The use of infusion paracetamol in the multimodal management of post myomectomy pain: A randomised control study

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Abstract

Objective: The study evaluated the use of infusion paracetamol in the multimodal management of post myomectomy pain and its analgesic sparing effects while comparing the side effect profile.

Methods: Sixty-two ASA I and II patients undergoing myomectomy under subarachnoid block were randomized into two groups which were either given infusion Paracetamol (perfalgan, Bristol-Myers Squibb) 100ml and rectal diclofenac (Voltaren, Novartis), or infusion normal saline 100ml and rectal diclofenac (voltaren, Novartis) after the last skin stitch. Pain was assessed using NRS (Numerical rating scale). Patients were assessed for the presence of motor or sensory complications, rectal bleeding or gastrointestinal discomfort, postoperative nausea and vomiting and sedation. The presence of other side effects was noted. Patients’ satisfaction with pain relief using the 5-point Likert scale was also evaluated.

Results: Time to first analgesic request was longer in the paracetamol/diclofenac group compared to the saline/diclofenac group. The mean pain scores at 2nd and 5th hour and at the time of first analgesic request were lower in patients in group P compared to the patients in the saline group. (4.83±1.6 vs 5.93±1.4) (P=0.012-test. Total analgesic consumption was more in the saline group.

Conclusion: Infusion paracetamol provides additional analgesia in the management of post myomectomy pain.

Keywords: Infusion paracetamol, multimodal analgesia, myomectomy

Introduction

Myomectomy could either be open or laparoscopic with pain being a major complaint by patients who had open procedure as compared with those who had laparoscopy.1 Open myomectomy is commonly done in our setting. Despite the progress in pathophysiology and treatment of pain, patients’ pain is still treated inadequately after surgery. It was noted that 30-75% of surgical patients complained of moderate to severe pain in the postoperative period.2

Insufficient pain treatment has negative effects on patients’ recovery in the postoperative period. Pain causes a reduction in respiratory muscle activity and reduced cough leading to atelectasis and other pulmonary complications. Pain increases catecholamine response, systemic vascular resistance, myocardial oxygen consumption and increases the risk of ischaemic events especially in patients with coronary artery disease. Increased catecholaminergic response also causes harmful results by reducing gastrointestinal motility and splanchnic circulation. Severe postoperative pain inhibits early mobilization and increases the risk of thromboembolism. Appropriate and efficient postoperative pain treatment reduces recovery time, hospitalization time and treatment expenditures.3

This study determined the efficacy of a combination of rectal diclofenac and infusion paracetamol in comparison to the use of rectal diclofenac alone for

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postoperative pain management after myomectomy. Spinal anaesthesia with bupivacaine and pethidine was used as a form of pre-emptive analgesia with the aim of improving post-operative analgesia. It was therefore hypothesized that infusion paracetamol when added to rectal diclofenac will prolong postoperative analgesia following spinal anaesthesia for myomectomy.

**Patients and methods**

Ethical approval for this study was obtained from the hospital ethics and research committee in UBTH. Study commenced on the October 2016 to March 2017. The study was a double blind, prospective randomized study. Women scheduled for myomectomy under subarachnoid block were recruited.

Using data from a previous investigation in a similar clinical setting using intrathecal pethidine, the mean duration of spinal analgesia was 256 mins. This study aimed to achieve a mean duration of analgesia of 340 minutes with the addition of infusion paracetamol and rectal diclofenac which was not used in the reference study. This gives a difference of 84 mins. The sample size was then calculated using the formula:

\[ N = \frac{4\sigma^2(Z_{\text{crit}} + Z_{\text{power}})^2}{D^2} \]

Where: 
- \( N \) = total sample size (the sum of the sizes of both comparison groups),
- \( \sigma \) = assumed SD of each group (assumed to be equal for both groups) which is 112.2 in the reference study
- \( Z_{\text{crit}} \) = value is that given for the desired significance criterion = 1.96
- \( Z_{\text{power}} \) = value is that given for the desired statistical power = 0.84
- \( D \) = minimum expected difference between the two means

Substituting the values,

\[ N = \frac{4 \times 112.2^2 \times 1.96 + 0.84^2}{84^2} \]

Value substitution equated to a sample size of 56. Assuming a dropout rate of 10%, this gives a value of 56. Sample size estimation came to 62 with 31 in each group. Follow up losses are not expected as the evaluation was done in the immediate postoperative period.

ASA I or II women scheduled for myomectomy under spinal anaesthesia were included in the study. Exclusion criteria included patients' refusal, known allergy to the study drugs, significant coexisting disease such as peptic ulcer disease, renal, hepatic disease, haematological disorder or asthma. Others were any contraindication to regional anaesthesia such as local infection and bleeding disorders, rectal diseases and history of chronic pain. If subarachnoid block failed, leading to conversion to general anaesthesia, such patients were also excluded from the study. A total of 62 patients were included in the study.

Consent was obtained during the preoperative review. Patients were instructed on the use of the numerical rating scale (NRS) for pain assessment from 0-10 (0 = no pain while 10 = maximum imaginable pain). The patient was asked to select a number that best describes her pain. The five point Likert 6scale was explained to them to enable grading of the level of satisfaction from excellent, very good, good, poor and very poor.

The researcher and the patients were blinded to the study drugs. Blinding was achieved by adequate briefing of the study protocol to the anaesthetists who participated in the study. The person who administered the drug was different from the one who assessed the pain scores. The study drugs were prepared by the principal investigator. The 100ml of normal saline was placed in a metronidazole bottle which has similar shape to the Perfalgan® bottle and prepared by the pharmacy. Each infusion (100ml normal saline or 100ml paracetamol infusion) was wrapped in a black bag thus the patients were also blinded to the drug choice.

Preoperative check of all equipment was carried out and drugs were drawn into labelled syringes. The patients were randomly allocated to group P or S by each patient drawing numbers kept in opaque sealed envelopes.

- **Group P:** Infusion Paracetamol (perfalgan, Bristol-Myers Squibb) 100ml and rectal diclofenac. (Voltaren, Novartis)
- **Group S:** Infusion normal saline of 100ml and rectal diclofenac. (Voltaren, Novartis)

On arrival in the theatre, a multiparameter monitor
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36.48±5.0 while that of group S was 35.70±5.3. (Table 1).

The indications for myomectomy and the commonest indication was menorrhagia accounting for 50% of the total number of patients. This was followed closely by infertility accounting for 42.9% of the total number of patients. Four of the patients (7.1%) had myomectomy on account of a huge fibroid.

The Baseline vital signs were similar in both groups. There was no statistical difference between groups with regards to pulse rate, blood pressure and Oxygen saturation. Subarachnoid block was established using the L3/4 interspace in 65% of the patients while 3(5.4%) had the block established at the L2/3 interspace. 28% of the patients had SAB established using the L4/5 interspace. There was no statistical difference between groups in relation to the interspace used for the establishment of SAB (P=0.13, chi square test). Regarding block height, 17.9% of the patients had maximum block heights of T3 in the paracetamol group compared to the saline group where 3.5% of patients had this same level of maximum block height. This attained statistical significance though both groups had equal doses of drugs and demographic parameters (P=0.014). A total of 21.4% in the saline group had a block height of T4 while 7.1% was recorded in group P.

Group P had longer duration of surgery compared to group S though this did not achieve statistical significance (127.07±7.6 vs 104.48±9.5) (P=0.07).

Estimated blood loss was more in group P compared to those in group S and this may also account for the longer duration of surgery (484.48±54.7 vs 346.30±47.8). This, however, was not statistically significant (P=0.06).

There were mild fluctuations in the intraoperative vital signs. There was a drop in the systolic, diastolic and mean arterial blood pressure in the first four minutes and up to the 25th minute as a result of spinal induced hypotension in both groups (Fig II). There was also a drop in the pulse rate in the first 10 minutes but noted to be stable hereafter (Fig III). There was, however, no statistical difference between groups at each point in time.

Intraoperative complications were also observed in both groups. In group P, 4(7.1 %) and 3(5.4%) in group S had hypotension. This was accompanied by bradycardia. In the paracetamol group 3(5.4%) of the patients had bradycardia as against 4(7.1%) in the saline group. Hypotension was managed with aliquots of ephedrine, 3mg till an improvement in the blood pressure with good outcome. Bradycardia was successfully treated with atropine 0.6mg. Sedation was noted in 2 patients, one in each group. Two patients in the saline group complained of pain radiating to the chest as a result of peritoneal irritation when the uterus was exteriorized. This however was transient and did not require supplemental analgesia. Three patients complained of nausea while two had an episode of vomiting. Nausea and vomiting were successfully treated with intravenous metoclopramide. The incidence of complications did not achieve statistical significance between groups. (P=0.4, chi square test).

Time to first analgesic request was longer in the paracetamol/diclofenac group compared to the saline/diclofenac group. The time from intrathecal injection of bupivacaine and pethidine to first request for analgesia was 319.12±9.5 minutes in the paracetamol group as against 213.29±9.5 in the saline group. This difference was significant (P=0.001, t-test) (Table 3). The mean time to first request for analgesia from administration of infusion paracetamol was 207.12±17.1 minutes compared to 107.96±7.0 minutes in the saline group. The difference observed was statistically significant (P=0.001, t-test) (Table 3).

With regards to pain scores, it was observed that patients in group P had lower pain scores compared to the Saline group in the postoperative period (Fig. III). At 30 minutes, pain scores were 0 in both groups. At the 2nd and 3rd hour, pain scores were less than 3 in the patients in group P compared to the patients in group S where pain scores were 3 and 4. Pain scores were noted to be highest at the 5th hour with the patients in group S compared to the patients in group P (6 vs 4) (Fig. III). Pentazocine at a dose of 0.5mg/kg was commenced at this time. The mean pain scores at the time of first request analgesic request were lower in patients in group P compared to the patients in the saline group. (4.83±1.6 vs 5.93±1.4) (P=0.012, t-test). pain scores in the postoperative period were found to be highest in the saline group.

Analgesic consumption in the first 24hs
(DASH 4000 General electric) was attached to the patients and baseline pulse, blood pressure, oxygen saturation, temperature, and electrocardiography tracing were obtained and recorded. Intravenous access was established with a 16G cannula. All patients received a preload of 10-15ml/kg normal saline solution before spinal anaesthesia. Intraoperative pulse rate, blood pressure, oxygen saturation, and electrocardiography were continuously monitored.

Every patient received subarachnoid block in the sitting position at the L2-3, L3-4 or L4-5 vertebral level using 3ml of 0.5% heavy bupivacaine and 10mg pethidine (0.2ml). Immediately after the spinal injection, patients were placed in the supine position. No additional analgesic was given unless indicated by patient.

Vital signs were continuously monitored and recorded in the data collection sheet. Systolic, diastolic and mean blood pressures were monitored every minute for the first 5mins and then every 2mins till the 10th minute and then every 5mins till the 30th minute and then every 15minutes till end of surgery and immediate postoperative period. Sensory block was assessed by loss of cold sensation to alcohol-soaked swabs. The maximal level of sensory block was evaluated every 5minutes for 25minutes till the same level is obtained twice and this was recorded as the maximum block height. Surgery began as soon as anaesthesia was judged adequate. Duration of sensory block was defined as time from intrathecal injection to regression to T12 segment. The duration of analgesia was the time of intrathecal injection to the first analgesic request. If patient complained of pain in the course of surgery, pain was treated with 0.5mg/kg pentazocine and patient excluded from the study. Motor block was assessed by the Bromage score (0- no motor loss, 1- cannot raise extended leg, but can move knees and feet, 2- inability to flex the knee, but can move feet, 3- cannot move any part of leg or feet).7

Systolic Blood Pressure (SBP) ≤20% below baseline or < 90mmHg was treated with IV normal saline and intravenous ephedrine 3mg aliquots as required. rate was < 55 beats/min, 0.6mg of atropine sulphate was administered. Side effects such as pruritus, dizziness, sedation, shivering, and vomiting were recorded. The presence of nausea was noted and vomiting treated with intravenous metoclopramide 10mg.

At the end of the last skin suture, the patients were given either rectal diclofenac (Voltaren, Novartis) 100mg and infusion paracetamol (parfalgan, Bristol-Myers Squibb) 1g to run for 15minutes or infusion normal saline 100ml and rectal diclofenac. Pain was assessed using NRS (Numerical rating scale) with anchors as; 0= no pain at all, 10=maximum imaginable pain and documented. Patients were discharged from the recovery room when the vital signs were within normal range and stable (Systolic Blood Pressure > 90mmHg, HR > 60b/min), absence of nausea and vomiting, and absence of severe pain (Numerical Rating Scale <4). Intramuscular Pentazocine 0.5mg/kg was given each time the patient complained of pain and the total amount of analgesics consumed in the first 24hours was recorded.

Patients were assessed for the presence of motor or sensory complications, rectal bleeding or gastrointestinal discomfort, postoperative nausea and vomiting and sedation. The presence of other side effects was noted and documented throughout the postoperative period up to 48 hours after surgery. Patients’ satisfaction with pain relief using the 5-point Likert scale was also evaluated.3 Patients’ biodata, haemodynamic parameters, intraoperative and postoperative events, and management of complications were recorded in the data collection sheet.

Results

Sixty-two patients of the American Society of Anaesthesiologists class I or II who were scheduled for myomectomy were recruited for this study. Fifty-six patients completed the study, twenty-nine in the paracetamol group (P) and twenty-seven patients in the saline group (S). Two patients in group P were excluded because supplemental analgesia was given before the end of surgery. Three patients required supplemental analgesia in Group S while one of the patients had failed spinal block and was converted to general anaesthesia.

There was no significant statistical difference in the demographic characteristics of the patients. Both groups had similar values with regards to age and weight. The mean±SD ages of the patients were similar with group P having a mean age of
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postoperatively was lower in the paracetamol group compared to the saline group. (52.58±26.1mg vs 80.19±34.6mg) The difference was also statistically significant (p=0.001, t-test). Fig III.

Table 3 shows the side effects that were observed following administration of study drugs. The incidence of side effects in the paracetamol group was 4 out of 29 (13.8%) as against 5 out of 27 (18.5%) in the saline group. Total incidence was 9/56(16.07%) Nausea and vomiting was observed by 2 patients in each group. Vomiting was treated with metoclopramide 10mg. One patient in the paracetamol group had pruritus that was treated with hydrocortisone 200mg. Two patients in the saline group was noted to be sedated but rousable. The difference in the incidence of side effects was not significant. (P=0.52, chi square test).

It was observed that patients in group P had higher satisfaction scores than those in group S. More patients in Group P rated their satisfaction as excellent or very good (24/29) as against 13/26 in the saline group. However, the duration of hospital stay was noted to be similar in both groups. The difference between groups was not significant. (p=0.036, chi square test) (Table 4)

### Table 1: Demographic Characteristics of the Patients

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Group P</th>
<th>Group S</th>
<th>P-value</th>
<th>Level of significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>n=29 Mean±SD</td>
<td>n=26 Mean±SD</td>
<td>P-value</td>
<td>Level of significance</td>
<td></td>
</tr>
<tr>
<td>Age (yrs)</td>
<td>36.48±5.01</td>
<td>35.70±5.33</td>
<td>0.55</td>
<td>NS</td>
</tr>
<tr>
<td>Height (m)</td>
<td>1.61±0.66</td>
<td>1.58±0.05</td>
<td>0.09</td>
<td>NS</td>
</tr>
<tr>
<td>Body Weight (kg)</td>
<td>72.31±2.50</td>
<td>69.59±1.15</td>
<td>0.39</td>
<td>NS</td>
</tr>
<tr>
<td>Body Mass index (kg/m²)</td>
<td>27.92±7.66</td>
<td>27.94±7.05</td>
<td>0.34</td>
<td>NS</td>
</tr>
</tbody>
</table>

### Table 2: Post-operative analgesic profile

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Group P</th>
<th>Group S</th>
<th>P-value</th>
<th>Level of significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>n=29 Mean±SD</td>
<td>n=27 Mean±SD</td>
<td>P-value</td>
<td>Level of significance</td>
<td></td>
</tr>
<tr>
<td>Time to first request for analgesia (mins)</td>
<td>207.12±17.10</td>
<td>107.96±7.05</td>
<td>0.001</td>
<td>S</td>
</tr>
<tr>
<td>Intrathecal injection to first request(mins)</td>
<td>319.12±9.56</td>
<td>213.29±9.56</td>
<td>0.001</td>
<td>S</td>
</tr>
<tr>
<td>Pain score at request for analgesia</td>
<td>4.83±1.69</td>
<td>5.93±1.47</td>
<td>0.012</td>
<td>S</td>
</tr>
<tr>
<td>Total pentazocine consumed in 24hrs(mg)</td>
<td>52.58±26.17</td>
<td>80.19±34.60</td>
<td>0.001</td>
<td>S</td>
</tr>
<tr>
<td>Duration of Hosp stay (median, range)</td>
<td>4(4-6)</td>
<td>4(4-6)</td>
<td>0.90</td>
<td>NS</td>
</tr>
</tbody>
</table>

S-Significant
NS- Not significant
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### Table 3: Side effects after administration of study drugs

<table>
<thead>
<tr>
<th></th>
<th>Group P N=29</th>
<th>Group S N=27</th>
<th>P value</th>
<th>Level of significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>25(44.6)</td>
<td>23(39.3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nausea</td>
<td>2(3.6)</td>
<td>1(1.8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pruritus</td>
<td>1(1.8)</td>
<td>0(0.0)</td>
<td>0.53</td>
<td>NS</td>
</tr>
<tr>
<td>Sedation</td>
<td>0(0.0)</td>
<td>2(3.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vomiting</td>
<td>1(1.8)</td>
<td>1(1.8)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NS- Not significant

### Table 4: Patients’ satisfaction with pain relief

<table>
<thead>
<tr>
<th></th>
<th>Group P N(%)</th>
<th>Group S N(%)</th>
<th>P value</th>
<th>Level of significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excellent</td>
<td>10 (17.9)</td>
<td>6 (10.7)</td>
<td>0.036</td>
<td>S</td>
</tr>
<tr>
<td>Very good</td>
<td>14(48.3)</td>
<td>7(12.5)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Good</td>
<td>5 (8.9)</td>
<td>13 (23.2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poor</td>
<td>0(0.0)</td>
<td>1(3.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Very poor</td>
<td>0(0.0)</td>
<td>0(0.0)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

S- Significant

### Table 5: Pain scores in the postoperative period

<table>
<thead>
<tr>
<th>Pain scores</th>
<th>Group P n=29 Mean±SD</th>
<th>Group S n=27 Mean±SD</th>
<th>P value</th>
<th>Level of significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>30mins</td>
<td>0</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1hr</td>
<td>0.31±0.89</td>
<td>2.41±2.06</td>
<td>0.001</td>
<td>S</td>
</tr>
<tr>
<td>2hr</td>
<td>2.00±1.98</td>
<td>3.96±2.71</td>
<td>0.001</td>
<td>S</td>
</tr>
<tr>
<td>3hr</td>
<td>2.83±1.83</td>
<td>4.81±2.09</td>
<td>0.001</td>
<td>S</td>
</tr>
<tr>
<td>4hrs</td>
<td>3.76±1.70</td>
<td>5.85±1.43</td>
<td>0.001</td>
<td>S</td>
</tr>
<tr>
<td>5hr</td>
<td>3.90±1.57</td>
<td>6.07±1.71</td>
<td>0.001</td>
<td>S</td>
</tr>
<tr>
<td>6hr</td>
<td>3.45±1.92</td>
<td>4.15±1.61</td>
<td>0.147</td>
<td>NS</td>
</tr>
<tr>
<td>12hrs</td>
<td>2.45±2.29</td>
<td>3.00±2.06</td>
<td>0.349</td>
<td>NS</td>
</tr>
<tr>
<td>24hrs</td>
<td>1.17±0.89</td>
<td>1.89±1.19</td>
<td>0.130</td>
<td>NS</td>
</tr>
</tbody>
</table>

NS- not significant
S - Significant
SBP - Systolic blood pressure.
DBP - Diastolic blood pressure.
MAP - Mean arterial blood pressure.
P - Paracetamol group
S - Saline group.

Figure I: Intraoperative variations in Systolic, diastolic and mean arterial blood pressures of the patients.

bpm - Beats per minute
PR - Pulse rate
P - paracetamol group
S - saline group

Figure II: Intraoperative trend of the Pulse rates of the patients
This study showed that a combination of infusion paracetamol and rectal diclofenac provided effective analgesia for post myomectomy pain as evidenced by prolongation of the time to first request for analgesia. It also demonstrated a reduction in the postoperative pain scores at different time points and on request for analgesia with subsequent reduction in the total amount of analgesics consumed. These findings showed the distinct advantages of infusion paracetamol in reducing postoperative pain following myomectomy with acceptable side effect profile.

The prolongation of post-operative analgesia following intrathecal administration of a combination of local anaesthetic and opioid was similar to findings in the literature. In a study by Imarengiaye et al\textsuperscript{4} pethidine 10mg was combined with bupivacaine 10mg for the induction of spinal anaesthesia for caesarean section. It was found that the time from intrathecal injection to first request for analgesia was 256 minutes. The longer duration of analgesia observed in the current study of 319 minutes could be attributed to the administration of a combination of rectal diclofenac and infusion paracetamol at the end of surgery and a higher dose of bupivacaine of 15mg used in the current study. The prolongation of postoperative analgesia achieved with this combination had shown again the benefits of multimodal analgesia. The reduction in the incidence of side effects is due to the lower doses of analgesics used.\textsuperscript{8} The rectal route offered a local effect in the pelvic region while the intravenous infusion paracetamol offered a stable state of analgesia as peak plasma concentration is obtained from the infusion within 15minutes.\textsuperscript{9} The time to first request observed by Yu and co workers\textsuperscript{10} using 10mg of pethidine and 10mg of bupivacaine for caesarean section was 234 minutes in the pethidine group as against 319 minutes in the current study. Although same dose of pethidine was added to bupivacaine, the difference in the outcome may be due to the higher dose of bupivacaine (15mg) used in the current study as against 10mg bupivacaine used in their study. Also, rectal diclofenac and infusion paracetamol were used at the end of the current study whereas their study did not utilize additional analgesics. This study also demonstrated a reduction in the pain scores at different time points and on request for analgesia. Pain scores ranged between 2.41 - 4.81 (NRS) in the first 3 hours postoperatively. Pain scores were noted

**Figure III: Pain scores (NRS) after study drug administration**
to be highest at the 4th, 5th and 6th hours after the administration of the study medications. This may be as a result of the local anaesthetic wearing off and consequent block regression. It may also be explained by the duration of action of the paracetamol/diclofenac combination of 4-6hrs. Supplemental analgesics were then commenced resulting in the reduction of pain scores thereafter. This combination reduced pain scores and analgesic demand and this was consistent with findings in the literature. A systematic review also noted the benefits of paracetamol/NSAID combination in reducing pain scores compared to each drug alone. Pain scores were also noted to be reduced in women who underwent caesarean section when infusion paracetamol 100mg (Perfalgan) was administered at skin closure. Indeed, the authors noted that the benefits of paracetamol outweighed the benefit of intravenous meperidine. Pain scores in the paracetamol group was 4 and 5 in the 2nd and 4th hour in their study, while lower scores of 2 and 3.7 were observed in the current study at this same time. While they used paracetamol as a sole analgesic agent in their study, which may not be appropriate for myomectomy, paracetamol was combined with rectal diclofenac in the current study with subsequent lower pain scores. Findings in the index study showed a reduction in the total amount of pentazocine consumed in the post-operative period. This observation was comparable to findings by Memis where paracetamol was infused in patients who had major abdominal or pelvic procedures under general anaesthesia 6hrly post operatively. It was found that morphine consumption via PCA was lower in the paracetamol group compared to those who had a placebo. Though surgery was done under general anesthesia, lower analgesic consumption may have been observed with regional techniques as it confers postoperative analgesia as seen in the index study. Montgomery and Kwan in two separate studies also noted morphine sparing effects of both combinations of diclofenac and paracetamol. Multimodal combinations has less potential for rescue analgesics compared to monotherapy. In contrast to the findings in this study, Siddik and colleagues could not demonstrate any significant reduction in analgesic consumption following diclofenac and propacetamol 2g which is equivalent to 1g paracetamol used in the current study. This difference may be as a result of the higher doses of bupivacaine and pethidine used in the current study compared to theirs. The burden of pain management is further exaggerated by the recent increase in the number of myomectomies performed in our centre following the introduction of the invitro fertilization programme. The commonest indications for myomectomy in the study under review was menorrhagia and infertility and these indications were similar to an earlier study in our centre where a majority of patients had myomectomy on account of infertility and menstrual irregularities. Indeed, these were also the indications in a study done in a larger scale in South Western Nigeria. Open myomectomies causes more tissue trauma compared to laparoscopic myomectomy and therefore severe postoperative pain. At present the mainstay for management of post myomectomy pain in our centre is intramuscular pentazocine given every 4 – 6hrs for the first 48hours. Intramuscular tramadol and rectal diclofenac are sometimes prescribed by the surgeons. Intramuscular pentazocine had also been shown to be ineffective in the management of post caesarean section pain which is a less painful surgery compared to myomectomy in a study done in our centre by Edomwonyi et al. In another study in our centre, a combination of paracetamol infusion (Perfalgan)± and intramuscular diclofenac was compared to pethidine for post caesarean section pain management by Edomwonyi et al The study demonstrated superior analgesic efficacy of the combination group compared to the pethidine group as evidenced by low VAS scores of less than 3, longer time to first analgesic request, reduced incidence of side effects and better patients’ satisfaction. Opioids are associated with unwanted side effects and limited availability. The rectal route was the preferred site in the studies by Colbert and Carrol. It was established that a good proportion of persons with preference for the intramuscular route will switch preference to the rectal route when the possibility of pain or discomfort is explained to them. Again, rectal insertion was done at the time when routine cleaning and assessment of the vagina for evidence of bleeding was done at the end of surgery and these
were both convenient for the patient and the caregiver. Although we did not assess acceptance of rectal route from the patients in the index study, a high level of acceptance has been previously reported among women in the childbearing age.26

Patients’ satisfaction which is determined by the quality of analgesia was overt in this study. A good number of patients in the paracetamol group rated their satisfaction as either excellent or very good compared with the saline group and this attained statistical significance.

Intraoperative complications which occurred included spinal hypotension and bradycardia accounting for 12.5%. Spinal induced hypotension is the commonest complication following SAB.27 In the current study, hypotension was managed with bolus administration of intravenous fluids and or 3mg aliquots of ephedrine with good response in all the cases.

Nausea and vomiting and shivering were the second and third most common intraoperative complications observed in this study. Spinal opioids can contribute to the incidence of nausea and vomiting and this usually occurs in a dose dependent fashion. Pruritus, shivering and sedation were also noted in the intraoperative period.

The side effects that were observed in the post-operative period were nausea, vomiting, and sedation. Paracetamol has very low incidence of nausea and vomiting and this may be attributed to the intrathecal opioids used.28,29 Repeated doses had also been shown to increase side effects. Hepatotoxicity following paracetamol was not assessed in this study as it was unexpected following a single dose of 1g. Again, patients with liver disease were excluded as paracetamol is known to worsen such conditions.29

**Conclusion**

The study showed that a combination of rectal diclofenac and infusion paracetamol was effective in prolonging post-operative analgesia following myomectomy with minimal side effect profile. Employing such a regime may therefore be invaluable in the management of post myomectomy pain.

**References:**


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