Effect of Hematoma Block Combined with Intravenous Diazepam versus Hematoma Block in Closed Colles' Fracture

Arun Woranuch, MD, Thanakorn Pinyo, MD, Thananit Sangkomkamhang, MD

Department of Orthopedic Surgery, Khon Kaen Hospital, Khon Kaen, Thailand

Introduction: *There are many different anesthesia options to reduce pain in reduction of Colles'fracture. The most convenient anesthesia option is a hematoma block but this procedure is not a good anesthesia because patients still experience moderate pain during reduction. From current observational studies show that hematoma block added through intravenous sedation can reduce pain in patients.*

Objective: *To compare the effectiveness of the hematoma block with intravenous (IV) diazepam versus hematoma block alone in relieving pain of the closed reduction of Colles' fracture in adult patients.*

Materials and Methods: *Closed Colles' fracture patients who visited emergency department, Khon Kaen hospital during December 2016-December 2017 and were performed close reduction were enrolled to the study and were randomly assigned to hematoma block combined with intravenous diazepam group and hematoma block group. Visual analog scale (VAS) before and during the procedure were evaluated in both groups. The primary outcome was the mean difference of visual analog scale.*

Results: *A total of 22 patients were enrolled in the study, 11 patients received hematoma block with IV diazepam and 11 received hematoma block alone. The average VAS scale during reduction was 3.09 for the hematoma block with IV diazepam group and 2.82 for the hematoma block alone group, with a mean difference of 0.27(-1.25-0.71) (p=0.28). No complications were experienced in both trial groups.*

Conclusion: *The effectiveness of hematoma block alone is not difference to hematoma block with IV diazepam to reduce pain during closed reduction in closed Colles' fracture.*

Keywords: *Reduction of Closed Colles' fracture, Hematoma block, Intravenous Diazepam, VAS*

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Introduction

The distal radius fracture is the most common fracture condition, the incidence is 17.5% of all fractures[1]. Most of them are classified as being extra-articular type, 57-66%[1]. The main treatment of this fracture is closed reduction which cause pain during procedure and make patients uncomfortable. Therefore, this procedure requires an adequate pain control. In general, the methods that use to control pain are hematoma block, general anesthesia, intravenous regional anesthesia, intravenous sedation. Hematoma block is the common method which is effective to relieve pain and and has advantages that can be performed at bedside[2-4]. However, using only hematoma block, patients will still have pain during reduction[2-6,10,11].

Currently, conscious sedation is used for various medical procedures. This procedure allows the patient to relax while is still communicable. Furthermore, the reflex remains to be uninhibited. Conscious sedation can be performed by intravenous injection of sedative drugs such as benzodiazepine[9]. Benzodiazepine acts at the GABA receptor, resulting in patients' relaxation and pain reduction[7,8]. However, we found that conscious sedation alone in fracture reduction was poor for pain reduction[2,11].

There was a prospective study of the use of hematoma block in combination with conscious sedation by using benzodiazepine during closed reduction of distal radius fracture reported a significant reduction of pain when compared to hematoma block[10]. Nevertheless, to our knowledge, there was no randomized control trial that compared this two methods for pain reduction in closed reduction of Colles' fracture.

The objective of the study is to evaluate pain reduction of hematoma block combined with IV Diazepam compared to hematoma block alone, in the reduction of closed Colles' fracture.

Objectives of the project

To evaluate pain reduction of hematoma block combined with IV Diazepam compared to hematoma block alone in reduction of closed Colles' fracture.

Correspondence to: Woranuch A, Department of Orthopedic Surgery, Khon Kaen Hospital, Khon Kaen, Thailand
E-mail: woraarun@gmail.com

Materials and Methods

Study design

Randomized controlled trial.

Target population

The patients with Colles' fracture group who have been treated with closed reduction and short arm cast aged 18-65 years who visited Khon Kaen Hospital.

Study Population

The patients with Colles' fracture group who have been treated with closed reduction and short arm cast aged 18-65 years who visited Khon Kaen Hospital.

Inclusion Criteria

1. Age 18-65 years
2. Closed Colles' fracture
3. Plan of definitive treatment with closed reduction
4. The fracture period of within 2 weeks after injury
5. Full consciousness (Glasgow coma score 15)
6. Good physical strength (American Society of Anesthesiologists Classification (ASA Class1,2))

Exclusion Criteria

1. Have had an allergic reaction to diazepam and anesthetic agents
2. Pregnancy
3. Multiple injuries
4. Compartmental syndrome
5. Pathological conditions in the brain and mental
6. Received pain relief medication before reduction
7. The abnormality in sensation.
8. Contraindications to benzodiazepine include acute narrow-angle glaucoma, myasthenia gravis, severe respiratory impairment, liver dysfunction (severe hepatic impairment) or having the same drug, interacting with diazepam

Sample Size Calculation

Based on the study of a pilot study of patients in the experimental group and the control group 4 case

Determine the value $\alpha = 0.05$, $\beta = 0.1$ Mean treatment = 1 Mean control = 3.5

SD t = 0.8 SD c = 2.8 ratio = 1

Study in 11 patients in each group

A total of 22 participants

Methods

Patients with Colles' fracture who visited at Khon Kaen Hospital were enrolled and assessed for the eligibility criteria. Then, they were randomly assigned into into two groups, the hematoma block alone and the hematoma block with IV diazepam group. In both groups, the physician performed hematoma block using 5 ml of 2% lidocaine injecting into the fracture site before closed reduction. In addition to hematoma block, the 10 mg of diazepam was slowly injected intravenously in combined hematoma block and sedation group during the procedure vital signs including blood pressure, pulse oximetry, heart rate, respiratory rate was monitored every 5 minutes. The closed reduction was performed by the well-trained orthopedic resident or staff on duty.

Visual analog scale (VAS) was used to assess and record before and during closed reduction.

The adverse reactions were observed after injection for 30 minutes. The abnormal symptoms and signs were as follows,

Cardiovascular system: hypotension

Central nervous system: amnesia, ataxia, confusion, depression, drowsiness, dysarthria, fatigue, headache, slurred speech, vertigo

Dermatologic system: skin rash

Gastrointestinal system: altered salivation (dry mouth or hypersalivation), constipation, diarrhea

Genitourinary system: urinary incontinence, urinary retention

Neuromuscular & skeletal system: tremor, weakness

Ophthalmic system: blurred vision, diplopia

Respiratory system: apnea, asthma, bradypnea

Data Collection

Outcome measurement

The physicians will evaluate the data recording of visual analog scale before reduction, during closed reduction.

The primary outcome: The mean difference of visual analog scale before closed reduction and during closed reduction in two groups.

Statistical Analysis

Baseline characteristics: percentage will be used for summarizing categorical data and mean with standard deviation will be used for continuous data.

Continuous data were analyzed by t-test or Mann-Whitney U-test as appropriate.

Categorical data were analyzed by Chi square test.

The primary outcome was analyzed by t-test.

The statistical significance was determined by *P*-value < 0.05.

Data analysis based on Intention to treat analysis.

The data was analyzed by using the STATA program.

Results

A total of 22 patients were included in the study. Eleven patients received hematoma block alone while 11 patients received hematoma block combined with IV diazepam.

The baseline characteristics of patients were not significantly different (Table1). Mean age of patients in hematoma block group was 51.72 years and hematoma block combined with IV diazepam was 55.54 years. The mean time from performed hematoma block to start closed reduction was 5 minutes in both groups. The reduction procedure in 2 groups was performed by the same group of physicians throughout this study.

Table 1 Baseline characteristics of patients.

Characteristics	HB only group(11)	HB+IV diazepam group(11)
Gender (F/M)	10/1	8/3
Age (y)	51.72	55.54
BMI	24.32	23.98
Time from injury to reduction (min)	175	190
Time from hematoma block to closed reduction (min)	5	5.09
Operators		
- Staff	3	5
- Resident	5	3
- Intern	3	3

Table 2 The VAS before and during the treatment.

	HB only	HB+IV diazepam	Mean difference(SD)	*P*-value
Pain score Before reduction	4.82	4.55	0.21(-1.11-1.66)	0.65
Pain score during reduction	2.82	3.09	0.27(-1.25-0.71)	0.28

VAS before reduction and during reduction into two groups was not significantly different with a mean difference of 0.27 (-1.25-0.71), 0.21 (-1.11-1.66), respectively.

Discussion

In this randomized clinical trial evaluated the effect of hematoma block alone compared to hematoma block with intravenous diazepam to reduce pain during closed reduction of Colles' fracture, the mean difference of VAS in before and during the procedures had no significant difference.

The previous prospective trial comparing methods to relieve pain during closed reduction reported that pain was greater in patients who received hematoma block alone than patients who received hematoma block combined with IV sedative drug (VAS 0.9 vs 3.7) of which results was different from our study. However, this study was a randomized clinical control trial which minimized the limitations of selection bias and other confounders.

In our study, VAS during closed reduction in the hematoma block alone group was 2.82/10 which was mild severity of pain. Therefore, this group of patients may not necessitate additive sedative drugs that would inevitably increase the risks of side effects such as cardiovascular compromised, retrograde amnesia, respiratory depression[21]. For the hematoma block with intravenous diazepam group, even though there were some side effects of sedative drugs reported in previous studies, none of our patients had experience of these events.

There were some study-limitations needed to be considered in our study. First, this study had a small sample size which may decrease statistical power and unable to detect an effect of the intervention. Second, the lack of information about degree of fracture's displacement and radiographic parameter in pre- and post-reduction that may effect to the results. Third, this was a single-center study and the different experience of the operators might affect the result generalizability.

Conclusion

The results of the technique using hematoma block alone had no statistical difference in controlling pain during closed reduction of Colles' fracture compared to the technique that combined hematoma block and intravenous diazepam.

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การฉีดยาชาในบริเวณรอยหักของกระดูกร่วมกับการฉีดยาไดอาซีแพมทางหลอดเลือดดำเทียบกับการฉีดยาชาในบริเวณรอยหักของกระดูกเพียงอย่างเดียวเพื่อระงับความเจ็บปวดระหว่างทำการดึงกระดูกเข้าที่ในผู้ป่วยกระดูกแขนส่วนปลายหัก

อรุณ วรนุช, พบ, ธนากร ภิญโญ, พบ, ธนนิตย์ สังคมกำแหง, พบ

บทนำ: การรักษาภาวะกระดูกแขนส่วนปลายหักชนิดคอลลีส์ (Colles' fracture) ส่วนใหญ่รักษาโดยการทำการดึงกระดูกเข้าที่ร่วมกับการใส่เฝือก ซึ่งขณะทำการดึงกระดูกที่หักจะทำให้มีอาการเจ็บปวดได้ ดังนั้นการดึงกระดูกให้เข้าที่จำเป็นจะต้องมีการควบคุมอาการเจ็บปวดที่เหมาะสม
วิธีการควบคุมการปวดที่สะดวกที่สุดคือการฉีดยาชาเข้าในรอยหักแต่ผู้ป่วยจะยังมีอาการปวดค่อนข้างมาก มีบางการศึกษาศึกษาเกี่ยวกับการฉีดยากลุ่มไดอะซีแพมเพิ่มเติมเพื่อช่วยลดอาการปวด

วัตถุประสงค์: ศึกษาระดับความเจ็บปวดเปรียบเทียบกันระหว่างการฉีดยา intravenous diazepam ร่วมกับการฉีดยาชา hematoma block เปรียบเทียบกับการฉีดยาชา hematoma block เพียงอย่างเดียวในผู้ป่วยกระดูกปลายแขนหัก โดยวัดระดับความเจ็บปวด (pain score) ระหว่างการclosed reduction

วัสดุและวิธีการ: การทดลองแบบสุ่มควบคุมผู้ป่วยที่เป็นผู้ใหญ่ทุกคนมีอายุระหว่าง 18 ถึง 65 ปี ที่มีกระดูกปลายข้อมือหัก (Colles' fracture) ในแผนกอุบัติเหตุและฉุกเฉินของโรงพยาบาลขอนแก่น รวมตั้งแต่เดือน ธันวาคม 2559 ถึง ธันวาคม 2560 ผู้ป่วยที่มีข้อห้ามจะได้รับการยกเว้น ผู้ป่วยถูกสุ่มเป็นสองกลุ่ม วัดระดับการรับรู้อาการปวด (คะแนน VAS) ก่อนและระหว่างดึงกระดูกให้เข้าที่และติดตามภาวะแทรกซ้อน

ผลการศึกษา: ผู้ป่วย 22 คน (หญิง 18 คนและชาย 4 คน) การวัดความเจ็บปวดทั้งก่อนการดึงกระดูกให้เข้าที่และระหว่างการดึงกระดูกให้เข้าที่ในสองกลุ่มคือ ผู้ป่วยที่ได้รับการฉีดยาชาในบริเวณรอยหักของกระดูกร่วมกับการฉีดยาไดอาซีแพมทางหลอดเลือดดำ (Hematoma block combined with intravenous Diazepam) และผู้ป่วยที่ได้รับการฉีดยาชาในบริเวณรอยหักของกระดูกเพียงอย่างเดียว (hematoma block only) พบว่าความปวดทั้งก่อนการดึงกระดูกให้เข้าที่และขณะดึงกระดูกให้เข้าที่ในทั้งสองกลุ่มไม่มีความแตกต่างอย่างมีนัยสำคัญทางสถิติ Mean difference 0.27 (-1.25-0.71), 0.21(-1.11-1.66) ตามลำดับ

สรุป: การควบคุมความความเจ็บปวดจากการดึงกระดูกแขนส่วนปลายหักชนิดคอลลีส์ (Colles' fracture) ให้เข้าที่ด้วยการฉีดยาชาอย่างเดียว (hematoma block only) มีความปลอดภัยเพียงพอสำหรับการดึงกระดูกให้เข้าที่ เนื่องจากมีความเจ็บปวดเพียง 2.82/10 ซึ่งถือได้ว่าเป็นความเจ็บปวดระดับอ่อน (mild pain)