

Safety and Efficacy of Dexmedetomidine Combined with Lidocaine for the Intravenous Regional Anesthesia in Upper-Limb Surgeries: A Randomized, Controlled, Clinical Trial

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ABSTRACT

Background: Using lidocaine for intravenous regional anesthesia (IVRA) or the Bier block is a common technique for limb surgeries but is limited by short block duration and tourniquet pain. Dexmedetomidine has shown promise as an adjuvant to lidocaine for the Bier block. This study aims to assess the safety and efficacy of adding dexmedetomidine to lidocaine.

Methods: In this randomized, double-blind, controlled trial, 32 candidates of upper-limb surgery were allocated to receive 3 mg/kg lidocaine 2% (group LS) alone or combined with 0.5 µg/kg dexmedetomidine (group LD), comparing the onset and duration of sensory and motor blocks between the two groups. Secondary outcomes included sedation levels, hemodynamic stability, and satisfaction scores of patients, surgeons, and anesthesiologists.

Results: Patients in the LD group showed significantly lower sensory block onset time (38.8 ± 19.0 vs. 60.6 ± 14.8 seconds, $P = 0.001$) and longer sensory (55.8 ± 15.9 vs. 31.0 ± 8.5 minutes, $P < 0.001$) and motor block durations (47.2 ± 17.4 vs. 26.6 ± 8.7 minutes, $P < 0.001$). They also experienced deeper sedation ($P = 0.028$) and greater satisfaction with the procedure ($P = 0.045$). Although the LD group showed statistically lower heart rate and systolic blood pressure after tourniquet deflation compared to the LS group, the differences were clinically negligible.

Conclusion: The addition of dexmedetomidine to lidocaine provides a faster onset of sensory block, prolongs sensory and motor blocks, and improves patient sedation and satisfaction with minimal clinical hemodynamic effects, enhancing efficacy while maintaining reasonable safety.

Introduction

Intravenous regional anesthesia (IVRA), also known as the Bier block, is a recognized method for administering anesthesia during upper-limb surgeries. It involves putting a tourniquet around the limb

and injecting a local anesthetic into the venous system to block both sensory and motor function [1]. Although it is simple, cheap, and avoids problems with general anesthesia, it has limitations such as short block duration, tourniquet-induced pain, and the potential for incomplete analgesia, which necessitate adjunctive interventions to enhance efficacy and patient comfort [2].

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To increase this method's practicality, previous studies have used various adjuvants, including ketamine, morphine, midazolam, clonidine, ketorolac, and acetaminophen, to increase analgesic efficacy, prolong block duration, and increase patient satisfaction [3-7].

Dexmedetomidine, a highly selective α_2 -adrenergic agonist, has emerged as a promising adjuvant capable of prolonging this analgesia [8].

Its pharmacological actions include sedation, analgesia, anxiolysis, and sympatholysis, mediated through presynaptic inhibition of norepinephrine release and modulation of nociceptive transmission [9-10]. When added to lidocaine in a Bier block, dexmedetomidine significantly shortens sensory and motor block onset times and prolongs block duration [8].

However, few studies have assessed patient satisfaction, and dosing strategies as well as administration protocols vary across trials, limiting generalizability [11]. Accordingly, further research is needed to standardize dexmedetomidine dosing in IVRA and to evaluate patient-centered outcomes.

The present randomized controlled trial was therefore designed to investigate the efficacy and safety of dexmedetomidine as an adjunct to lidocaine in a Bier block for upper-limb surgeries.

The study examines sensory and motor block onset and duration, tourniquet pain, postoperative analgesia, hemodynamic parameters, and satisfaction metrics, aiming to clarify the role of dexmedetomidine in optimizing perioperative care.

Methods

Study design

This study is a randomized, double-blind, controlled trial conducted at Sina Hospital, Tehran, Iran, from November 2024 to September 2025, aimed at comparing the efficacy and safety of IVRA with lidocaine alone or combined with dexmedetomidine in patients undergoing upper limb surgery.

This study was conducted in accordance with the Declaration of Helsinki. No prior publication of data in this manuscript was performed.

Participants

Adult patients (aged 18 years or older) who were candidates for elective upper-limb surgery and had American Society of Anesthesiologists (ASA) physical status I or II were included in the study.

Patients with a history of cardiovascular disease, respiratory distress, diabetes mellitus, allergy to local anesthetics, sickle cell disease, renal or hepatic impairment, substance abuse, epilepsy or use of antiepileptic medications, psychiatric disorders, infection or cellulitis in the upper limb, or pregnancy were excluded from the study.

Intervention, Randomization, and Blinding

After written informed consent was obtained, participants were randomized using a block-randomization tool (StudyRandomizer.com). Allocations were done in sequential order, with the allocations stored in an Excel file accessible only to the randomization coordinator. Patients were randomized to either the LS group, receiving 3 mg/kg 2% lidocaine, or the LD group, receiving 3 mg/kg 2% lidocaine plus 0.5 μ g/kg dexmedetomidine, both diluted to 40 mL using normal saline. After the corresponding arm was elevated higher than the patient's heart level for 3 minutes, the Esmarch bandage was applied from distal to proximal, after which the limb was covered with Webril cast padding. Next, using a double tourniquet, blood flow to the limb was occluded by inflating the tourniquet to 100 mmHg above the patient's systolic blood pressure. Then the solutions were injected at a rate of 1 mL/second into the dorsal vein of the operating limb. During surgery, all patients received 5 L/min of oxygen via face mask. The outcome assessors and analysts were blind to the intervention allocation. To provide weight-dependent doses of interventions and safety measures, the anesthesiologist responsible for administering them was unblinded.

Outcome Measures

Data were collected prospectively using a custom-designed form for demographic (age, sex, weight, height, and body mass index) and clinical variables (ASA status and comorbidities), patient medical records, and separate questionnaires for patient, anesthesiologist, and surgeon satisfaction.

Primary outcomes:

- Onset of sensory block (time until no response to pinprick every 30 seconds).
- Onset of motor block (time until inability to voluntarily move fingers or wrist).
- Duration of sensory block (from onset to return of pain or tourniquet pressure sensation).
- Duration of motor block (from onset to the return of voluntary finger or wrist movement)

Secondary outcomes:

- Sedation levels (assessed 30 minutes after intervention; 4-point Likert scale: 1 = Anxious/Restless, 2 = Cooperative/Calm, 3 = Responds to commands, 4 = Quickly responds to stimuli)
- hemodynamic stability (heart rate, systolic, diastolic, and mean arterial pressure measured before administration, after administration, and after tourniquet opening).
- Satisfaction levels (patient, surgeon, and anesthesia team; 4-point Likert scale: 1 = Very Dissatisfied, 2 = Dissatisfied, 3 = Satisfied, 4 = Very satisfied).

Sample size calculation

The sample size was determined based on the primary outcome of anesthesia duration, using data from a previous study by Mizrak et al., which reported a mean ($\pm$ standard deviation [SD]) sensory block onset of 1.46 ± 0.63 minutes for lidocaine with dexmedetomidine and 2.86 ± 1.35 minutes for lidocaine alone [12]. Assuming a type I error (α) of 0.05, a type II error (β) of 0.10 (90% power), and using G*Power software, a minimum of 13 participants per group were required, with a 20% oversampling; a total of 32 participants were gathered.

Statistical analysis

Analyses were performed using SPSS software (version 27, SPSS Inc., Chicago, Ill., USA). Continuous data are presented as mean $\pm$ standard deviation, and categorical/nominal variables are presented as counts (percentages). Baseline characteristics are presented with standardized mean differences (SMDs) to assess randomization quality. Sensory and motor block latency and duration time were compared between the two groups using the Student's t-test. Sedation was compared between the two groups using a generalized linear model (GLM) with a cumulative logit link and a multinomial distribution with group and sex as factors and age as a covariate. To assess the effects of time on hemodynamic stability, generalized estimating equation (GEE) models with normal distributions and identity links and an independent correlation matrix were developed, including time of assessment, group, and time * group interaction terms for HR, SDP, DBP, and MAP outcomes. Patient, anesthesiologist, and surgeon satisfaction were compared using ordinal regressions. Statistical significance was set at $P < 0.05$.

Results

After the initiation of the study in November 2024, an eligibility assessment was done for 41 candidates of upper limb surgeries, and nine were excluded due to surgery cancellation ($n=3$), decline to participate ($n=3$), history of cardiovascular disease ($n=2$), and history of diabetes mellitus ($n=1$). A total of 32 patients were randomized with a 1:1 allocation ratio to either receive lidocaine alone or in combination with dexmedetomidine. Fortunately, no patient was lost to follow-up (Figure 1). Baseline patient characteristics, including age, sex, and hemodynamics (HR, SBP, DBP, and MAP), were compared between the groups. Most hemodynamic parameters (i.e., MAP, DBP, and SBP) had negligible SMDs (<0.2).

However, due to a small sample size, age (SMD=0.34), sex (SMD=0.27), and HR (SMD=0.36) had moderate SMDs, but these differences were small (2.9 years for age, 2 male patients, and 5 beats per minute for HR) and clinically trivial (Table 1).

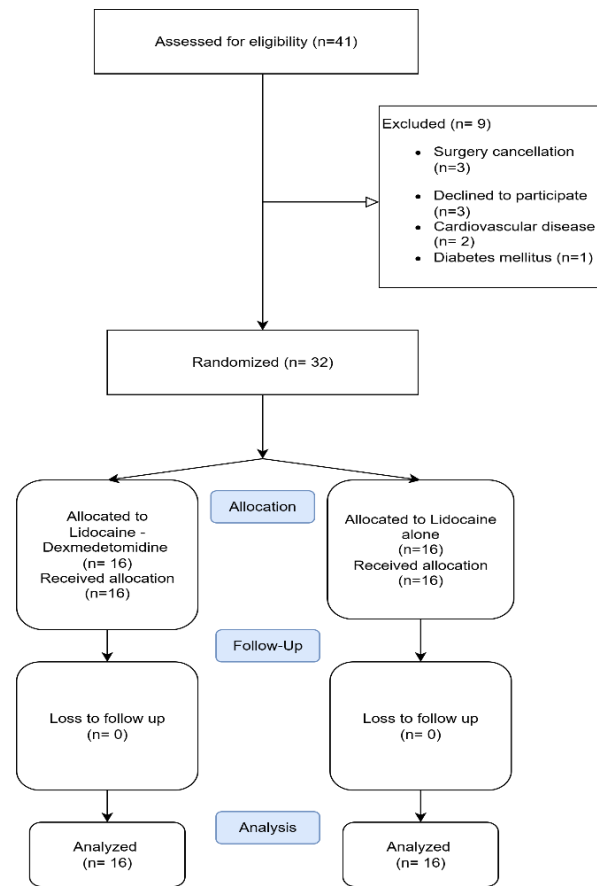


Figure 1- Consolidated Standards of Reporting Trials (CONSORT) Flow Diagram

We compared the time to sensory and motor block (latency) between the two groups and found a significantly lower sensory block latency in the LD group ($P < 0.001$). While motor block latency was lower in the LD group, the difference was not significant (262.5 vs. 333.8, $P = 0.198$). The duration of sensory and motor block was significantly longer in the LD group (sensory: 55.8 vs. 31.0; motor: 47.2 vs. 26.6, both $P < 0.001$). These results suggested a faster sensory block and a longer sensory and motor block in the combination group than the lidocaine alone group (Table 2).

We assessed the effect of the combination group compared with the lidocaine-alone group on patients' sedation (Table 3) and found significantly deeper sedation in the combination group ($B = 1.68$, $P = 0.028$), adjusted for age and sex. We assessed changes in hemodynamic variables (HR, SBP, DBP, and MAP) after tourniquet release in the two groups using generalized estimating equations (see supplement file). We showed significant reductions in HR ($B = 5.44$, $P < 0.001$), SBP ($B = 8.94$, $P < 0.001$), DBP ($B = 4.69$, $P = 0.001$), and MAP ($B = 5.12$, $P = 0.004$) after opening the tourniquet compared to after drug administration. After opening the tourniquet, patients in group LD also showed lower HR ($B = 9.69$, $P = 0.011$), SBP ($B = 9.25$, $P = 0.038$), DBP

(B = 6.00, P = 0.096), and MAP (B = 5.06, P = 0.222) compared to the group LS. While these differences were significant in HR and SBP, all the differences were small and clinically negligible (Figure 2). We assessed

patients', surgeons', and anesthesiologists' satisfaction and found overall higher satisfaction with the LD group; however, this higher satisfaction was only statistically significant with the patients (P = 0.045, (Table 4)).

Table 1- Baseline patient characteristics

Baseline Characteristics	Group LS	Group LD	Standardized Mean Difference
Age	32.1 ± 8.7	29.2 ± 8.5	0.34 ^a
Male (%)	10 (62.5)	12 (75)	0.27
Baseline HR	83.4 ± 12.3	78.8 ± 13.3	0.36 ^a
Baseline SBP	130.9 ± 15.2	130.1 ± 17.3	0.05 ^a
Baseline DBP	83.7 ± 12.2	83.3 ± 12.2	0.03 ^a
Baseline MAP	99.4 ± 12.7	96.9 ± 13.9	0.19 ^a

^a Cohen's D, LS: Lidocaine-Saline, LD: Lidocaine-Dexmedetomidine, HR: Heart Rate, SBP: Systolic Blood Pressure, DBP: Diastolic Blood Pressure, MAP: Mean Arterial Pressure.

Table 2- Sensory and motor block latency and duration

Characteristic	Group LS	Group LD	P value
Sensory block initiation time (S)	60.6 ± 14.8	38.8 ± 19.0	0.001
Motor block initiation time (S)	333.8 ± 150.2	262.5 ± 156.3	0.198
Sensory block duration (M)	31.0 ± 8.5	55.8 ± 15.9	<0.001
Motor block duration (M)	26.6 ± 8.7	47.2 ± 17.4	<0.001

S: Second, M: Minute, LS: Lidocaine-Saline, LD: Lidocaine-Dexmedetomidine.

Table 3- Comparison of the sedation depth between the intervention groups

Parameter	Estimate (B)	95% Confidence Interval		Wald Chi-Square	P value
		Lower	Upper		
LS group	1.68	0.18	3.18	4.83	0.028
LD group ^a	-	-	-	-	-
Female	0.097	-1.38	1.58	0.02	0.898
Male ^a	-	-	-	-	-
Age	- 0.055	-0.14	0.03	1.53	0.216

LS: Lidocaine-Saline; LD: Lidocaine-Dexmedetomidine.

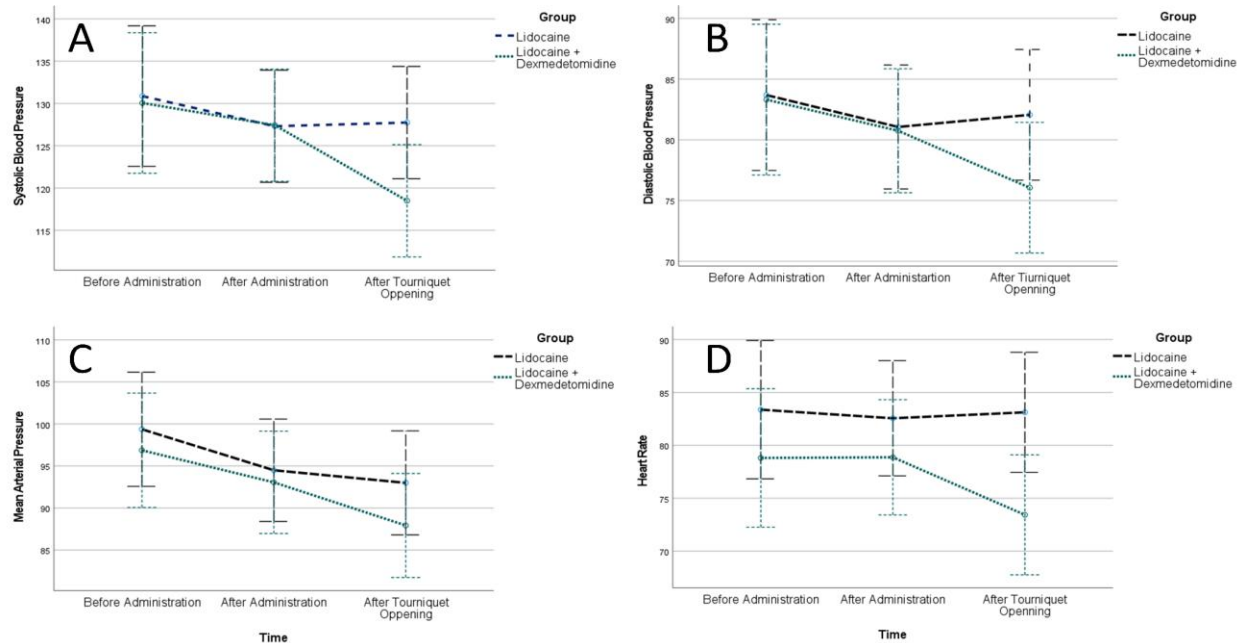


Figure 2- Comparison of the intervention effect on hemodynamics through time. A: Systolic blood pressure, B: Diastolic blood pressure, C: Mean arterial pressure, D: Heart rate

Table 4- Patient, surgeon, and anesthesiologist satisfaction

Satisfaction in LS compared to LD	Estimate	95% Confidence Interval		P value
		Lower	Upper	
Surgeons	-0.99	-2.29	0.32	0.138
Anesthetists	-1.14	-2.48	0.20	0.095
Patients	-1.37	-2.71	-0.03	0.045

LS: Lidocaine-Saline; LD: Lidocaine-Dexmedetomidine.

Discussion

In this randomized controlled trial, we assessed the safety and efficacy of adding dexmedetomidine to lidocaine for the Bier block during upper-limb surgeries. We showed faster sensory block latency with longer sensory and motor block durations when dexmedetomidine was added to lidocaine. This translates into faster anesthesia and longer-lasting blocks during surgery.

Previous studies have also assessed the effects of dexmedetomidine as an adjuvant to lidocaine on the duration and latency of the block. A study by El-Enin et al. showed a longer pain-free duration in the combination group than in the lidocaine-alone group (42.8 vs. 26.8 minutes, $P < 0.001$). While they didn't measure changes in hemodynamics after tourniquet deflation, unlike our study, they showed comparative MAP, HR, and arterial oxygen saturation during surgery between the two groups [13]. Similarly, we observed greater efficacy in the combination group for both sensory and motor block (55.8 vs. 31.0 and 47.2 vs. 26.6 minutes, respectively) and comparable hemodynamic variables during surgery. This longer-lasting sensory and motor block activity of the LD group was also accompanied by a deeper sedation in our study and previous studies [12,14], showing the overall higher efficacy of adding dexmedetomidine to lidocaine.

While we observed a lower sensory block latency in the LD group, we found similar motor block onset latencies between the two groups. However, a study by Bakri et al. showed that adding nalbuphine reduces the sensory and motor latency [15].

Lidocaine, an amino-amide local anesthetic, reduces pain through preventing nerve depolarization acting via sodium ion channels; while also acting as an NMDA receptor antagonist, it can reduce central pain perception [16-17]. However, lidocaine also causes vasodilation, which may increase the time to the onset of its analgesic action [18]. Dexmedetomidine, an α -agonist with sedative, anxiolytic, hypnotic, analgesic, and sympatholytic activities, is routinely used as an adjunct to other analgesics to enhance pain reduction [9,19]. Dexmedetomidine causes vasoconstriction, counteracting lidocaine's vasodilatory activity and thus increasing the drug's local concentration and resulting in a longer analgesic activity [20].

Although beneficial during surgery when the cuff is inflated, delaying peripheral absorption through vasoconstriction and preserving intravenous analgesics could cause systemic adverse events (e.g., hemodynamic instability) when the cuff is deflated [21]. To address potential hemodynamic instability after cuff deflation, we measured hemodynamic data (HR, SBP, DBP, and MAP) before and after drug administration and compared these results with those after cuff deflation. We found significantly decreased values after cuff deflation. Compared with the LS group, patients in the LD group also had lower HR (mean difference = 9.69), SBP (mean difference = 9.25), DBP (mean difference = 6.00), and MAP (mean difference = 5.06). Although these differences were statistically significant for HR and SBP, the differences were clinically trivial and not concerning. Our results were similar to those of Diwanmal et al., who showed that HR and MAP reductions of less than 20% occurred after cuff deflation in the group receiving dexmedetomidine in combination with lidocaine, thus affirming the reasonable safety of dexmedetomidine as an adjunct to lidocaine in Bier block procedures [22].

Lastly, we observed higher, but nonsignificant, satisfaction among anesthesiologists and surgeons in the LD group, a result that may be related to the combination of lower block latency, longer block duration, and deeper sedation. As a subject-oriented outcome, a study by Sardesai et al. showed significantly higher satisfaction of patients receiving dexmedetomidine, a result that was in accordance with ours [6].

Our study was limited by the small sample size, possibly lacking the required power to detect differences for the secondary outcomes, though it was adequately powered for the primary outcome. As a single-center study, our results' generalizability is limited and cannot be applied to emergency cases, patients with higher ASA classes, and various past medical histories, requiring further multicenter trials.

Due to the partial blinding of the anesthesiologist administering the interventions, our study is at risk of performance bias. Subjective outcomes, such as satisfaction assessed via the Likert scale, are susceptible to responder bias. Our study was also limited to the short-term perioperative effects without long-term follow-up outcomes. We propose that future studies use larger sample sizes, complete blinding, diverse populations, and extended follow-up.

Conclusion

Adding dexmedetomidine to lidocaine in intravenous regional anesthesia reduces the onset time of the sensory block, increases sensory and motor block duration, deepens patients' sedation, and increases their satisfaction with the procedure. It also causes minimal hemodynamic changes after cuff deflation, resulting in greater efficacy and a reasonable safety profile.

Ethics approval and consent to participate

Ethics approval statement: All procedures performed in this study were conducted in accordance with the ethical standards of the institutional and/or national research committee and with the Helsinki Declaration. Ethics approval and registration were obtained from the Ethical Board Committee of Sina Hospital at Tehran University of Medical Sciences (IRCT registration number: IRCT20220513054842N3). Informed Consent was obtained from all individual participants included in the study.

Authors' contributions

P.P. and M.N. conceptualized the study. E.I. and M.R.K. developed the methodology. E.I. and H.S. curated the data and administered the project. K.F. and R.B. performed the formal analysis. K.F. also handled validation and visualization and wrote the original draft. P.K., R.S.M., and F.E. also wrote the original draft. A.N. supervised the research and reviewed the manuscript. All authors reviewed and confirmed the final manuscript.

Data availability

All de-identified data would be available upon reasonable request from the corresponding author.

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Supplementary

Heart rate (HR) was significantly higher in the Lidocaine-Saline (LS) group compared to the Lidocaine-Dexmedetomidine (LD) group at the time of tourniquet opening ($B = 9.69$, 95% CI: 2.24 to 17.14, Wald $\chi^2 = 6.49$, $P = 0.011$).

This group difference was attenuated before administration (interaction $B = -5.13$, 95% CI: -12.07 to 1.82, $P = 0.148$) and after administration (interaction $B = -6.00$, 95% CI: -11.88 to -0.12, $P = 0.045$), with the latter reaching statistical significance.

HR was significantly higher from baseline (after tourniquet opening) in both groups before administration ($B = 5.38$, 95% CI: 1.61 to 9.14, $P = 0.005$) and after administration ($B = 5.44$, 95% CI: 2.80 to 8.08, $P < 0.001$) (Supplement Table S1).

Systolic blood pressure (SBP) was significantly higher in the LS group than in the LD group after tourniquet opening ($B = 9.25$, 95% CI: 0.52 to 17.98, Wald $\chi^2 = 4.32$, $P = 0.038$).

The group difference was significantly reduced before administration (interaction $B = -8.44$, 95% CI: -15.69 to -1.18, $P = 0.023$) and after administration (interaction $B = -9.38$, 95% CI: -14.20 to -4.54, $P < 0.001$). SBP increased significantly from baseline (after tourniquet opening) in both groups before administration ($B = 11.56$, 95% CI: 6.20 to 16.92, $P < 0.001$) and after administration ($B = 8.94$, 95% CI: 5.48 to 12.39, $P < 0.001$) (Supplement Table S2).

Diastolic blood pressure (DBP) showed a marginally non-significant trend toward higher values in the LS group compared to the LD group after tourniquet opening ($B = 6.00$, 95% CI: -1.07 to 13.07, $P = 0.096$).

The group difference was attenuated before administration (interaction $B = -5.62$, 95% CI: -12.54 to 1.29, $P = 0.111$) and significantly reduced after administration (interaction $B = -5.69$, 95% CI: -10.04 to -1.34, $P = 0.010$). DBP increased significantly from baseline (after tourniquet opening) in both groups before administration ($B = 7.25$, 95% CI: 2.97 to 11.53, $P < 0.001$) and after administration ($B = 4.69$, 95% CI: 1.89 to 7.49, $P = 0.001$) (Supplement Table S3).

Mean arterial pressure (MAP) showed no significant overall difference between the LS and LD groups after tourniquet opening ($B = 5.06$, 95% CI: -3.07 to 13.19, $P = 0.222$).

The group difference was not significantly modified before administration (interaction $B = -2.56$, 95% CI: -9.88 to 4.76, $P = 0.493$) or after administration (interaction $B = -3.62$, 95% CI: -8.71 to 1.47, $P = 0.163$). MAP increased significantly from baseline (after tourniquet opening) in both groups before administration ($B = 8.94$, 95% CI: 3.95 to 13.93, $P < 0.001$) and after administration ($B = 5.12$, 95% CI: 1.67 to 8.58, $P = 0.004$) (Supplement Table S4).

Supplement Table S1- Heart rate changes through time and between the intervention groups

HR	Estimate (B)	95% Wald Confidence Interval		Wald Chi-Square	P value
		Lower	Upper		
Before administration	5.38	1.61	9.14	7.82	0.005
After administration	5.44	2.80	8.08	16.32	<0.001
After tourniquet opening ^a	-	-	-	-	-
LS vs. LD	9.69	2.24	17.14	6.49	0.011
LS vs. LD * Before administration	-5.13	-12.07	1.82	2.09	0.148
LS vs. LD * After administration	-6.00	-11.88	-0.12	4.00	0.045
LS vs. LD * After tourniquet opening ^a	-	-	-	-	-

^a Comparison based on, HR: Heart rate, LS: Lidocaine-Saline, LD: Lidocaine-Dexmedetomidine.

Supplement Table S2- Systolic blood pressure changes through time and between the intervention groups

SBP	Estimate (B)	95% Wald Confidence Interval		Wald Chi-Square	P value
		Lower	Upper		
Before administration	11.56	6.20	16.92	17.88	<0.001
After administration	8.94	5.48	12.39	25.72	<0.001
After tourniquet opening ^a	-	-	-	-	-
LS vs. LD	9.25	0.52	17.98	4.32	0.038
LS vs. LD * Before administration	-8.44	-15.69	-1.18	5.20	0.023
LS vs. LD * After administration	-9.38	-14.20	-4.54	14.47	<0.001
LS vs. LD * After tourniquet opening ^a	-	-	-	-	-

^a Comparison based on, SBP: Systolic blood pressure, LS: Lidocaine-Saline, LD: Lidocaine-Dexmedetomidine.

Supplement Table S3- Diastolic blood pressure changes through time and between the intervention groups

DBP	Estimate (B)	95% Wald Confidence Interval		Wald Chi-Square	P value
		Lower	Upper		
Before administration	7.25	2.97	11.53	11.00	<0.001
After administration	4.69	1.89	7.49	10.79	0.001
After tourniquet opening ^a	-	-	-	-	-
LS vs. LD	6.00	-1.07	13.07	2.77	0.096
LS vs. LD * Before administration	-5.62	-12.54	1.29	2.54	0.111
LS vs. LD * After administration	-5.69	-10.04	-1.34	6.57	0.010
LS vs. LD * After tourniquet opening ^a	-	-	-	-	-

^a Comparison based on, DBP: Diastolic blood pressure, LS: Lidocaine-Saline, LD: Lidocaine-Dexmedetomidine.

Supplement Table S4- Mean arterial pressure changes through time and between the intervention groups

MAP	Estimate (B)	95% Wald Confidence Interval		Wald Chi-Square	P value
		Lower	Upper		
Before administration	8.94	3.95	13.93	12.33	<0.001
After administration	5.12	1.67	8.58	8.43	0.004
After tourniquet opening ^a	-	-	-	-	-
LS vs. LD	5.06	-3.07	13.19	1.49	0.222
LS vs. LD * Before administration	-2.56	-9.88	4.76	0.47	0.493
LS vs. LD * After administration	-3.62	-8.71	1.47	1.95	0.163
LS vs. LD * After tourniquet opening ^a	-	-	-	-	-

^a Comparison based on, MAP: Mean arterial pressure, LS: Lidocaine-Saline, LD: Lidocaine-Dexmedetomidine.