A Comparative Study of Clonidine And Dexamethasone as Adjuvants to Ropivacaine in Ultrasound-Guided Popliteal Sciatic Nerve Block for Surgeries of Foot and Ankle

[1]Dr. Sudarshini M., [2]Dr. Shashwathi Siddaramappa, [3]Dr. Puspanjali Jena

[1]Clinical Associate, Department of Anaesthesiology, P.D. Hinduja Hospital,Mumbai, Maharashtra, India.
[2]Junior Consultant, Department of Anaesthesiology, Manipal Hospital, Yashwantpur,Bangalore, Karnataka, India.
[3]Junior Consultant, Department of Anaesthesiology, Kalinga Institute of Medical Science, Bhubaneswar, Odisha, India.

Corresponding author: Dr. Sudarshini M., Clinical Associate, Department of Anaesthesiology, P.D. Hinduja Hospital,Mumbai, Maharashtra, India.

ABSTRACT

Background: Ropivacaine is commonly used for peripheral nerve blocks. Adding adjuvants to Ropivacaine has several advantages like faster onset of action, longer duration of analgesia and lesser complications. This study aims at comparing two such adjuvants with respect to onset of action, intraoperative haemodynamics, duration of postoperative analgesia and any associated complications**.**

Methods: This was a hospital-based prospective, randomized, comparative study, conducted among 90 patientswho underwent foot and ankle procedures. The study was conducted over a period of12 months after obtaining clearance from the institutional ethics committee and written informed consent from the study participants.

Results: The onset of motor blockade of common peroneal nerve shows a statistically significant difference between the two groups at 5 min and 10 minwith the duration for onset of motor blockade being longer in group 2. The onset of motor blockade of the tibial nerve shows a statistically significant difference between the two groups at 10 min with the duration for onset of motor blockade being longer in group 2. There was no significant difference between the two groups with respect to onset of sensory blockade.The difference in mean ± SD for the requirement of first rescue analgesia between group 1 and group 2 was found to be statistically significant with group 2 recording a longer mean analgesia time.

Conclusion: Dexamethasone as an adjuvant to Ropivacaine in popliteal sciatic nerve block significantly prolonged the duration of the onset of motor blockade.It also provided longer duration of postoperative analgesia when compared to Clonidine added to Ropivacaine.

Keywords: Clonidine, Dexamethasone, Ropivacaine, Ultrasound, Popliteal Sciatic Nerve Block, Foot and Ankle

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INTRODUCTION

Since the 1990s, virtually all minor, and a substantial proportion of major surgeries, in the West are performed in hospital–affiliated, freestanding, or office-based ambulatory surgery units.[1]

Peripheral nerve blocks are ideally suited for lower extremity ambulatory surgery because of the peripheral location of the surgical site and the potential to block pain pathways at multiple levels. In contrast to other anaesthetic techniques, such as general or spinal anaesthesia, properly conducted peripheral nerve blocks avoid hemodynamic instability and pulmonary complications, and facilitate post-operative pain management and timely discharge.[2] Additional advantages of peripheral nerve blocks are that they can be used in patients having lumbosacral disease and avoid the need for airway instrumentation.[3] The popliteal sciatic nerve block or block of the sciatic nerve in the popliteal fossa is an excellent anaesthetic choice for surgery of the leg, ankle and foot. Ultrasound has proven benefits such as higher success rates, and faster onset without an increase in block procedure time or complications. Unilateral anaesthesia provided by the combined block of peripheral nerves of the lower limbs can be a safe and effective option for outpatient surgeries.[4]The popliteal sciatic nerve block is an effective block that provides:

1. Safe and excellent surgical anaesthesia
2. Extended duration of anaesthesia
3. Reduced incidence of adverse hemodynamic changes
4. Post-operative analgesia
5. Reduction in post-operative nausea, vomiting, intubation and extubation responses, atelectasis, hypotension and other side effects of general anaesthesia.

Hence popliteal sciatic nerve block using ultrasound has evolved into a valuable and safe alternative to central neuraxial blockade for surgeries of the foot and ankle with better hemodynamic stability and good postoperative analgesia.Postoperative analgesia is an integral part of pain management. Various local anaesthetics, opioids and adjuvants have been used for the same.Ropivacaine has properties of fast onset of action, long duration of analgesia, less cardiotoxicity, less central nervous system side effects and stable hemodynamics.[5]Commercially available local anaesthetics have a limited duration of analgesia that frequently leave patients complaining of pain for the first time during their first postoperative night when they are most likely vulnerable. While there are longer-acting formulations and new concepts on the horizon, there are limitations to what local anaesthetics alone can provide. Many additives to local anaesthetics to prolong the duration of analgesia for peripheral nerve blocks have been studied. These include epinephrine, clonidine, dexmedetomidine, buprenorphine, dexamethasone, tramadol, sodium bicarbonate, and midazolam.[6]Clonidine, an alpha 2-adrenoceptor agonist, has been used for many years as an additive to short, intermediate, and long-acting local anaesthetics. Meta-analysis and systematic reviews clearly show an analgesic benefit from the addition of clonidine to local anaesthetics.[7]Dexamethasone, a highlypotent, long-acting glucocorticoid with little mineralocorticoid effect, has been shown to prolong peripheral nerve blockade.[8] The scope of this study within the institution is that it is a centre for vascular surgery and tertiary care hospital catering to a wide range of cases. The use of this technique and Ropivacaine with Clonidine or Ropivacaine with Dexamethasone in single-shot Popliteal sciatic nerve block for foot and ankle surgeries have reduced the anaesthetic morbidity and also simplified patient care.

AIMS AND OBJECTIVES

To compare Ropivacaine with Clonidine, and Ropivacaine with Dexamethasone, in ultrasound-guided popliteal sciatic nerve block for surgeries of foot and ankle with regard to onset of surgical anaesthesia, degree of motor blockade, degree of sensory blockade, time of requirement of first rescue analgesic, quality of analgesia and hemodynamic parameters.

METHODS

This was a hospital-based prospective, randomized, comparative study, conducted among 90 patients who underwent foot and ankle procedures in a tertiary care centre in South India. The study was conducted over a period of 12 months , after obtaining clearance from the institutional ethics committee and written informed consent from the study participants.

INCLUSION CRITERIA

- Patients undergoing foot and ankle procedures.
- Patient willing and able to sign an informed consent document.
- Patients of the American Society of Anaesthesiologists (ASA) Grade I,II,III,IV; Aged 18-80 years of either sex.

EXCLUSION CRITERIA

- Refusal to participate in the study.
- Contraindications to regional blockage include but are not limited to:
- ➢ Patient refusal of the regional blockade.
- ➢ Patients with infection at the site of needle insertion.
- ➢ Patients with bleeding diathesis or coagulopathy.
- ➢ Patients with documented neurological disorders.
- ➢ Patients with a history of allergies to local anaesthetics.

SAMPLE SIZE DETERMINATION

A medical biostatistician was consulted for sample size.

With reference to previous studies, the mean Block onset time in Ropivacaine with Clonidine was 13 min. [7]

Mean of Group 1:	13
Mean of Group 2:	16
Mean difference:	3
Standard Deviation:	5
Type I error (α):	0.05
Power of the test (1-β):	0.80
Confidence Level:	0.95
Sample Size required:	45 (for each group)

The sample size formula:

$n = [2\sigma^2 * (Z_{\alpha/2}+Z_{\beta})^2]/d^2$

where $Z_{\alpha/2}$ is the critical value of the normal distribution at α/2 (e.g. for a confidence level of 95%, α is 0.05 and the critical value is 1.96), Z_{β} is the critical value of the Normal distribution at β (e.g. for a power of 80%, β is 0.2 and the critical value is 0.84), σ^2 is the population variance, and d is the difference you would like to detect. The calculated sample size was 43.56 which was rounded to 45.

STUDY PROCEDURE

Patients were evaluated preoperatively and shifted to the operating room. Hemodynamics were monitored throughout the procedure. Patients were divided into 2 groups.

Group 1 patients received popliteal sciatic nerve block with 0.75% Ropivacaine 20 ml and Clonidine 1µg/kg.Group 2 patients received popliteal sciatic nerve block with 0.75% Ropivacaine 20 ml with Dexamethasone 8 mg. High frequency linear array ultrasound probe (8-12 MHz) was used to administer the block. The end of injection was noted (time zero).

Sensation was checked using alcohol swab and graded at 5 minutes interval as:

0 - No change from baseline,1 - Diminished sensation,2 - Complete loss of sensation.

Motor power was checked at five minutes interval by plantar flexion of foot (tibial nerve) and dorsiflexion of foot (common peroneal nerve) and graded as :

0- No change from baseline, 1- Diminished strength.,2- Complete loss of motor strength.

Block onset time was defined as the time taken for loss of sensation to alcohol swab with or without motor blockade.Patients who did not achieve sensory blockade till 20 minutes were labelled as block failuresand supplemented with local infiltration or Intravenous fentanyl or General Anaesthesia. For patients who complained of pain during the surgery after achieving a block onset time of 20 minutes, analgesic supplementation was done with intravenous Fentanyl (0.5-1µ/kg). Patient hemodynamics were monitored for 24 hours postoperatively.

Quality of block[9]was determined as:

1. Adequate: When neither sedation nor analgesics were required during the surgery.
2. Inadequate: Additional analgesia was required during the surgery.
3. Failed: General anaesthesia was supplemented.

The time duration, when the patient requests for supplementary analgesia from zero time was recorded as the duration of analgesia and the patients were followed for next 24 hours.
Complications and untoward consequences of the block like inadvertent arterial injection, hematoma formation, neurological damage and infections were noted.

STATISTICAL ANALYSIS

Statistical testing was conducted with the statistical package for the social science system version SPSS 17.0**.** The comparison of continuous variables between the groups was performed using Student's t test. Nominal categorical data between the groups was compared using Chi-square test or Fishers exact test . For all statistical tests, a p value less than 0.05 ($p<0.05$) will be taken to indicate a significant difference.

RESULTS

There was no statistically significant difference between the two groups and both groups were comparable with respect to age, gender, weight and ASA grade distribution.

Evaluation of onset of sensory blockade-Peroneal component in the two groups (Fisher's exact test)

Onset of sensory block-Peroneal		Group 1 (n=45)		2 (n=45)		p Value
		Frequency	%	Frequency	%	
Baseline	0	45	100. 0%	45	100. 0%	–
5 min		24	53.53%	28	62.63%	0.39329
	2	21	46.47%	17	37.37%	
10 mn	1	2	4.44%	3	6.67%	0.645388
	2	43	95.56%	42	93.33%	
15 min	1	1	2.23%	0	0	0.314607
	2	44	97.77%	45	100%	
	2	45	100%	45	100%	

Onset of sensory blockade of common peroneal nerve did not show significant difference between the two groups.

Evaluation of onset of sensory blockade – Tibial component in two groups (Fisher's exact test)

Onset of sensory block-Tibial		Group 1 (n=45)		Group 2 (n=45)		p Value
		Frequency	%	Frequency	%	
Baseline	0	45	0%	45	0%	–
5 min	1	21	46.47%	20	44.44%	0.832
	2	24	53.53%	25	55.56%	
10 min	1	1	2.23%	2	4.44%	0.557
	2	44	97.77%	43	95.56%	
15 min	2	45	100%	45	100%	-
20 min	2	45	100%	45	100%	-

Onset of sensory blockade of tibial nerve does not show significant difference between the two groups.

Evaluation of onset of motor blockade-Peroneal component in the two groups (Fisher's exact test)

Grade of motor block-Peroneal	Group 1 (n=45)		Group 2 (n=45)		p Value
	Frequency	%	Frequency	%	

Baseline	0	0	0	0	0	
5 min	0	21	46.67%	31	68.89%	0.033*
	1	24	53.33%	14	31.11%	
10 min	0	2	4.44%	5	11.11%	0.018*
	1	32	71.11%	38	84.45%	
	2	11	24.45%	2	4.44%	
15 min	1	17	37.78	22	48.89%	0.288
	2	28	62.22	23	51.11%	
20 min	2	45	100%	45	100%	

The onset of motor blockade of common peroneal nerve shows a statistically significant difference between the two groups at 5 min and 10 min with the duration for onset of motor blockade being longer in group 2. There was no significant difference between the two groups at baseline, 15 min and 20 min.

Evaluation of onset of motor blockade-Tibial component in the two groups (Fisher's exact test)

Grade of motor block-Tibial		**Group 1 (n=45)**		**Group 2 (n=45)**		**p Value**
		Frequency	**%**	**Frequency**	**%**	
Baseline	0	0	0	0	0	
5 min	0	19	42.22%	25	55.56%	0.206
	1	26	57.78%	20	44.44%	
10 min	0	3	6.67%	2	4.44%	0.017*
	1	29	64.44%	40	88.89%	
	2	13	28.89%	3	6.67%	
15 min	1	16	35.56%	22	48.89%	0.2
	2	29	64.44%	23	51.11%	
20 min	2	45	100%	45	100%	

The onset of motor blockade of the tibial nerve shows a statistically significant difference between the two groups at 10 min with the duration for onset of motor blockade being longer in group 2.
There was no significant difference between the two groups at baseline, 5 min, 15 min and 20 min.

Evaluation of block onset time (in min) in the two groups (unpaired t-Test)

Group 1		**Group 2**		
Mean	**Standard Deviation**	**Mean**	**Standard deviation**	**p value**
8.78	2.64	9.11	2.88	0.569

The present study revealed a mean block onset time of 8.78 minutes in Group 1 and 9.11 minutes in Group 2 which was not statistically significant (p value-0.569). Hence both the groups were comparable with respect to the block onset time.

Evaluation of onset of motor blockade (in min) in the two groups (unpaired t-Test)

Group 1		**Group 2**		
Mean	**Standard Deviation**	**Mean**	**Standard deviation**	**p value**
17	3.44	18.7	2.24	0.007*

In the present study, the time taken for motor block onset is 17 min in Group 1 and 18.7 min in Group 2.
The time taken for onset of motor block is significantly prolonged in Group 2 when compared to Group 1, the p value being 0.007.

Comparison of Quality of block in between the two groups (Chi Square Test)

Quality of Block	**Group 1**		**Group 2**		**p value**
	n	**%**	**n**	**%**	
1	43	96%	42	93%	

2	2	4%	3	7%	
Total	**45**	**100%**	**45**	**100%**	0.645

The quality of block between both the groups was not statistically different.

In the present study there was no statistically significant difference between the groups with respect to mean Heart rate,mean arterial pressure,mean SpO2.

DISCUSSION

Popliteal sciatic nerve block either alone or in combination with femoral or saphenous nerve blocks can be used as the anaesthetic technique of choice in patients scheduled for leg, foot and ankle procedures.

The advantages of ultrasound-guided blocks are:

- Visualisation of the needle and deposition of drug
- Rapid onset of action
- Dense anaesthesia of the leg with a single injection
- Longer duration of action
- Nil or minimal hemodynamic changes
- Decreased incidence of complications.

Surgeries of the foot and ankle are common procedures, especially in patients with diabetic feet. Invariably these surgeries result in severe postoperative pain with significant psychological suffering. Many of these patients present with multiple medical problems such as cardiovascular disease, uncontrolled diabetes mellitus, decreased pulmonary reserve, sepsis and systemic anticoagulation. Single shot or continuous popliteal sciatic nerve block presents an ideal anaesthetic package in many clinical situations including healthy patients and high-risk cases, a technique by which adverse effects of central neuraxial blockade or general anaesthesia can be avoided.

The present studyis comparable to the studies done by Andrea Casati et al[10](Sciatic Femoral nerve block), Jacques T Ya Deau et al[11](popliteal Sciatic nerve block)

K C Cummings etal[12] (Interscalenebrachial plexusblock), Ryosuke Kawanishi et al[13] (Interscalene brachial plexus block), Kris Vermeylen et al[14](popliteal sciatic nerve block)in terms of Age, Gender, weight. Owing to the safety feature of the block a few ASA IV patients have been included in the present study and results have been on similar lines to other patients with no untoward effects.

The onset of sensory blockade in the present study was 8.78 ±2.64 minutes in the clonidine group and 9.11 ±2.88 minutes in the dexamethasone group. This was comparable to the study done by Andrea Casati et al.[10] (10 mins).

Though statistically insignificant, the present study had shown the onset of sensory blockade in the dexamethasone group (9.11 ±2.88 minute) to be slightly longer than that seen in the clonidine group (8.78 ±2.64 minutes). This was comparable to the study done by Kris Vermeylen et al.[14](34±42 mins. for Group Dexamethasone and 20±18 for Group Clonidine)

In the present study, the onset of motor blockade was longer in the dexamethasone group(18.7 ± 2.24mins. versus17 ± 3.44 mins. for clonidine group) and was statistically significant. In the study done by Kris Vermeylen et al[14]also, the duration for the onset of the motor blockade in the Dexamethasone group was longer (43±58 mins. versus 24±18 mins. for clonidine group), though statistically insignificant.

In the present study, the duration of analgesia was significantly longer in the Dexamethasone group (20.68±2.13 hr.) in comparison to the Clonidine group (14.94±0.57 hr.). This was similar to study done by Kris Vermeylen et al.[14](31±9 hr for Dexamethasone group and 28±10 hr. for Clonidine group).

In the study conducted by Andrea Casati et al[10] all the patients were operated on solely under peripheral nerve block given using the Nerve Stimulator technique. 14% of patients in each group required supplementary analgesia and the block failure was 6.7%. In the present study, all the patients were operated solely under peripheral nerve block which was given under ultrasound guidance. 4% of patients in the clonidine group and 7% in the Dexamethasone group required supplementary analgesia. There was no case of block failure.

The present study did not show any significant hemodynamic changes or side effects. This was comparable to the studies done by Andrea Casati et al[10] (Sciatic Femoral nerve block),
Jacques T Ya Deau[11] et al (popliteal Sciatic nerve block),K C Cummings[12] etal (Interscaleneblock), Ryosuke Kawanishi[13] etal (Interscalene block), Kris Vermeylen[14] et al (popliteal sciatic nerve block).
As there were no significant side effects noted during the study, it can be considered that 1µg/kg Clonidine and 8 mg Dexamethasone can be used safely in popliteal sciatic nerve blockade.

LIMITATIONS OF THE STUDY

1. The dose equivalence of Clonidine and Dexamethasone when used in peripheral nerve block could not be calculated because no previous studies were available for the reference of dose equivalence. Each study had used adjuvants in different doses.
2. A continuous catheter technique to study for postoperative analgesia should be advocated as compared to a single shot technique.
3. Findings of the present study are applicable only in tertiary care settings as its generalizability in primary and secondary health care settings is limited due to high cost associated with the machine, requirement of skilled personnel for proper and accurate technique to give successful sciatic nerve block.

CONCLUSION

The study showed that Dexamethasone as an adjuvant to Ropivacaine in Popliteal Sciatic Nerve block significantly prolonged the duration of the onset of motor blockade. It also provided a longer duration of postoperative analgesia when compared to Clonidine added to Ropivacaine.

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