausea, vomiting, shoulder-tip pain, dyspepsia and skin rash. The degree of drowsiness was recorded on a four-point...
scoring system. The choice of analgesics and antiemetics was also recorded.

Before discharge, the patients were asked about their satisfaction with the whole procedure. They were advised to take paracetamol for pain, up to 4 g per 24 h, and a chart was given to record analgesics taken. If the pain was not relieved by the paracetamol regimen, they were told to contact their general practitioner.

Approximately 24 h after surgery, the patient was telephoned and asked about abdominal pain and analgesic use. Enquiries were also made about any other problems arising since discharge. Finally, each patient was asked if she would recommend laparoscopic sterilization as a day-case to a friend. Patients who had no telephone were given a questionnaire with identical questions together with a pre-paid envelope.

The time at which naproxen was given before surgery, the duration of surgery, patient age, height and weight were analysed using Student’s t test. Pain scores, satisfaction and degree of drowsiness were analysed using the Mann–Whitney U test. The chi-square test with Yates’ correction and the Fisher’s exact test were used to test for analgesic requirement, presence of nausea, shoulder-tip pain, dyspepsia and skin rash. \( P < 0.05 \) was considered significant.

Table 1  Patient data (mean (SD) [range])

<table>
<thead>
<tr>
<th></th>
<th>Naproxen</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr)</td>
<td>33.5 [26–44]</td>
<td>33.1 [24–46]</td>
</tr>
<tr>
<td>Height (m)</td>
<td>1.61 (0.53) [1.51–1.73]</td>
<td>1.61 (0.65) [1.44–1.76]</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>62.9 (9.3) [47–92]</td>
<td>62.5 (11.9) [40–94]</td>
</tr>
<tr>
<td>Time tablet taken preop. (min)</td>
<td>92.1 (31.0) [42–175]</td>
<td>89.6 (26.6) [55–170]</td>
</tr>
<tr>
<td>Operating time (min)</td>
<td>12.1 (5.0) [5–26]</td>
<td>13.4 (5.1) [5–28]</td>
</tr>
</tbody>
</table>

Results

Of the 80 patients entered into the study, six patients were excluded, five for study plan violations. The assessor was unavailable to perform the assessments at the appropriate time for one patient. This left 74 patients in the study; 39 received naproxen and 35 placebo.

There was no significant difference in age, height, weight, time the tablets were taken before operation and operating time between the patients in the control and treatment groups (table 1).

Figure 1 shows the pain scores in the recovery room at 2, 4 and 24 h after operation. The two groups were compared at each time of scoring. Six patients who had no telephone and had been given the questionnaire to take did not return them. Their 24-h data were therefore not available. There was no significant difference between the groups.

Table 2  Strongest analgesic requirement

<table>
<thead>
<tr>
<th></th>
<th>Naproxen ( (n = 39) )</th>
<th>Placebo ( (n = 35) )</th>
</tr>
</thead>
<tbody>
<tr>
<td>No analgesia</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td>Oral analgesia</td>
<td>10</td>
<td>4</td>
</tr>
<tr>
<td>I.m. opioid</td>
<td>13</td>
<td>18</td>
</tr>
<tr>
<td>I.v. opioid</td>
<td>8</td>
<td>9</td>
</tr>
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</table>

The incidence of side effects at 2 and 4 h was not significantly different between the groups. Eighteen naproxen patients (46%) and 23 placebo patients (65%) had an antiemetic. Satisfaction levels

Figure 1  Pain scores (1–5) in the recovery room (RR) and 2, 4 and 24 h after laparoscopic sterilization following preoperative naproxen or placebo. For naproxen, \( n = 39 \) except at 24 h when \( n = 35 \). For placebo, \( n = 35 \) except at 24 h when \( n = 32 \).
not significantly different between the two groups: 89% of patients who received naproxen would recommend the procedure, 81% of patients who had placebo would do the same.

Three patients were kept in hospital overnight. One patient in the naproxen group had severe abdominal pain which settled the next day. One patient who had received placebo developed urinary retention and required catheterization and the other placebo patient bled more than usual from the skin incision and was kept in hospital for observations. All three patients were discharged the next day.

Discussion

Pain after laparoscopic sterilization is complex and has distinct components; shoulder-tip pain caused by diaphragmatic irritation or stretching following carbon dioxide insufflation, colicky abdominal pain or backache similar to dysmenorrhoea caused by tubal ischaemia or trauma, and superficial wound pain as a result of skin incision. Removal of as much carbon dioxide as possible from the abdominal cavity after surgery may reduce shoulder-tip pain. Rectus sheath and mesosalpinx blocks [3] with local wound infiltration may relieve the latter two pain sources but only for a limited period, when the patient is still in hospital.

We studied naproxen given approximately 90 min before surgery to see if it would reduce pain after laparoscopic sterilization. We did not find better pain scores despite the large dose of naproxen given at an appropriate time. This is consistent with other studies. I.m. diclofenac given immediately after induction had no significant effect on the severity of postoperative pain [4]. Crocker and Paech [5] showed that preoperative rectal indomethacin resulted in insignificant clinical benefit. In contrast, Brodie and Casper have demonstrated previously that rectal indomethacin given after induction reduced analgesic requirements [6]. In our study, also, fewer women who had been given naproxen before operation required i.m. or i.v. opioids after surgery. This would be beneficial to the nursing and medical staff in a busy day-unit as opioid administration is time-consuming, and also to the patients who may be ready for discharge earlier.

There is an apparent discrepancy in our findings in that despite there being no difference in pain scores between the naproxen and placebo groups, there was significantly less opioid consumption in the naproxen group. We suggest the reason for this is that the inpatient assessments were made at intervals of 2 h and opioid given between assessment times would have made the subsequent pain score lower than if the patient had been denied analgesia. More frequent pain assessment might have demonstrated differences between the two groups. Ideally, to reflect a more continuous picture of analgesic requirement, patient-controlled analgesia should have been used. However, this is not practical in a day-case setting.

At present we cannot find a means of obtaining consistent prolonged analgesia after laparoscopic sterilization. Perhaps a multiple analgesic approach, with NSAID given before operation at an appropriate time, i.v. opioids at induction of anaesthesia, rectus and mesosalpinx blocks performed before clip insertion and NSAID administered regularly after operation may be effective. Patients should be informed that postoperative pain varies and may be significant. Return to normal lifestyle may take some days and domestic and employment arrangements can then be made appropriately. The facility for overnight inpatient stay if the need arises should be emphasized.

References