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Randomized control trial of comparison between low dose sodium bicarbonate and dexamethasone as an adjuvant to 0.75% ropivacaine in USG guided brachial plexus block and its peri op hemodynamic and analgesic effects

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Abstract

Background: Peripheral nerve blocks have taken over as the principal technique for upper limb surgeries. A number of adjuvants have been tried individually, but very few studies have investigated the cumulative effect of two or more adjuvants given together along with local anesthetic.

Material and Methods: Fifty ASA status I-II patients with elective shoulder arthroscopic surgeries under interscalene brachial plexus blocks were allocated randomly to receive; Group I– 0.75% ropivacaine (20 mL) plus 8 mg of dexamethasone. Group II –0.75% ropivacaine (20 mL) plus 2 mL of sodium bicarbonate. A nerve stimulation technique with ultrasound was used in all patients.

Results: Onset of sensory block was assessed by pinprick method and motor blockade by modified bromage scale for every minute till complete blockade occurs. Results showed that demographic data are comparable between both groups. The study results showed that 0.75% ropivacaine with sodium bicarbonate group had prolonged duration of sensory and motor blockade and longer duration of analgesia than 0.75% ropivacaine with dexamethasone group.

Conclusion: Sodium bicarbonate prolong the motor block enhances the quality of block and duration of analgesia significantly than dexamethasone in brachial plexus block. Sodium bicarbonate as an adjuvant offer smooth emergence in hemodynamic stability and analgesic effects than dexamethasone.

Keywords: Dexamethasone, Sodium Bicarbonate, Ultrasound-guided ultrasound guided brachial plexus block, 0.75% ropivacaine

Introduction

Brachial plexus block is a popular and widely employed regional nerve block of the upper extremity. Various approaches to brachial plexus block have been described such as interscalene, supraclavicular, infraclavicular, and axillary, but supraclavicular approach is the easiest and most consistent method for anesthesia and perioperative pain management in surgery below the shoulder joint.[1]

Brachial plexus block is a versatile and reliable regional anesthetic technique with multiple applications. The advantages are effective analgesia with good motor blockade, awake patient, extended postoperative analgesia, early ambulation, early resumption of oral feeding, and more cardiovascular and respiratory stability. A variety of local anesthetics have been used for nerve blocks.[2] Bupivacaine is the most commonly used local anesthetic with lower incidence of postoperative complications. Apart from bupivacaine, ropivacaine and lignocaine have also been put into clinical practice. The major limiting factors with the use of local anaesthetics are their short duration of action and delayed onset. To overcome these shortcomings, adjuvants such as opioids, magnesium, ketamine, and clonidine have been tried.[3]

Dexamethasone is a corticosteroid with analgesic, anti-inflammatory, and anti-emetic properties. It has found common use in the prophylaxis and treatment of postoperative nausea and vomiting and reducing post-extubation airway edema. Sodium bicarbonate is an alkali that causes alkalinisation of local anesthetics. Alkalinization allows the pH of injected solution to quickly approach normal tissue

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pH, which in turn liberates the free base and causes ion trapping. This increases the proportion of drug available to cross lipid membrane of nerve cells. Thus, theoretically, addition of sodium bicarbonate should lead to more rapid drug diffusion and a quicker onset of nerve block.[4]

In our study, we aimed at studying randomized control trial of comparison between low dose sodium bicarbonate and dexamethasone as an adjuvant to 0.75% ropivacaine in USG guided brachial plexus block and its peri op hemodynamic and analgesic effects.

Material and Methods

After obtaining approval of Institutional Ethical Committee and informed written consent from all patients, this study was conducted in the department of anesthesia between June 2022 and June 2023. This was a prospective, randomized, double-blind study.

Eighty American Society of Anesthesiologist (ASA) physical status Class I and II patients aged 18–60 years of either sex, who were scheduled for upper limb orthopedicsurgeries, wereselected for the purpose of this study. Patients with any neurological or bleeding disorder, Allergy to local anesthetic drug, Infection at puncture site and Body mass index (BMI) >35 kg/m^2 were excluded from study.

The patients were randomly allocated into three study groups:

Group I (n=40): Patients received 20 mL of 0.75% ropivacaine + 2 ml (8 mg) dexamethasone

Group II (n=40): Patients received 20 mL of 0.75% ropivacaine plus 2 mL of sodium bicarbonate.

Randomization was achieved by pulling out opaque envelops from a partially sealed box. Blinding was done by the preparation of medication according to the assigned group by one anesthesiologist while performance of the block and administration of drug was done by another anesthesiologist who was unaware of the group allocation. Data collection was done by the second anesthesiologist.

All the study participants underwent a preanesthetic visitduring which their basic demographic characteristics(age,sex, and BMI) were noted and they were explained aboutthe Visual Analog Scale (VAS) in detail. The patients werekept fasting 8h before surgery and given tablet alprazolam0.25 mg night before surgery. Upon being shifted to operation theatre, allroutine monitoring, namely heart rate (HR), non-invasive bloodpressure, pulse oximetry (SpO2), and electrocardiogram werestarted.

The following parameters were noted:

- Time of onset of motor block was taken as the time from drug injection to complete loss of motor power
- The time to demand of rescue analgesia was noted
- Duration of sensory block was taken as the time from the time of onset of sensory block to recurrence of pain to needle prick. This was recorded after the completion of surgery every hour for the first 3 h and then every 2 hourly till the return of pin prick.
- Duration of analgesia was taken from the onset of complete sensory block to the demand of first rescue analgesic
- VAS scoring was done at the end of surgery and then every hour for the first 3 h and then every 2 hourly till the demand of rescue analgesia
- Duration of motor block was taken as time from onset of complete motor block to the return of full motor power. This was assessed postoperatively every hour for 3 h and then every 2 hourly till the patient was able to move his fingers or raise his hand.
- The HR, systolic and diastolic blood pressure, mean arterial pressure, and arterial saturation (SpO2) were recorded every 5 min intraoperatively for the first 15min, thereafter every 15min until the end of surgery.
- The patients were monitored for bradycardia, hypotension, convulsions, drowsiness, or any other complications for 24 h postoperatively. Patients who did not develop complete sensory and motor block even after 30 min of block administration were excluded from the study and given general anesthesia. The primary outcome of our study was the duration of analgesia. Whereas onset of sensory and motor block, duration of sensory and motor block, VAS scoring, and any untoward side effects such as convulsions and neurological complications were the secondary outcomes of this study

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Statistical Analysis:

Microsoft Excel was used in creating the database and producing graphs, while the data were analyzed using the Statistical Package for the Social Sciences (SPSS) version 23 for Windows. Mean and standard deviation (±SD) were used to describe quantitative data meeting normal distribution. Continuous two independent groups were compared by parametric independent Student's t test, this was used. Discrete (categorical) groups were compared by chi-square ($\chi 2$) test. p values less than 0.05 ($p<0.05$) was considered statistically significant.

Results and Observations

The mean age of the cases of studied groups was44.21±6.87 and 46.43±5.90 years for group I and II respectively with female and ASA grade I predominance in both groups but the difference was insignificant ($p>0.05$). Duration of sensory block, motor block and analgesia were significantly higher in sodium bicarbonate (group II) than Dexamethasone (group I) ($p<0.05$). The VAS pain score was comparable between groups at 1, 2, 3, 4 hours but it was significantly lower for sodium bicarbonate at 5, 6, 8, 10, 12 and 16 hours ($p<0.05$) and no statistical difference was seen at 20 and 24 hours ($p>0.05$). On the basis of adverse events the cases given sodium bicarbonate and dexamethasone were having comparable side effects such as incidents of nausea, vomiting and evidence of hypotension and bradycardia ($p>0.05$) the majority of the cases in both the groups do not show any side effects.

Table 1: Demographic details of the studied cases

Variables		Group I (n=40)	Group II (n=40)	p-value
Age in years		44.21±6.87	46.43±5.90	0.125
Gender	**Male**	18 (45.0)	19 (47.5)	0.823
	Female	22 (55.0)	21 (52.5)	
ASA Grade	**I**	22 (48.0)	24 (60.0)	0.651
	II	18 (44.0)	16 (40.0)	

Table 2: Showing distribution of initial and post block characteristics.

Variables	Group 1 (N=40)	Group 2 (N=40)	P value
Onset of sensory block (minute)	5.86±1.20	5.50±0.88	0.180
Onset of motor block (minute)	8.65±1.62	7.66±1.38	0.090
Duration of sensory block (minute)	516.50±53.03	585.00±62.90	**<0.001**
Duration of motor block (minute)	423.90±3.56	470.20±66.10	**0.004**
Duration of analgesia (minute)	516.58±25.56	629.25±90.44	**<0.001**

Table 3: Showing distribution VAS score in both groups.

VAS Score	Group-1 (N=40)	Group-2 (N=40)	P value
	Mean	Mean	
1 Hour	4.17±1.23	3.95±1.18	0.417
2 Hour	4.26±1.17	3.98±1.07	0.267
3 Hour	4.89±1.12	4.47±1.24	0.116
4 Hour	5.25±1.14	4.78±1.36	0.098
5 Hour	5.41±0.6	4.26±0.8	**<0.001**
6 Hour	5.27±0.5	3.84±0.9	**<0.001**
8 Hour	4.71±0.7	3.73±1.0	**<0.001**
10 Hour	4.16±0.8	3.52±0.9	**<0.001**
12 Hour	3.95±0.9	3.35±0.8	**0.002**
16 Hour	3.72±0.9	3.24±0.7	**0.014**
20 Hour	4.17±1.23	3.95±1.18	0.417
24 Hour	3.26±0.7	2.98±0.6	0.058

Table 4: Showing distribution of adverse effect in both groups.

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Adverse effect	Group		P value
	Group 1 (N=40) (%)	Group 2 (N=40) (%)	
Evidence of bradycardia	0 (0%)	1 (2.5%)	0.385
Evidence of hypotension	3(7.5%)	2(5.0%)	
Vomiting	3(7.5%)	4(10.0%)	
Nausea	1(2.5%)	0(0%)	
Shivering	2(5.0%)	0(0%)	

Figure 1: Showing distribution of pulse rate (beats per minute) in both groups.

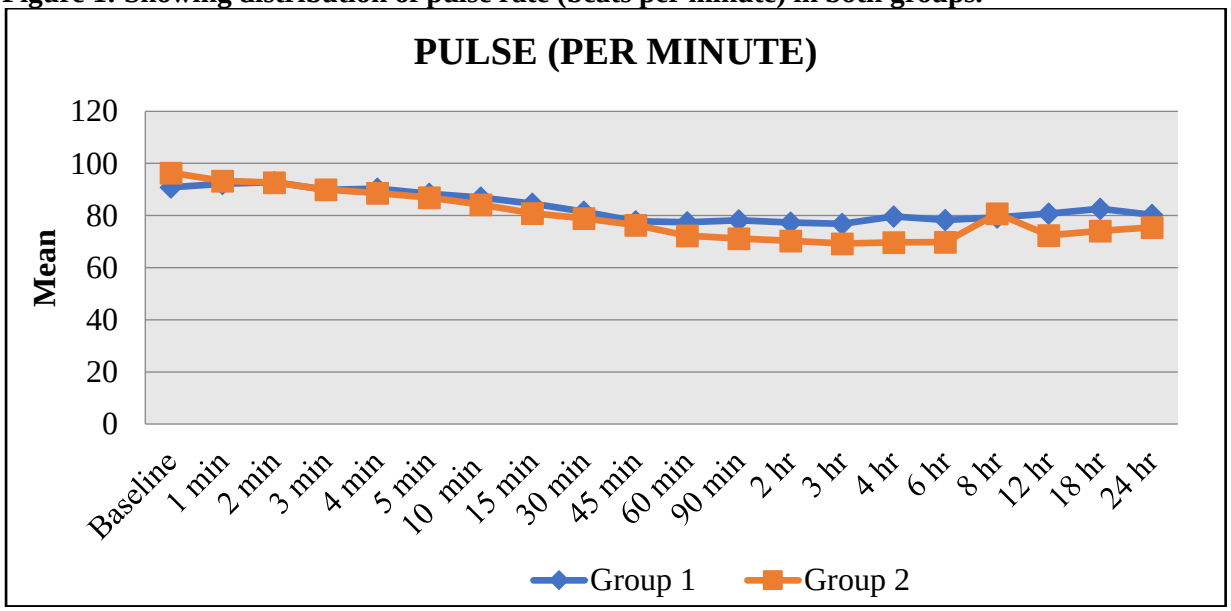

Figure2: Showing distribution ofsystolic blood pressure (mmHg)in both groups.

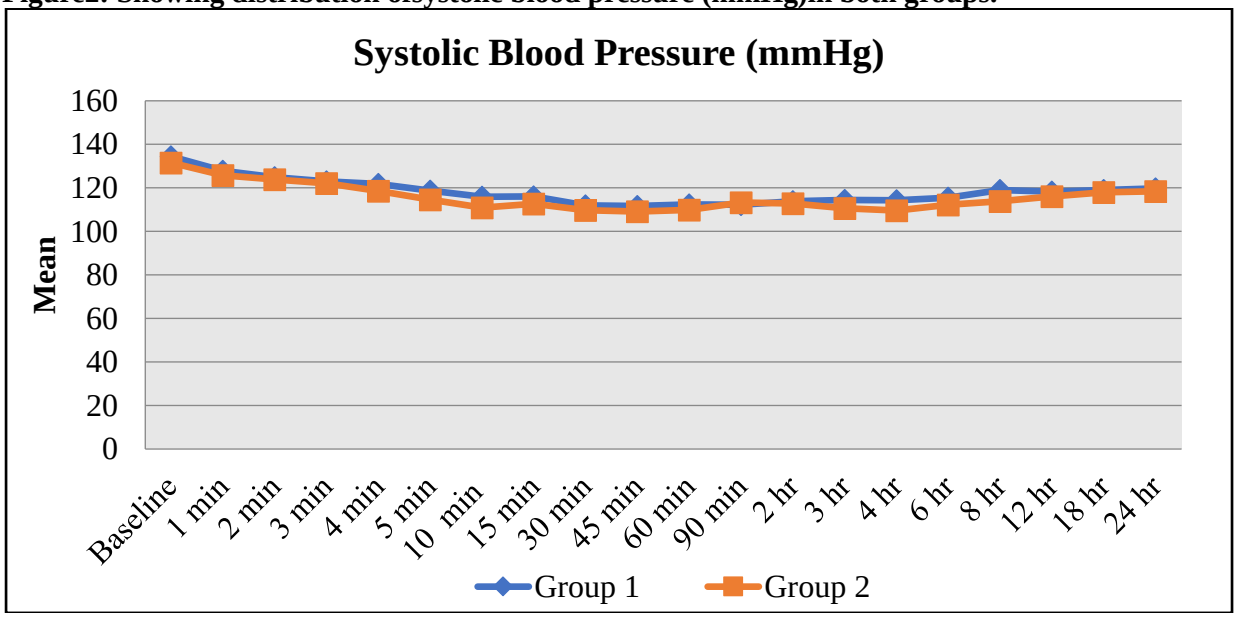

Figure 3: Showing distribution ofdiastolic blood pressure (mmHg) in both groups.

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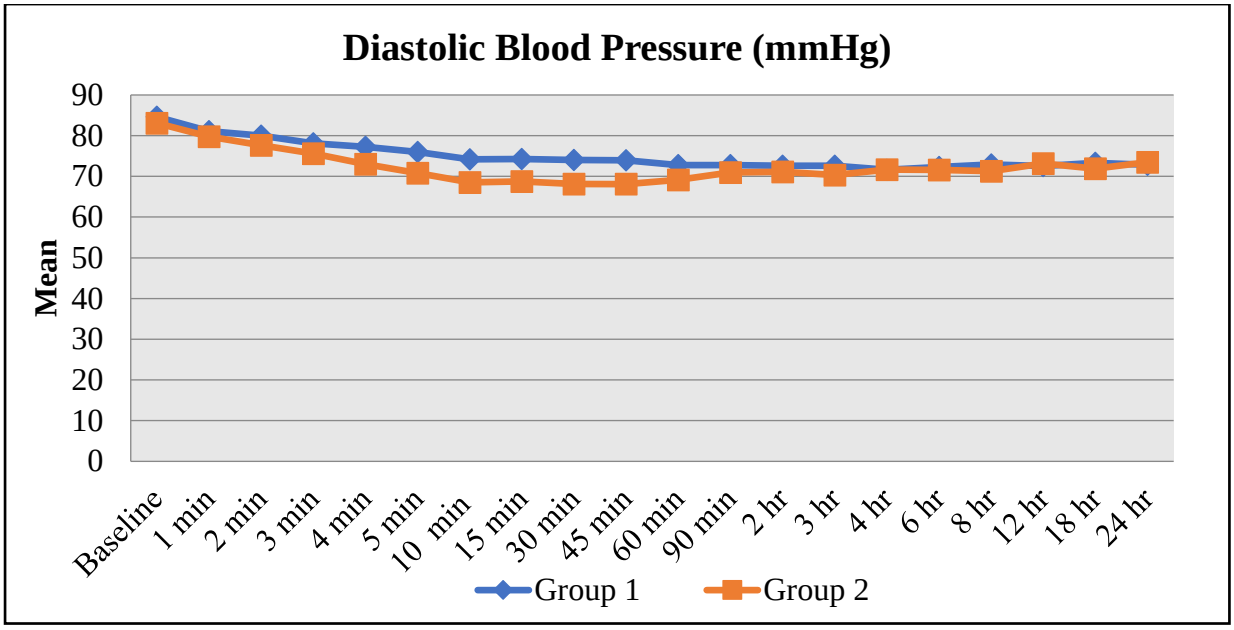

Discussion

In recent years, there has been a growing interest in the practice of regional techniques and, in particular, peripheral nerve blocks for surgical anaesthesia and postoperative analgesia. The development of local anaesthetic agents with lower toxicity and long duration of action had contributed to this change. Compared with general anaesthesia, regional anaesthesia is associated with multiple benefits including reduced morbidity and mortality. In our study, we intended to study the effect of between low dose sodium bicarbonate and dexamethasone as an adjuvant to 0.75% ropivacaine in USG guided brachial plexus block and its peri operative hemodynamic and analgesic effects.

The demographic data including age, weight, sex, and ASA grading were comparable between the studied groups (p>0.05). Our findings were in accordance with the findings of **Kour L et al**4, and **Gopalan BV et al**[5]**.**Hasan Me t al reported that the demographic parameters such as age, weight, sex ratio, American Society of Anesthesiologists grading, and duration of anesthesia were comparable in both the groups.

In the present study the duration of sensory block (585.00±62.90 min) and motor block (470.20±66.10 min) was significantly higher in sodium bicarbonate group than dexamethasone (p<0.05). Also, duration of analgesia was significantly higher in sodium bicarbonate group (629.25±90.44 min) than dexamethasone (516.58±25.56min). Our findings were consistent with the findings of **Kour L et al**4 who reported that the duration of sensory block was the longest with Group DB (dexamethasone + bicarbonate) – 1175±106.7 min; followed by Group D (dexamethasone + ropivacaine) 605 ± 86.40 min and shortest in Group R (ropivacaine alone) 280 ± 25.40 min. Similarly, the duration of analgesia in Group DB and Group D was significantly longer than in group R-320 ± 22.40 min; also, Group DB provided significantly longer analgesia 1285 ± 102.70 min than Group D 685 ± 62.30 min. The duration of motor block was significantly longer inGroup DB (920 ± 88.68 min) and Group D (520 ± 56.50 min)
than in Group R (250 ± 32.60 min). Furthermore, Group DBshowed longer duration of motor block than Group D.In another study by **Gopalan BV et al**5observed that the duration of analgesia in Group I (dexamethasone) had a mean duration of 579.30±56.91 (9.6 h) min and the mean duration of was 417.20±28.73-min (6.95 h) in Group II (plain ropivacaine) (P < 0.05).**Galindo A et al**[6] documented that by altering the pH of the local anesthetic solution with sodium bicarbonate, in a 1:10 mixture with lidocaine orbupivacaine, the time for the onset could be decreased and the distribution ofneural blockade enhanced significantly.

Sodium bicarbonate works by alkalinisation of local anaesthetic. Alkalinization of local anesthetics raise the pH of the solution and has been shown to increase the speed of nerve blocks. The pH of the injected solution more quickly approaches that of the normal tissue pH. It liberates the free

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base and causes ion trapping. This changes the ratio of nonionized to ionized species in solution and increases the proportion of drug able to cross the lipid membrane of nerve cells. The faster formation of a mixture with charged and uncharged forms results in more rapid drug diffusion and a quicker onset of nerve blocking. There were no such studies in the past which have compared dexamethasone with sodium bicarbonate along with ropivacaine.

Devaram V et al[7] studied the effect of addition of sodium bicarbonate to lignocaine and found it to provide a quicker onset as well as prolong the duration of action of the local anaesthetic. **Manjunath KR et al**[8] added sodium bicarbonate to a mixture of lignocaine and bupivacaine and observed results similar to **Devaram V et al**.7 However, **Ninan R and Kurien MB**[9]compared addition of sodium bicarbonate and potassium chloride to bupivacaine and concluded that addition of potassium chloride had significant clinical advantage over alkalinised bupivacaine. They further noted that alkalinized bupivacaine did not have any advantage over plain bupivacaine.

In this study the result of VAS score showed that from 5 hour to 16 hours sodium bicarbonate produces significantly lower pain than dexamethasone ($p<0.05$) and at 20 hours and 24 hours the pain output was comparable between the groups ($p>0.05$). According to **Kuor L et al**4VAS scores and demand of first rescue analgesic (duration of analgesia) also showed that addition of sodium bicarbonate to dexamethasone and ropivacaine mixture showed maximum duration of analgesia with significantly less postoperative VAS scores than dexamethasone group. Plain ropivacaine group had the shortest duration of analgesia.**Araf SK, El-Sayed AA**[10] reported that addition of sodium bicarbonate to local anesthetic mixture was the best way in lowering the IOP (intra ocular pressure) other than other groups and addition of fentanyl to local anesthesia provided more rapid onset and duration of anesthesia, more rapid onset and duration for lid and global akinesia, less pain, less analgesic requirement.

In our study on the basis of adverse events the cases given sodium bicarbonate and dexamethasone were having comparable side effects such as incidents of nausea, vomiting and evidence of hypotension and bradycardia ($p>0.05$) the majority of the cases in both the groups do not show any side effects. In both the groups, the incidence of unwantedhemodynamic response during emergence was low **Gopalan BV et al**5 reported that the side effects in our study compared are nausea, vomiting, and dry mouth, about 60.0% of the patients have no side effects in both groups and the side effects are also minimal and were comparable in both the groups.**Hasan M et al**[11] reported that majority of patients (>85.0%) in both the groups remained hemodynamic stable during emergence with no statistical difference between the groups.

Limitations of the study

- Relatively smaller sample size
- The findings of this study may not relate to short-duration surgeries.

Conclusion

Sodium bicarbonate prolong the motor and sensory block enhances the quality of block and duration of analgesia significantly than dexamethasone in brachial plexus block. Both bicarbonate and dexamethasone as an adjuvant to 0.75% ropivacaine offer smooth emergence in terms of tube tolerance and hemodynamic stability. It also leads to lowpostoperative VAS scores and hence has a significant analgesic sparing effect postoperatively.

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