Summary

Background: Effective control of immediate post operative abdominal pain following laparoscopic sterilization is challenging. The objective of the study was to estimate the incidence of immediate severe postoperative pain following laparoscopic sterilization under general anaesthesia by the proportion of patients with the pain assessed on a numerical rating scale. Methods: A cross sectional study was conducted with the approval of institutional review board and ethics committee. Fifty seven participants with written informed consent underwent the study over a period of six months. Pain was assessed by a trained recovery nurse and data was collected and analyzed. The main outcome measure was immediate severe post operative pain on numerical rating scale (NRS). Results: Among the 57 participants, 14 (24.6%) had immediate severe post operative pain with median score of five in the inter quartile range of 0 to 5.75 and 43 (75.4%) participants had no severe pain. Conclusion: The incidence of immediate severe postoperative abdominal pain after laparoscopic sterilization under general anaesthesia is high. Therefore, the management of pain following laparoscopic sterilization requires individually based multimodal analgesia.

Key words: Acute pain; laparoscopic sterilization; analgesics

Introduction

Minimally invasive surgical techniques and multimodal analgesia has made laparoscopic sterilization a popular method among western population, where the incidence of severe post operative pain is 18%1. Use of standard pain rating scales has improved the quality of assessment of post operative pain2. In laparoscopic sterilization the postoperative pain is disproportionately severe to the surgical trauma. Hence, pain management requires an individualized approach dependent on various perioperative factors3.

Aim of the study was to assess the proportion of patients with immediate severe postoperative abdominal pain in laparoscopic sterilization under general anesthesia. The objective was to measure the postoperative abdominal pain in laparoscopic sterilization under general anesthesia, on a numerical rating scale, within thirty minutes of completion of surgery, while the participant is in the post anaesthesia care unit.

Methods

This was a cross-sectional study, over a period of six months from January 2016 to June 2016 conducted in the post anaesthesia care unit as per the Helsinki declaration. The study was conducted after approval from the institutional review board and ethics committee. Written informed consent was obtained from all participants. No personal data of participants were collected. No funding was received for this study. The trial was retrospectively registered under Clinical Trials Registry India with registration number CTRI/2017/10/010277 dated 31/10/2017.

Study participants were women who underwent laparoscopic sterilization using rings under general anaesthesia. Inclusion criteria for the study were

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women in the age group of 24 to 40 years with American Society of Anaesthesiologists grading of Physical status I, II with written informed consent for the procedure and received a standard analgesic regime (Table 1). Patients who were ignorant about numerical pain rating scale, having drug allergy on medications used in the study, having other procedures along with sterilization (dilatation and curettage, cauterisation of cervix), and those who had laparoscopic sterilization by curettage or clips were excluded. Additionally, enrolled participants, who received adjuvants such as ketamine, dexamethomidine and/or magnesium sulphate in addition to the standard analgesic regime, were excluded. The proportion of participants with immediate severe postoperative pain was evaluated using numerical rating scale. Numerical rating scale is a method by which user can rate the pain in eleven points ranging from zero to ten from no pain to maximum sufferable pain she can imagine or has suffered4.

The study design was presented to all the eight qualified anaesthesiologists in the department so that they were made aware of the non-interventional nature of the study and the need for intensive perioperative pain management on a case by case basis. During the preanaesthetic check up, the participants were briefed about the study and informed consent was taken. The numerical rating scale for evaluation of pain was explained to the participants. The recovery nurse, who assessed the postoperative pain, was trained in pain assessment using numerical rating scale. She was blinded to the details of surgery and anaesthesia.

For attaining a precision of 10 % with confidence interval of 95% and proportion of cases with pain in previous study of 0.18, the sample size selected was fifty seven. The n Master software of Christian Medical college, Vellore was used for estimating sample size5. Based on the sample size calculated, seventy participants were enrolled. Among them, thirteen were excluded. Ten participants received other analgesic adjuvants such as dexametomidine, ketamine and/or magnesium sulphate administered in addition to the standard analgesic regime during their perioperative management and hence excluded from the study. Technique of sterilization was by application of electro coagulation in two of the participants and third one had partial accidental fallopian tube excision on one side, and therefore was excluded from the study.

On arrival in the operation room all participants were monitored with non-invasive blood pressure, electrocardiogram and pulse oximeter. A 20 G intravenous cannula was inserted on dorsum of right hand and Ringer Lactate was started. On the morning of surgery, while on the ward all participants received alprazolam 0.25 mg and metoclopramide 10 mg orally. While on operation table participants were premedicated with intravenous midazolam 1 mg and glycopyrrolate 0.2 mg. After preoxygenation for three minutes, general anaesthesia was induced with intravenous propofol 2–2.5 mg/kg and atracurium 0.5 mg/kg. Trachea was then intubated with tracheal tube of size 7–7.5 mm internal diameter. Maintenance of anaesthesia was with oxygen, air and sevoflurane 2–3%. All participants received standard analgesic regime as given in Table 1. The anaesthetic technique comprised of intravenous

<table>
<thead>
<tr>
<th>Medication</th>
<th>Route of administration</th>
<th>Dosage</th>
<th>Timing of application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fentanyl citrate</td>
<td>intravenous</td>
<td>2–3 microgram/kg</td>
<td>Pre operative</td>
</tr>
<tr>
<td>Morphine sulfate</td>
<td>intravenous</td>
<td>0.1 mg/kg</td>
<td>Intraoperative</td>
</tr>
<tr>
<td>Dexamethasone</td>
<td>intravenous</td>
<td>0.1 mg/kg</td>
<td>Intraoperative</td>
</tr>
<tr>
<td>Paracetamol</td>
<td>intravenous</td>
<td>1 gm</td>
<td>Intraoperative</td>
</tr>
<tr>
<td>Diclofenac</td>
<td>suppository</td>
<td>100 mg</td>
<td>Intraoperative</td>
</tr>
<tr>
<td>Ropivacaine 0.2%</td>
<td>intraperitoneal</td>
<td>20 ml</td>
<td>Intraoperatively by surgeon</td>
</tr>
<tr>
<td>Fentanyl citrate</td>
<td>intravenous</td>
<td>1–2 microgram/kg</td>
<td>Rescue analgesic</td>
</tr>
</tbody>
</table>
propofol, opioids like fentanyl, morphine, analgesics in the form of intravenous paracetamol 1 g and diclofenac suppository 100 mg and non-depolarizing neuromuscular blocker, atracurium.

On completion of surgery, all participants received intravenous ondansetron 0.1 mg/kg and neuromuscular blockade was reversed with intravenous neostigmine 0.05 mg/kg and glycopyrolate 0.02 mg/kg. After tracheal extubation patients were discharged to post anaesthesia care unit. The participants were assessed for pain using numerical rating scale by the trained nurse, on arrival to the post anaesthesia care unit and 1 hour later. On awakening to call, the participant was suggested to rate her pain. Her response was noted and recorded. If she was not able to accurately report the numerical value, her verbal response was noted and equated as per the verbal rating scale (no pain, mild to moderate pain or severe pain. If the pain score was more than 4/10, intravenous fentanyl one to two mcg/kg was administered as rescue analgesic, as per the recovery room protocol.

Patient characteristics and type of oral premedication received was recorded from the pre anaesthetic notes. Perioperative data were collected from anaesthesia chart. Participants who had reported pain of five or more on a numerical rating scale were noted. This was considered as severe pain.

**Results**

All the study participants were comparable with regard to patient demographics including educational status, employment and period past from child birth as given in Table 2.

**Table 2: Patient demographics**

<table>
<thead>
<tr>
<th>Patient Variable</th>
<th>Mean (SD)</th>
<th>p value</th>
</tr>
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<tbody>
<tr>
<td>Age</td>
<td>31.21 (4.0)</td>
<td>0.479</td>
</tr>
<tr>
<td>BMI</td>
<td>24.48 (3.78)</td>
<td>0.98</td>
</tr>
</tbody>
</table>

The p value of the demographic variables on comparing the two groups.

While assessing the immediate severe postoperative abdominal pain of the 57 participants, 14 (24.6%) were found to have severe pain and the rest 43 (75.4%) had no severe pain as explained in Table 3.

**Discussion**

Table 3: Proportion of patients with severe pain rated on numerical rating scale

<table>
<thead>
<tr>
<th>Pain score (numerical rating scale)</th>
<th>Number of participants with severe pain (numerical rating scale ≥ 5)</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>9</td>
<td>39.1</td>
</tr>
<tr>
<td>6</td>
<td>3</td>
<td>13.0</td>
</tr>
<tr>
<td>7</td>
<td>8</td>
<td>34.8</td>
</tr>
<tr>
<td>8</td>
<td>2</td>
<td>8.7</td>
</tr>
<tr>
<td>10</td>
<td>1</td>
<td>4.3</td>
</tr>
</tbody>
</table>

The components of pain in laparoscopic abdominal surgery are somatic pain (incisional pain), visceral pain and shoulder pain. In female laparoscopic sterilization using Fallopian rings, visceral pain being the maximum due to ischemia or vasospasm of the fallopian tubes is out of proportion to the minimally invasive surgical intervention. Therefore, a procedure specific multimodal individualized approach in the preoperative and intraoperative period is an essential prerequisite for the effective prevention and control of pain in day case. Hence this study was undertaken in the post anaesthesia care unit for estimating the incidence of immediate severe postoperative abdominal pain in laparoscopic sterilization under general anaesthesia with a standard anaesthetic technique.

In a review on postoperative pain on gynaecological laparoscopy, authors concluded that multimodal analgesia based on drug availability, social,
genetic and racial differences, regular pain scoring and encouraging patients to ask for analgesia, are the essential principles of pain management. Unlike the study by Ekstein et al, cut off for severe pain was taken as 5/10 on numerical rating scale. Participants reporting pain score of five or more were given rescue analgesic. As none of the study participants expressed their pain in the verbal rating scale like mild, moderate or severe on first instance, those with pain score up to four were assumed to have controllable pain.

A randomized controlled study found that patients after laparoscopic sterilization had significantly higher pain scores at one hour postoperatively, and at discharge, than patients after diagnostic laparoscopy. There are several studies referring to the onset of maximum intensity pain between zero to four hours and at one hour following laparoscopy. Tool et al had observed that local anaesthetic applied to the Fallopian tube had significant effect thirty minutes after the application of the local anaesthetic. Based on the above studies, for uniformity, we had reckoned thirty minutes as the maximum duration at the end of which the assessment of pain was conducted. In this study, the pain was assessed by a nurse trained in using numerical rating scale in the post anaesthesia care unit. All patients were able to communicate well within this period and no patient was excluded for delay due to sedation. Claxton et al found that, when equipotent doses of fentanyl and morphine are given during day care surgery, pain scores are higher with fentanyl group when patients are assessed in the ambulatory surgery unit.

The predictive factors of severe postoperative pain in postanaesthesia care unit are long duration of surgery and anesthesia and independent risk factors including higher intraoperative dose of sufentanil, general anesthesia, and preoperative treatment with analgesics. In our study, the duration of surgery was less than thirty minutes for all the cases. Rudin et al found that pre-surgical pain and heat pain sensitivity are important indicators of postoperative pain intensity while psychological factors like vulnerability and anxiety seem to contribute to a lesser degree after laparoscopic tubal ligation.

Intravenous tramadol at 1.5 mg kg compared with ketorolac is effective for postoperative pain control in day care laparoscopic sterilization. Diclofenac does not provide pre-emptive analgesia in patients undergoing laparoscopic tubal ligation. A randomized double blind controlled trial using intravenous glycopyrrolate 0.3 mg as premedication found significant reduction of immediate severe postoperative pain in laparoscopic sterilization with Filshie clips under general anaesthesia. This may be because laparoscopic visceral pain is maximum with application of Fallope rings when compared to Filshie clips.

Using the ProSeal laryngeal mask for airway management, compared with the tracheal tube on postoperative analgesia requirements following gynecological laparoscopic surgery, has found that early postoperative pain is lower for the ProSeal LMA group than the tracheal tube group. In our study, airway was secured using tracheal tube in all the participants.

All the participants in our study had intraperitoneal instillation of local anaesthetic, 20 mls of 0.2% ropivacaine Bupivacaine infiltration of the mesosalpinx in ambulatory surgical laparoscopic tubal sterilization using rings has significantly reduced post operative pain. Kaplan et al, claim their data support the value of topical bupivacaine applied to the serosal surface of the fallopian tubes for the reduction of immediate postoperative pain after outpatient laparoscopic mechanical (band or clip) tubal ligation. A randomized, parallel double blind trial found that topical application of bupivacaine on the fallopian tube is an easy and effective method of management of immediate post-operative pain in day care laparoscopic sterilization. Rohel et al had found that lipophilic bupivacaine when injected at surgical site gives longer pain relief when more fat is present. A randomized double blind study found that prophylactic intraperitoneal instillation of 10 ml of 0.5% bupivacaine significantly improve postoperative pain in the first hour of assessment but no difference was noted 24 hours after laparoscopic gynecological surgery. A randomised controlled study found that instillation of bupivacaine at the port sites in laparoscopic cholecystectomy irrespective of the timing of instillation is an effective method of achieving pain control in the post-operative period as long as 24 hours after surgery. Combined intraperitoneal instillation and periportal infiltration of bupivacaine reduced postoperative pain after laparoscopic...
cholecystectomy better than intraperitoneal instillation or periportal infiltration of bupivacaine alone. Intraperitoneal local anaesthetic is a simple and proven method of analgesia in day case laparoscopic surgery with the morphine sparing effect. Tobias et al. stated that optimal combination of medications to provide postoperative analgesia, as well as the potential role for regional anesthetic techniques in laparoscopic surgery is yet to be formulated.

Our study has limitations. Even though preoperative anxiety is a definite risk factor for severe pain postoperatively, history of anxiety was elicited in the pre-anaesthetic clinic without using any standardized anxiety questionnaire. A visual analogue scale was not used for assessing anxiety which could have affected the assessment of the pain postoperatively. Since participants receiving adjuvants like ketamine, dexmedetomidine and/or magnesium sulphate were excluded, the sample may not be representative.

Immediate severe postoperative abdominal pain after laparoscopic sterilization under general anesthesia is disproportionately high (24.6%). This needs early effective prevention and treatment for better patient satisfaction and popularity of the surgical procedure (Table 4). Therefore, multimodal analgesia with perioperative opioids titration preventive use of ketamine, local anesthetic instillation intra-peritoneally and infiltration at trocar site, adjuvants like dexmedetomidine, magnesium sulphate and judicious use of anti-inflammatory agents like diclofenac and dexamethasone are mandatory on an individual basis. Management of preoperative anxiety and stress response during induction of anaesthesia and surgery has a definite role to reduce the intensity of pain.

**Acknowledgements**

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**References**


**Table 4: Highlights of the study**

<table>
<thead>
<tr>
<th>Immediate severe postoperative abdominal pain after laparoscopic sterilization under general anesthesia is disproportionately high</th>
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<tbody>
<tr>
<td>Early effective prevention and treatment for better patient satisfaction</td>
</tr>
<tr>
<td>Titrated use of narcotics, preventive ketamine, local anesthetic instillation and adjuvants are necessary</td>
</tr>
<tr>
<td>Analgesic titration should be done on a case by case basis</td>
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<tr>
<td>Management of preoperative anxiety and stress response has a definite role in reducing intensity of pain</td>
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