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Buprenorphine Added As an Adjuvant To 0.5% Ropivacaine for Supraclavicular Brachial Plexus Block: A Randomized Control Trial

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ABSTRACT

Background and Aims

The supraclavicular brachial plexus block is the most commonly performed block for upper limb surgeries. Aim: To assess the postoperative analgesic duration of buprenorphine added as an adjuvant to ropivacaine.

Methods

A randomized control trial was done on 64 adult American Society of Anesthesiologists I and II patients, aged 18–60 years, and divided into two groups of 32 patients each. Group A received a 30 ml injection of 0.5% ropivacaine and a 1 ml (0.3 mg) injection of buprenorphine, and group B (Control) received a 30 ml injection of 0.5% ropivacaine and a 1 ml (0.3 mg) injection of normal saline. Patients were observed for the onset and duration of sensory block, the onset and duration of motor block, the duration of analgesia, and any complications.

Results

Postoperative analgesia was significantly longer (835.78 46.02 min) in group A, as compared to group B (445.78 35.2 min) with a p-value <0.001.

The duration of sensory block in group A and group B was 511.09±29.26 min and 372.34±31.95 min respectively, with a p-value <0.001. After 6 hours, the

pain score (NRS) in group A was significantly lower than in group B.

Conclusion

Buprenorphine 0.3 mg added to 30ml of 0.5% ropivacaine for supraclavicular brachial plexus block prolonged sensory and motor blockade and postoperative analgesia without increasing any adverse effects.

Keywords

Brachial plexus block; buprenorphine; ropivacaine; postoperative analgesia.

INTRODUCTION

Regional anesthesia is an essential component of successful orthopedic surgery, one of the world's most rapidly growing surgical specialties. Understanding the principles of regional anesthesia procedures for orthopedic surgery is associated with better respiratory and hemodynamic stability, improved clinical outcomes, and optimal patient safety. Early mobilization and improved postoperative analgesia result in a lower risk of deep vein thrombosis and a shorter hospital stay. Therefore, techniques of regional anesthesia provide advantages over general anesthesia, such as reduced side effects, excellent intraoperative analgesia, effective continuous postoperative analgesia, and thus improved outcomes [1–3].

Nowadays, the majority of upper limb orthopedic surgeries are performed with a brachial plexus block. Among the different brachial block techniques, supraclavicular brachial plexus block(SBPB) is preferred for upper limb surgeries by a majority of anesthesiologists all over the world because of the anatomical ease of the technique. However, due to the short duration of action of currently available local anesthetics, the block can be short-lived and have limited potential, resulting in block resolution before the worst postoperative pain period. As a result, optimal postoperative pain management in upper limb procedures has always attracted the attention of researchers.

Catheterization and continuous injection of local anesthetics are used in many centers, although they are expensive and require expertise. Ropivacaine, unlike bupivacaine, is a pure S (-) enantiomer with a broader safety margin due to its reduced lipophilicity, which results in a lower risk for central nervous system toxicity and cardiotoxicity as well as improved relative sensory and motor block profiles. One of the striking features of a long-acting local anesthetic is its ability to reversibly stop nerve impulses, resulting in a prolonged sensory or motor blockade suitable for anesthesia and analgesia in various procedures [4]. Sodium bicarbonate, epinephrine, tramadol, buprenorphine, dexamethasone, clonidine, midazolam, magnesium, and ketamine have all been tested as adjuvants to local anesthetics with varying degrees of success. On the other hand, poorly chosen or inappropriate additions may not have the desired impact and may even expose patients to extra dangers [5].

Buprenorphine is a semi-synthetic opioid that is easily available and cost-effective. Compared to other opioids, buprenorphine has fewer significant side effects such as sedation and respiratory depression [6].

The null hypothesis of our study is that there is no difference in the duration of analgesia when buprenorphine is added to 0.5% ropivacaine in the SBPB block anesthesia.

The current study aimed to determine postoperative analgesia improvement in patients given 0.3 mg buprenorphine as an adjuvant to ropivacaine for SBBP

block for all upper limb orthopedic surgeries, a reduction in total postoperative analgesic requirements, and study side effects and complications, if any, attributable to the drug.

METHODS

It was a randomized control trial conducted in the orthopedics OT under the department of Anesthesiology and Critical Care, Guwahati Medical College and Hospital, Guwahati from 28th July 2021 to 27th July 2022, with approval from the institutional ethics committee. (No. MC/190/2007/Pt-II/July-2021/TH-30). Our trial was registered in the clinical trial registry of India (Trial number CTRI/2022/06/043277). Our study included all adult patients of both sexes, aged between 18 to 60 yrs. of the American Society of Anesthesiology (ASA) physical status I and II waiting for elective upper limb orthopedic surgeries. Patients unwilling to participate, ASA≥III, having known hypersensitive to the study drugs and having coagulopathy disorder or on anticoagulation therapy were excluded from our study.

Sixty-four patients were randomized into 2 groups following computer-generated random numbers using a randomizer website. Patients were divided into two groups (Group A and Group B). Group A (n = 32) received a peripheral nerve stimulator-guided SBPB block with a 30 ml injection of 0.5% ropivacaine and 1 ml (0.3mg) injection of buprenorphine. Group B (n=32) patients received a peripheral nerve stimulator-guided SBPB block with a 30ml injection of 0.5% ropivacaine and 1ml normal saline.

The group sequence was concealed in sealed, opaque envelopes. Two 20-ml syringes containing 30 ml of the study drug were prepared by an anesthesiologist who was not involved in the study. The research substance was kept blind from the patients and the anesthesiologists who will record the observations.

All patients underwent standard preoperative evaluations and fasting protocols. All patients were seen and informed of the anesthetic process and its results the night before surgery. Written and informed consent was obtained. All participants had been informed about their Numeric Rating Scale (NRS) scores during the pre-anesthetic visit. A score of 0 denotes no pain, and a score of 10 denotes the worst possible pain. Standard monitoring equipment measuring non-invasive blood pressure (NIBP), heart rate (HR), percentage oxygen saturation (SPO2), and continuous electrocardiography (ECG) were attached in the operating room, and baseline recordings were taken. Under all aseptic and antiseptic precautions, the plumb–bob technique was used for the SBPB as described by Franco CD et al. [8]. A 22-gauge, 50-mm insulated stimulation short bevel needle (Stimuplex® @ DIG RC, BBraun Medical, Germany) was used for all the blocks. All the blocks were performed by a single anesthesiologist in both groups. A 3-point scale pin-prick test was used to assess the sensory block every 3 minutes for the first 30 minutes after the injection of local anesthetic. Motor block was evaluated every 3 minutes up to 30 minutes by a 3-point Modified Bromage Scale (0 = normal motor function with full extension and flexion of the elbow, wrist, and fingers; 1 = decreased motor strength, with the ability to move only the fingers, 2 = complete motor block with the inability to move the elbow, wrist, and fingers). Block failure was defined as the absence of full sensory block in at least one of the dermatomes evaluated 30 minutes after block administration, as per Duncan M et al [9]. In case of block failure, the patients were excluded from the

study and the surgery was carried out under general anesthesia (GA).

After the administration of the SBPB, primary and secondary objectives are noted.

Analgesia was assessed during the immediate postoperative period, 3rd, 6th, 9th, 12th, 15th, 18th, 21st, and 24th postoperative hours) using the NRS Scale. Postoperatively, all patients received an injection of paracetamol 1 gram intravenously 8hly. Intravenous (IV) tramadol 50 mg was used as rescue analgesia when the NRS score was≥ 4 or on the patient's request.

Hemodynamic parameters and adverse events such as hypotension, sedation, bradycardia, respiratory depression, nausea, and vomiting were monitored and treated accordingly. Procedural complications like arterial puncture, intravascular injection, dyspnea, Horner's syndrome, pneumothorax, etc. were observed intraoperatively as well as in the postoperative period.

The primary outcome was the duration of analgesia and the secondary outcomes were the onset time of sensory and motor block, duration of sensory and motor block, total analgesic consumption in 48 h, and side effects and complications if any.

The sample size was calculated using G-Power statistical software. The sample size required for this study was estimated from a previous study [7]. Based on a previous study, to detect a mean difference of at least 168 min with a standard deviation of± 48min between two groups with a level of significance of 5%, power of 80%, and an effect size of 67%, 29 patients are needed in each group. Considering an attrition rate of 10%, 32 patients was studied in each group, for a total sample size of 64 patients.

Statistical Analysis of Data

The data were entered into MS Excel spreadsheets. The description of the data is in the form of mean ± SD for quantitative data while in the form of % proportion for qualitative (categorical) data. Chi-square and Fisher's exact test were used to evaluate the association between categorical variables. Data were checked for normality using Kolmogorov-Smirnov and Shapiro-Wilk tests. The unpaired T-test was used to compare the mean difference between the two groups based on the normality assumption for continuous variables being met. For non-normal data, the Mann-Whitney test was used. The statistical analyses were done using PSW software version 21.0. A p-value<.05 was considered significant.

RESULTS

Data presented as mean ±SD or numbers of patients as a percentage (%) were tabulated and analyzed in a Microsoft Excel sheet. Eighty-six patients were assessed for eligibility, out of which 22 were excluded from the study [Figure 1]. Sixteen patients were excluded from preoperative visits due to not meeting inclusion criteria, and two patients declined to participate. Four patients had a failed or inadequate block or converted to general anesthesia and were therefore excluded from the study. A total of 64 patients were enrolled in our study, 32 patients in each group.

Demographic variables, side of surgery, and duration of surgery were comparable between each group. (P value >0.05) [Table 1].

Block characteristics of the groups are shown in Figure 2 and Figure 3. There was a statistically significant difference between the two groups with respect to the onset of sensory and motor block (P-value <0.05) [Figure 2].

There was a significant difference between the groups in terms of the mean duration of sensory and motor blocks. The mean duration of analgesia and time for first-time analgesia request was significantly higher in group A than in group B. The mean time when the NRS≥4 was significantly higher in group A. The mean tramadol consumption in the first 48 h was significantly higher in group B than in group A. (P-value <0.05) [Figure 3].

There was no statistical difference in NRS score between groups A and B up to the 3rd postoperative h. However, in the 6th postoperative h, there was a significant statistical difference in NRS scores and a highly significant statistical difference in NRS scores from the 9th to 24th postoperative h, with group A demonstrating significantly lower pain score values. [Figure 4].

The number of patients was categorized into 0-3, 4-6, and 7-10 NRS scales according to their pain at different time intervals, as shown in Figure 5. There was a statistically significant difference between the groups in terms of the number of patients at 9th, 12th, 15th,18^{th,} and 21st h.

There was a significant difference in the number of patients who scored NRS≥4 at 9th,12th, and 15th h between the groups (Figure 6).

There was no statistically significant difference between the two groups with respect to intraoperative mean arterial pressure (MAP) and HR (Figure 7).

A comparison of complications was shown in Table 2; neither group was statistically significant.

DISCUSSION

Our single-center, randomized trial found that patients receiving buprenorphine as an adjunct to a local anesthetic solution had a statistically significant longer duration of sensory and motor block, contributing to longer and higher-quality perioperative analgesia. Nowadays, much attention has been paid to improving postoperative pain management, which is critical since it can reduce surgical morbidity and mortality. Untreated or improperly treated pain can lead to chronic post-surgical pain (CPSP), which is much more frustrating for both the surgeon and the patient. [10]

The duration of analgesia in our study in group A (835.78±46.02 mins) was found to be significantly higher than in group B (445.78±35.2 mins). This finding of our study is similar to the findings of Jain N et al. [7], who also studied the effect of buprenorphine as an adjuvant to 0.5% ropivacaine for USG-guided supraclavicular brachial plexus block. Similar findings were also noted by Candido KD et al. [11], who conducted a trial to assess postoperative analgesia by the addition of buprenorphine to local anesthetic for brachial plexus block. Singam A et al. [12], and Patil S et al. [13] drew similar conclusions from their studies to evaluate postoperative analgesia by adding buprenorphine as an adjunct to bupivacaine. Another study conducted by Paramaswamy R et al. compared the effects of 0.5% ropivacaine with fentanyl, 0.5% ropivacaine with buprenorphine, and 0.5% ropivacaine with normal saline for axillary brachial plexus block and found that the statistical difference for the duration of analgesia between the normal saline group and the buprenorphine group [14].Beh et al. added buprenorphine to levobupivacaine for the middle interscalene brachial plexus block and found that the duration of analgesia was significantly enhanced with the addition of buprenorphine [15].In our study, we used ropivacaine for brachial plexus block as ropivacaine causes fewer CNS symptoms and is less toxic than bupivacaine regarding the tolerated

dose, thus providing an improved safety profile as compared to bupivacaine [4].

Jain N et al. [7], Vadhanan P et al. [16], and Paramaswamy R et al. [14] in their respective studies performed ultrasound-guided brachial plexus nerve block, while in our study we used a peripheral nerve stimulator-guided nerve block. Though USG provides real-time imaging of nerve plexuses, studies have demonstrated comparable success rates and block quality between USG-guided and PNS-guided peripheral nerve blocks [9, 17].

In our study, we have seen that up to the 3rd postoperative h, there was no statistical difference in NRS score between the two groups A and B. However, from the 6th postoperative h, there was a significant statistical difference in NRS scores, with group A demonstrating significantly lower pain score values. Our findings were consistent with those of Patil S et al. [13]. Singam A et al. [12] who noted significantly fewer pain scores in the 6^{th}, 12^{th}, and 24^{th} postoperative h when buprenorphine was added to 0.25% bupivacaine.

In our study, the onset of sensory and motor blockade was found to be statistically significantly lower in group A in comparison to group B. Our result was consistent with those conducted by Jain N et al. [7], and Paramaswamy R et al. [14], where the onset of sensory and motor blockade was faster when buprenorphine was added. The findings of our study were also in accordance with the study conducted by Nisha SaralJat et al. [18] who compared buprenorphine and clonidine added as an adjuvant to bupivacaine and found that buprenorphine hastens the onset of sensory block.

However, some contrasting findings were seen in the study carried out by Singam A et al. [12] and Patil S et al. [13] where they found no difference in the mean onset of a sensory block but the onset of a motor block was found to be significantly faster when buprenorphine was added to bupivacaine for supraclavicular brachial plexus block. The cause of this difference may be that none of the studies considered the onset of the sensory and motor block to be their primary outcome, and so, the sample size calculation was not based on it. Additionally, there were differences in how these studies defined the onset of sensory and motor blocks. The duration of sensory and motor block was found to be significantly prolonged in group A as compared to group B. Our study findings were consistent with the study carried out by Singam A et al., Patil S et al., Jain N et al., and Paramaswamy R et al, where the sensory and motor blockade was significantly prolonged when buprenorphine was added as an adjuvant [7, 12-14].

The hemodynamic parameters were also compared in our study, and no significant difference was noted between the two groups. These findings are similar to Jain N et al. where the hemodynamic parameters were stable throughout the perioperative period [7]. The incidence of adverse effects in both groups of our study was low. The groups had no incidence of hypotension, sedation, bradycardia, or respiratory distress. 6 patients from group A and three from group B complained of nausea and vomiting, which is statistically insignificant. Singam S et al, Nisha Saral J, Patil S et al., and Jain N et al. in their respective studies noted similar findings regarding the adverse effects [7, 12-13 18].

LIMITATIONS OF OUR STUDY

It is a single hospital study. A multi-hospital study is considered to be better for the evaluation of the parameters that we have used in our study. The

assessment of postoperative analgesia was limited to the first 24 h only. The study population was not large enough to adequately assess the difference in the occurrence of complications and the difference in the post-operative requirement of analgesics. A larger sample size would have added more precision to our results. The prior focus of adjuvant buprenorphine research, including that of our study, has been the prolongation of the duration of analgesia. However, the greater question of benefit to clinically relevant outcomes such as quality of recovery, patient satisfaction, and return to function time awaits further research.

CONCLUSION

1 ml (0.3 mg) of buprenorphine added as an adjuvant to 0.5% ropivacaine shortens the onset of sensory as well as motor blockade, prolongs the duration of sensory and motor blockade, and prolongs the duration of analgesia in supraclavicular brachial plexus block without an increase in side effects. It decreases the total analgesic consumption in the first 48 h postoperative period.

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TABLE

Table 1: Demographic variables, side of surgery, and duration of surgeries.

	Mean±SD		
Demographic Variables	**Group A**	**Group B**	**P-value**
Age	34.47±12.89	36.78±14.14	0.497
	Male=8(25%)	Male=11(29.7%)	
Gender	Female=24(75%)	Female=21(70.3%)	0.42
	ASAI=20(62.5%)	ASAI=13(40.6%)	
ASA status	ASAII=12(37.5%)	ASAII=19(59.4%)	0.08
Body weight (Kg)	68.34±8.46	65.06±9.02	0.13
Height(cm)	162.64±5.60	161.31±5.71	0.25
	Left=12(37.5%)	Left=19(59.4%)	
Side of surgery	Right=20(62.5%)	Right=13(40.6%)	0.08
Duration of surgery (min)	79.06±22.45	89.38±21.66	0.07

SD: Standard deviation. *P-value*<.05 is significant

Table 2: Comparison of complications between the groups

	Number of Patients		
Complications	**Group A**	**Group B**	**P-value**
Hypotension	0	0	1
Sedation	0	0	1
Bradycardia	0	0	1
Respiratory Distress	0	0	1
Nausea & Vomiting	4	3	0.28
vascular puncture	0	0	1
Pneumothorax	0	0	1

P-value> 05 is statistically insignificant.

Figure:

Figure 1: Consort flow diagram.

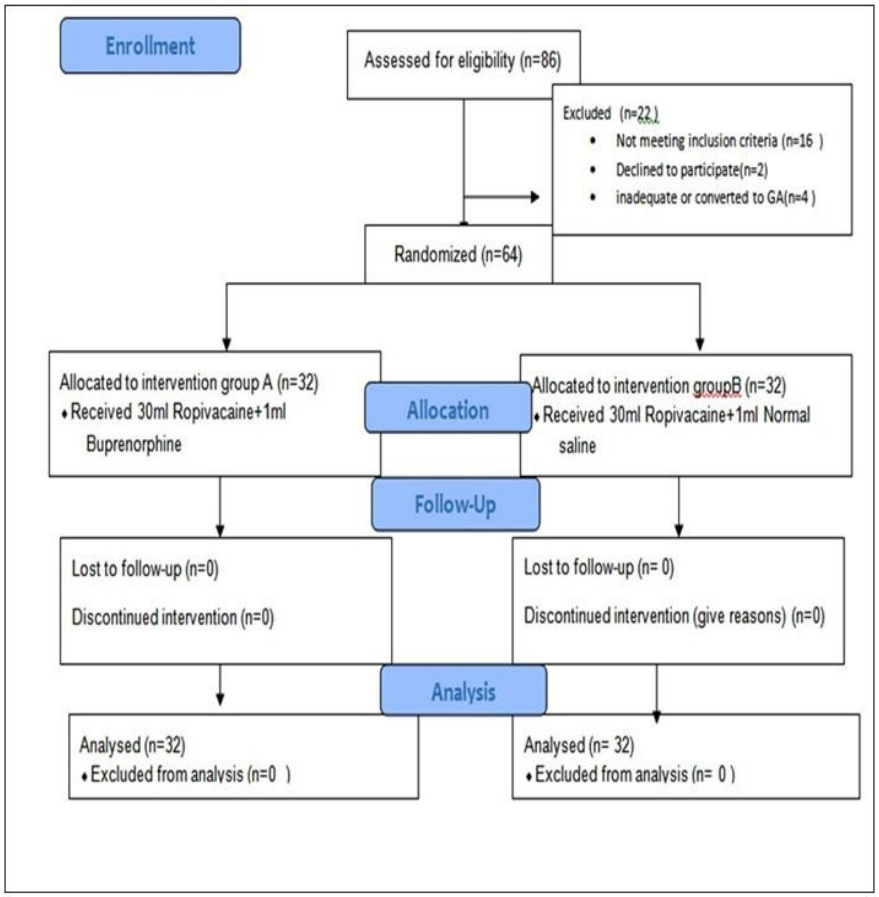

Figure 2: Comparison of the onset of the sensory and motor block between the groups.

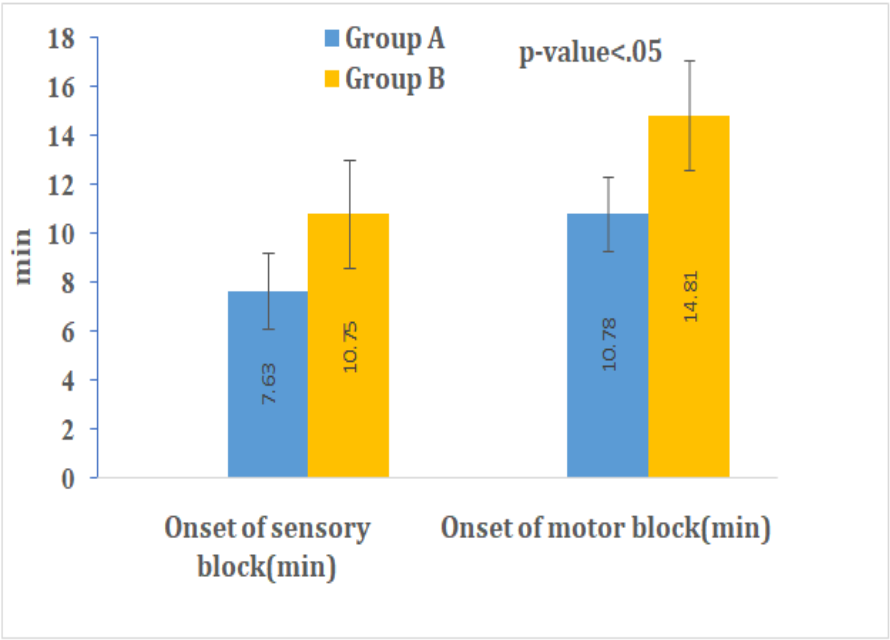

Figure 3: Comparison of duration of sensory and motor block, duration of analgesia, time for first analgesic requirement, total analgesic consumption in the first 48 h, and time to NRS≥ 4 between the groups.

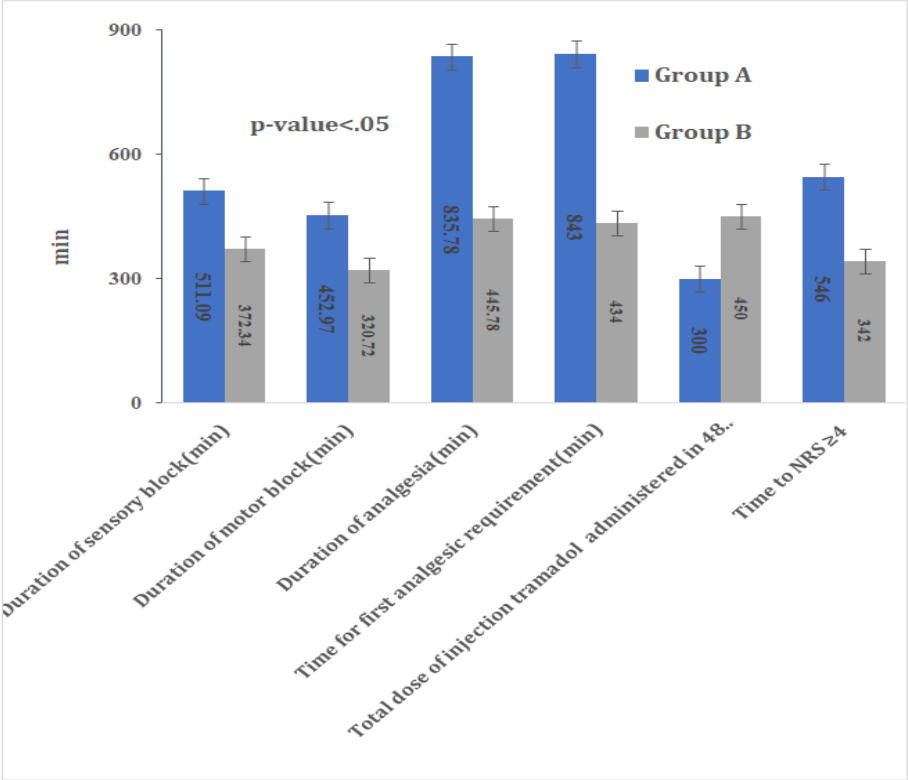

Figure 4: Numerical Rating Scale between the groups at different time intervals.

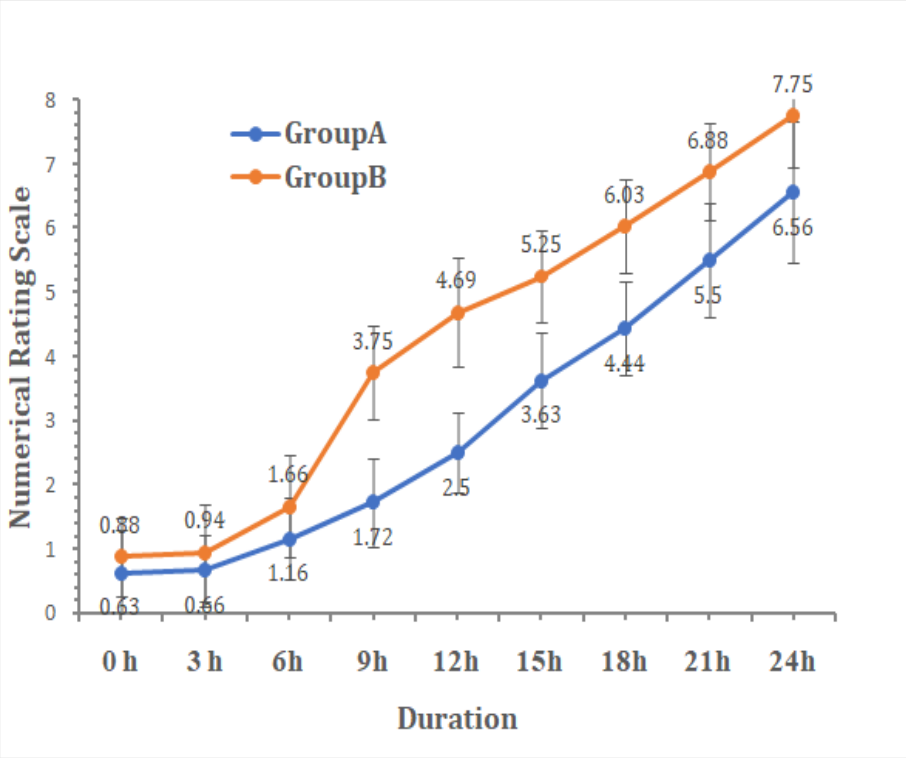

Figure 5: Number of patients who scored NRS in the category of 0-3,4-6 and 7-10 at different time intervals.

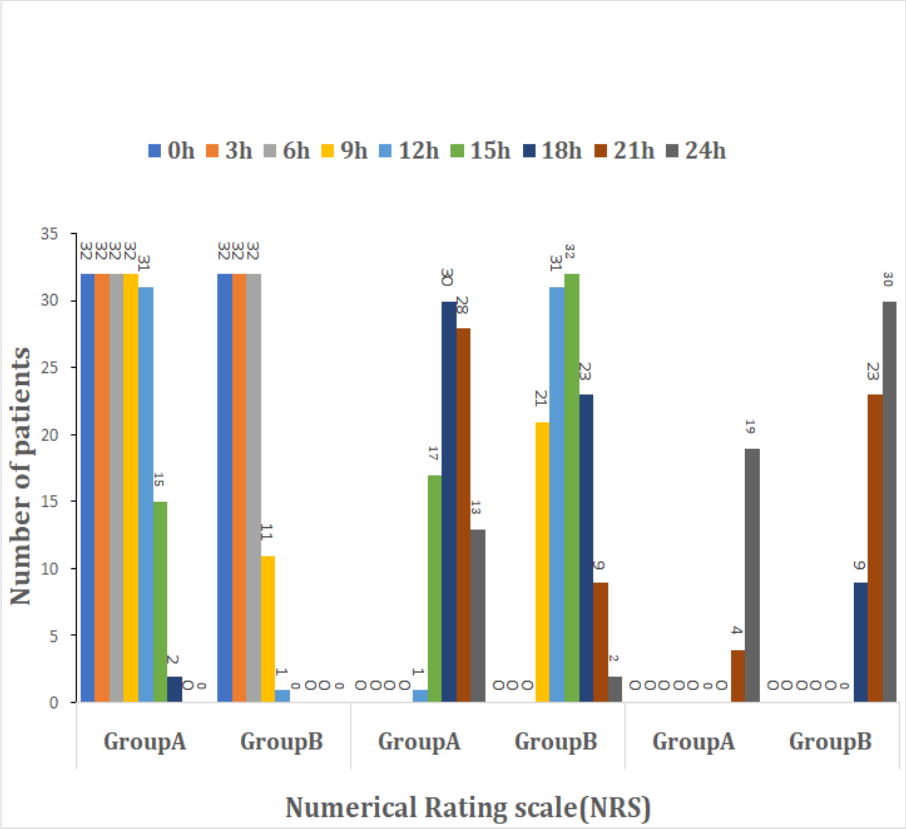

Figure 6: Comparison of the number of patients who scored NRS≥4 at different time intervals.

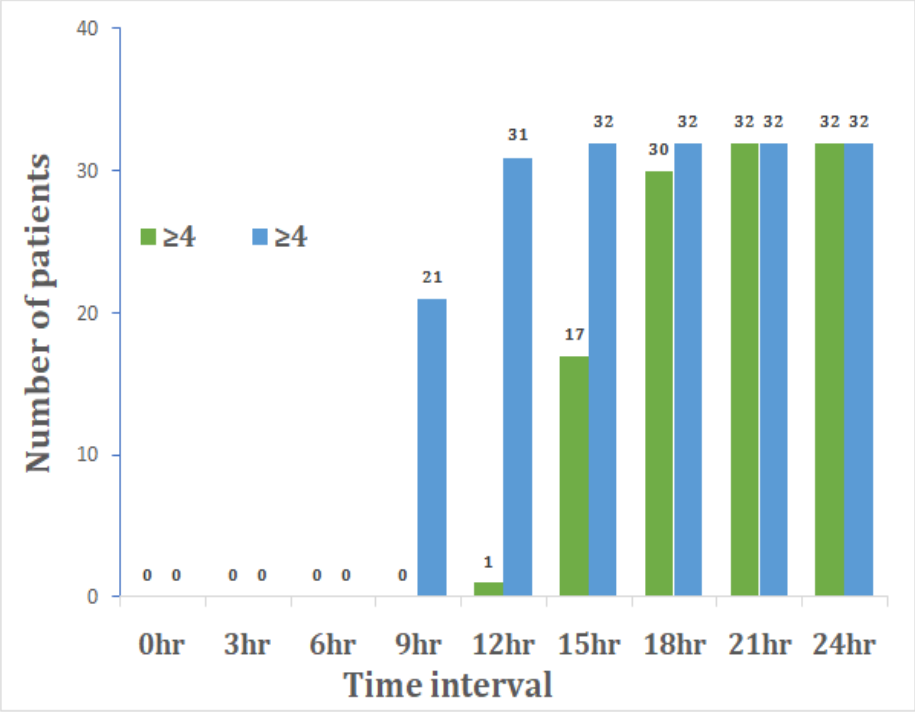

Figure 7: Comparison of mean arterial pressure and heart rate between the groups at different time intervals.