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Comparison of Sedoanalgesia Versus Ultrasound-Guided Supraclavicular Brachial Plexus Block for the Prevention of the Pain During Endovascular Treatment of Dysfunctional Hemodialysis Fistulas

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Abstract

Purpose Although intravenous sedation and analgesia have been widely used as a first choice to relieve pain during treatment of dysfunctional hemodialysis fistulas by interventional radiology, the sedoanalgesic drugs have a considerable risk of respiratory depression, especially in hemodialysis patients. In this study, we compared the utility and efficiency of ultrasound-guided supraclavicular brachial plexus block versus sedoanalgesia for the prevention of pain during endovascular treatment of dysfunctional hemodialysis fistulas

Materials and Methods Patients were randomized into two groups: ultrasound-guided supraclavicular brachial plexus block (n = 34) or sedoanalgesia group (n = 34). A visual analogue scale from no pain (= 0) to worst pain possible (= 10) was used to assess the pain intensity. Patient and operator satisfaction were graded from 0 to 2: 0, not satisfied at all; 1, partially satisfied; 2, satisfied (very well or complete satisfaction). Both groups were compared in terms of pain scores, patient and operator satisfaction as well as complications.

Results The median pain score was significantly lower in the block group compared to the sedoanalgesia group, 0 (0–4) versus 6 (2–10), p = 0.0001. Patient satisfaction and operator satisfaction were significantly higher in the block group than in the sedoanalgesia group (p = 0.0001). Severe oxygen desaturation occurred in five (14.7%) patients following the administration of sedoanalgesia. No side effects or complications related to block procedure occurred in any patient.

Conclusion Ultrasound-guided supraclavicular brachial plexus block has advantages over the sedoanalgesia during endovascular treatment of dysfunctional hemodialysis fistulas. It can provide safe and efficient analgesia with excellent procedural satisfaction in adult hemodialysis patients.

Level of Evidence Level 1 (randomized controlled trial).

Keywords Supraclavicular brachial plexus block · Ultrasound-guided regional anesthesia · Sedoanalgesia · Hemodialysis fistula · Endovascular treatment · Interventional radiology

Introduction

Intravenous sedation and analgesia are frequently used as a first choice for relieving anxiety and pain during the treatment of dysfunctional hemodialysis fistulas by interventional radiology. Nevertheless, sedoanalgesia may not always be effective in preventing procedural pain and therefore may require higher doses with increased risk of respiratory depression in hemodialysis patients [1–4].

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Brachial plexus block (BPB) has been used in the surgical creation or revision of autogenous fistulae or prosthetic grafts. Its use in these procedures results in regional anesthesia and sympatholytic effect that may offer desirable surgical conditions [5–7]. BPB has some potential advantages compared with general anesthesia that includes safety, fewer side effects, better postoperative analgesia, decreased length of hospital stay, and relatively low cost [8–10].

There are few studies describing the use of ultrasound (US)-guided BPB for analgesia during hemodialysis access procedures or endovascular treatment of dysfunctional hemodialysis fistulas [11–13]. These studies concluded that BPB provides excellent pain control and good procedural satisfaction in hemodialysis patients. However, these studies were single-arm studies, and the results were not compared with other options.

We designed this prospective randomized study to compare the utility and efficiency of US-guided supraclavicular BPB versus sedoanalgesia in the prevention of pain during endovascular treatment of dysfunctional hemodialysis fistulas.

Materials and Methods

Patients and Preparation

This study was approved by the Institutional Review Board and Ethics Committee. Between 2013 and 2014, sixty-eight consecutive adult hemodialysis patients were enrolled in this prospective study and randomized into two equal groups: US-guided supraclavicular BPB or sedoanalgesia group. All demographic information of included patients is shown in Table 1. Patients' characteristics were evenly distributed among the two groups (Table 1). All patients were evaluated by an anesthesiologist and interventional radiologist for possible inclusion into the study, potential risk of complications, contraindications, and alternative anesthetic techniques if required. All patients were informed about the procedure, and written informed consent was taken from each patient. Patient exclusion criteria were: inability to cooperate with study, a neurologic disorder affecting the ipsilateral upper limb, contralateral phrenic nerve damage, severe pulmonary disease, abnormal coagulation parameters, any contraindication to sedative/analgesic drugs and intolerance to contrast medium. The definition of criteria for percutaneous interventions in hemodialysis fistulas was based on reporting standards of Society of Interventional Radiology [14].

All patients were monitored with heart rate, cardiac rhythm, blood pressure, and oxygen saturation assessed throughout the procedure. Intraprocedural complications including hemodynamic and respiratory changes were recorded. Moderate oxygen desaturation was defined as between 90–95%, and severe oxygen desaturation was defined as less than 90%. All patients were informed about the symptoms of systemic local anesthetic toxicity, such as lightheadedness and circumoral numbness. A diagnostic fistulography was obtained in each patient to detect any vascular problems along the entire route of the dialysis fistula.

Sedoanalgesia Procedure

Sedoanalgesia was administered by a nurse experienced for using sedative and analgesic drugs, their side effects and reversal agents to be applied. Intravenous sedative and analgesic drugs were given in incremental doses as appropriate for the desired effect of sedation and analgesia or the medical condition of the patient. A single dose of 1 mg midazolam was given prior to beginning fistula treatment if a patient had anxiety. Skin anesthesia with local prilocaine was routinely achieved during puncture of the fistula. Throughout the treatment, patients received incremental doses of midazolam (1 mg) and fentanyl (50 mcg) if needed for pain control or up to desired sedation level.

Block Procedure

Sedative and analgesic medication was not given throughout the BPB and subsequent treatment procedure because good patient cooperation was required. Skin anesthesia was achieved prior to the BPB procedure, but not applied for fistula puncture to be able to assess the effectiveness of BPB.

US-guided supraclavicular BPB was performed by the same interventional radiologist (first author) to achieve the uniformity of the procedure. This operator also contributed to the treatment of hemodialysis fistulas with other interventional radiologists. The patients were painted and draped before positioned supine on the operating table with the head turned to the opposite side. A high-frequency linear transducer (Antares, Siemens AG, Erlangen, Germany) was placed on the supraclavicular fossa to locate the brachial plexus, guide needle advancement and confirm local anesthetic spread. After the brachial plexus was identified as lateral and superficial to the subclavian artery (Fig. 1A), skin anesthesia was obtained by using local prilocaine. A 21-gauge needle with a cutting tip was advanced toward the target nerve in a plane from lateral to medial (Fig. 1B). Once the needle tip reached the brachial plexus sheath, a mixture containing 5 mL of bupivacaine 0.5% and 5 mL of normal saline was injected into the sheath (Fig. 1B, C). The needle tip was redirected if the

Table 1 Patients' characteristics and fistula treatment data

	Sedoanalgesia (n = 34)	Brachial plexus block (n = 34)	p value
Age (years)	Mean age 52.6 ± 13.5 (age range 24–77)	Mean age 58.5 ± 12.2 (age range 36–77)	0.064
Gender			
Male	18 (52.9%)	22 (64.7%)	0.460
Female	16 (47.1%)	12 (35.3%)	
Mean treatment time (min)	52.5 ± 26.6	55.4 ± 19.5	0.606
Fistula			
Forearm (radiocephalic)	22 (64.7%)	22 (64.7%)	1.0
Upper arm (brachiocephalic or brachiobasilic)	12 (35.3%)	12 (35.3%)	
Native	33 (97.1%)	32 (94.1%)	
Graft	1 (2.9%)	2 (5.9%)	
Occlusion or significant stenosis or both			
Afferent artery	3	6	1.0
Anastomosis	25	25	
Efferent vein	29	31	
Central vein	3	5	
Vascular sheath			
Number	37	49	
Mean size (Fr)	6.2 ± 0.9	6.3 ± 1.1	0.609
Conventional balloon			
Number	82	78	
Mean size (mm)	6.7 ± 2	6.5 ± 2	0.484
Cutting balloon			
Number	12	11	
Mean size (mm)	6.1 ± 1.2	6.4 ± 0.9	0.532
Aspiration thrombectomy			
Number	4	11	0.079
Thrombolysis			
Number	5	5	1.0
Stent placement			
Number	0	1 (9 × 40 mm)	1.0

The values are shown as number, frequency (%) or means ± SD

spread of local anesthetic was considered inappropriate. If paresthesia occurred, the needle was withdrawn and redirected along a different path until the symptom disappeared.

Peri- and Postprocedural Management

All patients were evaluated by continual observation of qualitative clinical signs and monitoring for the presence of respiratory depression, Horner syndrome, and voice changes during and after interventional or other medical procedures. Supplemental oxygen was administered if oxygen saturation fell below 90%. The complications such as injury to blood vessels or a nerve, the side effects of local anesthetic agents were documented peri- and postprocedurally. Chest radiography was not obtained routinely if the patient was asymptomatic for hemi-diaphragmatic paralysis or pneumothorax. The patients were not discharged from the interventional radiology department until their condition was stabilized. All patients were given information about possible block resolution time and late risks or complications of the nerve block and asked to contact the operator if they had a problem.

Assessment of Block

The onset and extent of nerve block were observed by the same interventional radiologist (first author) each minute for 30 min after completion of the local anesthetic injection. A satisfactory block was considered as complete

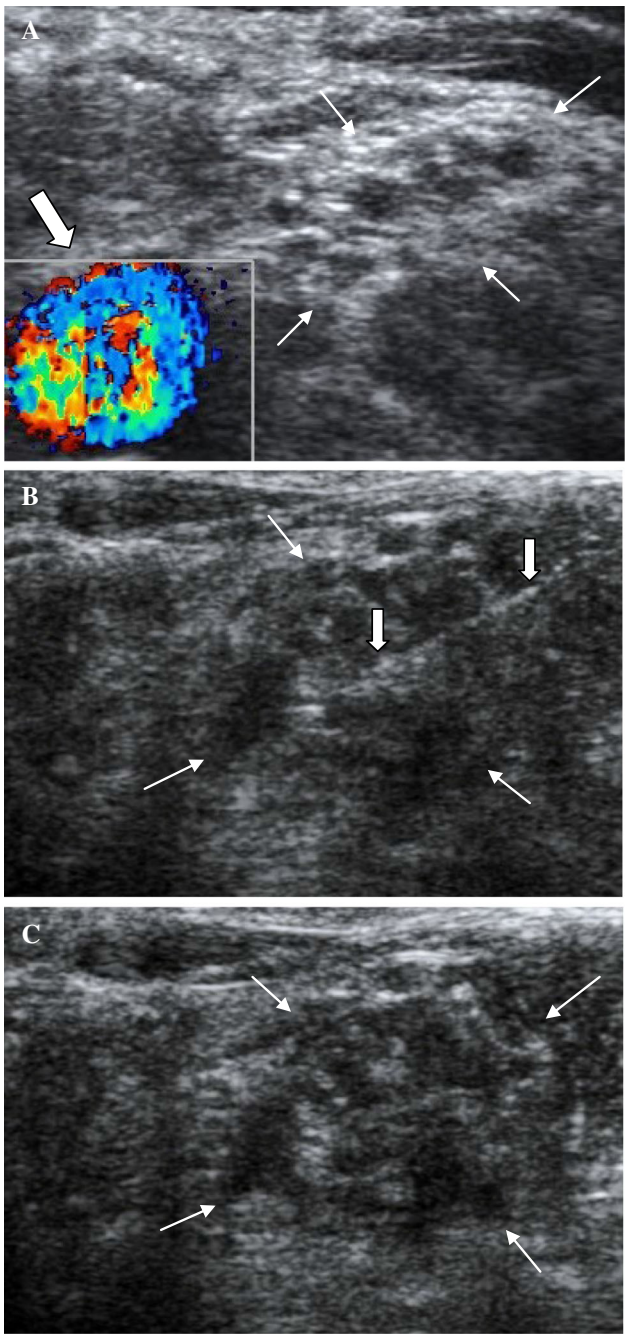

Fig. 1 A 55-year-old woman with occluded left forearm hemodialysis fistula (**A**) Ultrasound image of left brachial plexus at the supraclavicular level. Thin arrows: brachial plexus; thick arrow: subclavian artery; (**B**) ultrasound image of the needle (thick arrow) within the left supraclavicular brachial plexus sheath (thin arrows) during local anesthetic injection; (**C**) ultrasound image of the left supraclavicular brachial plexus after completion of the local anesthetic injection (thin arrows). In this case, the pain score was 1 (mild pain). Both patient satisfaction and operator satisfaction were 2 (complete satisfaction)

motor block and accomplishment of a pain-free state without additional medications. Either analgesia or anesthesia was defined as indicative of satisfactory sensory block. The quality of the motor block was tested by the inability to lift and abduct the arm. If paresis or paralysis was not adequate over the next 3 min, additional BPB was provided by injecting the same local anesthetic dose. After confirming the loss of fine motor control, the pain was initially checked with the puncture of the fistula. Local anesthesia was administered if the patient complained of pain. Sedoanalgesia was provided by using intravenous midazolam and fentanyl if the patient had pain during hemodialysis fistula treatment.

Treatment Procedure

Percutaneous interventions for the treatment of hemodialysis fistulas were performed by using our criteria based on reporting standards of Society of Interventional Radiology [14].

After the puncture of the fistula with a 21G or 18G needle under US guidance, a vascular sheath in sizes ranging from 5 to 9F was placed. Flow-limiting stenosis or occlusion was treated with conventional balloon angioplasty. If postangioplasty fistulography revealed persistent stenosis, balloon angioplasty was repeated with a larger balloon. Cutting balloons were used for some tight stenoses that were resistant to conventional balloon angioplasty. Thrombosis was treated using manual aspiration thrombectomy with or without thrombolysis. Elastic recoil was treated with stent implantation. Covered stents were reserved for balloon angioplasty-induced ruptures or pseudoaneurysms.

Parameters

All data were collected prospectively. We registered the following parameters: treatment data, time to perform the block, the number of needle passes, amount of local anesthetic, time to onset of complete block, need for local anesthetic administration, the requirement for sedoanalgesia, pain scores, patient satisfaction, operator satisfaction, and complications.

A 10-point linear visual analogue scale (VAS) from no pain (= 0) to the worst pain possible (= 10) was used to assess the intensity of pain. The patients were asked to mark their pain intensity on VAS. Patient and operator satisfaction with the pain management were assessed, and this was graded from 0 to 2: 0, not satisfied at all; 1, partially satisfied; 2, satisfied (very well or complete satisfaction). VAS score and patient and operator satisfaction were recorded immediately after the treatment procedure.

All complications were assessed based on the CIRSE classification system for grading the complications [15].

Statistics

An online sample size estimator was used to determine the necessary sample size with 95% confidence level, 80% power, 5% significance level, and 20% margin of error. Sixty-eight patients were allocated into two groups by simple randomization method using web-based randomization program.

Statistical analysis was performed using SPSS software (version 17.0, SPSS Inc., Chicago, IL, USA). If continuous variables were normal, they were described as the mean ± standard deviation ($p > 0.05$ in Kolmogorov–Smirnov test), and if the continuous variables were not normal, they were described as the median. Comparisons between groups were applied using Student's T test for normally distributed data, and Mann–Whitney U test was used for the data not normally distributed. The categorical variables between the groups were analyzed using the Chi-square test or Fisher's exact test. The level for statistical significance was predetermined at $p < 0.05$.

Results

Patient and Treatment Characteristics

The results are presented in detail in Table 1. Patient and fistula treatment characteristics of the two groups were similar. In both groups, all patients were treated successfully. No serious side effects or complications related to fistula treatment were observed during or after the procedure.

Parameters and Pain Control

All patients who underwent BPB had successful procedural anesthesia without a need for supplemental intravenous analgesia, and they were discharged the same day without any apparent complications. Two patients (5.9%) who had slight pain during insertion of a needle or a vascular sheath were anesthetized with local prilocaine.

In sedoanalgesia group, all patients complained of pain during the balloon angioplasty. All such patients required intravenous sedoanalgesia with midazolam and fentanyl. Midazolam median dose was 1 (1–4), and fentanyl median dose was 2 (1–6). Severe oxygen desaturation occurred in five (14.7%) patients who received midazolam and fentanyl. Supplemental oxygen is required in all such patients.

Median pain score was significantly lower in the block group compared to the sedoanalgesia group, 0 (0–4) versus 6 (2–10), $p = 0.0001$. In block group, pain scores were 0 (no pain) in 23 (67.6%) patients and 1 to 3 (mild pain) in nine (26.5%) patients. Only two (5.9%) patients complained of moderate pain with a score of 4. No patients experienced severe or worst pain possible. In sedoanalgesia group, pain scores were 1 to 3 (mild pain) in two (5.9%) patients, 4 to 6 (moderate pain) in 18 (52.9%) patients, and 7 to 9 (severe pain) in 13 (38.2%) patients. One (2.9%) patient had worst pain possible with a score of 10.

Patient and operator satisfaction was significantly higher in the block group than in the sedoanalgesia group ($p = 0.0001$) (Tables 2, 3).

The mean time required to perform block was 3.5 ± 1.5 min. The median number of needle passes was 3 (1–4). The mean amount of local anesthetic was 12.3 ± 3.5 mL. The mean time to onset of the complete block was 4.4 ± 1.6 min.

Discussion

In this prospective, comparative, randomized study, our data demonstrated that US-guided supraclavicular BPB is more advantageous and effective choice than sedoanalgesia in preventing of procedural pain during endovascular treatment of hemodialysis fistulas. No patient required additional analgesia, and no complications secondary to block were encountered. Both patient satisfaction and operator satisfaction were superior in the block group compared to the sedoanalgesia group.

Our findings are consistent with other studies [11–13] which concluded that BPB provides excellent pain control and good procedural satisfaction for patients undergoing dialysis access procedures or endovascular treatment of hemodialysis fistulas. These studies had a significant limitation that was the lack of a comparison group.

Endovascular treatment of the hemodialysis fistula is usually performed on an outpatient basis. Sedation/analgesia allows patients to better tolerate these stressful and painful procedures by relieving anxiety, discomfort, or pain. It also facilitates and may optimize imaging or image-guided interventions throughout the procedure. The use of sedative and analgesic drugs may potentiate respiratory depression. This risk is more pronounced in patients with renal failure. Thus, sedative and analgesic drugs should be administered individually as appropriate for the desired effect and the medical condition of the patient [1–4]. We used midazolam and fentanyl, which are the most commonly used drugs for this purpose. Our results showed that all patients complained of significant pain or discomfort secondary to balloon dilatation. Some of them had severe oxygen desaturation after administration of sedoanalgesia.

Simplicity, efficiency, and reliability of BPB anesthesia have made it desirable for ambulatory limb surgery, especially in patients with significant comorbidities such as severe respiratory and cardiovascular disease. The use of

Table 2 Patient satisfaction

	Sedoanalgesia (n = 34)	Brachial plexus block (n = 34)	p value
0 (not satisfied)	14 (41.2%)	0 (0%)	p = 0.0001
1 (partially satisfied)	19 (55.9%)	1 (2,9%)	
2 (complete satisfaction)	1 (2.9%)	33 (97.1%)	

Table 3 Operator satisfaction

	Sedoanalgesia (n = 34)	Brachial plexus block (n = 34)	p value
0 (not satisfied)	11 (32.4%)	0 (0%)	p = 0.0001
1 (partially satisfied)	21 (61.8%)	0 (0%)	
2 (complete satisfaction)	2 (5.9%)	34 (100%)	

BPB has also been in practice for decades in the surgical creation or revision of hemodialysis fistulas. BPB may offer potential benefits results in regional anesthesia, immobility of the arm and sympatholytic effect that achieve desired surgical conditions [5–10].

Many approaches can be used for BPB: interscalene, supraclavicular, infraclavicular, and axillary. Each approach has its own specific anesthetized area, advantages, disadvantages, indications for use, risks, and complications. The interscalene approach is the highest block and the best option for shoulder anesthesia. The supraclavicular approach is ideal for procedures of the arm, from the midhumeral level down to the hand. Nerves are superficial and most compact at the supraclavicular level. Because of the proximity of the pleura, the supraclavicular approach has more risk of pneumothorax than other approaches. Pneumothorax is possible, but rare with the interscalene and infraclavicular approaches. The infraclavicular approach can produce satisfactory anesthesia for procedures of the arm, but the plexus is not as compact as the more proximal trunks. The axillary block remains more appropriate approach for anesthesia distal to elbow [8, 16–18]. Since adequate anesthesia was achieved by using bupivacaine in our previous experience, the same agent was preferred in this study to be consistent.

US allows direct visualization of the target nerve, needle advancement, and local anesthetic spread. Therefore, the risk of nerve damage and unintended vascular punctures may be reduced by using US. The use of US also reduces significantly the risk of pneumothorax. This makes the supraclavicular approach a valuable alternative to other approaches for arm procedures. Furthermore, it allows a faster onset time of the block with a reduction in the local anesthetic dose [16–18]. For these reasons, US-guided supraclavicular block was considered the most appropriate approach for our study.

This study has some limitations. First, our results reflect a single interventional radiologist experience. To perform, block requires precise manual skills and experience. Thus, visualization of the nerve and resultant sensory and motor block may be poorer in daily clinical practice. Second, investigators who collected the data were not blinded since the parameters had to be recorded during and immediately after the procedure. Third, we could not record the exact recovery time from the motor block. The patients were treated on an outpatient basis and discharged from the interventional radiology department when their condition was stabilized.

In conclusion, US-guided supraclavicular BPB has advantages over sedoanalgesia during endovascular treatment of dysfunctional hemodialysis fistulas. It can provide safe and efficient anesthesia and results in excellent procedural patient satisfaction and operator satisfaction in adult hemodialysis patients.

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Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

Human and Animal Rights All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

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