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Pattern of use of analgesics in post-operative pain management in adults undergoing laparotomy surgery: a prospective observational study

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ABSTRACT

Background: 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.

Methods: A prospective observational study in 250 adult patients undergoing laparotomy surgery from General Surgery and Obstetrics and Gynaecology (OBG) at a tertiary care hospital.

Results: Among patients recruited, 161 (64.4%) were females, 134 (53.6%) from surgery department, mean age 37.29 ± 14.9 years. Caesarean section 85 (73.27%) followed by meshplasty 46 (34.3%) were most common.

Parenteral tramadol 100mg (40%) was the most common analgesic post-operative, subsequently shifted to oral. Epidural analgesia used in 31 (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 200 (80%) patients showed 76 (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.

Conclusions: 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

Acute pain can be defined as a normal and time limited response to trauma or other "noxious" procedures including pain related to medical procedures and other medical conditions.¹ Post-surgical pain is initially of acute nature and may be nociceptive, inflammatory or neuropathic in nature. It is a common post-operative complication. Pain is not just an unpleasant sensation but

acute pain, if poorly treated, may progress to chronic pain leading to prolonged rehabilitation and recovery.² In addition to this, post-operative pain may induce wound haemorrhage, complicated hypertension, myocardial ischemia, and other post-operative related complications.³ Each symptom or complication that contributes to postoperative morbidity is likely to prolong the duration of hospital stay. Anaesthetic and analgesic techniques not only aim to provide suitable conditions for surgery, but

also to prevent postoperative complications and to decrease postoperative morbidity and mortality. Several drug utilization studies on analgesics have been done across Europe. These studies found that most patients still continued to experience pain after surgery despite the use of analgesics.

Author conducted a search on PubMed using search terms analgesia, analgesic, surgery, and laparotomy, post-operative and India over the last 20 years, and did not find a similar study published from any centre in India. To understand the current Indian scenario, author conducted an observational study among adult patients who had undergone laparotomy surgery and recorded the analgesics that were prescribed up to 3 days after surgery.

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 post-operatively that affect numerical rating scale (NRS) score on post-operative day 1.

METHODS

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 1350 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 14 months, from April 2014 to June 2015, in the in-patient wards of general surgery and OBG. Author included adult subjects, who had undergone a laparotomy and had a stay of at least one-day post operatively. 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 250 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

Patient characteristics

Table 1: Characteristics of patients at baseline.

Characteristic	N = 250
Age [Mean (SD)]	37.29 (14.99)
Females [n (%)]	161 (64.4)
Obstetrics and gynaecology [n (%)]	116 (46.4)
Females from surgery department [n (%)]	45 (33.6%)
Hypertension [n (%)]	12 (4.8)
Diabetes mellitus [n (%)]	12 (4.8)
Previous history of surgery [n (%)]	76 (30.4)
Emergency surgery [n (%)]	108 (43.2)

Among the 250 patients recruited 161 (64.4%) were females and 89 (35.6%) were males. Of the recruited patients, 116(46.4%) were from the department of OBG and 134 (53.6 %) were from general surgery, of which 45 (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 76 patients (30.4%). In 108 (43.2%) patients, the surgery was indicated as an emergency and in 142 (56.8%) patients, was elective. Among the 250 patients, 12 (4.8%) patients had diabetes, 12 (4.8%) had hypertension and 6 (2.5%) had both diabetes and hypertension.

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 70 (28%), category 2 were 28 (11.2%) and category 3 were 152 (60.8%).

The most common surgical procedure performed was Caesarean section in 85 (73.27%) followed by meshplasty in 46 (34.3%), appendectomy in 24 (17.91%), exploratory laparotomy for surgical indication in 21 (15.67 %) and total abdominal hysterectomy with bilateral salpingo-oophorectomy in 15 (12.93%) patients. Spinal anaesthesia was used in 154 (61.6%) and general anaesthesia in 71 (28.4%) patients. The mean duration of anaesthesia was 2.23 ± 1.21 hrs.

Table 2: Surgery details.

OBG characteristics	N = 116 (46.4 %)
LSCS*	85 (73.27)
TAH with BSO**	15 (12.93)
Exploratory laparotomy	8 (6.89)
TAH	5 (4.31)
Laparotomy with tubal resection	3 (2.58)
General surgery characteristics	N = 134 (53.6 %)
Meshplasty	46 (34.3)
Appendectomy	24 (17.91)
Exploratory laparotomy for surgical indication	21 (15.67)
Laparotomy with intestinal resection	19 (14.17)
Stoma reversal	12 (8.95)
Open cholecystectomy	8 (5.97)
Whipple's procedure	2 (1.49)
Gastrectomy	2 (1.49)
Open splenectomy	2 (1.49)
Anaesthesia characteristics	N = 250 (100%)
Spinal	154 (61.6)
General	71 (28.4)
General + epidural	14 (5.6)
Epidural	8 (3.2)

* lower segment caesarean section; ** total abdominal hysterectomy with bilateral salpingo-oophorectomy

Drug prescription pattern: analgesics

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

Drug	Day 1 (%)	Day 2 (%)	Day 3 (%)
Tramadol	100 (40)	29 (11.6)	19 (7.6)
Pethidine	91 (36.4)	62 (24.8)	27 (10.8)
Parenteral paracetamol	72 (28.8)	42 (16.8)	28 (11.2)
Diclofenac	33 (13.2)	29 (11.6)	15 (6)
Epidural	31 (12.4)	5 (2)	-
Oral paracetamol	19 (7.6)	37 (14.8)	34 (13.6)
Lornoxicam	3 (1.2)	2 (0.8)	1 (0.4)
Etoricoxib	5 (2)	6 (2.4)	3 (1.2)
Nimesulide	2 (0.8)	1 (0.4)	2 (0.4)
Diclofenac + serratiopeptidase	-	68 (27.2)	54 (21.6)
Tramadol + paracetamol	10 (4)	15 (6)	12 (4.8)

On the first day after surgery the most common analgesic prescribed was injected tramadol in 100 (40%) patients followed by injected pethidine in 91 (36.4%) and then parenteral paracetamol (acetaminophen), either injection or suppository in 72 (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, 68 (27.2%) on day 2 and 54 (21.6%) on day 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 31 (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 [14, (45.16%)], pethidine [13, (41.93%)] and others [4, (1.6%)].

The use of opioids decreased from day 1 to day 3. On day 1, 192 (76.8%) patients were on opioids and 52 (20.8%) of them were also given non-steroidal anti-inflammatory drugs (NSAIDs). On day 2, 82 (32.8%) patients were on opioids alone and 29 (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 72 (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 17 (6.8%) in number.

Numerical rating scale

Of the 250 patients recruited in this study, NRS score was recorded for 200 (80%) patients on first day after surgery, 189 (75%) patients on day 2 and 106 (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, 76 (30.4%) had severe pain on day 1 which decreased to 12 (4.8%) on day 3. Mild pain was reported by 32 (12.8%) patients on day 1 and 73 (29.2%) by day 3.

Table 4: Numerical rating score on day 1-3

NRS Score	Day 1 N=200	Day 2 N=189	Day 3 N=106
Mild (1-3)	32 (12.8)	87 (34.8)	73 (29.2)
Moderate (4-6)	92 (36.8)	76 (30.4)	21 (8.4)
Severe (7-10)	76 (30.4)	26 (10.4)	12 (4.8)

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 ($p=0.042$).

Table 5: Comparison of severity of pain on day 1 with patient characters.

Variable		Mild N = 32 (16 %)	Moderate and severe N=168 (84%)	P value
Gender	Male	15(21.4)	55 (78.6)	0.124
	Female	17(13.1)	113(86.9)	
Age**		36.52 (14.68)	38.28 (16.24)	0.543
Department	Surgery	23(22.5)	79 (77.5)	0.01
	OBG	9 (9.2)	89 (90.8)	
Nature of Surgery	Emergency	9 (10.1)	80 (89.9)	0.042
	Elective	23(20.7)	88 (79.3)	
Duration of anaesthesia**	In hours	2.4(1.46)	2.15(1.22)	0.329
Surgical category	Category I	11 (20)	44 (80)	0.288
	Category II	5 (23.8)	16 (76.2)	
	Category III	16(12.9)	108(87.1)	
Analgesic	Opioid	24 (16)	126 (84)	1.000
	Non-opioid	8 (16)	42(84)	

* Chi squared test for categorical variables and Student's t-test for continuous variables; ** Mean±SD

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.

Author found that factors that significantly affected pain score were gender [Odd's Ratio=0.55 (95% CI - 0.25, 1.18), $p=0.13$], nature of surgery [2.32 (1.01, 5.31), $p=0.04$], department [0.34(0.15, 0.79), $p=0.01$] and surgical category [0.75 (1.02, 5.32), $p=0.04$]. On multivariate analysis however, none of them were found to be significant.

Table 6: Factors affecting severe and moderate pain on day 1 post-surgery.

Variable	OR	95 % CI	P value
Older age	1.008	0.983-1.033	0.541
Gender: female	0.552	0.257-1.186	0.128
Surgery department	0.347	0.152-0.795	0.012
Nature of surgery: emergency	2.32	1.015-5.317	0.046
Longer duration of anesthesia	1.154	0.877-1.518	0.307
Category of surgery	0.759	0.503-1.145	0.189
Opioid-analgesic	1	0.418-2.394	1.000

p <0.2 considered significant; * univariate logistic regression was done

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 250 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 inpatients 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

most common analgesic used.⁵ Vallano et al reported metamizole (68%) as the most common analgesic used.⁴ Metamizole is not approved for use in India. Author also followed up patients for 3 days post-surgery and found that most patients were changed to oral NSAIDs like diclofenac and paracetamol on post-operative days 2 and 3.

When the patients were changed to oral analgesics on the second day after surgery, the most commonly prescribed was a fixed dose combination of diclofenac and serratiopeptidase (68,27.2%) on day 2 and 54 (21.6%) on day 3. Shivani Bhagat et al, conducted a systematic review on the evidence available for the use of serratiopeptidase.⁶ They reviewed a total of 9 RCTs and concluded that the existing scientific evidence for serratiopeptidase is insufficient to support its use as an analgesic or health supplement. The data on long-term safety of this enzyme is lacking. The Bandolier online edition (2011) on evidence based healthcare found that while there were 9 RCTs on the efficacy of serratiopeptidase, these were small, outcomes were poorly defined, and in a few of them, different medical conditions were mixed.⁷

Since caesarean section was overall the most common surgery in present study, the analgesic prescribed for post-operative pain relief was paracetamol. The use of epidural analgesic however was nil in obstetrics and gynaecology and its use was seen only in surgery department [31 patients (12.4%)]. Ulrike et al, in their study done in Germany on 446 hospitals, to study the prevalence of acute pain services, found that epidural analgesia (EA) was present in nearly all departments (96.9%) and 75.6% of the departments performed EA on general wards.⁷ In present study, patients who were on epidural analgesics received refills of analgesics by the anaesthetist on call whereas Germany adopted the use of acute pain services (APS). Phua et al, in their study on APS in Singapore found that the most commonly used modality of analgesia by their APS was patient controlled analgesia (PCA). This trend was seen in 2004-07 while the earlier trend in 1998-2003 saw the use of neuraxial blockade.⁸ This change in trend is attributed to increased proliferation and availability of PCA pumps in recent years.

The PROSPECT (Procedure specific postoperative pain management) study recommends analgesia based on pain intensity.⁹ They recommend the following after herniorrhaphy: Conventional NSAIDs (grade A) or COX-2 selective inhibitors, paracetamol in combination with conventional NSAIDs/COX-2 selective inhibitors for routine pain therapy. Weak opioids recommended for moderate-intensity pain, when conventional NSAIDs/COX-2 selective inhibitors plus paracetamol are not sufficient or are contraindicated. Strong opioids are recommended only as rescue analgesia for high-intensity pain in addition to non-opioid analgesia. For Caesarean section, recommendations for use after transverse

incision are oral paracetamol with oral NSAID and a systemic opioid as rescue. For total abdominal hysterectomy, they recommend COX-2 selective inhibitors or conventional NSAIDs, in combination with strong opioids for high-intensity pain (VAS>50mm) or with weak opioids for moderate - (VAS<50>30) or low-intensity pain (VAS<30mm) (grade A). Strong opioids by IV PCA or by fixed IV dosing titrated to pain intensity (grade A). Paracetamol for moderate- (VAS>30, <50) or low-intensity (VAS<30mm) pain, in combination with COX-2 inhibitors or conventional NSAIDs (grade A) and epidural analgesia in high-risk patients (grade A and D) is recommended.

The use of rescue analgesic, which was defined as analgesic used over and above that which is prescribed, was found to be very limited in the current study [5, (2%)]. This was consistent with what was found in another study done in Spain where rescue analgesic was used in 57 (3.3%) of the 993 patients recruited in the study.¹⁰

Of the 250 patients recruited, authors were able to record pain score for 200 patients (80%), 24 hrs after surgery. The Italian observational study had 1952 patients from 24 hospitals in Italy.⁵ In that study, pain assessments were done 6 times using the visual analogue scale (VAS), the first reading being 4-6 hrs after surgery and the last assessment was done 48 hrs after surgery. Study done to assess pain in Catalonian hospitals found that pain was assessed in 42% (95% CI: 37.9-46.1) of the post-operative, and in 63.7% (CI 95%: 57.7-69.7%) of cancer patients.¹¹

Nearly a third of present patients had severe pain (score 7-10) on day 1 [76 (30.4%)], and few had severe pain even on third post-operative day [12, 4.8%]. In the study by Vallano, thirty eight percent (371/967) of patients rated their maximum pain on the first day as severe to unbearable.¹¹ The ITOSPOP study on the other hand showed moderate pain on the first assessment of pain 4-6 hrs after surgery.⁵

Author also studied factors that affected pain score. On univariate analysis author found that factors that affected pain score on day 1 were male gender, emergency surgery, department (surgery) and tramadol. These factors were not found to be significant on multivariate analysis. Vallano et al, found no apparent relation between the pain severity during the first day and the analgesics which were actually administered.¹¹ In the same study, they found that factors associated with a high prevalence of pain at the moment of the interview were age (younger patients), gender (women), surgery (presence), type of clinical ward (orthopaedic surgery and rehabilitation), type of hospital (large centres) and number of prescribed analgesics (more analgesics). However, the presence of a cancer diagnosis and years of education were not associated. Study done by Constantini et al. found that females reported significantly higher

levels of pain ($p<0.001$), a linear association was seen between days from surgery and pain, age and education did not have any association.¹²

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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