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Original Contribution

Ultrasound-guided interscalene nerve block vs procedural sedation by propofol and fentanyl for anterior shoulder dislocations☆,☆☆

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ABSTRACT

Background: Few studies were performed to compare ultrasound guided brachial plexus block with procedural sedation for reduction of shoulder dislocations in the Emergency Department (ED). This study was done to provide further evidence regarding this comparison.

Methods: This was a randomized clinical trial performed on patients presenting with anterior shoulder dislocations to the emergency department of an academic level 2 trauma center. Exclusion criteria were any contraindications to the drugs used, any patient which may not be potentially assigned into both groups because of an underlying medical condition, presence of neurovascular compromise related to the dislocation, presence of concomitant fractures, and patient refusal to participate in the study. Patients were randomly assigned into the Procedural Sedation and Analgesia (PSA) group with propofol and fentanyl or ultrasound guided Inter-Scalene Brachial Plexus Block (ISBPB) with lidocaine and epinephrine.

Results: A total of 60 patients (30 in each group) were included in the study. The emergency room length of stay was significantly lower in the ISBPB group, with mean (SD) values of 108.6 (42.1) vs. 80.2 (25.2) minutes ($p = 0.005$). However, pain scores in the PSA group during reduction showed advantage over ISBPB [0.38 vs. 3.43 ($p < 0.001$)]. Moreover, patient satisfaction was higher with PSA ($p < 0.001$).

Conclusion: Using ISBPB for reduction of anterior shoulder dislocations takes less time to discharge and may make it more feasible in conditions mandating faster discharge of the patient. However, since pain scores may be lower using PSA, this method may be preferred by many physicians in some other situations.

1. Introduction

The concept of perivascular anesthesia of Brachial Plexus, as we conceive it today, was first introduced in 1960. Inter-Scalene Brachial Plexus Block (ISBPB) was developed during the following 10 years and became accepted as an effective method of analgesia during shoulder surgery [1]. Thereafter, many surgeons began to use ISBPB for shoulder surgery, arthroscopy of shoulder, and postoperative analgesia after shoulder surgery [2-4].

In recent years, the popularity of using ultrasound to perform many invasive procedures has challenged ISBPB as well; many authors comparing the ultrasound guided nerve block with neurostimulator guided approach concluded that the success rate of the procedure is higher when performed under ultrasound guidance [5-9].

There are many studies comparing different drugs for procedural sedation with each other or with intra–articular injection of lidocaine in shoulder dislocation reduction [10-12]. However, using ISBPB with or without ultrasound guidance for reducing shoulder dislocations in the ED is not exercised extensively; there are few studies in the literature addressing this approach as an alternative to procedural sedation in the Emergency department (ED) for reduction of shoulder dislocations. In this Randomized Clinical Trial (RCT), we compared the clinical outcomes following reduction of anterior shoulder dislocations using ultrasound guided ISBPB with Procedural Sedation and Analgesia (PSA) using propofol and fentanyl.

2. Methods

2.1. Study design

This was a RCT performed in Bahonar Hospital, an academic level 2 trauma center in Kerman, which is a large city with a population of nearly 1 million in the southeast of Iran. Bahonar Hospital is a large referral trauma center with an annual ED census of nearly 70,000 [13]. This

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hospital has also a general ward for Internal Medicine (IM) and an oncology ward, but the main referral center for IM in Kerman is Afzalipoor Hospital [14].

Patients were randomized by block randomization with a block size of 6. The covariates noted for similarity among blocks were number of patients in each group, age, sex, type of anterior dislocation, and underlying diseases like diabetes, cardiovascular diseases, etc. [15].

This study was approved by Institutional Review Board of Kerman University of Medical Sciences and registered in Iranian Registry of Clinical Trials (IRCT2013122615941N1) before initiation of sampling.

2.2. Study population

A convenience sample of patients with isolated anterior shoulder dislocation presenting to Bahonar Hospital in a period of 11 months (January 30, 2016 to December 29, 2016) were randomly assigned for reduction of dislocation into 2 groups: group 1 using PSA with fentanyl and propofol, and group 2 using ultrasound guided ISBPB with lidocaine and epinephrine. All adult (aged 18 or more) patients presenting with anterior shoulder dislocation to the ED diagnosed by radiography in the working shifts of the researchers were included in the study. Exclusion criteria were defined as any contraindications to the drugs used in each group the patients assigned into, patients not potentially assignable to both groups because of an underlying medical condition, presence of neurovascular compromise related to the dislocation, presence of concomitant fractures (e.g. fracture of the greater tuberosity of humerus), and patient refusal to participate in the study. An informed written consent form was read and signed by all patients (or their companions with the permission of the patient) before the procedure.

2.3. Study protocol and procedures

After confirmation of anterior shoulder dislocation by an Antero-Posterior (AP) X-ray and a Y-view (trans-scapular view) of the shoulder, the patients were randomized into either the PSA group (group 1) or ISBPB group (group 2). A sensory and motor examination of axillary, median, radial, and ulnar nerves in addition to comparison of radial and ulnar arterial pulses between two hands were done by a resident of emergency medicine [Post-Graduate Year (PGY) 3] and confirmed by an attending physician of emergency medicine. The procedure to which each patient was assigned was explained for the patient in terms of benefits, potential complications, and alternative choices. Administration of analgesics (opioids are usually administered in this case) before transferring the patient to the radiology suite in the case of suspected shoulder dislocation is not routinely performed in our center unless the patients show intractable pain and agitation or the waiting time to enter the x-ray room is estimated to be too long (usually more than 30–35 min) (see also Results and Limitations).

Under cardiac monitoring and pulse oximetry and by the help of a third person (a PGY-2 resident of emergency medicine) for airway management if needed, PSA was done by an starting dose of 2 μg/kg of fentanyl (FENTANYL BP, Accord Healthcare, UK) and 1 mg/kg of propofol (Propofol-®Lipuro, BBraun, India), titrated to the desired sedation, analgesia, anxiolysis, and motion control for reduction of dislocation (most patients meet these requirements in the moderate sedation stage). According to the clinical policy for PSA [16], moderate sedation is a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by a light tactile stimulus. Preparation of drugs and intravenous injections were done by a nurse. Waveform capnography is not routinely practiced in our ED, and in most EDs of Iran.

Using the high frequency ultrasound transducer (DC-7 Mindray ultrasound machine, China), we performed all our ISBPBs by 2 board certified attending physicians of emergency medicine who had passed a 2 day training course of ultrasound guided nerve blocks in Tehran, Iran in September 2014 conducted by Tehran University of Medical Sciences and had at least 1 year experience in ISBPB with at least 1 weekly nerve block performed during this period. A PGY-3 resident of emergency medicine in (a single person) assisted the emergency physicians in all procedures, performed the cardiac monitoring, and recorded the variables and outcomes. The nerve blocks were performed after complete preparation and sterilization by chlorhexidine 2% and isopropyl alcohol 70% (BodyPrep, Iran) under cardiovascular monitoring and pulse oximetry in the ED resuscitation room and under real time ultrasound guidance. We used 15–25 ml of 1% lidocaine (depending on which volume was enough to cover and expand nerve fascicles apart) with 0.1 mg epinephrine (final concentration: 1/100,000) as a standard for all nerve blocks. The nerve block was done using transverse alignment of the tranducer [17]. The transducer was placed lateral to the trachea at the level of the thyroid cartilage and moved laterally until the bellies of the anterior and middle scalene muscles are visible lateral to internal jugular vein and carotid artery. After visualization of the nerve trunks with echogenic borders and hypoechoic centers, the anesthetic solution was injected via a 20 ml syringe attached to a 22 gauge needle and expansion of nerve fascicles was detected in the monitor. After the procedure was done, serial sensory examinations were performed with 5 min intervals until the patient reported complete analgesia in the shoulder region.

According to the success rates and ease of performance, we chose 3 maneuvers to be done consecutively [18]. The first maneuver tried for all patients was the Liedelmeyer technique (external rotation of the arm while maintaining adduction). With this maneuver being unsuccessful after 2 attempts, we proceeded to Milch maneuver (forward flexion, abduction, and external rotation with or without gentle traction). Finally, a traction-countertraction maneuver was done if the Milch maneuver was unsuccessful after 2 attempts. All maneuvers were attempted by the resident of emergency medicine for the first time and by the attending physicians after first-time failure. In our center, the curriculum of supervised reduction of shoulder dislocations for residents of emergency medicine begins in PGY 2, and the resident participating in our trial had enough experience in the procedure to attempt the first reduction maneuver.

During and after the procedure, all complications related to the procedures (e.g. respiratory depression, hypotension, systemic effects of lidocaine, hypersensitivity, sensori-motor deficits, etc.) were observed and recorded by the resident of emergency medicine. A standardized sheet was completed for each patient by recording all the variables and outcomes of the study. Since the procedures are totally different in their nature, blinding could not be performed in this study.

2.4. Study variables and outcomes

Age, gender, and type of dislocation (mainly: sub-glenoid and subcoracoid) were the demographic variables noted in our study. Fortunately, no major difference in variable distribution was seen among the blocks.

The primary outcome variables in our study were defined as Emergency Room Length of Stay (ERLOS) from beginning of the ISBPB or PSA to discharge and pain score during reduction [measured by a Numeric Rating Scale (NRS)]. The secondary outcomes were defined as, total number of attempts at reduction, number of techniques used for reduction, occurrence of complications, and patient satisfaction with the procedure (measured as a score of 1 to 4: poor, intermediate, good, and excellent, respectively).

2.5. Sample size

Similar studies used a sample size of 20 to 25 patients for nerve block or procedural sedation groups [19-20]. According to the mean (SD) values for length of stay in the emergency department in each group in the most similar one to our study [19] and with α value of 0.05 and study power of 0.9, we reached a sample size of 6 for each group. However, we performed the study with 30 patients in each group.

2.6. Statistical analysis

For description of quantitative variables with normal and non-normal distribution, mean (±SD) and median (±inter quartile range) were used, respectively. For qualitative (categorical) variables, percent of frequency was used. Odds ratio (OR) and 95% confidence interval (CI) for expressing the severity of this association was utilized.

A p value of less than 0.05 was considered statistically significant in all statistical tests. SPSS version 16.0 (SPSS Inc., Chicago, IL, USA) was used for analysis.

3. Results

3.1. Basic characteristics

A total of 60 patients were enrolled in the study period. During this period, 79 patients presented to the ED with anterior shoulder dislocation in the presence of the research team, of which 19 were excluded from the study (Fig. 1). Of patients enrolled, 58 (96.7%) were men and 2 (3.3%) were women. The mean (SD) value for age was 28.7 (7.7), with a minimum of 18 and maximum of 58 years. The mean (SD) time elapsed from dislocation to randomization was 65.9 (24.6) minutes, with a minimum of 30 and a maximum of 145 min. The mean (SD) period of time between patients' entrance to the ED and starting PSA or ISBPB was 28.9 (8.2) minutes. No patients received analgesics before PSA or ISBPB (see also Methods: study protocol and Limitations). Twenty four (40%) dislocations were diagnosed as sub-glenoid type and 36 (60%) as sub-coracoid at the discretion of the attending physician of emergency medicine. Fifty (83%) dislocations were recurrent and 10 (17%) had happened for the first time. In the ISBPB group, 17 (56.2%) blocks were performed by one of the attending physicians and 13 (44.8%) by the other one.

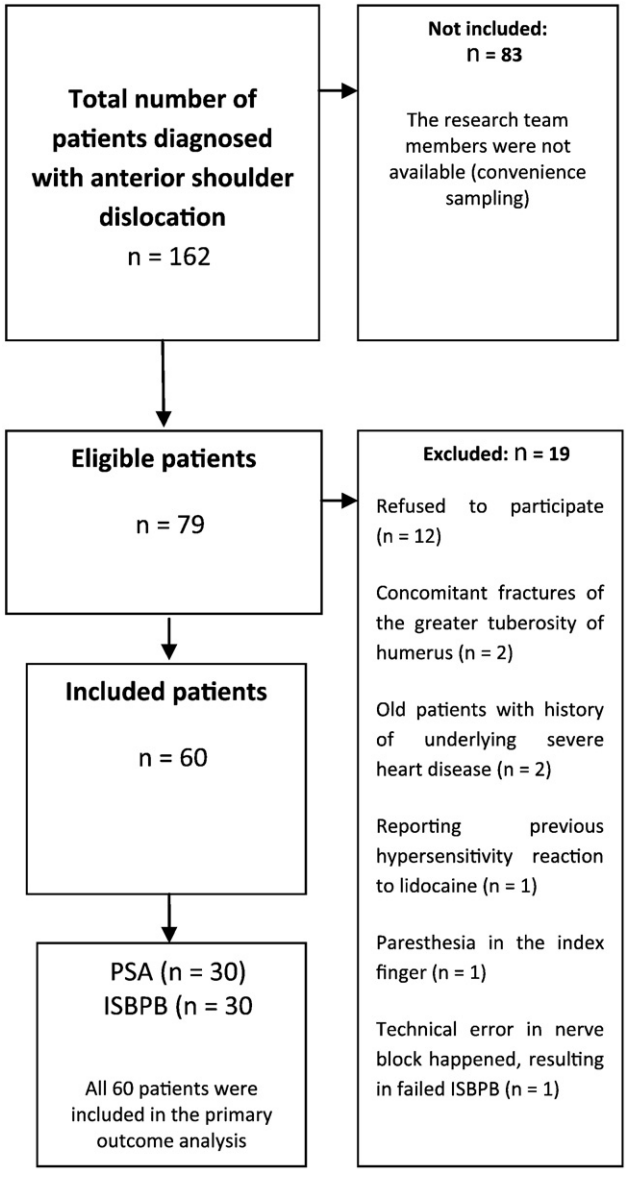

Fig. 1. Flow diagram showing inclusion of patients in the study.

3.2. Comparison between groups

Basic characteristics like age, gender, time elapsed to randomization, etc. did not show considerable difference between PSA and ISBPB groups (Table 1). As expected, transient hypotension with a mean (SD) drop in Systolic Blood Pressure (SBP) of 12 (12) mm Hg was seen only in the PSA group. There were also 3 patients in this group who developed a transient hypoventilation after reduction of shoulder, all of which were managed by simple positioning of the airway and oxygenation with a face mask. In contrast, one patient experienced a sense of total body numbness and tongue paresthesia after injection of lidocaine and epinephrine, which was attributed to a systemic toxicity. Fortunately, none of these complications lasted for more than 1 h. ERLOS in group 1 (PSA) was significantly more than group 2 (ISBPB) ($p = 0.005$). In contrast, pain score and patient satisfaction had a statistically significant advantage in group 2 over group 1 (Table 2).

In the ISBPB group, comparison between the 2 performers did not show any significant difference regarding mean values of total attempts at reduction, number of techniques used, ERLOS, pain scores during reduction, and patient satisfaction after reduction (p values = 0.34, 0.71, 0.42, 0.55, and 0.42, respectively).

4. Discussion

4.1. Previous studies

In 2006, a case series of 4 patients underwent ultrasound guided brachial plexus block for shoulder dislocation was presented in the literature [21]. However, our study was mainly inspired by the work of Blavias et al. [16], in which 42 patients (21 in each group) underwent procedural sedation with etomidate or ultrasound guided ISBPB. They found that there is an absolute advantage in the ISBPB group, with lower length of stay time, lower one-on-one healthcare provider times in this group, and no difference in pain scores or satisfaction between the two groups. In another study performed on 12 patients, similar results were obtained [22]. Suprascapular and supraclavicular nerve blocks were also addressed in the literature for reduction of shoulder dislocation, resulting in shorter length of stay than procedural sedation [20,23]. Overall, in contrast to post-operative pain relief, the literature seems to be scarcely evidenced regarding ultrasound guided brachial plexus block for procedures performed in the ED.

4.2. Our study

Regarding the ERLOS, our findings is in concordance with the previous studies: the ISBPB has a clear advantage over PSA for saving time in the ED; this can be helpful in preventing ED crowding, especially in the rush hours of the ED. The difference between our study and the study of Blavias et al. was in absolute values of this variable: our recorded stay times were less than their records in both groups. This is explained by our different definition for ERLOS, as we defined this variable from the

Table 1
Comparison of the basic characteristics between two groups.

	Age [mean (SD)]	Gender [n (%)]		Minutes elapsed from dislocation to randomization [mean(SD)]	Type of dislocation [n(%)]		First time vs. recurrent dislocations [n (%)]		Initial pain score (Numeric rating scale) [median (IQR)]
		Female	Male		Sub-coracoid	Sub-glenoid	First time	recurrent	
Group 1[a]	28.9 (8.4)	1 (3%)	29 (97%)	62.6 (20.7)	20	10	4 (13%)	26 (87%)	9 (2)
Group 2	28.5 (7.1)	1 (3%)	29 (97%)	69.1 (28.0)	16	14	6 (20%)	24 (80%)	10 (1)
P value	0.83	1.0[b]		0.31	0.29[b]		0.48[b]		0.21[c]

SD: Standard Deviation, IQR: Inter-Quartile Ratio.
[a] Group 1: Procedural sedation, Group 2: inter-scalene nerve block.
[b] Chi-square test performed.
[c] Mann-Whitney *U* test performed.

beginning of the PSA or ISBPB to discharge to reduce the effects of different environmental factors (availability of facilities and staff or speed of service) in different hours of the day. Moreover, one may assume that the possibility of creating a special pathway for patients participating in the trial may result in artificial time records, but this possibility is unlikely because of our definition for ERLOS. In addition, the research team members collected the samples in their regular working shifts and were aware of the probability of this source of bias.

The main difference between our findings with the data of Blavias et al. study were the advantage of the group 1 over group 2 patients regarding pain score during reduction and patient satisfaction with the procedure. This can be explained by various factors. First, patients' apprehension during an "awake" procedure may be different in two populations with different cultures, leading to less satisfaction with nerve block. Second, we have used a relatively lower dose of lidocaine in our study to avoid the systemic effects of the drug, and this may result in a less desirable analgesia. Although there were different agents used for PSA, we did not consider this as a source of different findings between two studies. However, when reviewing the absolute values of pain score, one may conclude that a mean pain score of 3.43 (with a maximum score of 5 reported by 2 patients) in the nerve block group is completely tolerable by the patients and may be acceptable in a busy ED during crowding times. The mean satisfaction score of 3 (equal to "good") in the nerve block group (no patient reported a score of 1 which is equal to "poor" satisfaction) also may be acceptable in the crowded ED of a referral trauma center.

4.3. Limitations

Although we had a 1 year experience of the ultrasound guided nerve block procedure before performing the study, one limitation of our study still seemed to be our limited experience relative to Blavias et al. study team. However, because most emergency physicians do not have such a good experience, this study may present a more realistic image of a procedure aimed to be used in the EDs in a more extensive fashion than it is used today. According to our experience, many emergency physicians still prefer to perform procedural sedation over nerve block even in a crowded ED or when there is a need for a faster patient discharge. The relatively high number of patients who did not accept to participate in the study may also act as a source of bias, but our main limitation in this study was the performance of ISBPB by only 2 physicians: the more the number of performers, the easier to extrapolate these results to other EDs. However, using 2 physicians for ISBPB in one study still seems to be acceptable relative to other similar studies. Clearly, the results of this study could not be generalized to all age groups since the vast majority of our patients were young males; however, in our experience, this group of age and gender commonly comprise the majority of patients presenting with shoulder dislocations to the ED.

In the literature, Assessment and treatment for pain is highly recommended to be done in the first 30 min of patient arrival [24]. However, inadequate analgesia in the ED is a well-known pitfall all over the world. We do not routinely administer analgesics (opioids are usually used for this purpose) before sending the patient to perform x-rays (see Methods: Study protocol) which makes the patients tolerate pain for some minutes before reduction. However, this makes reduction (which in most cases is the only way to provide complete satisfaction for the patient) to be done earlier for several minutes since administration of opioid analgesics mandates several minutes of stay in the emergency room for monitoring. Moreover, the mean time period from patient entrance to start PSA or ISBPB was near the recommended minutes (see Results), although in the case of ISBPB, it takes 10–20 min longer for the medication to provide full analgesia.

5. Conclusion

Since it consumes less time to reduce a shoulder dislocation, ultrasound guided ISBPB may be a reasonable option to obtain analgesia in a crowded and busy ED or when there is a need to accelerate patient turnover. Although PSA may provide the patient with less pain score during reduction, it seems that emergency physicians - at least those with proper training and experience- can perform the procedure with an acceptable pain score and patient satisfaction.

Sources of support

None.

Table 2
Comparison of the outcomes between two groups.

	Total attempts at reduction	Number of techniques used for reduction	Neurovascular complications	Pain score	Patient satisfaction score[b]	ERLOS in minutes
Group 1[a]: Mean(SD)	1.2 (0.4)	1.13 (0.3)	0	0.38 (0.5)	3.6 (0.4)	108.6 (42.1)
Group 2: Mean (SD)	1.4 (0.5)	1.16 (0.3)	0	3.43 (1.6)	3.0 (0.6)	80.2 (25.2)
P value	0.10	0.72		<0.001[c]	<0.001[c]	0.005[c]

SD: Standard Deviation, ERLOS: Emergency Room Length of Stay.
[a] Group 1: Procedural sedation, Group 2: inter-scalene nerve block.
[b] Mann-Whitney *U* test performed.
[c] Statistical significance.

Conflicts of interest

None.

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