DOI: 10.7860/JCDR/2024/65358.19218

Original Article

Anaesthesia Section

Comparison of Dexmedetomidine and Fentanyl added to Levobupivacaine in USG-guided Axillary Block for Upper Limb Surgeries: A Randomised Double-blinded Controlled Study

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ABSTRACT

Introduction: Apart from general anaesthesia, brachial plexus block by the axillary approach is one of the reliable sole anaesthetic techniques for patients undergoing upper limb surgeries. In this study, levobupivacaine was chosen due to fewer adverse effects compared to Bupivacaine, and fewer studies were available for the axillary approach to brachial plexus block. Adjuvants were added to hasten the onset and also to prolong their analgesic effect.

Aim: To compare the effect of Dexmedetomidine (D) 0.5 mcg/kg and Fentanyl (F) 0.5 mcg/kg when added to 0.5% Levobupivacaine (L) as an adjuvant in brachial plexus block by the axillary approach for upper limb surgeries.

Materials and Methods: A randomised double-blind controlled study was carried out at the Department of Anaesthesiology, Sree Balaji Medical College, BIHER, Chennai, Tamil Nadu, India from January 2020 to October 2021 on 60 American Society of Anaesthesiologists (ASA) I and II patients of either sex posted for various types of upper limb surgeries. Subjects were divided into two equal groups by computer-generated randomisation. Group A received 0.5% levobupivacaine and dexmedetomidine 0.5 mcg/kg, and Group B received 0.5% levobupivacaine and Fentanyl 0.5 mcg/kg. Both patients and the evaluator were unaware of the type of adjuvants added to the local anaesthetic. The onset time, duration of sensory and Motor blockade were recorded. Haemodynamic variables and duration of analgesia were recorded for 24 hours postoperatively. The Mann-Whitney U test demonstrated variations in the onset and duration of sensory and motor blocks. Adverse effects, including nausea, vomiting, and hypotension, exhibited significant differences according to Fisher's-exact test.

Results: Age and weight distributions were comparable between groups (mean age: Group A=45.20 years, Group B=44.80 years; mean weight: Group A=74.13 kg, Group B=74.43 kg). Group A exhibited faster sensory and motor block onset times (sensory: Group A=6.20 minutes, Group B=8.63 minutes; motor: Group A=8.27 minutes, Group B=10.00 minutes), longer block durations (sensory: Group A=11.63 hours, Group B=9.53 hours; motor: Group A=9.67 hours, Group B=8.20 hours), and required the first rescue analgesic (Group A=12.57 hours, Group B=10.27 hours) compared to Group B ($p<0.05$). Similarly, the mean time for the first rescue analgesia for patients among these two groups was also statistically significant ($p<0.05$).

Conclusion: The addition of 0.5 mcg/kg dexmedetomidine to 0.5% levobupivacaine in axillary block was more effective in prolonging the duration of blockade and providing adequate intraoperative analgesia when compared to 0.5 mcg/kg fentanyl with 0.5% levobupivacaine, without producing any adverse events.

Keywords: Adjuvants, Alpha agonist, Brachial plexus block, Local anaesthetic, Ultrasonography

INTRODUCTION

Brachial plexus block has become an integral part of regional anaesthesia, providing a precise and effective method of pain management for upper limb surgical procedures [1]. Amongst the various approaches, the axillary approach is preferred since this method offers numerous benefits, including decreased systemic opioid consumption, enhanced postoperative analgesia, and decreased incidence of opioid-related adverse effects [2,3]. Ultrasound guidance provides a better margin of safety than the landmark technique as it shows the real-time position of the plexus, blood vessels, and pleura [4]. It also allows for continuous needle visualisation while the needle is being advanced. To improve the quality of blockade, over the years, researchers have investigated various adjuvants in combination with local anaesthetics.

Levobupivacaine is a long-acting, amide-type local anaesthetic that is the S (–)\3- isomer of the racemate bupivacaine. The lethal dose of levobupivacaine was 1.3 to 1.6 times higher than that of bupivacaine in most animal studies, providing supportive evidence for a safety advantage over bupivacaine [5]. Dexmedetomidine is a centrally acting $\alpha 2$ agonist that mediates antinociception via peripheral $\alpha 2$ adrenoceptors. Clonidine, another centrally acting $\alpha 2$ agonist that is much less selective, has also been used as an adjuvant to local anaesthesia [6-8]. Fentanyl is a potent synthetic opioid analgesic with a strong agonistic action at the μ-opioid receptor and a rapid onset and short duration of action. When added to local anaesthesia in peripheral nerve blocks, fentanyl potentiates the action of local anaesthesia via central opioid receptor-mediated analgesia through the peripheral uptake of fentanyl into the systemic circulation [9].

Studies in this field have illuminated the potential benefits of adjuvants like clonidine, dexmedetomidine, fentanyl, and midazolam. These investigations have individually demonstrated promising results, showcasing the ability of these adjuvants to extend block duration and enhance the quality of postoperative pain control [10-12]. However, despite these advancements, a comprehensive comparative analysis between these adjuvants, particularly within the context of levobupivacaine-based axillary brachial plexus blocks, is currently lacking. Clinicians are continually faced with the challenge

of selecting the most appropriate adjuvant to achieve specific clinical objectives. These objectives may include the attainment of a rapid onset of action, the prolongation of block duration, or the enhancement of postoperative pain relief.

The present study aimed to contribute to the existing body of knowledge by comparing dexmedetomidine and fentanyl as adjuvants to levobupivacaine in Ultrasound-guided (USG) axillary brachial plexus blocks, so that the results will be helpful in enhancing patient care.

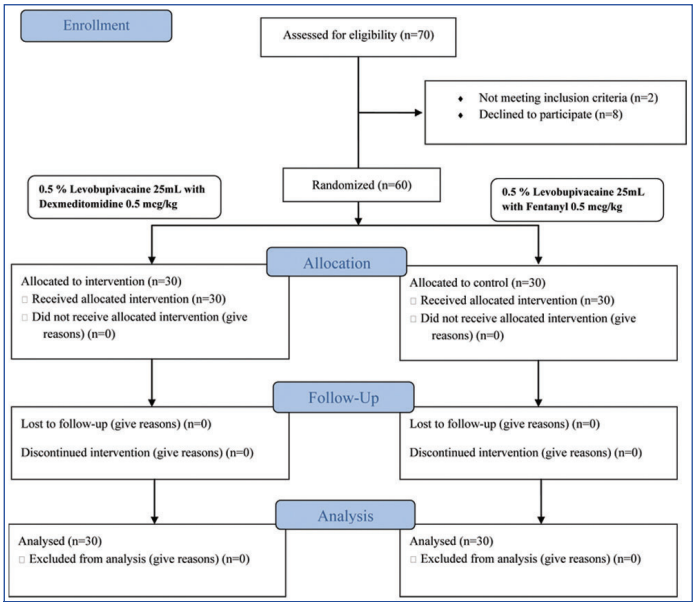
MATERIALS AND METHODS

The present was a randomised double-blind study comparing the efficacy of dexmedetomidine versus Fentanyl as an adjuvant to levobupivacaine in ultrasound-guided axillary approach to brachial plexus block. The study was conducted at the Department of Anaesthesiology, Sree Balaji Medical College, BIHER, Chennai, Tamil Nadu, India, from January 2020 to October 2021, after obtaining Institutional Ethics Committee approval on 30/09/2019 (reference 002/SBMC/IHEC/2019/1290). Written informed consent was obtained from all patients who consented to participate.

Sample size calculation: The sample size was calculated based on the primary objective of time for rescue analgesia in group A (L+D) and group B (L+F) from previous literature [13]. It was determined that the rescue analgesia for group A and group B was 1.15±0.14 and 1.20±0.15 (mean±SD), respectively. To detect this difference with a power of 80%, a total sample size of 66 patients (33 per arm) was required.

Inclusion and Exclusion criteria: Seventy patients of various ages between 18-60 years of both sexes undergoing elective and emergency procedures for elbow, forearm, and hand surgeries admitted in the orthopaedic surgery and general surgery departments were screened. Individuals with coagulopathies or those taking anticoagulants, as well as those with severe renal, hepatic, respiratory, or cardiac diseases were excluded. Additionally, participants with infections at the block site, pregnant individuals, those with neuromuscular disorders, and psychiatric illness were also excluded. Any contraindications to levobupivacaine, dexmedetomidine, or fentanyl, along with patient refusal, were also grounds for exclusion from the study.

A total of 60 subjects were chosen and randomly allocated into two groups: 30 in group A (L+D) and 30 in group B (L+F) [Table/Fig-1].



[Table/Fig-1]: Group A patients were administered 0.5% Levobupivacaine (25 mL) with Dexmeditomidine 0.5 mcg/kg. Group B patients were administered 0.5% Levobupivacaine (25 mL) with Fentanyl 0.5 mcg/kg for axillary brachial plexus block under USG guidance [13].

Study Procedure

The preoperative assessment included a detailed history, general physical examination, systemic examination, airway assessment, and routine investigations such as haemoglobin, total white blood cell count, differential white blood cell count, bleeding time, clotting time, platelet count, blood glucose, blood urea, and serum creatinine. Electrocardiography and chest X-ray were also performed. Preoperative fasting status of eight hours was ensured. The block procedure and the Visual Analogue Scale (VAS) score were explained to the patient.

Patients were shifted to the operation theatre, and routine monitors such as heart rate, pulse oximeter, non invasive blood pressure, and Electrocardiogram (ECG) monitors were connected. Intravenous fluids were started. All patients in both groups were given Inj. Midazolam 0.05 mg/kg intravenously before the start of the procedure. Patients were positioned supine with the arm abducted at 90 degrees and the elbow flexed at 90 degrees [Table/Fig-2]. A high-frequency linear array probe of the ultrasound machine was placed at the axillary fold. The axillary artery was visualised as a superficial pulsating structure, and the axillary vein was located caudal to the artery and collapsed under pressure. The median nerve was found anterolateral to the axillary artery, while the radial nerve was seen posteromedial. The ulnar nerve was visualised medial to the artery. The biceps and coracobrachialis were located lateral to the artery, and the musculocutaneous nerve ran between these two muscles. The axillary sheath was approached with a sterile needle with a catheter under ultrasound guidance. After frequent negative aspiration for blood, the drug mixture, which contained either 25 mL of 0.5% levobupivacaine with dexmedetomidine 0.5 mcg/kg or 25 mL of 0.5% levobupivacaine with Fentanyl 0.5 mcg/kg, was injected around the radial, ulnar, median, and musculocutaneous nerves.

[Table/Fig-2]: Ultrasound probe position and injection of the drug in-plane technique.

Sensory and motor block were evaluated for onset and duration. Pinprick sensation loss was tested every three minutes until it was lost, and then postoperatively every 30 minutes until it was regained. The modified Bromage scale was used to assess motor blockade, with Grade-I indicating complete motor block with no active movement of the limb, Grade-II indicating almost complete block with slight movement of fingers on command, and Grade-III indicating no block. Motor block was evaluated by assessing muscle strength and function, checking for the presence or absence of voluntary movement and muscle strength in the affected area. This assessment was performed every three minutes until movement was no longer detected, and then postoperatively every 30 minutes until normal motor function was regained. An anaesthesiologist who was unaware of the adjuvant drug administration performed the intraoperative and postoperative evaluations, making it a double-blind study.

The total duration of sensory block was measured as the time interval from complete sensory block to total resolution of pinprick sensation. The total duration of motor blockade was calculated as the time interval from complete motor block to total recovery of

motor functions of the upper limb. The duration of analgesia was calculated as the time interval between complete sensory block and a VAS score greater than 6, or the patient's demand for rescue analgesia. When patients complained of pain, it was documented, and they were administered inj. Paracetamol 1 g intravenously as rescue analgesia. Patients were monitored for side-effects such as bradycardia, hypotension, nausea, vomiting, or pruritus, as well as complications such as hemodynamic instability and local anaesthetic toxicity. Side effects if any were treated and documented.

STATISTICAL ANALYSIS

At the end of the study, all data were compiled and statistically analysed. Unpaired t-tests (for normally distributed continuous data) and Mann-Whitney U tests (for skewed data) were used for statistical tests on continuous data. The Chi-square test was employed for the analysis of categorical data to identify significant differences between groups, with a threshold of $p<0.001$ indicating statistical significance. Both groups were comprehensively compared in terms of age, weight, gender, and American Society of Anaesthesiologists (ASA) grade. The student's unpaired t-test was used for statistical analysis of age, while the Mann-Whitney U test was applied for weight assessment. Gender and ASA grade were analysed statistically using the chi-square test. The onset and duration of sensory and motor blocks were compared using the Mann-Whitney U test, and the Fisher's-exact test was used for a detailed analysis of adverse effects, including nausea, vomiting, and hypotension.

RESULTS

Both groups [Table/Fig-3], group A (L+D) and group B (L+F), had similar age distributions (mean ages: group A=45.20 years, group B=44.80 years) and gender representation. Weight distributions were comparable (group A=74.13 kg, group B=74.43 kg), and ASA physical status classifications indicated similar health statuses.

Characteristics	Group A (L+D) n (%)	Group B (L+F) n (%)	p-value
Age			
≤ 20 years	0	2 (7 %)	**0.886**
21-30 years	3 (10 %)	2 (7 %)	
31-40 years	7 (23 %)	3 (10 %)	
41-50 years	11 (37 %)	12 (40 %)	
51-60 years	9 (30 %)	11 (37 %)	
Gender			
Male	16 (53%)	19 (63%)	**0.432**
Female	14 (47%)	11 (37%)	
Weight			
≤ 60 kgs	0	1 (3%)	**0.881**
61-70 kgs	11 (37%)	8 (27%)	
71-80 kgs	11 (37%)	10 (33%)	
81-90 kgs	8 (26%)	11 (34%)	
ASA physical status classification system			
ASA I	13 (43%)	18 (60%)	**0.196**
ASA II	17 (57%)	12 (40%)	

[Table/Fig-3]: Socio-demographic and medical details of the study participants (n=30).

Anaesthesia parameters and time to the first rescue analgesic has been provided in [Table/Fig-4]. Group A showed a faster onset of motor (8.2 mins) and sensory block (6.2 mins) than group B (motor: 10 mins, sensory: 8.6 mins, $p<0.001$). Group A also had longer durations of motor (9.6 hours) and sensory block (11.6 hours) compared to group B (motor: 8.2 hours, sensory: 9.5 hours, $p<0.001$). Group A exhibited delayed demand for rescue analgesia (6% within 10 hours), whereas 60% of group B required it. The time to the first rescue analgesic was significantly longer in group A (12.57 hours) than in group B (10.27 hours, $p<0.001$).

Parameters	Group A (L+D) n (%)	Group B (L+F) n (%)	p-value
Mean onset of block in minutes			
Motor block	8.2±1.3	10±1.2	**<0.001***
Sensory block	6.2±1.1	8.6±1.0	**<0.001***
Mean duration of block (hours)	**Group A (L+D) n (%)**	**Group B (L+F) n (%)**	**p-value**
Motor block	9.6±0.9	8.2±0.8	**<0.001***
Sensory block	11.6±1.1	9.5±0.8	**<0.001***
Time of first rescue analgesia (hours) (VAS >6)	**Group A (L+D) n (%)**	**Group B (L+F) n (%)**	**p-value**
≤10 hours	2 (6%)	18 (60%)	**<0.001***
11 hours	2 (6%)	9 (30%)	
12 hours	9 (30%)	3 (10%)	
13 hours	11 (37%)	0	
14 hours	6 (20 %)	0	
Mean	12.57	10.27	

[Table/Fig-4]: Comparative analysis of block onset, block duration, and time to first rescue analgesia among the study participants.
*Unpaired t-test

Various complications among study participants has been provided in [Table/Fig-5]. In group A, 90% had no complications, 6.67% had bradycardia, and 3.33% had hypotension. Group B had no complications. Fisher's-exact test p-value was 0.206, indicating no significant difference in complication rates between groups. The mean pulse rate, Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) were lower in group A [Table/Fig-6-8].

Complications	Group A (L+D)	%	Group B (L+F)	%
Nil	27	90.00	30	100.00
Bradycardia	2	6.67	0	0
Hypotension	1	3.33	0	0
Total	30	100.00	30	100.00
p-value Fischer's-exact Test	**0.206**			

[Table/Fig-5]: Various complications among study participants (n=30).
p-value Fisher's-Exact Test

Mean pulse rate (beats per min)	Group A (L+D)		Group B (L+F)		p-value unpaired t-test
	Mean	SD	Mean	SD	
0 min	78.60	8.52	77.40	5.99	0.531
5 min	75.67	8.02	76.00	6.30	0.859
15 min	71.87	7.22	74.53	5.85	0.122
30 min	69.07	7.59	74.93	5.94	0.002
60 min	**67.13**	**5.16**	**75.33**	**6.40**	<0.001*
2 h	**65.80**	**3.91**	**75.67**	**6.77**	<0.001*
6 h	**66.87**	**5.00**	**76.27**	**6.82**	<0.001*
12 h	**67.87**	**6.54**	**76.47**	**6.68**	<0.001*
24 h	71.27	7.78	77.00	6.53	0.003

[Table/Fig-6]: Mean pulse rate distribution.
*Difference in mean pulse rate of patients amongst the groups turned out to be statistically significant

Mean systolic blood pressure (mmHg)	Group A (L+D)		Group B (L+F)		p-value unpaired t-test
	Mean	SD	Mean	SD	
0 min	116.40	8.01	120.33	9.47	0.088
5 min	115.47	7.70	120.53	9.78	0.030
15 min	111.20	8.28	117.13	9.45	0.012
30 min	110.27	8.89	114.20	9.59	0.105
60 min	113.20	7.69	114.27	9.14	0.627
2 h	114.73	7.90	117.47	9.50	0.231
6 h	114.80	7.38	120.33	9.44	0.014

12 h	115.53	8.01	123.53	9.42	0.001*
24 h	116.20	7.32	125.07	7.48	<0.001*

[Table/Fig-7]: Mean systolic blood pressure distribution.
*The difference in mean systolic blood pressure of patients amongst the groups was statistically significant

Mean diastolic blood pressure (mmHg)	Group A (L+D)		Group B (L+F)		p-value unpaired t-test
	Mean	SD	Mean	SD	
0 min	74.53	5.41	81.20	4.60	<0.001*
5 min	73.13	5.77	81.33	5.36	<0.001*
15 min	72.93	5.87	78.20	5.47	<0.001*
30 min	71.97	5.96	74.93	5.67	0.053
60 min	73.07	5.43	71.87	5.41	0.394
2 h	74.07	5.84	75.27	5.64	0.422
6 h	73.60	5.72	78.73	5.84	0.001*
12 h	74.13	5.56	82.00	5.85	<0.001*
24 h	74.40	5.57	85.20	5.91	0.000*

[Table/Fig-8]: Mean diastolic blood pressure distribution.
*The difference in mean diastolic blood pressure of patients amongst the groups was statistically significant

DISCUSSION

Esmaoglu A et al., concluded in their study that dexmedetomidine, as an adjuvant to levobupivacaine for axillary brachial plexus block, shortened the onset time, prolonged the duration of the block, and consequently extended the duration of postoperative analgesia [14]. However, they noted that dexmedetomidine led to a statistically significant incidence of bradycardia. The results of the present study demonstrated similar benefits of USG axillary block with dexmedetomidine as an adjuvant compared to fentanyl, but without statistically significant side-effects. According to Chan VWS, USG has been chosen in recent years for nerve block treatments due to its accuracy and precision, which is reflected in the decision to employ USG in the present study [15].

A significant difference between Group A (dexmedetomidine) and Group B (fentanyl) in the onset and duration of sensory and motor blockade was one of the primary results observed in the present study. There was a mean difference of 2.43 minutes for sensory blockade and 1.73 minutes for motor blockade between Group A and B. This corresponds to 28% and 17% faster onset, respectively, indicating that dexmedetomidine appears to be more efficient in achieving a rapid blockade. This trend seen in the present study was echoed by Dharmarao PS et al., [16]. These results are consistent with earlier research by Kaur M et al., who compared fentanyl and dexmedetomidine as additives to 0.5% levobupivacaine in the supraclavicular block and found the fastest onset time as well as a longer duration of sensory and motor block in the dexmedetomidine group compared to the fentanyl group [13]. Swami SS et al., also demonstrated the benefits of using dexmedetomidine as a local anaesthetic addition in supraclavicular brachial plexus nerve block procedures [17]. Tripathi A et al., compared clonidine and dexmedetomidine with 0.25% bupivacaine in the supraclavicular block and found that dexmedetomidine, when added to the local anaesthetic in the supraclavicular brachial plexus block, enhanced the duration of sensory and motor block as well as the duration of analgesia [18]. The time for rescue analgesia was prolonged in patients receiving dexmedetomidine. When dexmedetomidine was combined with levobupivacaine in an axillary block study by Kenan K et al., they found that adding dexmedetomidine to the axillary brachial plexus block shortened sensory block onset time, increased the sensory and motor block duration and time to first analgesic use, and decreased total analgesic use without side-effects [19]. This trend reiterates that dexmedetomidine, when used as an adjuvant, prolongs the duration of analgesia postoperatively, consequently reducing opioid requirements as well.

When comparing the distribution of mean systolic blood pressure statistically amongst the two groups, the mean overall SBP and DBP observed were significantly lower and stable within the normal range in Group A compared to Group B. There was a drop in blood pressure to 88/54 mmHg in one patient at the 30th minute, which quickly returned to baseline blood pressure within 10 minutes without any intervention. These findings in the present study were consistent with previous studies that demonstrated dexmedetomidine's ability to help maintain blood pressure stability when administered as an adjuvant in regional anaesthetic procedures, with quicker onset times, longer block durations, and reduced analgesic needs [17-19]. In a study conducted by Swami SS et al., the SBP remained around 120 mmHg in the dexmedetomidine group throughout the observation period [17], while the DBP remained stable at 78 and 80 mmHg in the same group. Tripathi A et al., observed that patients in the dexmedetomidine group experienced stability in systolic and diastolic blood pressure at 120 mmHg and 80 mmHg, respectively [18]. However, to mitigate potential adverse effects such as bradycardia and hypotension, careful dose adjustment and monitoring are necessary [19]. In a study by Shamjith K et al., where 100 mcg of dexmedetomidine was added to levobupivacaine in a supraclavicular block, approximately 20% of patients who received dexmedetomidine developed bradycardia [20]. The incidence of bradycardia and hypotension was relatively low in the present study and did not require any intervention due to the lower dosage of dexmedetomidine (0.5 mcg/kg) used. Other parameters were not significantly different. The use of USG significantly improved the precision and success rate of the block, allowing authors to conclude on the efficacy of the adjuncts used in the present study [15]. The findings in the present study led to the conclusion that even with a minimal dosage of 0.5 mcg/kg, dexmedetomidine as an adjuvant significantly shortens the onset and prolongs the duration of sensory and motor blockades. Additionally, the incidence of complications is minimal, and postoperative analgesic and opioid requirements are greatly reduced. Postoperative rehabilitation and early ambulation are also significantly facilitated by the pain-free period.

Limitation(s)

According to the sample size calculation, 33 patients were required in each group, totalling 66 patients. However, after scrutinising, authors selected 68 patients, but eight patients did not provide consent, leading the authors to conduct the study with only 60 patients. The plasma levels of the study drugs were not measured due to a lack of facility. Patients in the paediatric and geriatric age groups, as well as those with co-morbid conditions, were not included.

CONCLUSION(S)

The present study highlights the clinical importance of utilising dexmedetomidine as an adjuvant in regional anaesthetic procedures compared to Fentanyl. Dexmedetomidine, at a dose of 0.5 mcg/kg, enhances patient comfort and safety with consistent findings of quicker onset times, longer sensory and motor block durations, and reduced analgesic needs, while maintaining stable haemodynamics. These findings provide a compelling rationale for considering dexmedetomidine as a valuable tool in regional anaesthetic procedures. To fully harness its benefits, however, cautious dosing and patient selection are essential. Dexmedetomidine shows promise in improving patient outcomes and advancing anaesthetic practice as its uses continue to be investigated.

Acknowledgement

The authors would like to acknowledge Professor Dr. S. Selvamani for her constant encouragement to do scientific research, article submission for publication.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: May 13, 2023
- Manual Googling: Aug 16, 2023
- iThenticate Software: Jan 23, 2024 (22%)

ETYMOLOGY: Author Origin

EMENDATIONS: 8

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

Date of Submission: **May 11, 2023**
Date of Peer Review: **Aug 04, 2023**
Date of Acceptance: **Jan 25, 2024**
Date of Publishing: **Apr 01, 2024**