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Study on drugs used in post operative management in surgery

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ABSTRACT

Previous studies on post-operative pain document that most patients continue to experience pain after surgery. This study was done to record the drug use for post-operative pain in laparotomy and to determine the patient characteristics that affect their pain score. A prospective observational study in 64 adult patients undergoing laparotomy surgery from General Surgery and Obstetrics and Gynaecology (OBG) at a tertiary care hospital. Among patients recruited, 161 (64.4%) were females, 134 (53.6 %) from surgery department, mean age 37.29 ± 14.9 years. Caesarean section 64 (73.27%) followed by meshplasty 34.3% were most common. Parenteral tramadol 100mg (40%) was the most common analgesic post-operative, subsequently shifted to oral. Epidural analgesia used in 12.4% patients, only from surgery department. First analgesic received within 6 hrs in 55.5 % in surgery and 44.5 % in OBG (Pearson $\chi^2 = 2.535$, $p = 0.111$) with mean time to first analgesic 2.85 ± 2.33 hrs. Pain score, using Numerical Rating Scale (NRS) recorded for 80% patients showed 30.4% had severe pain on day 1 which decreased to 12 (4.8%) on day 3. Speciality ($p=0.01$) and nature of surgery ($p=0.05$) were significantly associated with severity of pain. Gender [OR = 0.55 (95% CI = 0.26, 1.19), $p=0.13$], nature of surgery [2.32 (1.02, 5.32), $p=0.05$], speciality [0.35 (0.15, 0.80), $p=0.01$] and surgical category [0.76 (1.01, 5.32), $p=0.05$] affected pain score on univariate logistic regression, but were not significant on multivariate analysis. Despite the use of opioids and combination analgesics, one third of patients reported severe pain on the first day after surgery.

Keywords: Analgesics, Laparotomy, Numerical rating scale

INTRODUCTION

Laparoscopy invented by George Kelling in 1901, in Germany, is an operation performed in the abdomen or pelvis using small incisions (usually 0.5–1.5 cm) with the aid of a camera. The laparoscope aids diagnosis or therapeutic interventions with a few small cuts in the abdomen.[1]

Laparoscopic surgery, also called minimally invasive surgery (MIS), banded surgery, or keyhole surgery, is a modern surgical technique. There are a number of advantages to the patient with laparoscopic surgery versus the more common, open procedure. These include reduced pain due to smaller incisions, reduced hemorrhaging and shorter recovery time. The key

element is the use of a laparoscope, a long fiber optic cable system which allows viewing of the affected area by snaking the cable from a more distant, but more easily accessible location.

Keyhole surgery is a type of surgery in which the surgeon uses only small cuts to get through the skin. It requires special training. People who have keyhole surgery usually recover quite quickly.

Laparoscopy is keyhole surgery used to examine or operate on the interior of the abdominal or pelvic cavities. It is performed under general anaesthesia, usually by a surgeon or gynaecologist (women's health specialist).

During laparoscopy (also known as peritoneoscopy), a small cut is made in the abdomen. A thin tube containing a light and camera, known as a laparoscope, is then inserted to look inside the abdomen and pelvis. Gas is used to inflate the belly so the surgeon can see the organs properly.

One or more other small incisions may be made for other small instruments if needed. Laparoscopic surgery includes operations within the abdominal or pelvic cavities, whereas keyhole surgery performed on the thoracic or chest cavity is called thoracoscopic surgery. Specific surgical instruments used in a laparoscopic surgery include forceps, scissors, probes, dissectors, hooks, and retractors. Laparoscopic and thoracoscopic surgery belong to the broader field of endoscopy.

Laparoscopy, also known as diagnostic laparoscopy, is a surgical diagnostic procedure used to examine the organs inside the abdomen. It's a low-risk, minimally invasive procedure that requires only small incisions.

Laparoscopy uses an instrument called a laparoscope to look at the abdominal organs. A laparoscope is a long, thin tube with a high-intensity light and a high-resolution camera at the front. The instrument is inserted through an incision in the abdominal wall. As it moves along, the camera sends images to a video monitor.

Laparoscopy allows your doctor to see inside your body in real time, without open surgery. Your doctor also can obtain biopsy samples during this procedure.

Laparoscopy is often used to identify and diagnose the source of pelvic or abdominal pain. It's usually performed when noninvasive methods are unable to help with diagnosis.

As well, your doctor may be able to perform an intervention to treat your condition immediately after diagnosis.

Laparoscopy is a type of surgery that uses smaller cuts than you might expect.

The process takes its name from the laparoscope, a slender tool that has a tiny video camera and light on the end. When a surgeon inserts it through a small cut and into your body, they can look at a video monitor and see what's happening. Without those tools, they'd have to make a much larger opening. Thanks to special instruments, your surgeon won't have to reach into your body, either. That also means less cutting.

Have you heard people talk about "minimally invasive" surgery? Laparoscopic surgery is one kind. Doctors first used it for gallbladder surgery and gynecology operations. Then it came in play for the intestines, liver, and other organs. Before this system came along, a surgeon who operated on his patient's belly had to make a cut that was 6-to-12 inches long. That gave them enough room to see what they were doing and reach whatever they had to work on. In laparoscopic surgery, the surgeon makes several small cuts. Usually, each one is no more than a half-inch long. (That's why it's sometimes called keyhole surgery.) They insert a tube through each opening, and the camera and surgical instruments go through those. Then the surgeon does the operation.

The mechanism mentioned in the second type is mainly used to improve the image quality of flexible endoscopes, replacing traditional fiberscopes. Nevertheless, laparoscopes are rigid endoscopes. The rigidity is required in clinical practice. The rod-lens based laparoscopes dominate overwhelmingly in practice, due to their fine optical resolution (50 μm typically, dependant on the aperture size used in the objective lens), and the image quality can be better than that of the digital camera if necessary. The second type of laparoscope is very rare in the laparoscope market and in hospitals.

Also attached is a fiber optic cable system connected to a "cold" light source (halogen or xenon), to illuminate the operative field, which is inserted through a 5 mm or 10 mm cannula or trocar.

The abdomen is usually insufflated with carbon dioxide gas. This elevates the abdominal wall above the internal organs to create a working and viewing space. CO₂ is used because it is common to the human

body and can be absorbed by tissue and removed by the respiratory system. It is also non-flammable, which is important because electrosurgical devices are commonly used in laparoscopic procedures.[3]

Laparoscopic cholecystectomy is the most common laparoscopic procedure performed. In this procedure, 5–10 mm diameter instruments (graspers, scissors, clip applier) can be introduced by the surgeon into the abdomen through trocars (hollow tubes with a seal to keep the CO₂ from leaking). Over one million cholecystectomies are performed in the U.S. annually, with over 96% of those being performed laparoscopically.

AIM AND OBJECTIVES

Aim

This study was done to record the drug use for post-operative pain in laparotomy and to determine the patient characteristics that affect their pain score.

Objective

- A prospective observational study in adult patients undergoing laparotomy surgery from General Surgery and Obstetrics and Gynaecology (OBG) at a tertiary care hospital
- The objective of this study was to record the pattern of drug use for post-operative pain and to determine the patient characteristics and analgesics used postoperatively

MATERIALS AND METHODS

Study Site:	Om sai Hospital
Study Population:	54 subjects
Study Duration:	Dec 2018- Mar 2019
Study Condition:	Post-operative management after Laparoscopic surgery
Study Type:	Observational study

Study Population

All patients were provided details about the study and methods and then a written informed consent was taken. This study was conducted by the Department of Pharmacology, in collaboration with Departments of General Surgery, Obstetrics and Gynaecology (OBG) in a 150 bed tertiary care hospital.

It is well equipped with modern diagnostic and treatment facilities. Patients visiting this hospital come from different geographic regions with fair representation of urban and rural population as well as socioeconomic strata. The present study was conducted for 4 months, from Dec 2018 to March 2019, in the in-patient wards of general surgery and OBG.

Inclusion Criteria

Included adult subjects, who had undergone a laparotomy and had a stay of at least one-day post operatively.

Exclusion criteria

Patients with cognitive impairment and patients who were critically ill or intubated were excluded.

STUDY DESIGN AND PROTOCOL

The present study was a prospective observational study. Author collected data on patient characteristics, surgery and anaesthesia details and the analgesics prescribed and recorded NRS score for pain up to 3 days after surgery. This data was collected on a structured case report form. Selection bias was minimized by approaching all consenting eligible patients.

Sample Size

A sample size of 64 patients fulfilling eligibility criteria was taken for the study. This is a convenient sample based on the number of surgeries performed per week

Statistical Analysis

Descriptive statistics were used to analyse patient characteristics (like age, gender, co-morbidities). Categorical variables (like NRS score, speciality, duration of surgery and anaesthesia) were expressed as frequencies and mean±Standard deviation was used for continuous variables (like age). Chi squared test was used to compare categorical variables. This manuscript adheres to the STROBE (EQUATOR) guidelines.

RESULTS AND DISCUSSION

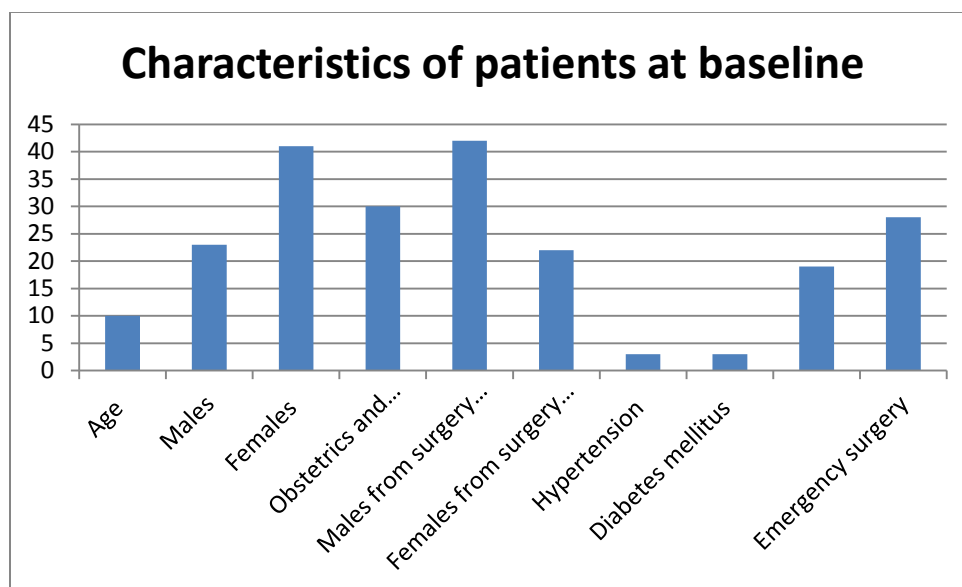
Among the 64 patients recruited 41 (64.4%) were females and 23 (35.6%) were males. Of the

recruited patients, 30(46.4%) were from the department of OBG and 30(53.6 %) were from general surgery, of which 22 (33.6%) were females. The mean age of recruited patients was 37.29 ± 14.99 years, 43.58 ± 16.40 years among males and 33.81 ± 12.94 years among females. Previous history of surgery was present in 19

patients (30.4%). In 28 (43.2%) patients, the surgery was indicated as an emergency and in 36 (56.8%) patients, was elective. Among the 64 patients, 3(4.8%) patients had diabetes, 3(4.8%) had hypertension and 2 (2.5%) had both diabetes and hypertension.

Table 1: Characteristics of patients at baseline

Characteristic	N = 64
Age [Mean \pm SD]	10 \pm 14.99
Males[n (%)]	23(35.6)
Females [n (%)]	41 (64.4)
Obstetrics and gynaecology [n (%)]	30 (46.4)
Males from surgery department [n (%)]	42 (66.4)
Females from surgery department [n (%)]	22 (33.6%)
Hypertension [n (%)]	3 (4.8)
Diabetes mellitus [n (%)]	3 (4.8)
Previous history of surgery [n (%)]	19 (30.4)
Emergency surgery [n (%)]	28 (43.2)



Graph 1: Characteristics of patients at baseline.

Surgery details

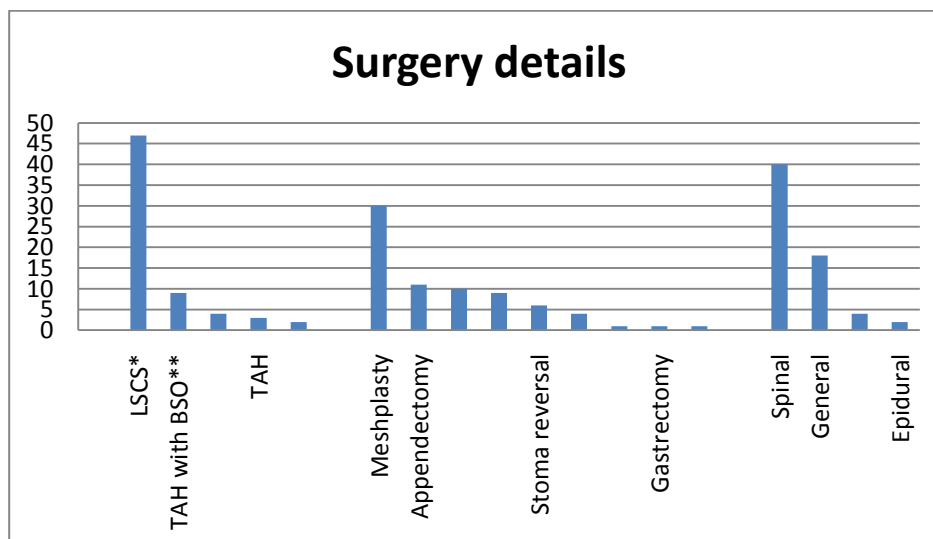
There were 14 types of surgeries that were recorded. Author categorised them into 3, based on duration and invasiveness. Number of surgeries that belonged to category 1 were 18 (28%), category 2 were 7 (11.2%) and category 3 were 39 (60.8%).

The most common surgical procedure performed was Caesarean section in 47 (73.27%)

followed by meshplasty in 22 (34.3%), appendectomy in 11 (17.91%), exploratory laparotomy for surgical indication in 10 (15.67 %) and total abdominal hysterectomy with bilateral salpingo-oophorectomy in 8 (12.93%) patients. Spinal anaesthesia was used in 39 (61.6%) and general anaesthesia in 18 (28.4%) patients. The mean duration of anaesthesia was 2.23 ± 1.21 hrs.

Table 2: Surgery details.

OBG characteristics	N = 30 (46.4)
LSCS*	47 (73.27)
TAH with BSO**	9 (12.93)
Exploratory laparotomy	4 (6.89)
TAH	3 (4.31)
Laparotomy with tubal resection	2(2.58)
General surgery characteristics	N = 34 (53.6)
Meshplasty	30 (34.3)
Appendectomy	11 (17.91)
Exploratory laparotomy for surgical indication	10 (15.67)
Laparotomy with intestinal resection	9 (14.17)
Stoma reversal	6 (8.95)
Open cholecystectomy	4 (5.97)
Whipple's procedure	1(1.49)
Gastrectomy	1 (1.49)
Open splenectomy	1 (1.49)
Anaesthesia characteristics	N = 64 (100%)
Spinal	40 (61.6)
General	18 (28.4)
General + epidural	4 (5.6)
Epidural	2 (3.2)

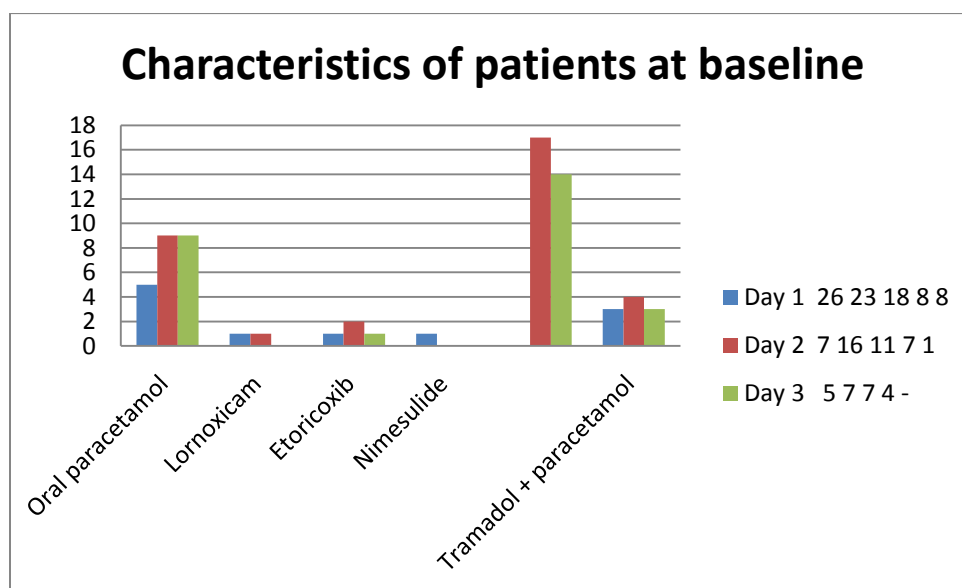
**Graph 2: Surgery details**

On the first day after surgery the most common analgesic prescribed was injected tramadol in 23 (40%) patients followed by injected pethidine in 23 (36.4%) and then parenteral paracetamol (acetaminophen), either injection or suppository in

18 (28.8%) patients. By the second day post-surgery, most patients were switched to oral analgesics, the most common being a combination of diclofenac and serratiopeptidase, 17 (27.2%) on day 2 and 13 (21.6%) on day 3.

Table 3: Analgesics used on post-operative day 1-3.

Drug	Day 1 (%)	Day 2 (%)	Day 3 (%)
Tramadol	26(40)	7 (11.6)	5 (7.6)
Pethidine	23 (36.4)	16(24.8)	7 (10.8)
Parenteral paracetamol	18 (28.8)	11 (16.8)	7 (11.2)
Diclofenac	8(13.2)	7(11.6)	4 (6)
Epidural	8 (12.4)	1 (2)	-
Oral paracetamol	5 (7.6)	9 (14.8)	9(13.6)
Lornoxicam	1(1.2)	1(0.8)	0 (0.4)
Etoricoxib	1(2)	2(2.4)	1(1.2)
Nimesulide	1 (0.8)	0(0.4)	0(0.4)
Diclofenac + serratiopeptidase	-	17 (27.2)	14 (21.6)
Tramadol + paracetamol	3 (4)	4 (6)	3(4.8)

**Graph 3: Analgesics used on post-operative day 1-3**

The 31 patients who were on injected pethidine on day 1 after surgery, were also on oral paracetamol.

The use of epidural analgesia was seen in 8 (12.4%) patients, all of whom were from surgery department. The combination of drugs used for epidural analgesia was bupivacaine with fentanyl. These patients were also on other drugs, most commonly injected tramadol [29, (45.16%)], pethidine [27, (41.93%)] and others [1, (1.6%)].

The use of opioids decreased from day 1 to day 3. On day 1, 49(76.8%) patients were on opioids and 13(20.8%) of them were also given non-steroidal anti-inflammatory drugs (NSAIDs). On day 2, 21 (32.8%) patients were on opioids alone and 7 (11.6%) were on opioids in combination with NSAIDs.

A 82.7% patients in surgery department and 17.3% in OBG department received 2 or more than 2 analgesics 24 hrs after surgery (Pearson $\chi^2 = 54.705$, $p = 0.000$).

The mean time to first analgesic after surgery was 2.85 ± 2.33 hours. Most patients received first analgesic in 1-3 hrs after surgery 18(28.8%). First analgesic was received <6 hrs after surgery among 55.5% in surgery and 44.5% in OBG department (Pearson $\chi^2 = 2.535$, $p = 0.111$). Patients who received first analgesic more than 6 hrs after surgery were 4 (6.8%) in number.

Numerical rating scale

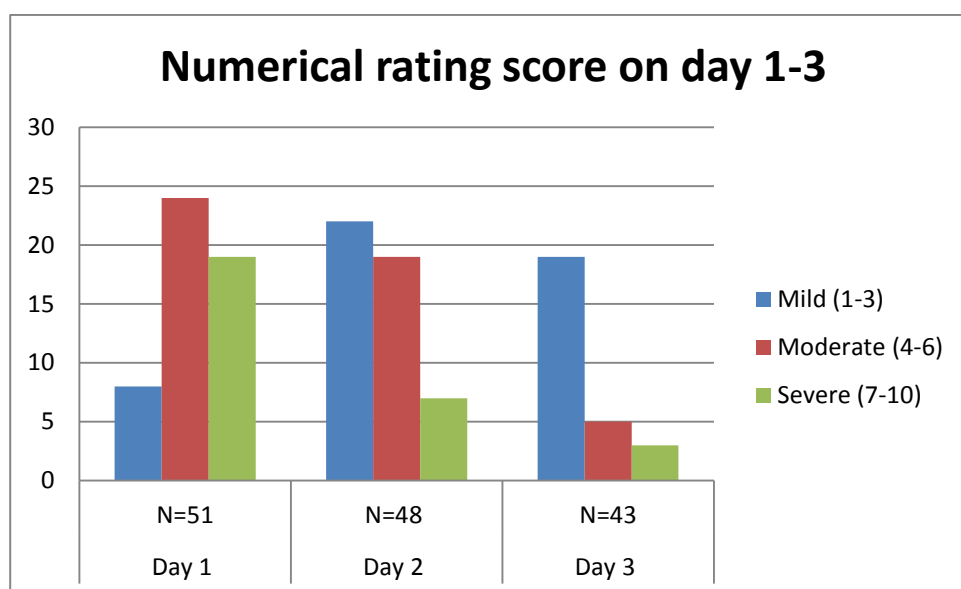
Of the 64 patients recruited in this study, NRS score was recorded for 51 (80%) patients on first day after surgery, 48 (75%) patients on day 2 and 43 (42.4%) on day 3. The mean NRS score on day one was 5.9 ± 2.29 , day 2 was 4.03 ± 2.08 and by day

3 was 2.84 ± 2.25 . Most patients with missing scores were discharged by the end of second post-operative day.

Severity of pain varied from day 1 to day 3, 19 (30.4%) had severe pain on day 1 which decreased to 3 (4.8%) on day 3. Mild pain was reported by 8 (12.8%) patients on day 1 and 19 (29.2%) by day 3.

Table 4: Numerical rating score on day 1-3

NRS Score	Day 1 N=51	Day 2 N=48	Day 3 N=43
Mild (1-3)	8 (12.8)	22(34.8)	19 (29.2)
Moderate (4-6)	24 (36.8)	19 (30.4)	5 (8.4)
Severe (7-10)	19(30.4)	7 (10.4)	3 (4.8)



Graph 4: Table 4: Numerical rating score on day 1-3

In the present study, author compared characteristics of patients who had mild pain with those who had moderate to severe pain. Author found more females with severe pain than males, but this difference was not significant. More patients from surgery department had moderate to severe pain compared to OBG and this difference was significant ($p=0.01$). More patients undergoing elective surgery had severe to moderate pain compared to emergency surgery ($p=0.042$).

Based on previous studies, author selected factors that are reported to be associated with post-operative pain and subjected them to univariate analysis. Author selected the following factors: age, gender, nature of surgery, department, category of surgery and drugs.

Strengths and limitations

To the best of present knowledge this is the first study of its kind in India to provide a

comprehensive overview of prescription patterns of analgesics in adults undergoing laparotomy surgery. From a single tertiary care centre, Author recruited 64 patients. In order to provide a uniform baseline for assessment, author included only those undergoing laparotomy surgeries.

This study has several limitations. First, it is a single centre study and results cannot be extrapolated to larger populations from different healthcare settings. Second, author was unable assess pain scores on all three days for all patients due to various reasons. Third, author included caesarean section in laparotomy surgeries in present study whereas most other studies did not include obstetric procedures. Last, the use of NRS score for measurement of pain has its inherent challenges. It does not take into consideration impact of pain on activity, sleep, negative emotions and non-pharmacological methods used. This scale

is however used by most other investigators to assess pain.

DISCUSSION

The mean age of patients in present study was median age being 32 years, with 161 (64.4) females and 89 (35.6%) males. This is lower than reported in most other studies. In a multicentre drug utilization study, done by Vallano et al, on management of post-operative pain after abdominal surgery in Spain, the median age was found to be 58 years (ranging from 14-91); 13% were older than 70 years and 547 (55%) were men.⁴ In a survey done on in-patients in Italian hospitals (ITOSPOP), to determine pain prevalence and predictors of pain, the mean age was 61.1 (20.9) years and ranged from 6 to 99 years.

The number of males in this survey were 422 (47.3%) and 470 (52.7%) females.⁵ The reason for lower mean age in present study may be that this is a single centre study with 46.4% of included patients being from OBG department who had a mean age of 29.4 years, and a median age of 27 years.

The surgical procedures found more common in the current study, among both departments were, LSCS (85, 34%), meshplasty (46, 18%), appendectomy (24, 9.6%), exploratory laparotomy for surgical indication (21, 8.4%) and total abdominal hysterectomy with bilateral salpingo-oophorectomy (15, 6%). While Vallano et al reported the more common surgical procedures as inguinal hernia repair (315 patients, 32%), cholecystectomy (268, 27%), appendectomy (140, 14%), bowel resection (137, 14%), and gastric surgery (58, 6%).⁴ This study did not include obstetric indications for laparotomy.

The most common analgesic used on the first day after surgery was injection tramadol (100, 40%). In contrast to present finding, the most common analgesic class used in ITOSPOP was NSAIDs (60.0%) and ketorolac was the The mean age of patients in present study was median age being 32 years, with 161 (64.4) females and 89 (35.6%) males.

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CONCLUSION

In conclusion, multimodal analgesia was used in most patients for management of post-operative pain. Despite the use of opioids and combination analgesics, nearly one third of patients reported severe pain on the first day after surgery. The use of newer modalities like epidural analgesia was limited and patient controlled analgesia was not used.

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