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Original Research Article

To Assess Pain through the Visual Analogue Scale (VAS) and the Requirement of Postoperative Opioid Consumption & Incidence of Postoperative Nausea and Vomiting (PONV)

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Abstract

Aim: To assess pain through the visual analogue scale (VAS) and the requirement of postoperative opioid consumption & incidence of Postoperative nausea and vomiting (PONV).

Materials and methods: The present Randomized double blind, placebo controlled study was carried from September 2019 to August 2021 at Indira Gandhi Institute of Medical Sciences, Patna. After enrollment in the study all patients were prescribed 0.5 mg of alprazolam and ranitidine 150 mg orally the previous night. Patients were advised to be NIL oral from 10 PM onwards on the previous day of surgery. By the use of computer-generated random number patients were allocated to either lidocaine infusion (L) or Saline group (S) with 50 patients in each group. All patients were asked for pain sensation during postoperative period and incidence of pain was scored. Incidence of pain was scored on the basis of visual analog score (VAS). Also postoperative opioid requirement, incidence of PONV, any other adverse effects and vitals was noted. Assessment was done just after terminating the lignocaine infusion and thereafter 2 hourly for 6 hours and then 6 hourly till 24 hour.

Results: Mean age of the study population in group L was 38.40±11.54 and group S was 34.14±11.78 ($p<0.05$). In both the groups female outnumbered male population. Majority of the patients in both the groups showed ASA grade I. Pain assessment time (Score) was statistically significant between the groups just after stopping normal saline infusion followed by 2 hr, 4 hr, 18 hr and 24 hr post operatively. Incidence of post operative nausea and vomiting was found more prevalent in group L (28%) and group S (16%).

Conclusion: Perioperative infusion of nontoxic dose of lidocaine can be considered as an inexpensive, easy, relatively safe and effective modality as a part of multimodal approach for post operative analgesia in patients undergoing upper abdominal surgery.

Keywords: lidocaine, normal saline, upper abdominal surgery.

Introduction

Lidocaine (originally Xylocaine, and previously lignocaine) was developed in the first half of the twentieth century and approved for use in humans by the US Food and Drug Administration in 1948. [1,2] By 1958, intravenous lidocaine mixed was being used to support postoperative analgesia in medical practice. [3] The postoperative analgesic &anti-hyperalgesic consequence of i.v.lidocaine was determined after studies. [4,5]

Currently, i.v. lidocaine is practice as a peri-operative analgesic through a vast number of fields, in operation theatre, recovery room, ICU & surgical ward.[6] In a present review in Scotland, 12 out of the 16 responding hospitals were either already using i.v. lidocaine mixture for acute pain. [7] Lidocaine has anti-nociceptive, anti-hyperalgesic & anti-inflammatory actions, it is presumably these actions, comparatively than a direct local anaesthetic consequence, which describe the apparent prolonged consequence hours after a mixture has been completed. [6,8–10]

In day-to-day clinical practice, as well as in many medical and surgical procedures, pain is normal complaints encountered. There have been developed so many kinds of things to decrease and control pain. Pain is the most important cause of disability and is the source of significant financial burden for the patients and community. [11]

It is seen that anti hyperalgesia therapy e.g ketamine, lidocaine, clonidine, pregabeline have demonstrated decrease in pain score. Lidocaine is unique analgesic adjuvant in this group because it has shown to improve fascinated recovery after surgery, early perambulate and feeding, early fitness for discharge & most importantly increased patient satisfaction. [12]

In moderate to severe post-operative pain, opioids are widely used as initial treatment, however it is related with post paralytic ileus and delaying the patient recovery. So, a better choice for opioids is always a concern in ongoing research. Systemic lidocaine found to show its beneficial effects regarding pain after open surgery, but the studies are not sufficient. [13-16]

Acute pain which are not properly controlled remains mostly unwanted effects after surgery. A significant number of patients when go through surgery experience moderate to severe pain and thus dissatisfied with their pound management in despite of enhanced awareness and largely efforts to address this. [17]

The improvement in a patient regarding post operative pound& other perioperative result presents a significant challenge and debate among perioperative clinicians. [18]

Not rendering proper management for post-operative pain leads to unwanted physiological as well as psychological effects which may lead to increased morbidity &mortality. Managing pain does not affect only the recovery quality but also decreases the chronic pain and less stay in the hospital after the operation. [19] Time of hospital stay after surgery and pain has also affect the patient quality of life, increases chances of deep vein thrombosis and financial burden on family. [20]

Postoperative pain is a major barrier in improvement of patients which goes through laparoscopic surgeries, mostly in the initial 24 hrs. Laparoscopic approach for colorectal resections has increased in acceptability because of less pain, bleeding and decreased complication rates when compared to open surgical approaches. The pain associated with laparoscopic surgeries is largely undermined and inadequately treated. There are conflicting results with regard to lidocaine dose,

duration and efficacy as analgesic even though it is part of ERAS guidelines for open abdominal surgeries. ERAS are an evidence-based fast track surgical protocol which has improved perioperative care, with shortened recovery time and early discharge. Even though studies have demonstrated the superiority of epidural in open abdominal surgeries, its benefit in laparoscopic procedures is debatable. We think to compare intravenous lidocaine infusion with thoracic epidural analgesia to decide the most desirable management of cost cutting, protection of non-opioid mode of analgesia for laparoscopic surgeries as the scope of lidocaine infusion in laparoscopic surgeries is still under debate. Postoperative pain, by itself, does not reflect the quality of resumption of a patient. Hence, in addition to analgesia, we use the quality of recovery 15 score to quantify postoperative recovery. Integrating IV lidocaine with laparoscopic surgeries could potentially allow early discharge with an overall improvement in the quality of patient recovery.

Most common problem which is seen after surgery includes pain, nausea and vomiting, illeus, hypercoagulation state and finally cognitive dysfunction. Jokinen J , Kranke P, Pace NL et al. evaluated the consequences of perioperative i.v. lidocaine mixture on postoperative pound and resumption in patients undergoing several surgical procedures and revealed that I.V. lidocaine is useful mostly in general anesthesia for patients which goes abdominal surgery due to its useful effects on different results during postoperative recovery. [21]

Materials and methods

The present Randomized double blind, Placebo controlled study was carried from September 2019 to August 2021.

Methodology

The study protocol, informed consent form (in Hindi & English) and case report form (CRF) were submitted to the ethical committee of Indira Gandhi Institute of Medical Sciences, Patna for approval. Study was done after taking approval from institute ethical committee. Written informed consent was taken from each participant of the study. (**CTRI/2020/09/027564)**

Inclusion criteria

- Patients of ASA physical status 1 and 2.
- Patients Age between 18 - 60 years of either sex.
- Patients willing to participate
- Patients scheduled to undergo Elective surgery

Exclusion criteria

- Patients refusal to participate
- Patients with known sensitivity to lidocaine
- Patients in whom lidocaine is contraindicated.

Sample size

The sample size (n) is calculated according to the formula $n=Z^2* P* (1-P)/e^2$

Where Z =, 1.96 for a confidence level (α) of 95%, P= Proportion (expressed as a decimal), e=margin of error

Z= 1.96, P=0.07, e= 0.05

$n=1.96^{2*}0.07 * (1-0.07)/0.05^2$

n = 0.2501/0.0025=100.035

The sample size is equal to 100 (50 each group)

Randomization and grouping

After obtaining written informed consent, the patients were randomized by computer-generated random table numbers inserted into an envelope and assigned into two groups.

Group - L – Lidocaine group

Group - S – Saline group

Intervention and data collection methods

After enrollment in the study all patients were prescribed 0.5 mg of alprazolam and ranitidine 150 mg orally the previous night. Patients were advised to be NIL oral from 10 PM onwards on the previous day of surgery. By the use of computer-generated random number patients were allocated to either lidocaine infusion (L) or Saline group (S) with 50 patients in each group.

On arrival of patient to operating room, a 20-gauge i.v. cannula will be inserted at the dorsum of hand after ECG, noninvasive blood pressure and pulse oximeter monitoring was instituted. Patients in the lidocaine infusion group was receive IV bolus injection of lidocaine (1.5 mg/kg slowly over 10 min) 30 minutes before the skin incisions followed by a continuous IV infusion at the rate of 1.5mg/kg/h via infusion pump where as the patients in the saline group was receive 0.9% normal saline in equal volume and in the same manner. The infusion was continued throughout the surgery and terminated 60 min after the skin closure. In all the patients, anesthesia was induced with inj. Propofol 2.0 mg/kg, fentanyl 2.0mcg/kg, followed by vecuronium 0.1mg/kg intravenously to facilitate the Laryngoscopy and or tracheal intubation. After tracheal intubation, anesthesia was maintained with isoflurane in oxygen with intermittent intravenous boluses of vecuronium 1 mg as needed. All patients were asked for pain sensation during postoperative period and incidence of pain was scored. Incidence of pain was scored on the basis of visual analog score (VAS). Also postoperative opioid requirement, incidence of PONV, any other adverse effects and vitals was noted. Assessment was done just after terminating the lignocaine infusion and thereafter 2 hourly for 6 hours and then 6 hourly till 24 hour.

Drugs

- Inj. Fentanyl
- Inj. propofol
- Inj. Vecuronium

Intravenous Fluids

- Normal saline (NS)

Parameters

- Age, sex, weight, height, ASA grade, Type of surgery, Duration of surgery

Timing of rescue analgesia

Analgesics were avoided until demand by the patient. The time interval for the first analgesic consumption was noted.

Assessment of analgesia

Pain was assessed by Visual analogue score (VAS)

First advocated by Revill and Robinson in 1976, VAS consists of a 10cm line anchored at one end labeled as 'No pain' and at the other end labeled as 'Worst pain imaginable' or 'Pain as Bad as can Be'. The patients simply mark the line to indicate the pain intensity then measures the length of the line to mark a point scale. All the patients were instructed about the VAS and to point out the intensity of pain on the scale.

0 = No pain 10 = Worst pain

Statistical Analysis

All the data were analyzed using SPSS package (Stata, version 23.0 SPSS INC, Chicago, IL, USA) for windows. The data were presented as descriptive statistics for continuous variables and percentage for categorical variables and was subjected Chi-square test and t-test. Other values were represented in number, proportions (%) and mean ± SD.

Results

Mean age of the study population in group L was 38.40±11.54 and group S was 34.14±11.78 ($p<0.05$). In both the groups female outnumbered male population. Majority of the patients in both the groups showed ASA grade I. (Table 1)

Pain assessment time (Score) was statistically significant between the groups just after stopping normal saline infusion

followed by 2 hr, 4 hr, 18 hr and 24 hr post operatively. (Table 2)

Incidence of post operative nausea and vomiting was found more prevalent in group L (28%) and group S (16%). (Table 3)

Table 1: Profile of the study population

Age group (in yrs.)	Group L		Group S	
	N	%	N	%
18-17	11	22%	19	38%
28-36	9	18%	13	26%
37-46	17	34%	9	18%
47-55	9	18%	6	12%
>55	4	8%	2	4%
Total	50	100%	50	100%
Mean±SD	38.40±11.54		34.14±11.78	
Gender				
Male	17	34%	23	46%
Female	33	66%	27	54%
ASA grades				
I	46	92%	48	96%
II	4	8%	2	4%

Table 2: Pain assessment time (Score) different groups in different time interval

Pain assessment time (Score)	Group L	Group S	't' test	P. Value
	Mean ± S. D	Mean ± S. D		
Post operative Just after stopping normal saline infusion	0.24±0.43	1.16±0.97	-6.103	<0.001
2 hr.	0.76±0.82	1.84±0.81	-6.404	<0.001
4 hr.	2.04±0.44	2.86±0.94	-5.358	<0.001
6 hr.	2.62±1.25	3.16±1.04	-1.979	0.053
12 hr.	2.94±0.89	2.56±0.64	2.319	0.025
18 hr.	2.34±0.62	3.66±1.42	-6.571	<0.001
24 hr.	2.50±0.61	3.54±0.86	-6.542	<0.001

Table 3: Incidence of post operative nausea and vomiting distribution in groups

Incidence of post operative nausea and vomiting	Group L		Group S	
	Number	%	Number	%
Yes	14	28%	8	16%
No	36	72%	42	84%
Total	50	100%	50	10%

Discussion

The present study demonstrated that perioperative intravenous infusion of no toxic doses of lidocaine reduces postoperative pain intensity and analgesic requirement without causing any significant adverse effects in patients undergoing upper abdominal surgery.

The overall mean VAS scores in our study both at rest and on movement were less in lidocaine group than in normal saline group with the exception 12 hour after surgery. This finding may be attributed to the fact that most of the patients of normal saline group had already received rescue

analgesic post operatively and intraoperatively when duration of surgery more than or equal to 45 minutes.

Our study supports the finding of the studies by Groudine et al. [10] and Kaba et al. [1] which showed impressive effect on postoperative pain with reduction in total pain scores compared with control groups. Koppert et al. [5] also demonstrated the preventive effects of perioperative intravenous lidocaine infusion on postoperative pain and reduced analgesic consumption after major abdominal surgery. We also observed lower postoperative pain ratings in lidocaine infusion group compared to normal saline group during movement and at rest.

Our study showed significantly less total postoperative analgesic requirement in lidocaine group than in normal saline group. None of the patient in lidocaine group required further analgesia intraoperatively but some of the patients in normal saline group received further analgesia intraoperatively after 45 minutes or later. These findings clearly showed confirm postoperative analgesic effects of perioperative infusion of nontoxic dose of lidocaine.

In our study all the procedures were major upper abdominal surgeries and we do not use any additional regional anesthesia for pain relief. In upper abdominal surgery with extended tissue damage, there is major input from chemonociceptors to be central nervous system and in humans especially, the mechanoinsensitive nociceptors are reported to be tonically activated by chemicals. [18] This class of nociceptors has also been shown to be linked to the induction of central sensitization in experimental and clinical settings. [17,19] In line with these results, mechanoinsensitive nociceptors has been reported to be particularly sensitive to small dose lidocaine, thus preventing the induction of central hyperalgesia and improving the postoperative pain therapy. [20] This probably explains longer time duration for the first request of analgesia in lidocaine group in our study. Similar observation has been reported by Koppert at al [5] also.

The persistence of analgesic effect of lidocaine even after the infusion was discontinued in our study indicates prevention of spinal or peripheral hypersensitivity or both to painful stimuli reflecting its effects on inhibition of spontaneous impulse generation arising from injured nerve fibres and from dorsal root ganglion neurons proximal to the injured nerve segments and suppression of primary afferent evoked polysynaptic reflexes in the spinal dorsal horn. [21,22]

The intravenous lidocaine is most of the previous studies has been administered preoperatively and the infusion maintained for varying durations postoperatively. Kaba et al. [1] and Cassuto et al. [23] administered lidocaine in small dose regimen starting 30 minutes before surgery and continuing for 24 hours after surgery. Koppert et al. [5] and Groudine et al. [10] administered lidocaine starting prior to anesthesia and surgery and continuing until 1h postoperatively. We also started the lidocaine infusion 30 minutes prior to anesthesia and continued until one hour after completion of surgery. In view of feasibility and patient, safety, continuing the infusion would have required a prolonged PACU stay or transfer to a hospital bed with electrocardiogram monitoring facility that would have made the use of IV lidocaine impractical and more expensive.

Since we continued lidocaine infusion up to only one hour postoperatively, we cannot ascertain whether prolonging the lidocaine infusion could have improved analgesia further.

In our study, we administered lidocaine 1.5mg/kg as slow i.v bolus injection followed by a continuous infusion of 1.5mg/kg/hr. We did not measure the serum level of lidocaine, based on the

evidence from previous studies which have shown that plasma level of lidocaine remaining well below toxic level (i.e. 5 μg/ml) even when it is used at a dose higher than that we used. [10,22,24]

The higher incidence of sedation in the lidocaine group in our study until one hour after surgery is quite expected and is obviously explained by central nervous system represent effect of the drug [25]. We speculate this finding to be due to difference in the demographic and other patient characteristics. As reported in other studies [5,9], they did not show any difference in the incidence of nausea and vomiting. But our study shows that 28% nausea and vomiting in lidocaine group and 16% nausea and vomiting normal saline group. Light headache was reported by 3 patients during post operative period in the lidocaine group. [26]

Conclusion

Perioperative infusion of nontoxic dose of lidocaine decreases the intensity of postoperative pain, reduces the postoperative analgesics requirement, and blunts the hemodynamic responses during laryngoscopy and endotracheal intubation without causing significant adverse effects. Therefore, it can be considered as an inexpensive, easy, relatively safe and effective modality as a part of multimodal approach for post operative analgesia in patients undergoing upper abdominal surgery.

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