Articaine and Dexmedetomidine – supplemented Articaine for arteriovenous fistula creation under ultrasound-guided supraclavicular block

CURRENT STATUS: POSTED

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DOI: 10.21203/rs.2.20199/v1

SUBJECT AREAS
Anesthesiology & Pain Medicine

KEYWORDS
renal failure, hemodialysis fistula creation, supraclavicular block, Articaine, dexmedetomidine, ultrasound guided
Abstract
Background: Articaine has emerged as local anesthetic, that produce sensory and motor blockade shorter than bupivacaine and lower in neurotoxicity than lidocaine. Studies have shown that adding dexmedetomidine to local anesthetic produce prolongation of sensory and motor block duration. Early regain of motor power with adequate analgesia is needed in hemodialysis fistula creation, for early start of physiotherapy. We designed this study to test efficacy of adding dexmedetomidine to Articaine on the duration of sensory and motor block.

Methods: After university review board approval, informed written consent to participate in the study was obtained. Patients with chronic renal failure undergoing radiocephalic hemodialysis fistula creation were eligible for enrollment in this double blind, randomized trial. Patients receive either 40 ml of 2% Articaine hydrochloride or 40 ml of Articaine 2% mixed with dexmedetomidine (1 µg/kg). Sensory block duration in minutes is assessed by pinprick test and motor block duration in minutes is tested by Bromage scale, both are recorded as a primary outcome. Secondary outcome included onset of sensory and motor block, time for rescue analgesia, hemodynamic changes, over sedation and possible side effect all were recorded.

Results: fifty patients were enrolled in the study (25 in Articaine group A and 25 in Articaine dexmedetomidine group AD). Longer sensory block duration was in group AD (230 to 260 min) than in group A (172 to 185min) with p <0.001. Also, motor block duration was significantly longer in group AD 220±110min than in group A 165±45. The duration of effective analgesia was significantly longer in group AD (363 ± 134 min) versus (244 ± 84) min in group A. The onset of block was short and similar between groups. In group AD one patient didn’t ask for analgesia in 24 h postoperative and another patient showed excessive somnolence. There was no other difference in both groups.

Conclusion: The addition of dexmedetomidine to Articaine during ultrasound guided supraclavicular block increase duration of sensory and motor block and prolong time of first analgesia required. Although we didn’t detect significant reduction in onset time of block. Further study is needed with larger sample size.

Background
The incidence of end-stage renal disease (ESRD) cases is growing up, by 2040 it is expected to become the 5th cause of death worldwide. Usage of ultrasound guided nerve blockade has been shown to improve various surgical parameters in patients with (ESRD) undergoing arteriovenous fistula (AVF) creation. Blood flow through the fistula was shown to be augmented in those patients having regional anesthesia either brachial plexus blockade or axillary blockade, as both decreases the time for AVF maturation and improves the success rate (1).

The supraclavicular brachial plexus block is used successfully in AVF creation due to blockade of both ulnar and musculocutaneous nerves. These nerves can be missed during either interscalene or axillary approach respectively (2).

For the early start of physiotherapy, motor function of upper limb muscle should recover as early as possible after adequate anesthesia. Thus, the ideal local anesthetic (LA) drug used, should have shorter motor blockade than sensorial blockade to facilitate early pain free movement of upper extremity (3).

Articaine is an amide LA produced in the 1960s and first used in clinical trials in 1974 and emerge to market as pharmaceutical product since 1988. Although it is an amide LA that is similar to prilocaine in chemical structure, but it contains a thiophene ring rather than a benzene ring. Articaine is a rapidly acting, short-duration LA, that has low neurotoxicity and appears to diffuse through tissues more readily than the most commonly used LA (lidocaine). It is metabolized by nonspecific plasma esterases both in blood and tissues, leading to its rapid clearance (4).

α2-adrenergic receptor agonists have been the focus of interest for their sedative, analgesic, perioperative sympatholytic, and cardiovascular stabilizing effects along with providing reduction in anesthetic requirements (5). Dexmedetomidine, an imidazole compound, dextroisomer of medetomidine, displays specific and selective α2-adrenoceptor agonist. Dexmedetomidine may act on supraspinal (locus coeruleus) or spinal level or peripheral α2-adrenoceptor to reduce nociceptive transmission, leading to analgesia (6).
Previous trials focused on adding dexmedetomidine to either levobupivacaine and bupivacaine, found augmentation of both sensory and motor block along with prolong duration of effective analgesia \(^6\), \(^7\), other trials tested adding Fentanyl to Articaine \(^8\). However, there remains limited knowledge of the analgesic efficacy and clinical utility of adding dexmedetomidine to Articaine during peripheral nerve block in humans. Therefore, we conducted this study to verify the effect of adding dexmedetomidine to articaine on the onset and duration sensory and motor block, analgesia time, analgesic requirement and quality of block during (AVF) surgery under ultrasound-guided supraclavicular brachial plexus block.

**Methods**
This randomized double blind study was conducted in Ain Shams University Hospital from June to October 2019. The study was approved by the Research Ethics Committee of Ain Shams University and followed CONSORT guidelines. Fifty adult patients with ESRD requiring renal replacement therapy (RRT) in form of hemodialysis, American Society of Anesthesiologist (ASA) physical status ranged from II to III, aged from 21 to 75 years. scheduled for primary Radio-cephalic AVF creation under brachial plexus block were included in the study. Details of anesthetic technique and procedure were explained to the patients at the preoperative assessment clinic; written and informed consent was obtained from each patient before inclusion in the study. Patients were excluded if allergic to local anesthetics, those having infection at the site of needle insertion, those having international normalized ratio more than 1.5, coagulopathy, neuromuscular, those with proximal vascular disease as brachial, subclavian or axillary artery stenosis or occlusion, patients who refused to participate, and those having epilepsy. Patients underwent dialysis session day before surgery. On the day of surgery patients underwent physiotherapy, then were randomly allocated to two parallel-groups (25 patients in each group) based on a computer-generated sequence, which was kept in sealed envelopes. just before the surgery, the envelope was opened by an attending pharmacist who had no other role in the data collection or analysis. All health care providing team (patients, anesthetists, surgeons, and nurses) were blinded to the patients’ allocation. The Articaine group (group A) received 40 ml of Articaine HCL 2% (Ultracaine, Sanofi-Aventis, Germany) (Articaine 20mg.ml\(^{-1}\)) and the
Articaine-dexmedetomidine (group AD) received 40 ml of Articaine 2% mixed with dexmedetomidine (1 μg.kg\(^{-1}\)) (Precedex; Abbott). The solution for block was prepared in similar-looking 40 ml syringes. On arrival to the operating room patients were monitored for ECG, heart rate (HR), respiratory rate (RR), noninvasive arterial blood pressure (BP), and oxygen saturation (SpO\(_2\)). Base line HR, BP and SpO\(_2\) were recorded. An intravenous line was secured in the contralateral limb. With the patient in supine position, head tilted to contralateral side, transportable ultrasound system (SonoSite M-Turbo; SonoSite Inc., Bothell, WA, USA) with 38 mm 8-13 MHz linear high-frequency transducer (HFL–38) was used to obtain clear ultrasound images, the brachial plexus block was performed in both groups by ultrasound experienced anesthesiologist. After aseptic skin preparation and LA infiltration, ultrasound transducer was placed in the supraclavicular fossa, through a blunt-tipped 22-G needle (Stimplex D; B. Braun Melsungen, Germany) 40 ml of LA solution was injected in 5 ml increments, Intercosto brachial nerve (T2) was blocked with 5 ml lidocaine in 1:200 000 adrenaline solution. Sensory and motor block were tested every 5 minutes, to ensure adequate block, then surgery can be commenced after 30 minutes.

Sensory block was assessed by the pinprick method (Table1). It was performed in four nerve areas [musculocutaneous (lateral side of forearm), median (thenar eminence), radial (radial dorsum of the hand), and ulnar nerves (hypothenar eminence)], and compared with the contralateral arm. Motor block was assessed with modified Bromage scale for upper extremities on a three-point scale: 0 = full motor function, Grade 1 = decreased motor strength, Grade 2 = lack of movement, it was tested by thumb abduction and adduction (radial and ulnar nerve, respectively), finger flexion (median nerve), and elbow flexion (musculocutaneous nerve). The time between the end of the drug injection and the total abolition of pinprick sensation along the distribution of all nerves (median, ulnar, radial, or musculocutaneous) was considered as onset time of sensory block, and the time between the end of the drug injection and Grade 1 motor block was considered as onset time for motor block, both were recorded as secondary outcome.

Sensory block duration was the time between the onset of sensory block to the complete resolution of
anesthesia on all nerves distribution, and motor block duration was the time interval between the onset time of motor block and the recovery of complete motor function of that limb, the duration of sensory and motor block was considered as primary outcome.

Analgesia time (= time interval between the administration of local anesthesia solution and onset of pain at surgical site) was recorded. Rescue analgesia for the first pain was consisted of 1 g Paracetamol iv infusion, given for a pain visual analog scale score of ≥ 4. The time to first dose rescue analgesia was also recorded as a secondary outcome.

The block was considered incomplete when any of the blocked segments supplied by median, radial, ulnar, and musculocutaneous nerve were not satisfactory even after 30 min of drug injection. These patients were supplemented with IV dexmedetomidine (1 μg.kg⁻¹), fentanyl 25μg and local infiltration of lidocaine (10mg.mL⁻¹), as needed. When one or more nerve remains unblocked, it was considered a failed block. In this case, we convert to general anesthesia, and those patients with failed block were excluded from the study. Patient's hemodynamics were monitored including HR, BP, RR, and SpO₂ before block and 5, 10, 20, 30, 45, 60, 120, and 180 min after block. Sedation score using Ramsay sedation scale (1: Awaken and respond to verbal stimuli, 2: Sedated but responding to mild physical stimuli, 3: Sedated but responding only to strong physical stimuli, and 4:unarousable) were measured at the same time interval points. All patients were monitored for any side effects either intra or postoperative such as anaphylaxis, urticarial rash, nausea, vomiting, dryness of mouth, agitation, convulsion, headache, circumoral and tongue numbness, tinnitus, visual blurring, respiratory affection, pneumothorax, accidental vascular puncture, phrenic nerve block and subsequent diaphragmatic paralysis, any hemodynamic variability and post block brachial plexus neuropathy.

Statistical method

Sample size calculation was done using Power Analysis & Sample Size (PASS) 11 software program (NCSS, LLC. Kaysville, Utah, USA). The power analysis was carried out on the basis of the duration of motor block, which was the primary outcome. Group sample sizes of 22 patients per group would
achieve an 80% power to detect a difference of 55 min in the duration of motor block with estimated means of 165 and 220 min and with estimated group Standard deviation (SDs) of 3.0 and 5.3 and with a significance level (α) of 0.05000 using a two-sided two-sample t-test. Twenty-five patients per group were included to replace any missing data.

The statistical analysis was carried out using a standard Statistical Package for Social Science (SPSS) software package (version 17; SPSS Inc., Chicago, Illinois, USA). Student’s t-test was used to analyze parametric data that were expressed as mean ± SD values; discrete (categorical) variables were analyzed using the Chi-squared test and were expressed as numbers (%) median (25th-75th percentiles), or mean ±SD. P-value less than 0.05 was considered statistically significant.

Result
A total number of 50 adult patients in Ain Shams University Hospitals, with CRF scheduled for elective AVF creation surgery were eligible and agree to participate in our study. There was no statistically significant difference among the patients in the two groups with respect to age, weight and sex ratio (table 2). The onset of sensory and motor block among different nerve distribution was similar, it was fast in both groups (Table 3).

The mean duration of sensory block ranged from 172 to 185 min in group A, where as it ranged from 230 to 260 min in group AD, according to each nerve distribution. In the other hand, the duration of motor lock ranged from 161 to 211 min in group A, where as it ranged from 220 to 250 min in group AD for each nerve (table 4).

The first rescue analgesia was 244 ± 84 min in Group A and 363 ± 134 min in Group AD (p = 0.001). One patient in Group AD did not need analgesic in the postoperative 24 h period. There were no episode of hypoxemia or respiratory depression or hemodynamic side effects, such as hypotension or bradycardia, in either group during 24 hours period postoperatively. In Group A, 2 patient had a RSS of 2 and other patients had a score of 3. In Group AD, most patients had sedation scores of 3. No statistically significant differences in sedation scores were found between the two groups (p = 0.274).

No major complications occurred as accidental intravascular injection or post-operative neuropathy. No episode of nausea and vomiting. No resuscitation or other treatment was required. No patient
required readmission to the hospital after home discharge.

Discussion

High failure rate of arteriovenous fistula (AVF) at an early stage (one third), may be influenced by anesthesia technique which determine pre and postoperative vascular diameter and flow through the AVF, different approaches to brachial plexus block is a well acceptable anesthetic techniques for AVF creation (3), peripheral nerve block is associated with sympathetic block which results in an increased intraoperative vascular diameter and blood flow, both intra-operatively and, for several hours, post-operatively. Maintenance of high flow through the fistula post-operatively can prevent thrombosis, fistula failure and is important for fistula maturation.

Articaine was introduced into UK clinical practice in 1988 as a local anesthetic. it is amide LA that contain a thiophene ring, this increases lipid solubility leading to greater portion of the administered dose entering neurons, this lead to rapid onset of action and increase drug potency. Yopp et al. (9), Articaine also possesses an ester link that allows hydrolysis by plasma esterases as well as liver, thus it can be considered safe and less nephrotoxic LA (10). Rapid hydrolysis of Articaine after injection to metabolically inactive product called Articaine acid is correlated with its lower systemic toxicity, and short duration of action making it widely used as LA in dental and ophthalmic surgeries (9,10). To date, there has been an increasing use of LA agent’s adjuvants like (e.g., opioids, $\alpha_2$-adrenoreceptor agonists and magnesium sulfate) to improve the block quality and extend duration (7,8).

Dexmedetomidine is a selective $\alpha_2$ adrenoreceptor agonist. It provides dose-dependent sedation and analgesia without relevant respiratory depression, now dexmedetomidine is used as adjuvant to LA drugs in peripheral nerve blockade to prolong analgesia time (11,12).

From our research we found previous data concerning use of articaine in brachial plexus block. Simon et al. (13) they studied both lidocaine and Articaine in axillary block, they found that both drugs share similar pharmacodynamics properties but differ in pharmacokinetic behavior. Further study Sert et al. (9) they evaluated addition of fentanyl to articaine in axillary block. In this randomized double-blind study, we evaluated the effect of adding dexmedetomidine (1 $\mu$g.kg$^{-1}$). as an adjuvant to Articaine
2% in ultrasound-guided supraclavicular block for the patients with (ESRD) undergoing AVF and found no decrease in onset time of sensory and motor block and increase in duration of sensory, motor block, and duration of effective postoperative analgesia without any adverse effect in Articaine dexmedetomidine group (AD). In spite of this, adding dexmedetomidine didn’t modify the rate of successful blocks.

Although safe home discharge after dental procedure under Articaine nerve block was recorded (14), evidence demonstrate safe hospital discharge with insensate limb, without regain of protective reflexes remain point of controversy because of the possibility of accidental limb injury (15,16). The onset of sensory and motor blockade was rapid and similar in both study groups 7±2 min. with the use of Articaine, which a rapid acting LA, Das et al. (17) studied 84 patients posted for elective forearm and hand surgeries to evaluate the effect of adding dexmedetomidine to ropivacaine for supraclavicular brachial plexus blockade. They found that the onset of the block was earlier in dexmedetomidine group 13.95±1.34 min. the difference in onset time is related to their use of ropivacaine which is a long acting LA with an onset time not less than 15 min. while in a previous study Marhofer et al. (18) added dexmedetomidine as adjuvant to ropivacaine in ultrasound guided ulnar nerve block and showed that the time for the onset of motor block is decreased without effect on time to the onset of sensory block.

The duration of sensory block was longer in group AD versus group A (230 to 260 min vs 172 to 185min), Das et al. (17) also found that sensory block duration was longer in dexmedetomidine group (379.4±55.59 min). longer motor block duration in group AD versus group A (220±110 min vs 165±45min) also goes with longer motor block in Das study(312±49.91min). Although sensory and motor block duration was longer in Das study than our study, as they use ropivacaine. Block duration correlates with finding of Sert et al. (9), they evaluated addition of opioid to articaine in axillary block. Lack of prolonged analgesia is a disadvantage with short acting LA, so α2-adrenoreceptor agonists were added to prolong duration of effective analgesia and improve intensity of motor block, Addition of dexmedetomidine in brachial plexus is reported to improve success rate and postoperative
analgesia in some studies Swami et al. (19) whereas others have found no effect. We recorded significantly increased duration of effective analgesia in Articaine dexmedetomidine (AD) group 250±130 min. A similar result was found by Gandhi et al. (20) who observed increased duration of analgesia in dexmedetomidine Group D to 732.4±95.1 min. compared to 194.8±60.4 min in control group. Also, Swami et al. (19) observed significant (P = 0.001) increase in duration of analgesia in dexmedetomidine group as compared with clonidine. Esmaoglu et al. (5) also, reported significant increased duration of analgesia when they added dexmedetomidine to levobupivacaine. We found increased sedation score among patients of dexmedetomidine group, but this was statistically insignificant between both groups, Singh et al. (11) found significant increased sedation score when added dexmedetomidine to levobupivacaine during supraclavicular block, but they use dexmedetomidine 2 μg.kg⁻¹, while we use only 1 μg.kg⁻¹.

In accordance with study by Swami et al. (17) and Esmaoglu et al. (6) in our study no significant serious side effects were reported upon adding α₂adrenergic receptor agonists in a dose 1 μg.kg⁻¹ to LA except for lower pulse rates, blood pressure and one patient experienced excessive somnolence were observed in dexmedetomidine group, all were managed conservatively.

Conclusion
The addition of dexmedetomidine to Articaine during supraclavicular block for chronic renal failure patients prolong duration of motor block and analgesia however it doesn’t affect onset of sensory and motor block. It allows early start of physiotherapy and hospital discharge. The action of dexmedetomidine is most probably peripheral rather than centrally mediated. However further trials with larger sample size is needed to determine the exact dose and possible neurotoxicity of dexmedetomidine.

List Of Abbreviations
AVF: arteriovenous fistula
ESRD: end stage renal disease
LA: local anesthetic
ASA: American Society of Anesthesiologist

RRT: Renal Replacement Therapy

BP: Blood Pressure

HR: Heart Rate

RR: Respiratory Rate

SPO$_2$: Oxygen saturation

Declarations

Ethics approval and consent to participate
This was a prospective study and was granted permission by the ethics committee of Ain Shams university on 25/11/2017 (R-82).

Consent for publication
Not applicable.

Availability of data and materials
The data is available at https://www.synapse.org/#!Synapse:syn21458740/files/
Also, the data of this article is available from the corresponding author. The email address of the corresponding author is simondr106@gmail.com.

Competing interests
The authors declare that they have no competing interests.

Funding
This research was supported by authors; no funding was obtained for this study.

Authors’ contributions
SH and GA conceived the study and share in its design. SH undertook data collection, data capturing and handling. GS coordinate data analysis with the assistance and review by GA. SH and GA drafted the manuscript. Both SH and GA read and approved the final manuscript.

Acknowledgments
None

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Tables
**Table (1):** Grade of sensory block.

| Grade  | Description                       |
|--------|-----------------------------------|
| 0      | Sharp pin felt                    |
| 1      | Analgesia, dull sensation felt    |
| 2      | Anesthesia, no sensation felt     |

**Table (3):** Demographic Data

|        | Age (years) |        | WT. (kg) |        | Sex |
|--------|-------------|--------|----------|--------|-----|
|        | Group A     | Group AD | Group A  | Group AD |     |
| Mean   | 50.48       | 52.08   | 70.64    | 70.84   | F/M |
| SD     | 5.4         | 6.3     | 5.89     | 6.06    | 8/17|
| t&x2   | T=0.964     | T=0.118 |         |         |     |

Data expressed as median values and standard deviation, t-test for age and sex, Chi-square test for sex

**Table (3):** Onset time of sensory and motor blocks of each nerve.
| Nerve                  | Onset time of sensory block (min) | Onset time of motor block (min) | p-Value | Onset time of sensory block (min) | Onset time of motor block (min) |
|------------------------|----------------------------------|---------------------------------|---------|----------------------------------|---------------------------------|
|                        | Group A (n= 25)                  | Group AD (n= 25)                | p-Value | Group A (n= 25)                  | Group AD (n= 25)                |
| Median nerve           | 6(5-10)                          | 7(5-9)                          | 0.804   | 7(6-12)                          | 8(6-9)                          |
| Ulnar nerve            | 7(5-10)                          | 7(5-8)                          | 0.586   | 8(7-12)                          | 7(7-9)                          |
| Radial nerve           | 8(5-10)                          | 7(5-8)                          | 0.282   | 8(7-11)                          | 8(7-9)                          |
| Musculocutaneous nerve| 8(6-11)                          | 8(6-9)                          | 0.594   | 8(7-12)                          | 8(7-9)                          |

Data expressed as median values with 25th and 75th percentiles

**Table (4):** Duration time of sensory and motor blocks of each nerve.

| Nerve                  | Duration time of sensory block (min) | Duration time of motor block (min) | p-Value | Duration time of sensory block (min) | Duration time of motor block (min) |
|------------------------|----------------------------------|---------------------------------|---------|----------------------------------|---------------------------------|
|                        | Group A (n= 25)                  | Group AD (n= 25)                | p-Value | Group A (n= 25)                  | Group AD (n= 25)                |
| Median nerve           | 178(148-230)                     | 230(190-270)                    | 0.008   | 161(130-203)                     | 220(150-250)                    |
| Ulnar nerve            | 185(150-230)                     | 250(200-330)                    | 0.001   | 165(128-210)                     | 220(150-250)                    |
| Radial nerve           | 180(140-226)                     | 250(190-320)                    | 0.002   | 165(127-211)                     | 220(140-260)                    |
| Musculocutaneous nerve| 172(133-212)                     | 260(190-320)                    | 0.001   | 150(136-205)                     | 220(140-260)                    |

Data expressed as median values with 25th and 75th percentiles

**Supplementary Files**

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