

COMPARATIVE STUDY OF NALBUPHINE VS. PENTAZOCINE FOR POSTOPERATIVE ANALGESIA

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ABSTRACT

BACKGROUND

To provide postoperative pain relief is a prime duty of health care providers. Failure to relieve pain is morally and ethically unacceptable. Post-operative pain may results in adverse effects such as: a) Physiological Changes: Reduced pulmonary functions, e.g. vital capacity, tidal volume, functional residual capacity; sympathetic stimulation; reduced the physical activity of patients; thereby increasing the risk of venous thrombosis. b) Psychological disturbances: Anger, Resentment, Depression, Adversarial Relationship with Doctors, Insomnia.

Aim of this study was

To investigate whether "Postoperative analgesia with Nalbuphine is longer than Pentazocine".

To investigate whether "Side effects/complications are less with Nalbuphine as compared to Pentazocine".

MATERIALS AND METHODS

It was a prospective randomized double blind observational study. Eighty patients of hydrocoele & inguinal hernia were operated under spinal anaesthesia of age group 20-70 years, ASA grade I & II & patients with controlled co-morbid conditions. In postoperative period, Group N- Inj. Nalbuphine (0.3 mg/kg IM) or Group P- Inj. Pentazocine (0.5 mg/kg IM) was administered to provide postoperative pain relief & to know the duration of pain relief & its side effects.

RESULTS

On statistical analysis, demographic data i.e. age, sex had no influence on outcome of study. Mean VAS score in group N was highly significant (p-value <0.0001) as compared to Pentazocine. Statistically duration of analgesia was highly significant (p-value <0.0001) with longer duration in Group 'N' as compared to Group 'P'. Sedation was more in Nalbuphine group as compared to Pentazocine group. Incidence of nausea and vomiting was more in Pentazocine group as compared to Nalbuphine group.

CONCLUSION

Duration of analgesia in Inj. Nalbuphine group was > in Inj. Pentazocine group.

Side Effects - Incidence of sedation was more in Nalbuphine group as compared to Pentazocine group. Nausea & Vomiting were more so in Pentazocine group as compared to Nalbuphine group. Limitation of the present study was that sample size was very small.

KEYWORDS

Nalbuphine vs. Pentazocine, Postoperative analgesia, Side effects, Inguinal Hernia/Hydrocoele surgery, Spinal anaesthesia.

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BACKGROUND

Pain is defined as an unpleasant sensory and emotional experience associated with actual and potential tissue damage.^[1] Acute pain is commonly seen after surgery & persists for 24-48 hours. Pain is a protective mechanism designed to alert the body to potentially injurious stimuli.

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To provide postoperative pain relief is a prime duty of health care providers. Failure to relieve pain is morally and ethically unacceptable. Post-operative pain may results in adverse effects such as a) Physiological changes: Reduced pulmonary functions -e.g. vital capacity, tidal volume, functional residual capacity; sympathetic stimulation; reduced the physical activity of patients; thereby increasing the risk of venous thrombosis b) Psychological disturbances: Anger, resentment, depression, adversarial relationship with doctors, insomnia.^[2,3]

Despite euphoria and some hypnotic effect, which take care of psychological aspect of pain, other side effects like respiratory depression, nausea vomiting, and itching & addiction liability lead to search for safer opioids derivatives.



In the search for opioid analgesics with less abuse potential than pure mu agonist opioids, a number of semi synthetic drugs were developed. These substances are referred to as mixed agonist-antagonists analgesics e.g. Nalbuphine. The mixed agonists-antagonists drug class exerts their analgesic actions by agonistic activity at opioid kappa ("κ") receptors. While all drugs in this class possess opioid mu ("μ") receptor antagonistic activity leading to less abuse potential, Nalbuphine is the only approved drug in the mixed agonist-antagonist class and selectivity's on opiate receptors as a full mu antagonist as well as a full kappa agonist.^[2] Nalbuphine is a potent analgesic. Nalbuphine is associated with fewer hemodynamic and systemic side effects.^[3] Present study was undertaken to study duration of analgesia, side effects of Nalbuphine vs. Pentazocine for postoperative pain relief.^[2,4]

AIM OF THE STUDY

1. To study that, "Duration of postoperative analgesia with Nalbuphine is longer than Pentazocine".
2. To study that, "Side effects are less with Nalbuphine as compared to Pentazocine".

Plan of Study

The present study was conducted in department of anaesthesiology at Government Medical College Nagpur. It was a prospective, randomized controlled, double blinded study. Institutional ethical committee approval was obtained. A total of 80 male patients were included in the study.

Inclusion Criteria

- a) Consent to participate in study design.
- b) Age group- 20-70 Yrs.
- c) ASA grade I, II.
- d) Patients with co-morbid conditions e.g. Diabetes mellitus, Hypertension, Past Myocardial Infarction patients (> 6 months old) were also included in study.

Exclusion Criteria

- a) No consent.
- b) Pts. Age <20 & >70 Yrs.
- c) ASA grade III and IV,
- d) Emergency cases e.g. obstructed inguinal hernia, hydrocoele with Pyocoele.
- e) Patients with inadequate level of spinal anaesthesia requiring intra-operative general anaesthetic drug supplementation, Neurological disease, MI within 6 months & absolute contraindication to spinal anaesthesia like bleeding disorders.

Plan of Study

Eighty patients of Inguinal Hernia repair and or Hydrocoele surgery were divided into two groups of 40 patients in each group using the sealed envelope technique.

- **Group 'N'**: Pts. receiving Inj. Nalbuphine (0.3 mg/kg IM) for post-operative analgesia.
- **Group 'P'**: Pts. receiving Inj. Pentazocine (0.5 mg/kg IM) for post-operative analgesia.

Sample size of 40 patients in each group was estimated using n Master software version 2.0 considering Visual Analogue Scale score in each group, with α-error of 10% and power of the study of 80%. Preanaesthetic evaluation was done 24 hours prior surgery at ward. It included detailed present & past history of patient, general & systemic examination to rule out any major illness & associated comorbidities. Relevant investigations were done. Each patient was kept NBM for 4- 6 hours prior surgical procedure. A night before surgery (12-16 hours prior surgery), patient was given Tab. Diazepam 10 mg. & Tab. Pantoprazole 20 mg orally. Informed consent was obtained from patient & or from relatives. Preoperative pulse rate, systolic and diastolic blood pressure were noted at operation room before intravenous access & application of monitoring gadgets. Intravenous access was established with 20 G intracath. Multipara monitor was attached to patient. Preloading was done with 10 ml/kg of Ringer's Lactate solution & Inj. Ranitidine 50 mg IV as premedication.

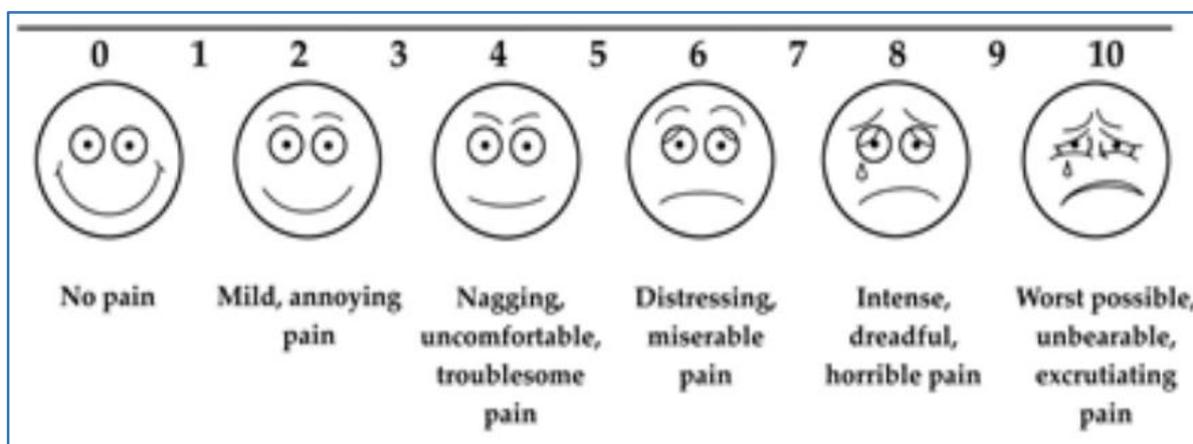
Under all aseptic precautions, spinal anaesthesia was given (Patient in right/left lateral position & OT Table in horizontal position) with Quincke type 23 gauge spinal needle at L3-L4 or L4-L5 site. Inj. Levo-Bupivacaine (3.5 ml 0.5%) was administered at the rate of 0.2 ml per second into subarachnoid space. Patient was immediately turned supine keeping position of operation table horizontal. Intraoperative monitoring Pulse rate, Blood pressure, Respiratory rate were done every 5 Minutes from administration of spinal drug up to 30 Minutes & later every 10 Minutes till completion of surgery. None of the patients were administered intra-operative sedation and/or analgesic drugs (i.e. Midazolam, Pentazocine, Nalbuphine, Diclofenac sodium etc.).

Hypotension (Fall in SBP by 30% of baseline value) was managed with oxygen supplementation & injection Mephentermine 6 mg bolus as and when required. Bradycardia (fall in basal pulse rate < 60 per Minute) was treated with injection Atropine 0.6 mg as and when required. Intraoperative nausea & vomiting were noted. Any anaesthetic drug supplementation (Inj. Ketamine, Propofol, and Thiopentone) was noted and such patients were excluded from study. On completion of surgery, patients were shifted to recovery room of operation theatre for following observations.

Visual Analogue Scale

A scale of 0 - 10 cm.

Each patient was preoperatively explained about VAS & asked to mark the severity of pain. As most of our patients were illiterate, the verbal expression was converted into visual analogue scale with score 0 = no pain and score 10 = unbearable pain.



On complain of pain by patient & at VAS score of ≥ 4 (i.e. Minimal pain), Inj. Nalbuphine 0.3 mg/kg to Group 'N' patients and Inj. Pentazocine 0.5 mg/kg to Group 'P' patients was administered intramuscularly in deep gluteal region. Time of IM injection of analgesic drug was noted as zero hour. At the same time pulse rate, blood pressure, and respiratory rate were noted. All patients were observed for next four hours in the surgical ward. Instructions were given not to give any analgesic medication to patients under study by surgery residents/staff members of surgical wards, nursing staff, till the instructions by investigators.

The assessment of pain & vital parameters (Heart rate, blood pressure, and respiratory rate) were done before injection of analgesic drug & then at 5, 10, 15, 30, 45, 60, 75, 90, 120, 150, 180, 210, 240 Minutes interval or till the time patient again complains of pain at surgical site. The duration of action was defined as drug action from the time after which there is decrease in VAS score to the time required for VAS score to return to a score i.e. ≥ 4 . The rescue analgesia was provided either with Inj. Nalbuphine or Inj. Pentazocine or Inj. Diclofenac IM. The patient satisfaction was assessed on the subjective scale of as Fair/Good/Excellent. Side effects e.g. sedation, nausea, vomiting, respiratory depression, pruritus, headache, irritability, skin rash, hypersensitivity reaction, local effect of drug at injection site as pain, rash, itching, swelling if any were noted. Sedation was assessed with Ramsay sedation score.

RESULTS

Demographic data age, sex, weight and height were comparable in both groups. In Group 'N', out of 40 patients, 28 patients (70%) were of ASA grade I and 12 patients (30%) were of ASA grade II. In Group 'P', out of 40 patients, 30 patients (75%) were of ASA grade I and 10 patients (25%) were of ASA grade II. There was no difference in preoperative mean heart rate, systolic and diastolic blood pressure and respiratory between Group 'N' and Group 'P'. Before intramuscular injection, the mean VAS score in Group 'N' was (4.78 ± 0.62) and in Group 'P' was (4.50 ± 0.60) .

Group 'N'- There was decrease in mean VAS score after 10 Min of administration of intramuscular injection (Mean VAS score: 4.95 ± 0.81) to Mean VAS score of 3.83 ± 1.22 at

15 Min. Mean VAS score was zero from 60 Min to 90 Min. Later there was gradual increase in mean VAS score from 90 Min onwards till 240 Min (Mean VAS: 5.00 ± 0.00). Group 'P'- There was no decrease in mean VAS score till 45 Min., rather there was increase in VAS score (Mean VAS score: 6.20 ± 0.91). There was a decrease in VAS score at 60 Min (Mean VAS score: 4.33 ± 1.02).

Mean VAS score was then decreased and was Minimal at 90 Min (Mean VAS 0.53 ± 0.91). Later there was gradual increase in mean VAS score till 210 Min (Mean VAS: 4.40 ± 0.55). When observed mean VAS score was compared to VAS score before IM injection of the drug, statistical difference was found to be insignificant at 5 Min (p-value: 0.1646). There was a significant change in VAS score at 10 Min (p-value: 0.0116) suggesting faster onset of pain relief in group 'N'. The change in VAS score was highly significant from 10 Min till 180 Min (p-value < 0.0001) which suggested that decrease in VAS score was more so in Group 'N' as compared to Group 'P'. In both groups, from 210 Min and onwards, the change in VAS score was insignificant (p-value - 0.8694). When mean VAS score (Group N: 2.30 ± 0.31 , Group P: 3.79 ± 0.46) was compared, statistically it was highly significant (p-value < 0.0001) with lower scores in Group 'N' as compared to Group 'P'. Duration of analgesia was noted from the time after which there was a decrease in VAS score to the time the VAS score was ≥ 4 . Duration of analgesia in Group 'N' was 135-230 Min (Mean- 193.75 Min). In Group 'P', duration of analgesia was 105 - 165 Min (Mean duration- 135.75 Min).

Statistically duration of analgesia was highly significant (p-value < 0.0001) with longer duration in Group 'N' as compared to Group 'P'. Sedation was seen in 30 patients (75%) in Group 'N' and in 19 patients (47.5%) in Group 'P'. On statistical comparison, the difference was highly significant in both the groups. Four patients in Group 'N' (10% pts - after 30-45 Minutes of IM injection) and 12 patients in Group 'P' (30% pts- after 60-90 Minutes of IM injection) had complained of nausea. Six patients (15% pts- after 90 Minutes of IM injection) had vomiting in Group 'P'.

None of the patients had vomiting in Group 'N'. There was statistical significant difference in p-value for nausea between two groups: 0.025 and for vomiting the p-value was

0.026). Pruritus, respiratory depression or any other side effect were not observed in both the groups.

Data	Group-N		Group-P		P-Value
Age (yrs.)	47.47	11.53	47.55	10.85	0.9762, NS
Weight (kg)	57.9	6.51	59.92	7.47	0.2003, NS
Height (cm)	164.72	5.31	165.77	4.71	0.3529, NS

Table 1. Demographic Data

Parameters	Group-N	Group-P	p-value
Mean Heart Rate	83.42 (SD±9.34)	83.22 (SD±9.10)	0.9243, NS
Mean SBP	122.57 (SD±9.20)	122.78 (SD±10.19)	0.9211, NS
Mean DBP	77.41 (SD±7.38)	77.23 (SD±6.76)	0.9129, NS
Mean resp. Rate	17.36 (SD±1.37)	17.63 (SD±1.44)	0.3961, NS

Table 2: Haemodynamic Parameters

Time	Group-N		Group-P	
	Mean	SD (±)	Mean	SD (±)
Before IM INJ.	4.78	0.62	4.50	0.60
5 Min	5.02	0.69	4.62	0.62
10 Min	4.95	0.81	5.15	0.77
15 Min	3.83	1.22	5.25	0.81
30 Min	2.18	1.13	5.95	0.71
45 Min	0.55	0.78	6.20	0.91
60 Min	0.00	0.00	4.33	1.02
75 Min	0.00	0.00	2.57	1.36
90 Min	0.00	0.00	0.53	0.91
120 Min	0.33	0.62	0.58	0.67
150 Min	1.02	1.14	1.7	1.22
180 Min	2.78	0.95	4.08	1.08
210 Min	4.78	1.01	4.40	0.55
240 Min	5.00	0.00	-	-

Table 3. Mean Vas Score

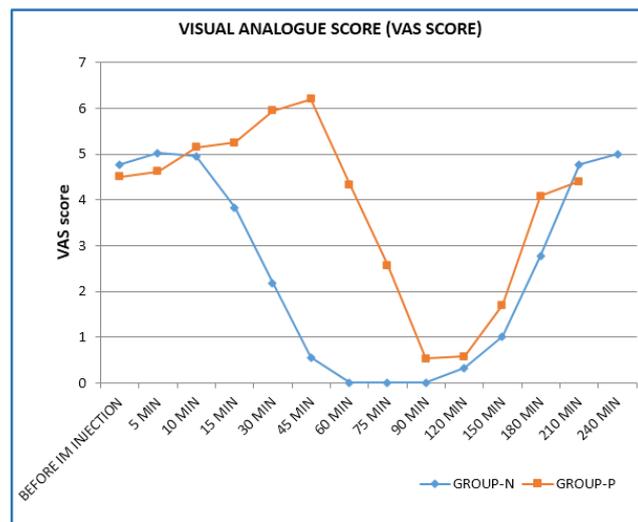


Table 4. Visual Analogue Score Graph

Time	Group-N		Group-P		P-Value
	Mean	SD (±)	Mean	SD (±)	
5 Min	-0.25	0.49	-0.12	0.33	0.1646, NS
10 Min	-0.17	0.90	-0.65	0.48	0.0116, S
15 Min	0.95	1.34	-0.75	0.44	<0.0001, HS
30 Min	2.60	1.13	-1.45	0.55	<0.0001, HS
45 Min	4.23	0.92	-1.70	0.69	<0.0001, HS
60 Min	4.78	0.62	0.18	0.90	<0.0001, HS
75 Min	4.78	0.62	1.92	1.29	<0.0001, HS
90 Min	4.78	0.62	3.98	1.12	0.0004, HS
120 Min	4.45	0.88	3.92	0.94	0.0081, HS
150 Min	3.75	1.27	2.8	1.43	0.0026, HS
180 Min	2.00	0.88	0.44	1.20	<0.0001, HS
210 Min	-0.03	0.89	0.00	0.70	0.8694, NS
240 Min	-0.75	0.5	-	-	-

Table 5. Variation in Mean Vas Score

Scores	Group-N	Group-P	P-Value
Mean Vas Score	2.30 (SD±0.31)	3.79 (SD±0.46)	<0.0001, HS

Table 6. Mean Vas Scores

	Group-N (Minutes)	Group-P (Minutes)
Mean	193.75 (SD±21.53)	135.75 (SD±14.39)
Range	135 - 230	105 - 165
P-Value	<0.0001, HS	

Table 7. Duration of Analgesia

Side Effects	Group-N		Group-P		P Value
	Number	%	Number	%	
Sedation	30	75	19	47.5	<0.001
Nausea	4	10	12	30	0.025
Vomiting	0	0	6	15	0.026
Pruritus	0	0	0	0	-
Hypotension	0	0	0	0	-
Respiratory Depression	0	0	0	0	-
Other Side Effects	0	0	0	0	-

Table 8. Side Effects/Complications

DISCUSSION

Nalbuphine is an agonist-antagonist opioid. When used as a sole opioid analgesic, it can satisfactorily cover mild to moderate pain with a low incidence of common opioid side effects.^[3] It is equal in potency as an analgesic just like Morphine and is about one fourth as potent as Nalorphine as antagonist. Most clinically useful opioids achieve their analgesic effect through binding and activation of mu-opioid receptors.^[2] What is less well appreciated is that significant analgesia can be obtained through activation of the kappa-opioid receptor alone.^[2,5] The greatest concentrations of kappa-receptors in nociceptive regions are in laminae I and II in spinal cord dorsal horn, as well as in the spinal nucleus of the trigeminal nerve (Substantia Gelatinosa). Nalbuphine binds avidly to kappa-receptors in these areas.^[6] Kappa-opioid receptors exist in the afferent neurons having cell bodies in the dorsal horn of the spinal cord.^[7]

Naloxone reverses the agonist effect of Nalbuphine. Its onset of action occurs within 2-3 Minutes after intravenous administration and in less than 15 Minutes following subcutaneous or intramuscular injection.^[2] Plasma half-life of Nalbuphine is 5 hours and in clinical studies the duration of analgesic activity has been reported to range from 3-6 hours.^[2] Pentazocine is a synthetically-prepared prototypical mixed agonist-antagonist narcotic (Opioid Analgesic) drug of the benzomorphan class of opioids used to treat moderate to moderately severe pain.^[8] Analgesia produced by Pentazocine is primarily related to κ -receptor stimulation.^[9] There were no statistical significant differences in the demographic data in both the groups and were comparable with respect to age, sex, weight and height. In our study, in Group 'N' (Inj. Nalbuphine- 0.3 mg/kg), mean baseline heart rate was 86.85±13.16 per Min while in Group 'P' (Inj. Pentazocine- 0.5 mg/kg) it was 84.08±11.01 per Min. The mean heart rate in both the groups was compared and differences were statistically non-significant.

In Group 'N' & Group 'P', the mean baseline systolic blood pressure were 127.25±13.11 mm Hg and 122.15±14.27 mm Hg respectively. The mean systolic blood pressure was compared in both the groups and statistically the difference was non-significant. Shaila S. Kamath, Arun Kumar B. C., et al,^[10] in 2013 found no statistically significant difference in the systolic blood pressure in both the groups when they compared the analgesic efficacy of IV Nalbuphine (0.2 mg/kg) vs. IV Tramadol (1 mg/kg). We compared I.M. Nalbuphine (0.3 mg/Kg) with I.M. Pentazocine (0.5 mg/Kg) and found similar results. Our observations were also similar to the study of Dr. V. V Lokeswari, Dr. B. Annapurna Sarma, et al.^[11] in 2015. Mean baseline diastolic pressure were 79.80±9.12 mm Hg & 76.20±7.78 mm Hg. In Group 'N' & Group 'P' respectively. We found no statistically significant difference in diastolic blood pressure in both groups. Shaila S. Kamath, Arun Kumar B. C., et al,^[10] (2013) found no statistically significant difference in the diastolic blood pressure. Dr. V. V Lokeswari, Dr. B. Annapurna Sarma, et al.^[11] in 2015 compared the analgesic efficacy of IM Nalbuphine (10 mg) with IM Butorphanol (2 mg) and found no statistically significant

difference in diastolic blood pressure. In Group 'N', baseline mean respiratory rate was 17.78±1.87 per Minute while in Group 'P' it was 18.08±1.68 per Minute. The mean difference in RR was statistically non-significant. Shaila S. Kamath, Arun Kumar B. C., et al.^[10] monitored respiratory rate & SpO₂. They found no statistically significant difference.

Vas Score

When VAS score was ≥ 4 , intramuscular injection of study drug was administered to pt. Baseline mean VAS score in Group 'N' was (4.78±0.62) and in Group 'P' was (4.50±0.60). Minimum mean VAS score was zero from 60 Min to 90 Min in Group 'N' while Minimum mean VAS score was 0.53±0.91 to 0.58±0.67 from 90 to 120 Min in Group 'P'. When change in mean VAS score was compared to VAS score before IM injection, statistical difference was found to be significant at 10 Min & was highly significant from 15 Min till 180 Min. Decrease in VAS score was more so in Group 'N' as compared to Group 'P'. Mean VAS score (After intramuscular injection) in Group 'N' was 2.30±0.31 and in Group 'P' was 3.79±0.46. The difference was highly significant (p - value <0.001) with lower VAS score in Group 'N' compared to Group 'P'. Shaila S. Kamath, Arun Kumar B. C., et al.^[10] (2013) used VAS score to assess subjective feeling of pain. At 10 Minutes (after drug administration), percentage of pain relief was significant (p=0.04) mean VAS score 6.77±0.61 in Nalbuphine group as compared with mean VAS score 7.20±0.64 in Tramadol group. At 30 Minutes, percentage of pain relief was highly significant (p<0.001), mean VAS score 0.72±0.64 in Nalbuphine group as compared with mean VAS score 1.72±0.75 in Tramadol. In our study, I.M. Nalbuphine (0.3 mg/Kg) was compared with I.M. Pentazocine (0.5 mg/Kg). When the VAS score was 4 or more, the drug was administered to patients. The VAS score was significant at 10 Min (p-value: 0.0116) which was similar to author's observation. Mean VAS score at 10 Min in Group 'N': 4.95±0.81 and in Group 'P' was 5.15±0.77.

It was highly significant at 15 Min (p-value <0.001) with mean VAS score of 3.83±1.22 in Group 'N' and 5.25±0.81 whereas the author's observations were about VAS score were highly significant difference at 30 Min in their study between analgesic effects of IV Nalbuphine (0.2 mg/Kg) with IV Tramadol (1 mg/Kg). A. O. Tade, B.A. Salami.¹² et al. (2009) did study to evaluate Pentazocine pain relief in adult patients with acute abdominal pain in seventy adult patients & used normal saline in control group and Pentazocine 30 mg in other group. VAS score to Pain was measured with a standard 0-100 mm Visual analogue scale (VAS). A VAS score change > 12 mm was considered as clinically significant. They found that, initial VAS score was 81±12 mm in Pentazocine group and in Control group it was 78±11 mm. Post injection VAS score (Mean mm) was 53 mm in Pentazocine group and 69 mm in Control group. Mean VAS score change was 28 mm in Pentazocine group and it was 9 mm in Control group. VAS score drop of >12 mm was seen in 62.5% in Pentazocine group and 30% in Control group.

We have used VAS scale from 0-10 cm which is similar to 0- 100 mm. There was no control group in our study. The Minimum post injection mean VAS score in group 'N' was zero from 60 Min to 90 Min & mean VAS score at 90 Min in Pentazocine group was 0.53 ± 0.91 (i.e. 5.3 ± 9.1 mm).

Duration of Analgesia

Duration of analgesia in Group 'N' (Inj. Nalbuphine- 0.3 mg/Kg) was 135 - 230 Min (Mean- 193.75 Min). In Group 'P' (Inj. Pentazocine- 0.5 mg/kg) it was 105 - 165 Min (Mean duration- 135.75 Min). Statistically observation was highly significant (p - value < 0.0001) in Group 'N' as compared to Group 'P' suggesting longer duration/postoperative analgesia in Group 'N' as compared to Group 'P'. In 1977, Tammisto T, Tigerstedt I.^[13] compared analgesic effects of intravenous Nalbuphine (0.07 or 0.14 mg/Kg) and Pentazocine (0.3 or 0.6 mg/Kg) in patients with immediate postoperative pain after upper abdominal operations in one hundred patients. The duration of action seemed to be slightly longer with intravenous Inj. Nalbuphine as compared to intravenous Inj. Pentazocine, but after 2 hours 30 Minutes after injection, pain had returned to pre-injection level in 2/3 of the patients, even after the higher doses of both drugs.

In our study, mean duration of action of Nalbuphine was found to be 193.75 Min (3.2 hours) and that with Pentazocine was found to be 135.75 Min (2.3 hours). The duration of analgesia was longer in Nalbuphine group as compared to Pentazocine group. Hew E, Foster K, et al.^[14] in 1987 compared the analgesic efficacy and side effect profile of a) Nalbuphine 20 mg IV and b) Nalbuphine 40 mg IV to those of Meperidine 75 mg IM in the immediate postoperative period in 150 patients. The mean time to additional analgesic medication was approximately 207 Minutes in each group. Thus, they found the mean duration of action of Nalbuphine to be 207 Min. Mean duration of analgesia was up to 193.75 Minutes in Nalbuphine group which was slightly less in relation to author's observation. In study Dr. V. V. Lokeswari, et al.^[11], duration of analgesia in Nalbuphine group ranged from 4-12 hours with a mean 6.05 ± 3.14 hours. In Butorphanol group, it ranged from 4-8 hours with a mean 5.20 ± 0.71 hours. We found that duration of action of Nalbuphine ranged from 135- 230 Min (2.2 - 3.8 hours) with a mean of 193.75 Min (3.2 hours). Duration of analgesia of Pentazocine ranged from 105 - 165 Min (1.75 - 2.75 hours).

Side Effects

In Group 'N', incidence of side effects were sedation (75%), nausea (10%) after 30-45 Minutes of IM injection, vomiting (Zero %). In Group 'P', there were cases of sedation (47.5%), nausea (30%), vomiting (15%) after 90 Minutes of IM injection. Difference between the groups was statistically significant. Pruritus and respiratory depression were not observed in both groups. Zheng Zeng, Jianhua Lu, et al.^[15] (2015) described the effect of Nalbuphine as well as its safety compared to Morphine by analyzing published randomized controlled trials (RCTs) with meta-analysis approach.

They concluded that Nalbuphine provides a better safety profile than No pruritus/itching or respiratory depression were noted in our study. Dr. V. V. Lokeswari, Dr. B. Annapurna. Sarma, et al.^[11] noted side effects in Nalbuphine group like sedation (26.7%), nausea (9.9%), vomiting (6.7%) and pruritis (0%) and were less when compared to Butorphanol Group- sedation (66.7%), nausea (33.3%), vomiting (33.3%), vomiting (26.7%), pruritis (0%). These differences were statistically significant. They considered this lower incidence of nausea and vomiting in the Nalbuphine group (similar to our observations), which is consistent with lesser inhibition of gastrointestinal motility by partial agonists. T. Jamuna et al.^[16] in June 2015- Side effects observed in study with Tramadol were nausea and vomiting (24%), excessive sweating (12%), drowsiness (14%), dysphoria (8%), psychotomimetic effects (4%). With Pentazocine side effects observed were nausea and vomiting (40%), drowsiness (22%), sweating (16%), dysphoria (12%), psychotomimetic effects (18%) like anxiety, night mares, weird thoughts and hallucinations. Thus, side effects were more in Pentazocine group. We have noted side effects of Pentazocine- sedation (47.5%), nausea in 30% patients and vomiting in 15% patients. Statistical analysis was done by performing one way repeated measure ANOVA, Mann Whitney Test for non-normalize variables. Categorical variables were compared by performing Pearson's chi-square test & using STATA Version No.13.

CONCLUSION

We conclude that, duration of analgesia was more with Inj. Nalbuphine as compared to Inj. Pentazocine. The side effects e.g. Sedation was more in Nalbuphine group as compared to Pentazocine group. Incidence of nausea & vomiting were more in Pentazocine group as compared to Nalbuphine group.

Limitation of Study

Small sample size- 40 patients.

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