# **ORIGINAL ARTICLE**

# Onset and recovery of ultrasound guided out-of-plane versus in-plane interscalene block in arthroscopic shoulder surgery

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# Abstract

**Background:** The aim of this study was to assess the out-of-plane versus the in-plane approaches for the interscalene brachial plexus block, as regards the performance time, the onset, the progression and the recovery of sensory block, the onset and progression of the motor block as well as, the postoperative pain score, and the duration of analgesia for arthroscopic shoulder surgery. A total of 60 patients of American Society of Anesthesiologists (ASA) physical status I-II were randomly divided to receive either the in-plane approach (group I), or the out-of-plane approach (group O).

**Results:** The block performance time was statistically significant shorter in group O. The onset of sensory block was statistically significant faster in group O. The progression of sensory block over the first 20 min was statistically significant fast for  $C_5$  and  $C_6$  nerve roots in group O. The motor block showed statistically and clinically significant rapid onset and progression in group O. All patients in group O and group I felt no pain in the post-anesthesia care unit (PACU), and the first call for analgesia was at 24 h in both groups.

**Conclusion:** The out-of-plane approach offers short performance time, rapid onset and progression of sensory and motor blocks, as well as postoperative analgesic effect lasting for 24 h in arthroscopic shoulder surgery.

Keywords: Out-of-plane block, In-plane block, Onset of sensory block, Duration of postoperative analgesia

### Introduction

Interscalene brachial plexus block is the commonly used block for anesthesia and postoperative analgesia for shoulder surgeries (Mariano et al., 2009a). It blocks the nerve roots/trunks of the brachial plexus (Madison et al., 2013; Sarah et al., 2013); the local anesthetic (LA) is directed towards  $C_5$ - $C_6$  nerve roots.  $C_7$  and even  $C_8$  nerve roots may be blocked depending on the volume of the LA used. Ulnar sparing ( $C_8$  and  $T_1$  nerve roots) often occurs with the block (Mariano et al., 2009a).

Ultrasound guided interscalene block decreases the number of needle passes, offers rapid onset, and improves the LA distribution, thus the sensory block, with decreased risk of major vessels and nerve injury (Liu

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Department of Anesthesia, Intensive Care and Pain Management, Ain Shams University, Embassies Area, Symphony Tower, Cairo 11471, Egypt et al., 2009). It could be performed as a single LA injection or by a catheter insertion technique (Joseph & Ajit, 2011). Also, it could be performed with an in-plane or an out-of-plane needle approaches. The in-plane approach is commonly used for single injection blocks, whereas the out-of-plane approach is commonly used for block with catheter insertion (Antonakakis et al., 2009; Ushma & Herman, 2015).

# **Patients and methods**

After obtaining the approval of Ain-Shams University Hospitals' ethical committee (FMASU R59/2018), informed consent was taken from 60 patients of ASA physical status I-II, greater than or equal to 30 years old and smaller than or equal to 60 years old, scheduled to undergo arthroscopic shoulder surgery in the lateral position, under ultrasound-guided interscalene brachial

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plexus block (ISPB) in this randomized study at Ain-Shams University Hospitals, from December 2018 until June 2019. Randomization was done using computergenerated random number tables with sealed opaque envelopes.

Preoperative evaluation included a detailed history, physical examination along with neurological assessment and investigations, which included the following: complete blood count, the coagulation profile, liver and kidney function tests, and electrocardiography (ECG). During the pre-anesthetic visit, the procedure was explained to the patients to allay anxiety and the visual analogue scale (VAS) to assess the postoperative pain was also explained to the patients.

# **Exclusion criteria**

The exclusion criteria are obesity classes II and III (body mass index  $\geq$  35 kg/m<sup>2</sup> body surface area) (Stephani, 2018), anticipated difficult airway, infection at the injection site, known LA allergy, contralateral phrenic nerve dysfunction, history of cardiac, hepatic, renal disease, coagulopathy, chronic obstructive pulmonary disease, or neuropathy involving the brachial plexus.

#### Preparation of the study drugs

Twenty milliliter of 0.5% bupivacaine (Sunny Pharmaceutical (Egypt) under license of Hamelin Pharmaceuticals (Germany) added to them 50  $\mu$ g adrenaline in a concentration of 1:400,000, were prepared by an assistant immediately before administration (Andrew & Lisa, 2012).

#### The anesthetic technique

On arriving to the operating theater, patients had an 18G intravenous cannula inserted in the non-operative upper limb side. All patients received 0.05 mg/kg IV midazolam hydrochloride (Dormicum, 5 mg/ml; Roche, Basel, Switzerland) and 30 mg pethidine (pethidine hydrochloride, 50 mg/ml; Misr Co., for Pharmaceuticals, Alexandria, Egypt).

Intraoperative basic monitors were applied using 5leads ECG, pulse oximetry, non-invasive blood pressure (NIBP), and capnography (sample tube inserted under the  $O_2$  mask). The monitor used was Dash 5000; General Electric, Medical Systems Information Technologies, Inc. Tower Ave., Milwaukee, WI, USA, and the anesthetic machine used was Datex-Ohmeda, Inc. 3030 Ohmeda Drive, Madison, WI 53707-7550, USA. A simple  $O_2$  mask at a flow of 6 L/min was applied. Infusion of Ringer's solution was then started at a rate of 5 ml/ kg/h throughout the surgery. Back up general anesthesia with all airway equipment are as follows: oropharyngeal airways, laryngeal mask airway, endotracheal tubes, and a laryngoscope were prepared. Patients were placed in the supine position with their heads rotated towards the non-operative side. Iodine solution was used as an antiseptic on the operative neck side and then the patient head, neck, and chest were draped. Local infiltration of the skin at the point of needle insertion was carried out with 2 ml lidocaine hydrochloride 1% (Sigma Tec Industries Co packed by Al-Debeiky pharmaceutical Industries, A.R.E., Obour City Ind. Zone), then a sterile 50-mm 22-G insulated needle (Stimuplex; B. Braun, Melsungen, Germany) was used for performance of the block.

The ultrasound (M-Turbo; SonoSite, Washington, DC, USA) with a high frequency linear transducer (frequency 10–15 MHz) was used, with the depth setting of 2–4 cm. Distal to proximal (trace back) approach was used; the supraclavicular fossa was scanned first to identify the subclavian artery as it passes over the first rib, by placing the probe against the clavicle and scanning in a caudate direction. The brachial plexus was easily identified as bunch of grapes superolateral to the artery. The plexus was followed medially and cephalad along its course by keeping the nerves in the center of the screen, to identify the brachial plexus roots between the anterior and the middle scalene muscles at the level of the sixth cervical vertebra deep to the sternocleidomastoid muscle.

# Patients were then divided into 2 equal groups of 30 patients each

Group I

An in-plane approach was used for the interscalene block. The needle was brought in the same plane as the probe at a shallow angle to the skin, some distance away from the edge of the probe in a lateral to medial direction so that the whole length of the needle can be visualized. After negative aspiration and assurance that high resistance to injection was absent, the LA was injected in a 5-ml increment below the lower root, between the 3 roots, and above the upper root.

#### Group O

An out-of-plane approach was used for the interscalene block. The needle was inserted cranial to the probe and after negative aspiration and assurance that high resistance to injection was absent, the LA was injected in a 10-ml increment, lateral and medial to the nerve roots. The needle appeared as a bright dot on the screen and by tilting the probe, the tip was identified as the point where further tilting leads to no longer visualization of the bright dot on the screen.

After completion of the LA administration, the time was recorded as a baseline for the time interval. The assistant who recorded the data was blind to the patient groups.

The sensory block was assessed by a pin-prick test using a 3-point scale (Calderon et al., 2015):

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Variable	Group   <b>N</b> = 30	Group O <b>N</b> = 30	<b>P</b> value
Age (years)	50.97 ± 13.415	48.37 ± 14.197	0.469
Sex (M/F)	10/20	11/19	0.787
Weight (kg)	73.67 ± 0.661	74.90 ± 3.507	0.063
ASA (I/II)	17/13	16/14	0.795

 Table 1 Patients' demographic data

Data presented as mean  $\pm$  SD or number of patients. P values > 0.05 are non-significant

0 = normal sensation

1 = loss of sensation of pin prick (analgesia)

2 = loss of sensation to touch (anesthesia)

The motor block was assessed according to the shoulder, arm, and fingers' movement using a 3-point scale (Santvana et al., 2013):

1 = diminished but not totally absent motor strength (paresis)

2 = unable to elevate the shoulder, flex the arm, or move the fingers (lack of movement)

Postoperative pain was measured at rest using the VAS score (Santvana et al., 2013); patients were asked to make a mark on a 10-cm line corresponding to their pain level, with 0 = no pain at all and 10 = the worst pain possible.

### Primary outcome

The onset of sensory block (time to  $C_5$  block): defined as the period between the completion of the LA administration and the loss of sensation to pin prick (sensory score = 1) in  $C_5$  dermatome performed every 1 min

#### Secondary outcomes

The procedure time: time from the skin infiltration by the lidocaine until removal of the stimulating needle from the skin

Progression of sensory block over the first 20 min of LA injection performed by pin prick every 5 min in  $C_6$ ,  $C_7$ ,  $C_8$ , and  $T_1$  dermatomes

The onset of motor block: defined as the period between the completion of LA administration until lack of movement (motor score = 2) of the shoulder, arm, and fingers' muscles assessed every 1 min The progression of motor block over the first 20 min of LA injection in the shoulder, arm, and fingers' muscles assessed every 5 min

The duration of motor block: defined as the period between the onset of motor block until complete recovery of motor function (motor score = 0). It was assessed in the PACU and at 4, 8, and 12 postoperative hours, then every hour until 24 postoperative hours.

Postoperative pain score: intensity of pain was monitored at rest in the PACU and at 4, 8, 12, and 24 h after the end of surgery using the VAS score.

The duration of analgesia: defined as the time interval between the onset of sensory block until the first call for analgesia. Postoperative analgesia was standardized; a patient with a VAS score of more than 4 was treated with 1 g paracetamol (Perfalgan vial, 100 ml of 10 mg/ml; Bristol-Myers Squibb Australia Pty Ltd). If the patient's VAS remained greater than 4 after 1 h, intravenous boluses of 25 mg of pethidine were given and the total dose of pethidine given was recorded.

#### Statistical analysis

Statistical analysis was done using PASS program, setting alpha error at 5% and power at 80%. Results from pilot study showed that the mean time to loss of sensation at  $C_5$  dermatome among patients in the out-of-plane group was 4.5 min, while for patients in the in-plane group was 6.5 min with 2.5 min standard deviation within each group. Based on this, with taking in consideration 10% drop out rate, the needed sample was 30 cases per group.

Data were analyzed using Statistical Package for Social Science (SPSS) version 21.0. Chicago, Illinois, USA. Quantitative data were expressed as mean  $\pm$  standard deviation. Qualitative data were expressed as count (and percent). The independent samples *t* test was used to compare between means in the two groups for quantitative parametric data. Mann-Whitney *U* test was used for skewed data. Chi square test or Fisher's exact test was used as appropriate to compare proportions between two qualitative parameters. *P* value < 0.05 was considered significant and *P* value < 0.01 was considered highly significant.

# Results

Sixty patients were enrolled in the study and were divided into 2 groups of 30 patients each. The 2 groups were comparable according to the demographic data (age, sex, weight, and ASA physical status) with P values of 0.469, 0.787, 0.063, and 0.795 respectively (Table 1).

Table 2 The block performance and operative times

Variable	Group   <b>N</b> = 30	Group O <b>N</b> = 30	<b>P</b> value
Block performance time (min)	7.85 ± 0.47	6.3 ± 0.36	< 0.001
Duration of surgery (min)	94.10 ± 4.421	92.10 ± 4.105	0.075

Data presented as mean  $\pm$  SD. *P* values > 0.05 are non-significant

<sup>0 =</sup> normal movement

Table 3 Onset of sensor	y block (time to	o C₅ block) in	minutes
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Group I <b>N</b> = 30	Group O <b>N</b> = 30	<b>P</b> value
6.42 ± 0.26	4.78 ± 0.28	< 0.001

Data presented as mean  $\pm$  SD. *P* values > 0.05 are non-significant

According to the block performance time, it was statistically significant shorter in the out-of-plane approach than in the in-plane approach (6.3  $\pm$  0.36 versus 7.85  $\pm$ 0.47 min respectively with *P* value < 0.001). There was no statistically significant difference between the 2 groups regarding the duration of surgery with *P* value of 0.075 (Table 2).

The onset of sensory block was statistically significant faster in the out-of-plane approach than in the in-plane approach (4.78  $\pm$  0.28 versus 6.42  $\pm$  0.26 min respectively with *P* value < 0.001). The progression of C<sub>5</sub> block was statistically significant faster in the out-of-plane approach than in the in-plane approach (*P* value = 0.01, 0.001, 0.001, 0.008, and < 0.001 at 1, 2, 3, 4, and 5 min respectively). The 30 patients were blocked by 5 min versus 10 min in the in-plane approach and the out-of-plane approaches respectively (Table 3 and Fig. 1).

The progression of sensory block over the first 20 min was statistically significant fast for  $C_6$  nerve root in the out-of-plane approach as the 30 patients (100%) showed  $C_6$  block in the first 5 min, whereas it took 10 min in the in-plane approach (*P* value < 0.006). Regarding the progression time to  $C_7$  block, there was no statistically significant difference between both groups as 83.3% of patients were blocked by 15 min in the out-of-plane

Table 4 Progression of the sensory block over the first 20 min

Variable		Group I <b>N</b>	Group O	Р
Sensory root	Time	= 30	<b>N</b> = 30	value
C <sub>6</sub>	5 min	15 (50%)	30 (100%)	0.006
	10 min	30 (100%)	30 (100%)	-
	15 min	30 (100%)	30 (100%)	-
	20 min	30 (100%)	30 (100%)	-
C <sub>7</sub>	5 min	7 (23.3%)	10 (33.3%)	0.390
	10 min	12 (40%)	16 (53.3%)	0.121
	15 min	23 (76.7%)	25 (83.3%)	0.519
	20 min	30 (100%)	30 (100%)	-
C <sub>8</sub>	5 min	2 (6.7%)	3 (10%)	0.640
	10 min	5 (16.7%)	10 (33.3%)	0.136
	15 min	12 (40%)	10 (33.3%)	0.592
	20 min	27 (90%)	29 (96.7%)	0.301
T <sub>1</sub>	5 min	0 (0%)	1 (3.3%)	0.313
	10 min	2 (6.7%)	10 (33.3%)	0.01
	15 min	10 (33.3%)	15 (50%)	0.190
	20 min	25 (83.3%)	28 (93.3%)	0.228

Data presented as number of patients (percentage)

approach compared to 76.7% of patients in the in-plane approach (*P* value = 0.519), and by 20 min, the 30 patients (100%) of both groups were blocked. Regarding the progression time to  $C_8$  block, it was not completely blocked in both groups, by 20 min, 96.7% of patients were blocked in the out-of-plane approach compared to



90% of patients in the in-plane approach (P value = 0.301). Regarding the progression time to T<sub>1</sub> block, 50% of patients in the out-of-plane approach were blocked by 15 min and increased to 93.3% of patients by 20 min compared to 33.3% and 83.3% of patients at 15 and 20 min respectively in the in-plane approach (P values = 0.190 and 0.228 respectively) (Table 4).

Regarding the motor block, it showed statistically and clinically significant rapid onset and progression in the out-of-plane approach than in the in-plane approach; as by 3 min, 50% of patients were unable to elevate their shoulders and 33.3% of patients showed only diminished shoulder movement in the out-of-plane approach compared to 50% of patients with diminished shoulder movement and 50% of patients with normal movement in the in-plane approach (P value < 0.001). By 4 min, 50% of patients were unable to flex the arm in the out-of-plane approach compared to 53.3% of patients with normal range of motion in the in-plane approach (P value < 0.001). By 10 min, 100% of patients in the out-of-plane approach were unable to elevate their

shoulders, 93.3% of patients were unable to flex their arms, and 50% of patients were unable to move their fingers in the out-of-plane approach compared to 83.3%, 66.7%, and 0% of patients respectively in the in-plane approach (*P* value 0.02, 0.031 and < 0.001 respectively). By 15 min, 100% of patients were unable to flex their arms in the out-of-plane approach compared to 93.3% of patients in the in-plane approach. By 20 min, 100% of patients of both groups were unable to elevate their shoulders and flex their arms, with 93.3% of patients in the out-of-plane approach and 83.3% of patients in the in-plane approach unable to move their fingers (Table 5).

Regarding the duration of motor block, there was no statistical significance between the 2 groups (P value 0.474) (Table 6).

# Postoperative pain score

Regarding postoperative pain assessed in the PACU and at 4, 8, and 12 postoperative hours, all patients felt no pain (VAS = 0).

**Table 5** Onset and progression of the motor block over the first 20 min

Variable		Group   <b>N</b> =	30		Group O <b>N</b> :	= 30		<b>P</b> value
Muscle	Time	Score 0	Score 1	Score 2	Score 0	Score 1	Score 2	
Shoulder	1 min	30	0	0	30	0	0	-
	2 min	29	1	0	27	3	0	0.301
	3 min	15	15	0	5	10	15	< 0.001
	4 min	12	18	0	3	8	19	< 0.001
	5 min	9	21	0	0	10	20	< 0.001
	10 min	0	5	25	0	0	30	0.02
	15 min	0	2	28	0	0	30	0.150
	20 min	0	0	30	0	0	30	-
Arm	1 min	30	0	0	30	0	0	-
	2 min	29	1	0	28	2	0	0.554
	3 min	25	5	0	9	9	12	< 0.001
	4 min	20	10	0	2	13	15	< 0.001
	5 min	16	14	0	0	14	16	< 0.001
	10 min	2	8	20	0	2	28	0.031
	15 min	0	2	28	0	0	30	< 0.150
	20 min	0	0	30	0	0	30	-
Fingers	1 min	30	0	0	30	0	0	-
	2 min	30	0	0	30	0	0	-
	3 min	30	0	0	30	0	0	-
	4 min	23	7	0	22	8	0	0.766
	5 min	22	8	0	20	10	0	0.573
	10 min	20	10	0	3	12	15	< 0.001
	15 min	5	10	15	0	5	25	0.01
	20 min	0	5	25	0	2	28	0.228

Data presented as number of patients

Table 6 The duration of motor bloc	k
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Variable	Group I <b>N</b> = 30	Group O <b>N</b> = 30	<b>P</b> value
The duration of motor block	18.81 h ± 0.51 min	18.73 h ± 0.38 min	0.474

Data presented as mean  $\pm$  SD. P values > 0.05 are non-significant

#### The duration of analgesia

The first call for analgesia was at 24 h in both groups. At 24 h, there was no statistical or clinical significance between the 2 groups as 50% of patients of both groups showed VAS = 3 with only one patient in the out-ofplane approach with VAS = 7 (Fig. 2), and the pain for patients of both groups with VAS more than 4 was relieved with 1 gm Perfalgan and did not require pethidine.

### Discussion

In our study, the block performance time was statistically significant shorter in the out-of-plane approach than in the in-plane approach. This could be attributed to the simplicity of the 2 points injection on both sides of the plexus in the out-of-plane approach rather than the 4 points injection in the in-plane approach. Our results go with those found by Tomassetti and his colleagues in 2008; where the time of performance was 220±80 sec for the in-plane approach and 120±30 sec in the out-of-plane approach with *P*-value < 0.01. However,

Schwenk and his colleagues in 2015 found no difference in the mean procedure time for the out-of-plane and the in-plane catheter technique groups (257.8 sec, 95% CI, [238.1 - 277.4] versus 296.1 sec; 95% CI, [255.2 - 336.9] respectively with P-value=0.093. The difference between our results and those by Schwenk and his colleagues in 2015, may be attributed to the time consumed for the catheter insertion in their study.

Ultrasound guided out-of-plane approach is done by needle insertion and LA deposition on either side of the brachial plexus (Mariano et al., 2009). It provides a shorter path to the plexus but, with more risk of complications compared to the in-plane approach; especially to the recurrent laryngeal nerve on the right side where it lies close to the plexus, and the phrenic nerve in case of proximal site for needle insertion (Borgeat and Ekatodramis, 2002; Bowens et al., 2011; Capdevila et al., 2008). Thus, choosing a distal point for needle insertion may be a safer route where the phrenic nerve is away from  $C_5$  root (Ushma and Herman, 2015). Ultrasound guided in-plane approach is used for single injection blocks and



is considered to be safer as the entire length of the needle is seen. For more complex procedures; continuous catheter techniques allow prolonged analgesia; thus earlier mobilization with improved rehabilitation (Fredrickson et al., 2008). But, catheter threading through the middle scalene muscle, could be painful and could also be difficult in morbidly obese patients (Ilfeld et al., 2010).

In the current study, the onset of  $C_5$  block was statistically significant faster in the out-of-plane than the in the in-plane approach. In the study done by Tomassetti et al. (Tomassetti et al., 2008), they also found rapid onset for the out-of-plane approach than the in-plane approach (450 ± 150 versus 510 ± 180 s respectively).

In the present study, the progression of sensory block over the first 20 min showed statistically significant rapid onset for C<sub>6</sub> block in the out-of-plane than in the inplane approach, and clinically significant rapid onset and progression for  $C_7$  block in the out-of-plane than in the in-plane approach with  $C_8$  and  $T_1$  sparing in both groups. In the study done by Schwenk et al. (2008), there were no differences in the percentage of patients in both groups with sensory block at any time, but the block progression was slower than in our study. As regards  $C_6$ block, at 10 min, 90 and 84.2% of patients in the out-ofplane and in the in-plane approaches respectively were blocked. Regarding C7 block, 55.5% of patients were blocked in the out-of-plane approach at10 min compared to 76.3% in the in-plane approach. Regarding  $C_8$ block, it was not completely blocked until patients were transferred to the PACU where 75.6 and 73.7% of patients were blocked in the out-of-plane and the in-plane approaches respectively.

Regarding the motor block, it showed statistically and clinically significant rapid onset and progression in the out-of-plane block than in the in-plane block in the first 20 min. In the study done by Schwenk et al. (2008), there were no differences in the proportion of patients in each group with motor block at any time. However, it showed rapid similar results to our study. This difference could be attributed to the rapid onset of  $C_5$  and  $C_6$  blocks in our study. As our injection was in a cephalad to caudate direction, Schwenk and his colleagues used a caudate to cephalad direction.

In the current study, the differences in the onset and progression of the sensory and the motor blocks in the 2 groups could be attributed to the 2 points' injection of 10 ml of the bupivacaine on either sides of the plexus, with greater volume encircling  $C_5$  and  $C_6$  roots than dividing the 20 ml of bupivacaine into 5 ml increments, distributed above, between, and below the plexus; thus, lesser volume encircling the  $C_5$  and  $C_6$  roots. In shoulder surgery,  $C_5$  and  $C_6$  dermatomes have the main concern to be blocked than  $C_7$ ,  $C_8$ , and  $T_1$ .

Patients undergoing arthroscopic shoulder surgery suffer severe postoperative pain which is exacerbated during rehabilitation by movement (Trompeter et al., 2010). Regarding postoperative analgesia, it was assessed in the PACU, at 4, 8, and 12 postoperative hours, where all patients felt no pain (VAS = 0). At 24 h, there was no statistical or clinical significance between the 2 groups and the patient in the out-of-plane approach with VAS = 7, pain was relieved by intravenous infusion of 1 gm paracetamol. Our results are similar to those in the study done by Schwenk et al. (2008), as there were no differences in the median VAS pain rating recorded in the PACU between the out-of-plane and the in-plane approaches (1.0; IQR, [0-3.5] vs. 0.25; IQR, [0-2.5]; P = 0.08) and at 24 h between the 2 groups respectively (1.50; IQR, [0-4.38] vs. 1.25; IQR, [0-3.75]; P = 0.57). In contrast to the results in 2010 by Fredrickson et al. (Fredrickson et al., 2010), who found that patients in the out-of-plane group were more frequently pain free in the PACU and required less tramadol in the first 24 postoperative hours.

In conclusion, single injection out-of- plane approach to the interscalene brachial plexus block provides similar analgesia to the in-plane approach for 24 h, with less performance time, rapid onset, and progression of sensory and motor blocks. So, it is an appropriate alternative to the in-plane approach.

#### Abbreviations

ASA: American Society of Anesthesiologists; ECG: Electrocardiography; LA: Local anesthetic; NIBP: Non-invasive blood pressure; PACU: Postanesthesia care unit; SPSS: Statistical Package for Social Science; VAS: Visual analogue scale

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#### Authors' contributions

MG contributed the idea and participated in the design of the study, data collection, and data analysis. GS participated in the design of the study, data collection, statistical analysis, and manuscript editing. All authors read and approved the final manuscript. The manuscript have not been published, simultaneously submitted or accepted for publication elsewhere.

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#### Availability of data and materials

Not applicable.

#### Ethics approval and consent to participate

Ain-Shams University Hospitals ethics committee approval; (FMASU R59/ 2018). Informed consent to participate in the study was taken from all participants.

#### Consent for publication

Not applicable.

#### **Competing interests**

The authors declare that they have no competing interests.

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