A RANDOMIZED TRIAL OF CLOSED REDUCTION WITHOUT ANALGESIA, INTRAMUSCULAR NSAIDS, AND INTRAVENOUS SEDATION-ANALGESIA FOR ACUTE ANTERIOR SHOULDER DISLOCATION

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ABSTRACT

INTRODUCTION

The glenohumeral joint is a highly movable, unstable joint prone to dislocation.

AIM

To evaluate the clinical outcomes of closed reduction of acute anterior shoulder dislocation without analgesia, intramuscular NSAIDs (IM NSAIDs), and intravenous sedation with analgesia (IVSA), in terms of pain reduction, reduction time, ER stay duration, complications, and disability severity.

METHODS

Sixty patients with AASD aged 15 to 35 were randomly distributed into three groups for reduction without analgesia (Group 1), IM NSAIDs (Group 2), and IVSA (Group 3). Senior orthopedic residents unaware of patients' treatment groups measured clinical outcomes. Statistical analysis utilized paired t-test, one-way analysis of variance (ANOVA), and chi-square test at 0.05 significance level.

RESULTS

The three groups were comparable in demographic profile, pain scores at baseline and one-hour post-reduction, and disability severity ($p>0.05$). However, IVSA had a significantly higher quantity of pain reduction ($p=0.0003$), shorter reduction time ($p=0.0001$), and more prolonged ER stay ($p=0.0001$). There were no complications observed.

CONCLUSION

The similar pain-relieving effects of no analgesia, IM NSAIDs, and IVSA suggests their acceptable use for AASD treatment. Patients with severe pain may benefit from IVSA because it affords more pain relief and a faster reduction time.

KEYWORDS

AASD, closed reduction, trial

INTRODUCTION

The glenohumeral joint is the most movable and commonly dislocated body articulation, often anteriorly.[1] The unstable nature of the shoulder joint is owing to a shallow glenoid attaching to the humeral head.[2] The overall incidence rate of shoulder dislocations in the United States is 23.9 with 46.8% of all dislocations among patients aged 15 to 29.3 In Taiwan, the annual incidence rate of acute orthopedic dislocation is 42 (95% CI 38.1 to 46.1), mostly (15.3%) involving the shoulder.[4] The typical mechanism of injury is a blow to an abducted, externally rotated, and extended extremity.[2] Alternatively, a fall on the shoulder can impact the posterior humerus, forcing the humeral head anteriorly.[5] In the general population, traffic accidents and falls are frequent causes of injury.[4, 6]

Management of anterior shoulder dislocation (AASD) involves stabilization by employing a reduction technique. Ideally, the reduction procedure, aside from being effective, should be safe, cause minimal pain, fast, short hospital stay, and avoid complication risks.[7] Closed reduction of shoulder injury using the traction-counter traction technique, can induce discomfort to patients. They can experience pain, albeit less in severity than the leverage approach.[8] Studies have suggested the suitability of non-operative treatment for the primary AASD. Research has found that immobilization was sufficient to stabilize and avoid the reoccurrence of dislocations.[9] However, some others have refuted its efficacy given the risk of recurrence.[10-11] Yet, surgery is still controversial.

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Resistance of the shoulder muscles can affect the reduction. Pain contributes to resistance. Reducing pain and achieving optimal relaxation of the muscles around the shoulder joint is essential for the reduction to proceed well.[12] The moderate relaxation of the patient is inevitable during the reduction as spasms of the shoulder joint gets in the way of the successful reduction.[13-14] Minimizing the pain to lessen the resistance of shoulder muscles is medically achievable through the use of intramuscular non-steroidal inflammatory drugs (NSAIDs) or requires the increasing use of intravenous sedation and analgesia. Traction-counter traction essentially counteracts muscle contraction.[15]

Non-operative treatment using closed reduction with or without sedation and analgesia is typical for managing first-time shoulder dislocation patients in the emergency department (ED) setting.16 Studies that used sedation during traction-counter traction of AASD found reduction time was 470.88 seconds, with 73% and 100% success rates for first and second attempts, respectively.[17] Randomized trials that studied traction-counter traction with IVAS showed variable success rates from 44 to 100%, with a 13% complication rate.[18] However, the ED physician can also perform closed reduction slowly and gently with no analgesia, careful not to increase the current pain severity and muscle resistance.[12] Reduction with no analgesia showed a high successful reduction of 86%, without complications, and well-tolerated by patients.[19] Interestingly, a study reported 100% success in the reduction of 76 shoulders without complications using a traction method without general anesthesia.[20] On the other hand, the use of intramuscular NSAIDs during closed reduction of acute shoulder injury is not a well-explored subject. Nonetheless, a study investigating acute pain revealed intramuscular NSAIDs' efficacy for pain relief, and all patients were discharged with no complications. However, a minimal number of patients required rescue analgesics to reduce the pain severity during the investigation.[21]

Generally, we sought to compare the clinical outcomes of no analgesia, IM NSAIDs, and IVSA during closed reduction of AASD among patients aged 15 to 35 years. Specifically, we aimed to describe the demographic profile of patients randomized into the three groups, namely no analgesia (Group 1), IM NSAIDs (Group 2), and IVSA (Group 3). Further, to compare these three groups in terms of pain score using visual analog scale (VAS), reduction time, duration of ER stay, complications using clinical assessments and x-rays, and disability severity using disabilities of the arm, shoulder, and hand (DASH) score.

Establishing these comparisons can enable physicians to make sound decisions on the best treatment option for their patients. Hence, we conducted this study at the Philippine Orthopedics Center.

MATERIALS AND METHODS

Our institution's ethics review board approved this prospective randomized trial. All patients enrolled in the trial were informed about it and consented voluntarily. The study employed block randomization to randomly allocate an equal number of patients to the treatment groups.

SAMPLE SIZE DETERMINATION

At 95% confidence level and 80% power of the test, the minimum required sample size per treatment group in the present study is at least 18. The basis for the computation was the study by Ho et al.,21 who found that the standard deviation for the change in VAS after two hours for the two groups was 25.47 and 25.98, respectively. The sample size requirement of 18 assumes at least a minimum detectable difference of 25.

Study Criteria

This study included patients who were (a) 15 to 35 years old, (b) of all genders, (c) admitted to the Emergency Room of the Philippine Orthopedics Center between June 2017 to March 2018, (e) diagnosed with acute anterior shoulder dislocation (AASD), (f) the injury occurred within the past 48 hours, (g) agreed to undergo closed reduction using traction-counter traction either without analgesia, intramuscular NSAIDs, or intravenous sedation and analgesia, and (h) signed the informed consent.

However, this study excluded patients who have (a) multiple trauma, (b) comorbidities that may contraindicate the use of sedation (e.g., asthma, pulmonary conditions, and cardiac conditions), and (c) recurrent anterior shoulder dislocation (two or more).

Diagnostic Tool

X-ray was the diagnostic imaging of the study. The subjects underwent x-rays three times - initially before the closed reduction, immediately after reduction, and two weeks after.

Before managing the shoulder injury, the study participants had shoulder x-rays in anterior-posterior position with scapular views to assess the laterality of injury and direction of dislocation.

For post-reduction and two weeks after reduction assessments, axillary x-ray views were obtained. It showed maintained reduction and if additional injuries or fractures occurred.

Randomization and Single Blinding

The study applied block randomization[22] to produce the allocation sequence of research subjects into three treatment groups. An independent statistician used a generator to produce the allocation sequence based on the randomly permuted blocks method.

The principal investigator determined what treatment type should the research subject receive. The senior orthopedic residents responsible for performing the intervention were unaware of the allocation until the PI assigned the research subject to a treatment group, removing selection bias.

The PI disclosed the study procedures and treatment to all patients. However, senior orthopedic residents designated to assess clinical outcomes of research subjects, particularly pain scores, reduction time, complications, and disability severity, were unaware of the treatment group of research subjects. Blinding was imperative to prevent measurement bias.

Data Gathering Procedures

Patients admitted to the ER for shoulder injury were assessed for demographic information, history, and physical examination. They were placed on NPO immediately upon assessment. X-rays of the affected shoulder were taken and subsequently diagnosed.

Group 1 (No Analgesia). Patients assigned under the no analgesia group received the standard treatment for the AASD. The patient was placed in a well-lit room and instructed to relax for about 15 minutes before performing the reduction procedure. The senior resident placed the patient in a supine position, with a sheet around the lateral chest wall of the affected side, while an assistant held the sheet from the opposite side another sheet was placed on the inferior axillary area with traction superiorly by another assistant. The physician applied traction by grasping the patient's wrist in an externally rotated position and pulling using the body weight, with the shoulder abducted approximately 45 degrees.

Group 2 (Intramuscular NSAIDs). Tramadol 50mg was administered to the patient through an intramuscular injection before the reduction maneuver, as described in Group 1.

Group 3 (IV Sedation and Analgesia). The anesthesiologist on duty administered the intravenous sedation with analgesia to the patient before reduction, as described in Group 1. The patient was on NPO for a minimum of six hours after the reduction upon clearance from the anesthesiologist.

The manual reduction was attempted for about five to ten minutes only. Two failed reduction attempts indicated a change in the anesthetic procedure and, thus, a crossover, a ground for disqualification in the study. The present investigation completed the reduction in all patients after one attempt only. Hence, all patients completed their participation successfully.

OUTCOME MEASURES

Primary Outcome Measure

The primary outcome measure of this study was pain. We utilized the Visual Analog Score (VAS), a 10-point numeric pain scale. We obtained the pain score before the reduction and reassessed one hour after performing the reduction procedure.

Secondary Outcome Measures

Reduction time was the duration between commencing and completing the traction-counter traction technique. An observer physician monitored the time using a stopwatch and recorded it in the datasheet.

Emergency room stay was the duration of time from the initial patient interview to the order of patient discharge by the resident doctor. The resident doctor monitored the time of patient admission and discharge and recorded it in the datasheet.

Complications were any adverse conditions resulting from the reduction, such as nerve injuries, cardiac or central nervous system depression, nausea, vomiting, and dizziness. The resident doctor documented any complications that occurred during and after the reduction. Monitoring devices were employed, such as pulse oximeters, cardiac monitors, and oxygen.

Disability severity depicted the difficulty in performing physical activities of patients with shoulder dislocation, the severity of symptoms, and the impact of the problem on social functioning, work sleep, and self-image.[23] The resident doctor assessed the disability severity of patients Immediately after the reduction and reassessed two weeks after the reduction procedure using DASH (Disability of Arm, Shoulder, and Hand) questionnaires. The DASH Score Ortho Toolkit calculated the total scores of each patient.

STATISTICAL ANALYSIS

Our study utilized descriptive statistics, such as mean and standard deviation, to present continuous variables and ordinal variables such as pain score while frequency and percentage for categorical variables. The paired t-test per group was applied to determine the significant difference in baseline and post pain score. The one-way analysis of variance (ANOVA) compared the three groups according to change in pain score, reduction time, duration of the emergency room stay, and disability severity score. Comparison in terms of complications was via chi-square test. The level of significance was at 5%. MedCalc statistical software version 20 was applied to carry out statistical calculations.

RESULTS

Sixty patients with acute anterior shoulder dislocation admitted for treatment at our institution were randomized to three intervention groups, with 20 patients in each group (Table 1). The mean age of research subjects who underwent closed reduction traction-counter traction was not significantly different across the three treatment groups. The distribution of research subjects by sex was not statistically significant in the three treatment groups, wherein males comprised most participants. Laterality of the injury mainly affected the right shoulders, and most of the participants in all treatment groups were right-handed, which were also not significantly different. These results imply that the profile of the subjects randomly allocated in the three treatment groups was comparable.

The visual analog scale (VAS) defined patients' pain levels before the closed reduction process and was revisited one hour later (Table 2). Results revealed no significant difference in mean baseline pain scores and pain scores one-hour after reduction in three treatment groups. However, pain reduction after one hour was significantly higher in IVSA (6.0) than IM NSAIDs (4.9) or no analgesia (4.9). These findings suggest that integrating IVSA in the closed reduction procedure has better pain relief than IM NSAIDs. However, closed reduction without analgesia resembled IM NSAIDs in decreasing pain severity.

We compared the reduction time and duration of ER stay in the three groups (Table 3). In the IVSA group, it took a lot less time for senior orthopedic residents to finish the reduction process at 0.15 seconds than the IM NSAIDs group at 5.1 min or no analgesia group at 5.5 min. On the other hand, the total time of ER stay was significantly shorter in the no analgesia group at 120 min than the IM NSAIDs group at 126.8 min or IVSA group at 334.5 min. These findings indicate that, the reduction time was rapid with IVSA, the duration of the ER stay was significantly longer. Closed reduction without analgesia, on the other hand, has a more prolonged reduction time but a shorter length of stay in the ER.

The current investigation found no evidence of any complications associated with all treatment groups (Table 4).

The DASH scores assessed the disability severity of AASD patients (Table 5). Evaluation of the three treatment groups immediately and two weeks after closed reduction was not significantly different. The decrease in DASH scores of patients in all groups indicate an improvement in their shoulder injuries two weeks after.

DISCUSSION

The demographic profile of AASD patients randomized into three treatment groups in our study was comparable. These findings were congruent with earlier research, revealing that AASD disproportionately affected males [20,24] Our findings also confirm prior investigations that have found AASD prevailed in the second decade of life. For instance, Longo et al.[25] found that the mean age was 28 in their systematic review of articles. AASD patients investigated by Singh et al.[7] involving 56 patients mostly revealed right side dislocation (76.8%) and right-hand dominance (91%). The regular usage of the dominant arm may be a contributing factor to the shoulder instability on the same side. These inconsistencies with our data may be owing to the study's small sample size or the diversity of patients who may sustain AASD.

IVSA seems to have a better pain-reducing performance among the three treatment types. Our finding agrees with Mahshidfar et al.,[26] who observed a pain reduction in IV midazolam with fentanyl, with a mean pain drop of 6.3 points among patients with recurrent anterior shoulder dislocation. It seems conceivable that IVSA can aid pain reduction associated with complicated and uncomplicated shoulder dislocation.

Conversely, Tamaoki et al.[27] found traction-counter traction without analgesia reduced pain from a baseline mean score of 7.1 to 4.9 one minute after reduction and down to 4.0 five minutes after. Our result's differences may be due to the timing of pain evaluation and the uncomplicated cases of AASD, excluding those with fracture-dislocations. Nevertheless, surgeons emphasized that using anesthetics during traction-counter traction is necessary because the method requires more force to reduce the dislocation, otherwise painful.[28]

Administering IVSA requires close patient monitoring before and after reduction until fully awake to protect airways.[29] However, the reduction time of the no analgesia group differed in previous studies. The research by Tamaoki et al.[27] reported 4.9 minutes, while Kaleem et al.30 showed a much smaller value of 3.9 minutes. The contrasting findings may be owing to the interaction of other factors like body mass index and perioperative time.[31] According to Turturro et al.,[32] only 81% of uncomplicated AASD are reducible using the traction-counter traction method without additional analgesia.

We did not note any issues or complications during or after the closed reduction of AASD. Our findings were consistent with Mahshidfir et al.,[26] who did not find any associated complications in using IV sedation, such as airway compromise, retracted respiratory depression, or circulatory failure. Moreover, Jiang et al.[13] indicated that patients administered with IVSA are significantly at risk of respiratory depression, vomiting, and thrombophlebitis. Rehabilitation is initiated at two weeks follow-up starting from pendulum exercises and Range of motion exercises, with gradual progression to strengthening exercises if necessary.

CONCLUSION AND RECOMMENDATION

In conclusion, closed reduction with traction-counter traction without analgesia, IM NSAIDs, and IVSA had comparable pain-relieving effects in uncomplicated primary AASD. As a result, it is acceptable to use these interventions in the ER to treat shoulder dislocations. However, because IVSA produces a greater quantity of pain relief and reduces the time required for reduction, patients with severe pain may benefit from sedation with analgesia during closed reduction.

This study did not intend to assess the satisfaction of AASD patients who had closed reduction by traction-counter traction with no analgesia, IM NSAIDs, and IVSA. While this was a drawback, our analysis advances current understanding by contrasting the performance of the three therapies during AASD closure. We suggest conducting a retrospective study focusing on determining the predictors of recurrent anterior shoulder instability after a primary dislocation among adult patients.

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APPENDICES

RESULTS TABLES

Table 1. Demographic Profile of Patients

	No Algesia (n=20)	IM NSAIDs (n=20)	Sedation (n=20)	p value
Age (years), mean ± sd	21.7 ± 3.4	23.7 ± 5.4	24.5 ± 6.3	.810^{ns}
Sex, n, %				
Male	20 (100)	19 (95.0)	18 (90.0)	0.441^{ns}
Female	0 (0.0)	1 (5.0)	2 (10.0)	
Affected Sides				
Right	13 (65.0)	13 (65.0)	9 (47.4)	0.4555^{ns}
Left	7 (35.0)	7 (35.0)	10 (52.6)	
Handedness				
Right	15 (75.0)	16 (80.0)	16 (84.2)	0.8537^{ns}
Left	5 (25.0)	4 (20.0)	3 (15.8)	

significant, ns not

Table 2. Comparison of Pain Scores

	No Algesia	IM NSAIDs	Sedation	p value
Before	**8.5 ± 1.4**	**8.9 ± 1.2**	**9.1 ± 1.2**	0.287ns
After one Hour	3.6 ± 1.4	4.0 ± 1.5	3.1 ± 1.4	0.177 n
Amount of change	4.9 ± 1.2	4.9 ± 1.2	6.0 ± 1.7	0.003*

significant, ns not

Table 3. Comparison of Reduction Time and Duration of Emergency Room Stay

	No Algesia	IM NSAIDs	Sedation	p value
Reduction Time (minutes)	5.5 ± 2.2	5.1 ± 2.8	0.15 ± 0.1	0.0001*
Duration of Stay (minutes)	120 ± 50.2	126.8 ± 55.4	334.5 ± 86.7	0.0001*

significant, ns not

Table 4. Comparison of Complications

	No Algesia	IM NSAIDs	Sedation	p value
Yes	**0 (0.0)**	0 (0.0)	**0 (0.0)**	-
No	20 (100)	20 (100)	20 (100)	-

significant, ns not

Table 5. Comparison of *DASH* Score

	No Algesia	IM NSAIDs	Sedation	p value
Immediate post Reduction	50.5 ± 9.4	52.3 ± 6.6	51.7 ± 5.5	0.731^{ns}
Final follow-up	16.2 ± 4.5	15.8 ± 4.0	16.1 ± 4.3	0.932^{ns}

significant, ns not

Figure 1. Closed reduction of acute anterior shoulder dislocation using the traction-counter traction technique

Figure 2. Three-Point Traction-Counter Traction Reduction Technique.

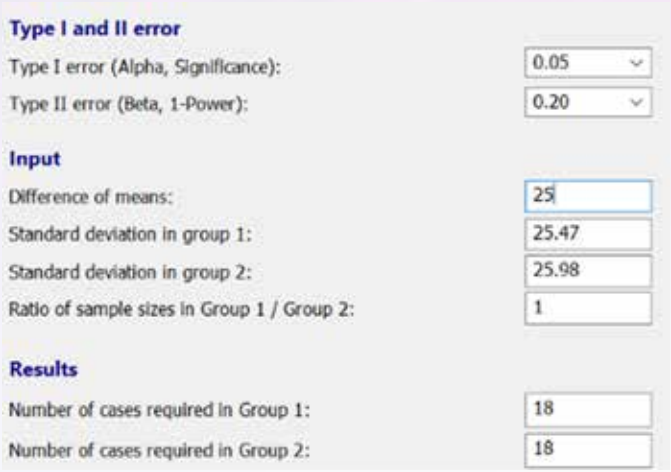

Figure 3. Sample size calculation