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Comparative Study of Intrathecal Bupivacaine with Additives Buprenorphine and Fentanyl for Post Operative Analgesia.

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Abstract: In current day practice various additives are used intrathecally to have good post operative analgesia and optimal operative conditions. Presently alfa 2 agonists like dexmedetomidine and clonidine are routinely used which may be associated with side effects. We have tried to evaluate buprenorphine and fentanyl as additives which offer similar benefits of alfa2 agonists and are associated with less side effects. We have compared buprenorphine 100mcg and fentanyl 50 mcg as additives to bupivacaine 0.5% heavy 17.5mg for lower limb orthopedic procedures. it was found that in buprenorphine group 24 hour analgesic requirements were significantly less with good VAS scores and minimal side effects in both the groups.

Keywords: Bupivacaine, Buprenorphine, Fentanyl, Postoperative Analgesia, Subarachnoid Block.

I. Introduction

Spinal anaesthesia is the most common method of providing anaesthesia and analgesia for most of the surgical procedures. Bupivacaine is the time-tested long acting local anaesthetic used, addition of opioids can improve the quality of anaesthesia and analgesia in terms of onset of sensory block, duration of sensory block and thereby prolonging the duration of analgesia in to postoperative period. In our study we will be comparing opioid additives Buprenorphine and Fentanyl as additives to Bupivacaine. Opioids may have additive or synergistic effect with local anaesthetics for post operative pain relief and also may improve quality of anaesthesia [1].

II. Objective

To compare the efficacy of additives to Bupivacaine (Buprenorphine and Fentanyl), in terms of:

- 1) Onset and duration of Sensory Block
- 2) Duration of post operative analgesia with VAS(Visual analog scale)

Hemodynamic changes, Any side effects, 24 hour analgesic requirements also was noted.

III. Material & Methods

After institutional Ethical Clearance, 60 patients will be included of American Society of Anesthesiologist (ASA) I & II, posted for elective orthopedic procedure of lower limbs. Randomization will be done by computerized random table and double blinding method will be followed. After taking informed consent, all the patients will be preloaded with Ringer's Lactate 10ml/kg and Group A will be given 3.5ml of Heavy Bupivacaine with 100micrograms of Buprenorphine (made up to 4 ml with NS) and Group B will be given 3.5ml of Heavy Bupivacaine with 50micrograms of Fentanyl (made up to 4 ml).

Inclusion criteria was A.S.A. grade I & II patients, aged 20-75yrs, undergoing elective lower limb orthopedic surgery scheduled to last less than 180 minutes, and willing to participate in study. Exclusion criteria was patient refusal, morbidly obese patients, contraindication to subarachnoid block, general or epidural anesthesia given in addition to subarachnoid block, patient on opioids.

Preoperatively detailed medical, surgical history, allergies was noted. Preoperative detailed general & systemic examination was done and vitals recorded and necessary investigations done. Demographic data like age, weight (kg), height (cm) obtained for each case. The patients were familiarized with the 10 point visual analogue scale (V.A.S) for pain during the pre-anesthetic visit. Patients were kept fasting for 6-8hrs prior to anesthesia. After shifting the patients to operation theatre, baseline monitoring of E.C.G, noninvasive blood pressure, oxygen saturation, and respiratory rate was recorded. The onset of Sensory, Motor block; highest level of sensory block, motor block; hemodynamic changes-HR, BP; SpO₂; Time to 2 segment regression; VAS scores during the postoperative period were noted. If VAS >4, Rescue analgesia Inj. Tramadol 50 mg was given. Side effects- hypotension, hypoventilation, itching were noted and treated appropriately.

IV. Results & Analysis

The observations made was entered in to MS Excel and Demography details are presented as Mean & SD; The other parameters were analysed with Student T test.

Table 1: Age distribution of patients studied

| Age in years | Buprenorphine | | Fentanyl | |
|--------------|---------------|-------|-------------|-------|
| | No | % | No | % |
| <20 | 0 | 0.0 | 2 | 6.7 |
| 20-30 | 11 | 36.7 | 7 | 23.3 |
| 31-40 | 1 | 3.3 | 6 | 20.0 |
| 41-50 | 9 | 30.0 | 5 | 16.7 |
| 51-60 | 5 | 16.7 | 6 | 20.0 |
| 61-70 | 3 | 10.0 | 2 | 6.7 |
| >70 | 1 | 3.3 | 2 | 6.7 |
| Total | 30 | 100.0 | 30 | 100.0 |
| Mean ± SD | 43.83±17.69 | | 42.13±17.96 | |

Samples are age matched with P=0.713

Table 2: Gender distribution of patients studied

| Gender | Buprenorphine | | Fentanyl | |
|--------|---------------|-------|----------|-------|
| | No | % | No | % |
| Female | 12 | 40.0 | 2 | 6.7 |
| Male | 18 | 60.0 | 28 | 93.3 |
| Total | 30 | 100.0 | 30 | 100.0 |

P=0.002**, Significant, Chi-Square test

Table-1 and 2 depicts the demographic profile of the study subjects. Comparing the mean ± SD and calculating the p value both groups were found to be comparable with respect to age (yrs) and gender.

Table 3: Comparison of study variables in two groups of patients studied

| | Buprenorphine | Fentanyl | P value |
|---|---------------|--------------|----------|
| Onset of sensory block (in seconds) | 287.77±12.72 | 301.30±11.25 | <0.001** |
| Onset of motor block (in seconds) | 406.93±13.50 | 407.43±26.77 | 0.928 |
| Duration of Motor blockade (in minutes) | 108.67±3.50 | 105.03±2.43 | <0.001** |
| Duration of analgesia (in minutes) | 351.53±9.18 | 232.87±4.77 | <0.001** |

(Student t test)

Onset of sensory and motor blockade is comparable in both the group . Onset is earlier in Fentanyl group(P<0.001) compared to buprenorphine group. But duration of analgesia(P<0.001) and duration of motor blockade is comparatively more with Buprenorphine group.(Table 3)

Table 4: Distribution of VAS Score in two groups of patients studied

| VAS Score | Buprenorphine | | Fentanyl | |
|-----------|---------------|-------|-----------|-------|
| | No | % | No | % |
| 0 | 0 | 0.0 | 0 | 0.0 |
| 1-3 | 5 | 16.7 | 0 | 0.0 |
| 4-6 | 25 | 83.3 | 30 | 100.0 |
| 7-10 | 0 | 0.0 | 0 | 0.0 |
| Total | 30 | 100.0 | 30 | 100.0 |
| Mean ± SD | 4.20±0.81 | | 4.97±0.72 | |

P<0.001**, Significant, Student t test

Time to rescue analgesia (time from the injection of intrathecal drug to time of request for analgesia). Pain intensity was significantly lower with Buprenorphine group with Mean ± SD of 4.20±0.81 and p<0.001 comparing to Fentanyl group as evaluated by VAS score. Results were analysed using student t test (Table 4).

Table 5: Number of rescue analgesia doses in 24 hrs in two groups of patients studied

| Number of rescue analgesia doses in 24 hrs | Buprenorphine (n=30) | | Fentanyl (n=30) | |
|--|----------------------|------|-----------------|------|
| | No | % | No | % |
| No | 21 | 70.0 | 8 | 26.7 |
| Yes | 9 | 30.0 | 22 | 73.3 |
| 1 | 9 | 30.0 | 14 | 46.7 |
| 2 | 0 | 0.0 | 8 | 26.7 |

P=0.0019**, Significant, Chi-Square test

Table 5 depicts the number of rescue analgesia doses in 24 hrs which were less in Buprenorphine group compared to Fentanyl group . analysed using Chi-square test.

Table 6: Side Effects in two groups of patients studied

| Side Effects | Buprenorphine (n=30) | | Fentanyl (n=30) | |
|--------------|----------------------|------|-----------------|------|
| | No | % | No | % |
| No | 25 | 83.3 | 23 | 76.7 |
| Yes | 5 | 16.7 | 7 | 23.3 |
| Nausea | 2 | 6.7 | 4 | 13.3 |
| Hypotension | 1 | 3.3 | 2 | 6.7 |
| Bradycardia | 1 | 3.3 | 1 | 3.3 |
| Pruritis | 1 | 3.3 | 0 | 0.0 |

P=0.751, Not significant, Chi-Square test, Side effects in both the groups were not significant

V. Discussion

Because of its simplicity, speed, reliability and minimal exposure to depressant drugs, Subarachnoid block has been most extensively used for lower abdominal and lower limb surgeries. The aim of good post-operative analgesia is to produce a long lasting, continuous effective analgesia with minimum side effects. Commonly used local anaesthetics for intrathecal anaesthesia are Lignocaine and Bupivacaine in India. Bupivacaine 0.5% heavy single intrathecal injection provides analgesia for 2-2.5hrs, but the post-operative analgesic duration is limited.

Hence, an intrathecal additive to these local anaesthetics forms a reliable and reproducible method of prolonging post-operative analgesia and to prolong the duration of anaesthesia [2]. This technique has gained a wide acceptance for being simple and less cumbersome. The most common adjuvants used are clonidine and dexmedetomidine and they have formed a cornerstone option for the treatment of post-operative pain [3].

Safiya et al. showed that 1 µg/kg Buprenorphine to a maximum of 50 µg when added to 15 mg of 0.5% heavy Bupivacaine intrathecally provides analgesia for 476.6±93.7 minutes [4]. G capogna et al showed that ,when Buprenorphine is used intrathecally in combination with Bupivacaine, it improved the quality and duration of postoperative analgesia compared to Bupivacaine alone and had minimal disturbance of consciousness and comfortable breathing and with a higher dose (45 mcg) it improved the quality and duration of analgesia [5].

In one study with dexmedetomidine, clonidine, and fentanyl they found that dexmedetomidine(5 mcg) prolonged the sensory and motor block more than fentanyl (25 mcg) [6]. Ding Z says Buprenorphine exhibits analgesic property both at spinal and supraspinal levels [7]. In one more study they found that Buprenorphine 30mcg in combination with bupivacaine 0.75% 2 ml provided analgesia of comparable clinical onset and longer duration than with fentanyl 10 mcg; but was associated with a clinically increased incidence of nausea and vomiting in elderly patients with buprenorphine [8].

In a study with fentanyl 25 mcg as additive to bupivacaine, it showed that quality of analgesia was good with minimal side effects [9]. . The results from one more study shows that addition of 25 µg of fentanyl to 10 mg of 0.5% hyperbaric bupivacaine intrathecally for open reduction and internal fixation of lower limb fractures significantly prolonged the duration of complete analgesia as well as effective analgesia thereby reducing the need for early postoperative analgesic use [10].

In our study demographic variables were not much significant . Onset of sensory and motor blockade is earlier in Fentanyl group(with Mean ± SD 301.30±11.25 and 407.43±26.77 respectively) compared to Buprenorphine group. But duration of analgesia(Mean ± SD of 108.67±3.50 and P<0.001) and duration of motor blockade(Mean ± SD of 351.53±9.18) is comparatively more with Buprenorphine group. We had also observed that number of rescue analgesia required were comparatively less with Buprenorphine group i.e, only 9 out of 30 patients required only one rescue analgesia in 24 hrs. VAS scores were less with buprenorphine group (Mean ± SD of 4.20±0.81) compared to Fentanyl group (Mean ± SD of 4.97±0.72). Side effects were not much significant, only 4 out of 30 in buprenorphine group and 7 out of 30 in Fentanyl group experienced side effects.

VI. Conclusion

Our study concluded that the use of Bupivacaine with Buprenorphine (100 µg) in spinal anaesthesia provides longer duration of postoperative analgesia as compared to intrathecal Bupivacaine and Fentanyl (50 µg).

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