ORIGINAL RESEARCH

To study the effect of dexamethasone added as adjuvant to ropivacaine for brachial plexus block by supraclavicular approach

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ABSTRACT

Background: Brachial plexus block is a popular approach for upper limb surgeries and emerging as alternative to general anesthesia due to lesser complications. Brachial plexus block is effective in terms of cost and performance, margin of safety, along with good postoperative analgesia. The local anesthetics were commonly used to produce the regional anesthesia but many studies have proved that addition of other drugs produces synergistic effects. **Aims**: Aim of this study was to assess the effects of addition of dexamethasone as adjuvant to ropivacaine on postoperative analgesia. **Materials and methods**: A randomized controlled prospective double-blind study was undertaken involving 60 patients of both sex exposed for upper limb surgeries under brachial plexus block. These patients were randomly divided into 2 groups as Control group: Group R: Would receive 30ml, ropivacaine 0.5%+ 1.5 ml (0.9%) saline (placebo). Study group: Group D: Would receive 30ml of mixture of ropivacaine 0.5%and +1.5 ml dexamethasone(4mg/ml). **Results**: A randomized prospective placebo controlled double blind study was taken up in two groups of thirty patients each. The mean age of patients was 37.73±10.64years and 34.67±9.75years in ropivacaine and ropivacaine – dexamethasone groups respectively. Majority of them belonged to below 50 years age group. The two groups were comparable with respect to age. The mean time of onset of sensory block in ropivacaine group was 21.00±3.32 minutes and 13.83±5.20 minutes in ropivacaine – dexamethasone group which was statistically significant. The mean time of onset of motor block in this study in ropivacaine group was 28.83±2.15 minutes and the mean onset of motor block in ropivacaine – dexamethasone group was 22.17±4.68 minutes. The difference was statistically significant. The mean duration of postoperative analgesia in ropivacaine group was 15.92±3.53hours and in ropivacaine-dexamethasone group was 20.84±3.13 hours. There was statistically significant difference between ropivacaine and ropivacaine- dexamethasone groups. The mean rescue analgesic doses were lower in ropivacaine- dexamethasone group compared to ropivacaine group. **Conclusion:** Dexamethasone being a potent corticosteroid it has beneficial effect on addition as a local anesthetic in terms of postoperative pain and requirement of rescue analgesic.

Keywords: Brachial plexus block, Dexamethasone, Ropivacaine, rescue analgesic.

INTRODUCTION

Brachial plexus block is a popular approach for upper limb surgeries as an alternative to general anesthesia and also with general anaesthesia to achieve ideal operating conditions by producing muscular relaxation, maintaining stable intraoperative hemodynamic condition and sympathetic block which reduces postoperative pain, vasospasm and edema.[1]

The available literature has also shown that this type of block mainly avoids the untoward effects of general anesthesia including upper airway instrumentation and thus prevents the consequences of it. It has also been shown that it is attractive due to its effectiveness in terms of cost and performance, margin of safety, along with good postoperative analgesia.A variety of approaches of brachial plexus block have been described in the

literature. However, supraclavicular block is a consistent and easiest method for anesthesia and postoperative pain management.[2,3]

Ropivacaine one is of the local anesthetic used most frequently as it has a longer duration of action varying from 3 to 8 hours. However, it has limiting factors like delayed onset, patchy or incomplete

The steroids have been shown to reduce the inflammation and also have shown analgesic effects. The pain relief after administration of steroids is due to reduction of inflammation by inhibition of Phospholipase A2 and also blocks the transmission in nociceptive C – fibers to reduce the pain6. Phospholipase A2 has been found to induce membrane injury and edema by generating inflammatory mediators. It is the enzyme responsible for liberation of arachidonic acid leading to the production of prostaglandins and leukotrienes. They also sensitize small neurons and enhance pain generation by abnormal conduction and intraneural edema.

Dexamethasone is very potent and highly selective glucocorticoid. Basically, it is used as anti-inflammatory and immunosuppressant. Its potency is about 40 times that of hydrocortisone. Clinical uses of dexamethasone are for treatment of many inflammatory and autoimmune conditions but Glucocorticoid are also used to treat patients suffering from neuropathic pain and complex regional pain syndromes (CRPS). So, steroids have anti-inflammatory as well as analgesic effects.3Many studies have successfully proved the usefulness of Dexamethasone as an effective analgesic.[4,5]However, the studies are scant in this part of the country about the analgesic efficacy of the dexamethasone. Hence, this study was taken up to assess the efficacy of Dexamethasone as an analgesic especially for upper limb surgeries.

MATERIALS AND METHODS

This study was conducted on 60 patients undergoing upper limb surgeries aged between 20 to 60 years under brachial plexus block in Prathima Institute of Medical Sciences, Karimnagar from November 2018 to November 2020.

Ethical clearance was obtained before Institutional Ethical review committee. An informed, bilingual and written consent was obtained from all the patients.

INCLUSION CRITERIA

Patients of both genders aged between 20 to 60years, with ASA class I and II.

EXCLUSION CRITERIA

Severe lung disease, Contralateral diaphragmatic paralysis

Pre-existing neuropathy involving the surgical limb, Coagulopathy, Contraindication due to use of dexamethasone, Hypersensitivity to the drugs uses, Diabetes, Acid peptic disease, Systemic use of corticosteroids for 2 weeks or longer within 6 months of surgery, Pregnancy, Patients with abnormal BT, CT or on anticoagulation therapy, severe anemia, hypovolemia, shock, septicemia and h/o seizures and Local infection at the site of proposed puncture for supraclavicular block.

A randomized controlled prospective double-blind study was undertaken involving 60 patients of both sex exposed for upper limb surgeries under brachial plexus block. These patients were randomly divided into 2 groups:

Control group: Group R: Would receive 30ml, ropivacaine 0.5%+ 1.5 ml (0.9%) saline (placebo)

Study group: Group D: Would receive 30ml of mixture of ropivacaine 0.5%and +1.5 ml dexamethasone(4mg/ml).

All the study drugs used were preservative free.30ml solution for „single shot" brachial plexus blockade would be administered.Demographic (age, gender, comorbidities) characteristics were recorded.Morphometric (height, weight) characteristics of participating patients were recorded

Patients were fasted overnight.IV line secured and patients would be connected to monitors to record pulse, O2 saturation, NIBP and ECG.Premedication with Inj. Midazolam 1mg & Inj. Glycopyrrolate 0.2 mg before the procedure.

Patient lies supine, arms by the side and head turned to other side.The choice of block and technique (nerve stimulator paraesthesia stroke) was dependent on availability of resources.

Anaesthetist who was not involved the study was asked to give the block.After incremental injection of local anaesthetic mixture, patients were evaluated at 5 min interval for 30 mins for developing the sensory and motor block.

In case of inadequate blockade due to any reason the case was converted to general anesthesia and it was not considered in the study.The severity of postoperative pain was assessed by using verbal response score (VRS). Patients reporting severe pains were given intravenous Fentanyl (1 mcg/kg body weight) repeated till comfortable.

Data collected were analyzed using appropriate statistical method.The time of onset for sensory blockade, defined as the time between injection of local anaesthetic and abolition of pinprick response was evaluated in four nerve areas (radial, ulnar, median, musculocutaneous) at every 5 mins until 30 mins after the injection. The block was judge failed if anaesthesia was not present in 2 or more peripheral nerve distribution and such patients were excluded from study.

For motor block, the inability to flex or extend the following joints: musculocutaneous nerve (flex elbow), median nerve (flex distal interphalangeal joint of 2nd finger), radial nerve (extend wrist), ulnar nerve (abduct 3rd and 4th fingers) was tested. Time of onset of motor block, defined as the time between injection of local anaesthetic and inability to move the joints was evaluated every 5 mins and time to block at least 2 major nerves was noted.

The duration of sensory blockade, defined as the time between onset of action and return of pinprick response, was assessed every 60 minutes in at least 3 major nerve territory.

The duration of analgesia, defined as the time between onset of action and the onset of pain, was the time when the patients received the first dose of rescue analgesic.

The duration of motor blockade, was assessed every 60 mins till return of complete muscle power in at least 2 major nerve distributions.

Pain was assessed by standardized verbal response score (VRS) at 0, 1, 3, 6, 9, 12, 24 hours postoperatively.VRS score more than 3 was considered inadequate analgesia.Time to first dose of rescue analgesia and total amount of fentanyl required in first 24 hrs postoperatively was noted.

Statistical Methods: Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5% level of significance. The following assumptions on data is made. Assumptions: 1. Dependent variables should be normally distributed, 2. Samples drawn from the population should be random. Cases of the samples should be independent.

Student "t" test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameters. Chi-square/ Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups.The Statistical software namely SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1, Systat 12.0 and R environment ver.2.11.1 were used for the analysis of the data and Microsoft Word and Excel have been used to generate graphs, tables etc.

RESULTS

Table 1: Demographic distribution of patients studied

	Group D		Group R	
Age in years	**No.**	**%**	**No.**	**%**
21-30	13	43.3	8	26.7
31-40	8	26.7	11	36.7
41-50	8	26.7	8	26.7
51-60	1	3.3	3	10.0
Total	30	100.0	30	100.0
Mean ± SD	34.67±9.75		37.73±10.64	
Gender				
Female	6	20.0	10	33.3
Male	24	80.0	20	66.7
Height (cm)	167.07±5.69		165.93±6.01	
Weight (kg)	68.03±7.44		67.10±8.07	
ASA grading				
Grade 1	23	76.7	23	76.7
Grade 2	7	23.3	7	23.3

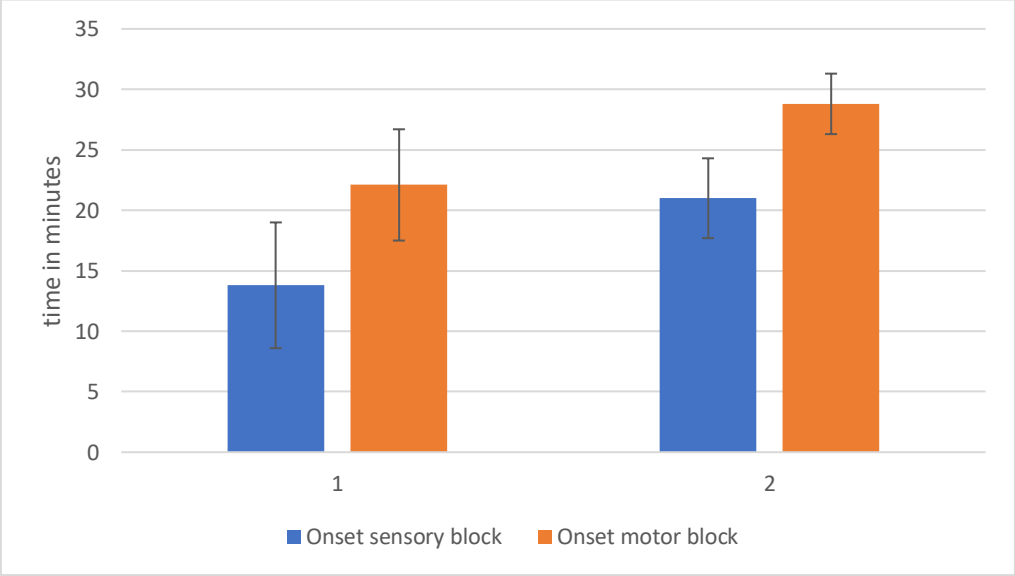
The youngest patient was of 20 years and the eldest was 60 years old. The majority of patients fall in the age group of 21-30 years. The distribution of patients with respect to age was comparable in both the groups (p=0.249).Since the age groups were similar the groups were comparable in age.

group had 10 females and 20 male patients whereas ropivacaine – dexamethasone group had 6 female patients and 24 male patients.

The average height of patients receiving ropivacaine was 165.93±6.01 and weight was 67.10±8.07 and the patients receiving ropivacaine – dexamethasone group were of height of 167.07±5.69 and weight of 68.03±7.44. Hence, both groups were comparable.

Results show that majority of patients in this study belonged to ASA 1, 76.7% in both the groups and 23.3 % were of ASA grade II. Hence, the distribution of patients with respect to ASA physical status was comparable in both the groups.

Figure 1: Onset sensory block, onset motor block in minutes in the two groups studied



The mean time of onset of sensory block in ropivacaine group was 21.00±3.32 minutes and 13.83±5.20 minutes in ropivacaine – Dexamethasone group. This difference in onset of sensory block was statistically significant between the two groups.

The mean time of onset of motor block in this study in ropivacaine group was 28.83±2.15 minutes and the mean onset of motor block in ropivacaine – Dexamethasone group was 22.17±4.68 minutes. There is significant difference between the onset of motor block in minutes and ropivacaine and ropivacaine – Dexamethasone groups.

Table 2: Comparison of hemodynamic variables in two groups studied

Pulse rate	**Group D**	**Group R**	**p value**
0 min	83.57±12.23	80.50±13.98	0.370
5 min	83.37±11.74	80.70±13.25	0.413
10 min	82.70±10.87	80.87±13.39	0.563
15 min	83.00±10.95	81.20±13.28	0.569
20 min	82.97±11.06	80.83±12.57	0.488
25 min	82.77±11.16	81.17±12.63	0.605
30 min	82.67±10.89	81.00±12.26	0.580
MAP (mmHg)			
0 min	92.74±8.25	93.04±8.50	0.890
5 min	93.31±8.40	93.13±7.71	0.932
10 min	92.60±8.45	93.04±7.91	0.834
15 min	92.60±8.42	92.91±7.03	0.877
20 min	92.47±8.66	92.58±8.05	0.959
25 min	92.24±8.74	92.49±7.89	0.910
30 min	91.96±8.33	92.76±7.50	0.697
SpO2%			
0 min	98.97±0.32	99.03±0.49	0.535

5 min	99.30±0.70	98.97±0.85	0.103
10 min	99.10±0.84	95.73±16.41	0.266
15 min	99.17±0.79	98.60±0.86	0.010**
20 min	99.00±0.59	98.67±0.80	0.071+
25 min	98.97±0.67	98.63±0.76	0.078+
30 min	98.93±0.64	98.83±0.59	0.532

There was no statistically significant difference between ropivacaine and ropivacaine – dexamethasone groups in heart rate at different time intervals.

The difference in systolic blood pressures at different time intervals between ropivacaine and ropivacaine – dexamethasone groups were not statistically significant in the initial time.

The difference between the oxygen saturation was not statistically significant between ropivacaine and ropivacaine – dexamethasone group.

Table 3: Comparison of time first complaint pain/ Time first rescue analgesia/ Total dose fentanyl

	Group D	Group R	p value
Time first complaint pain (hours)	20.84±3.13	15.92±3.53	<0.001**
Time first rescue analgesia (hours)	21.44±3.16	16.67±3.62	<0.001**
Total dose fentanyl (mcg)	25.33±7.19	105.33±51.86	<0.001**

The primary objective of this study is to evaluate the postoperative analgesia in both the groups. The patients receiving ropivacaine only first complained of pain at 15.92±3.53 hours and the patients of ropivacaine- dexamethasone group complained of pain at 20.84±3.13 hours, which is very significant.

The first time of rescue analgesia and the total dose of rescue analgesia required by ropivacaine group was 16.67±3.62 hours and 105.33±51.86 mcg respectively, whereas the first time of rescue analgesic given was at 21.44±3.16 hours and the total dose of fentanyl used was 25.33±7.19 mcg in ropivacaine- dexamethasone group. These values were statistically very significant. We infer that patients receiving ropivacaine only required rescue analgesic earlier and in larger quantities where as those receiving ropivacaine-dexamethasone was much later and lesser.

Table 4: Comparison of pain score in two groups studied

Pain score	Group D (n=30)	Group R (n=30)
No pain	13(43.3%)	0
Slight pain	3(10.0%)	0
Mild pain	7(23.3%)	0
Moderate pain	7(23.3%)	11(36.7%)
most intense pain	0	2(6.7%)
Severe pain	0	10(33.3%)
Extreme pain	0	7(23.3%)

When comparing the pain score in the two groups, the ropivacaine group had moderate to extreme pain while the ropivacaine-dexamethasone group had no pain to moderate pain in the first 24 hours postoperatively. This shows that adding dexamethasone to ropivacaine improves the postoperative pain relief in patients significantly.

DISCUSSION

Brachial plexus block has been emerged as a popular technique among the anesthetists for upper limb surgeries. This type of anaesthesia avoids the untoward effects of general anaesthesia like complications related to upper airway instrumentation. Research has also shown that this approach is a good approach and effective in terms of cost, performance, margin of safety and also provides good postoperative analgesia.[6]Several drugs have been tried in brachial plexus block and ropivacaine is used for its longer duration of action. However, ropivacaine is condemned for its delayed onset, patchy or incomplete analgesia. Adjuvant drugs have been used to treat the side effects of ropivacaine, making the drug more effective for surgery and postoperative analgesia.

This study was done at PIMS, Karimnagar, to examine the effect of dexamethasone as an adjuvant to ropivacaine for brachial plexus block. This study was unique in that it was designed to detect a modest interaction between dexamethasone and ropivacaine: an interaction that proved to be both statistically significant and clinically important.In a study done by Cummings KC et al of USA[7], dexamethasone was more effective in prolonging analgesia from interscalene block using ropivacaine than bupivacaine.However, the studies are scant to evaluate the efficacy of ropivacaine alone and when used in combination with corticosteroids like

dexamethasone. Hence, this study was undertaken in this part of the country to evaluate its efficacy of it. A randomized double blinded study was taken up among 60 patients posted for upper limb surgeries who were aged between 20 to 60 years.

The mean age of patients posted was 37.73±10.64 years in ropivacaine and 34.67±9.75 in ropivacaine-dexamethasone groups. There was no statistically significant difference in age between the two groups. Hence, the two groups were comparable in the aspect of age. Majority of the patients in this study belonged to 31-50 years in both the groups. In a study by Cummings KC et al of Lakewood, USA, the mean age was 55 years in ropivacaine group and 59 in Dexamethasone group.

The mean time of onset of sensory block in ropivacaine group was 21.00±3.32 minutes, which was longer as compared to ropivacaine-dexamethasone group, 13.83±5.20 minutes.The mean onset of motor block in ropivacaine group was 28.83±2.15 minutes, which was also longer as compared to ropivacaine-dexamethasone group which was of 22.17±4.68 minutes.In a study by Sheshtha et al in Nepal[8], who compared bupivacaine plain with bupivacaine-dexamethasone the mean onset of action was 18.15±4.25 minutes with bupivacaine plain while it was 14.5±2.1 with bupivacaine-dexamethasone mixture.However, in our study ropivacaine was used as local anaesthetic and addition of dexamethasone as adjuvant reduced the time of onset of motor and sensory block.

In this study, the mean time of first complaint of pain with ropivacaine- dexamethasone was 20.84±3.13 hrs and with ropivacaine alone was 15.92±3.53hrs. In the year 2011, a study by Cummings KC et al,[7] the mean duration of postoperative analgesia was around 22 hours in a group who received ropivacaine with dexamethasone and its was around 11.8 hours in group receiving ropivacaine only. These values are similar to values of this study and hence this shows that the addition of steroid prolongs the duration of anesthesia and also produces earlier onset of action. This might be due anti- inflammatory effect of Dexamethasone. It has also been proved in other studies that the addition of Dexamethasone to local anesthetic prolongs the duration of action.

The mean heart rate in ropivacaine-dexamethasone group was slightly higher (82.67±0.89 bpm) than the ropivacaine group (81.00±12.26 bpm). There was no statistically significant difference between the pulse rates of the dexamethasone group than local anesthetic group. But it was within normal limits. The mean systolic and diastolic pressure was also almost similar in both the groups and within normal limits. The mean oxygen saturation did not vary much in both the groups. In summary, the hemodynamic responses are crucial in maintenance of patient during anesthesia. However, ropivacaine has already proved its safety especially when used as local anesthetic in brachial plexus block. Since the hemodynamic responses were similar, the study concludes that the ropivacaine-dexamethasone combination is also safer to use in brachial plexus block.

The mean numbers of rescue analgesic doses were lesser in dexamethasone group than ropivacaine alone group significantly. In a study by Cummings KC in 2011, the mean number of rescue analgesic dose was also lesser in Dexamethasone group than other two groups, which is in favour of this study.[7]

No adverse effects were reported in both the groups in this study.Dexamethasone, being a glucocorticoid, has emerged as a potent corticosteroid when used along with ropivacaine. Many studies have successfully proved the usefulness of Dexamethasone as an effective analgesic.[8,9]The mechanism of action of corticosteroids in prolonging peripheral neural blockade is not clearly understood. In brief, the prolongation of analgesic duration after perineural administration of dexamethasone maybe secondary to a local action on nociceptive C-fibersmediated via glucocorticoid receptors and the up-regulation of function of potassium channels in excitable cells.[10,11]

The safety of perineural adjuvants has recently been the subject of debate that centers on the potential for neurotoxicity of adjuvant drug itself or any co-administered preservatives.[12]The use of dexamethasone at doses between 4-12 mg via intravenous, perineural and epidural routes is described in regional anaesthesia and pain medicine reviews and literature.

Despite the concern surrounding the “off label” use of perineural adjuvants,[78]the safety profile of dexamethasone is promising. No trial has reported neurotoxicity attributable to dexamethasone, although sample sizes to date are insufficient to detect rare outcomes and most studies did not follow patients for weeks after surgery. In this study, there were no adverse events in 60 patients receiving dexamethasone.

Reassuringly, though, animal studies demonstrated no long term changes in nerve structure or function after local steroid administration.From a mechanistic point of view, toxicity attributed to corticosteroids may in fact be due to the particulate natureor vehicle usedin different preparations- neither of which applies to the formulation of dexamethasone (dexamethasone sodium phosphate) used in this study. Additionally, corticosteroids have a long history of safe use in the epidural space for the treatment of radicular pain arising from nerve root irritationand dexamethasone specifically has been studied as an adjuvant to epidural local anaesthetics.The neurologic risk, if any, of dexamethasone thus appears to be minimal. In fact, the use of dexamethasone as an adjunct to local anaesthesia for nerve blocks is discussed in reviews andliterature.[12,13]

Systemic toxicity from a single dose of

dexamethasone is also unlikely. It is effective[84] and widely administered intravenously by anaesthesiologists for prophylaxis against postoperative nausea and vomiting. Concerns about steroid-induced hyperglycemia have been borne out in high-dose intravenous regimens,but have not been reported in practice (American Society of Anaesthesiologists Annual Meeting, October 2009, Abstract A955).[14]

Perineural glucocorticoids are eventually absorbed and thus may exert systemic effects. Given intravenously, several steroids have been shown to improve postoperative pain and reduce postoperative nausea and vomiting.[15]Any systemic analgesic effect, however, should be minimal due to slow systemic uptake: a human volunteer trial of intercostal bupivacaine and dexamethasone microsphere injection resulted in negligible blood dexamethasone levels.[73] Nonetheless, it remains possible (although unlikely) that some or even all of the block prolongation observed could have been obtained by intravenous injection of dexamethasone.

In studies Dexamethasone as an adjuvant to local anaesthetics like bupivacaine and ropivacaine demonstrated significant beneficial dose dependent effect on duration to the first analgesic request and the number of patients not requiring analgesics in the 1st 48 hrs. after the surgery. And also Dexamethasone 10mg equally effective as other drugs such as Dexmedetomidine in extending the duration of block.[16] As an adjuvant to local anaesthetics Dexamethasone prolongs the duration of analgesia when injected perineurally[90,91]and improves the analgesic effect. However, the studies are scant to evaluate the efficacy of Ropivacaine alone and when used in combination with corticosteroids like Dexamethasone. Hence, this study was undertaken in this institute to evaluate its efficacy.

This study has shown that addition of 6 mg of Dexamethasone effectively and significantly prolongs the duration of analgesia by producing early onset of action. This study has also shown that the early onset of action in steroid group can be attributed to synergistic action with local anesthetic on blockage of nerve fibers. The prolongation of duration of block is the local effect of steroid than the systemic action. The effects are mainly mediated by glucocorticoid receptors. The blockade is not produced by the action of steroid alone. Hence, it should be used in addition to a local anesthetic.This study demonstrates that dexamethasone significantly prolongs the analgesic effect of plain ropivacaine 0.5% used as a single injection brachial plexus block.

CONCLUSION

Brachial plexus block has been popular technique in delivery of anesthesia in patients undergoing upper limb surgeries. The elegancy in the technique helps in safe delivery anesthesia and also assures prolonged analgesia by preventing the side effects of general anesthesia. Steroids are commonly used along with the local anesthetics due to their anti-inflammatory and analgesic effects.

Dexamethasone being a potent corticosteroid is becoming popular for the regional blocks. This study has made an effort to compare the Ropivacaine alone with Ropivacaine-Dexamethasone. The study is methodologically elegant since it is a randomized prospective placebo controlled double blind study. This study has shown the beneficial effect of addition of steroid to a local anesthetic in terms of postoperative pain and requirement of rescue analgesic. The further research with calculation of sample size is needed to study the beneficial or adverse effects of addition of steroids along with local anesthetics for producing the blockade.

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