The Efficacy Of The Hematoma Block For Fracture Reduction In The Distal Forearm Fractures: A Double Blind Randomized Controlled Trial

S Bajracharya, S Singh, G Singh, M Singh, T Bajracharya

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Abstract

Objectives: To evaluate the Efficacy of the hematoma block for reduction in distal forearm fractures

Design: Double Blind Randomized Control Trial

Setting: Tertiary care Hospital

Patients/Participants: The patients having radiologically confirmed distal forearm fractures less than 96 hours old in 100 patient (46 males and 54 females) included after giving informed consent

Intervention : 50 patients receiving Brachial Plexus Block (BPB group), and 50 patients receiving Hematoma Block (HB group) during reduction of distal forearm fractures,

Main Outcome Measurements: Pain measured by Visual Analogue Scale (VAS) was recorded before, during, and after reduction.

Results: The study showed that Hematoma block with (mean \pm SD) VAS scores of 2.08 \pm 0.85 was as effective as Brachial Plexus mean \pm SD VAS=1.7 \pm 0.64 in term of producing analgesia, p=0.013 with the advantage of no motor paralysis and a significantly higher reduction rate, odds 3.45, 95% CI 1.52 -7.85. 1/50 patients in brachial plexus block had bronchospasm needing intubation and ICU care where as 1/50 patient with hematoma block and infection which needed incision drainage and external fixation for complete healing.

Conclusions: Visual Analogue Scale during reduction in both the groups was comparable meaning that pain relief during reduction was not significantly different in both the groups. The Quality of reduction was found to be more in the HB group than the BPB group thereby meaning the chances of the perfect reduction in the HB group is three times higher than that of the reduction in the BPB group.

INTRODUCTION

Fractures of the distal radius are extremely common, accounting for one sixth of all fractures seen in emergency rooms $_1$. They more commonly involve children and elderly. These fractures more frequently effect women, increase in frequency with advancing age, and result from low energy falls more often than from high energy trauma $_{1,2}$. The characteristic features of ideal analgesia during reduction are determined by safety, simplicity, affectivity and costs. Given the logistic difficulty of providing such anesthesia to such large number of patients requiring management at peripheral setups simpler alternatives to conventional anesthesia have been tried. Hematoma Block alone, Hematoma Block with sedation, Bier's Block (Intravenous regional anesthesia), regional nerve blocks, sedation have been compared to general anesthesia to evaluate the efficacy, effectiveness, safety in treating distal radial fracture in adults. ³⁷⁴⁵⁵⁶⁷⁷⁸⁸⁹⁹¹⁰¹²²¹⁴¹⁹⁹²⁰ Brachial Plexus Block in most centers needs trained anesthesiologist increasing costs and patients preoperative waiting time which are scarce commodities in a developing country setups. If simpler procedures administered by orthopedic surgeons are as safe and equally affective then they can be viable alternatives to the conventional management. Hence this trial was conducted at a tertiary care center, comparing a simple, safe technique of hematoma block administered by orthopedic surgeon to the conventional brachial plexus block administered by anesthetists to quantify advantages in costs, affects and safety.

MATERIAL AND METHODS

The present study was carried out in the tertiary care hospital. All adult patients with distal forearm fractures were included in the study after an informed consent. Patients were randomized (by computerized random number generation technique) into two equal groups namely Group A; in short "BPB group", receiving Brachial Plexus Block; and Group B; in short "HB group", receiving Hematoma Block for reducing distal forearm fracture. This was Prospective Randomized Control Trial comprising 50 patients in each group. The parameters/variables studied were a) Level of pain before, during and after reducing the fractures by Visual Analogue Scale (VAS); b) Vital parameters before, during and after manipulation (Pulse rate, Respiratory Rate, Blood Pressure and Oxygen saturation); c) Quality of reduction after manipulation radiologically and; d) complications during and post reduction.

STATISTICAL ANALYSIS

Following statistically methods were employed:

- Measurement of magnitude of difference between values of outcomes in the two groups;
- Measurement of significance of difference:
- Qualitative data analysis by Chi Square or propionate Test,
- Quantitative data analysis by Student T test,
- Quantitative Not normally distributed data by non parametric test like KW statistics;
- 1. Control of residual confounding if any by regression analysis; and lastly
- 2. Control of measurements bias by Blinding/ Objective measurement.

METHODOLOGY

Pre-anesthetic evaluation was done in both the groups. In all cases Intra venous assess was opened by Intra venous cannula and electronic monitor was connected to continuous record of Pulse rate, Respiratory rate, Blood pressure and Oxygen saturation by Pulse Oximeter. In all cases, hypersensitivity for lignocaine (Xylocaine) was tested. After tests for Xylocaine (Astra Band of Lidocaine Hydrochloride) 29 sensitivity, the A group was given Brachial Plexus Block (dose according to body weight 4.5-7mg/kg $_{27}$) in the supraclavicular region of the patient whereas the B group was given 1.5% Xylocaine (amount according to body weight-4.5 mg/kg $_{25,26,27,28}$) at the fracture hematoma site from the dorsal aspect. 24 Prior to the injection of the drugs, the part was painted first with Spirit (95% alcohol), then with 7.5% Povidone iodine. The calculated amount of Xylocaine was taken in 20 ml disposable syringe with 22^{1/2} Gauze needle. The needle was placed at the fracture hematoma site which was determined by aspirating about 1 to 2 ml of hematoma blood. No massage was done at the fracture site after injection of the drug. The drug was given by Junior Resident (J₁) posted at Fracture Clinic. After ten to fifteen minutes 27 the reduction and immobilization of the fracture was done by Junior Resident blinded to the anesthesia technique (J₂). Visual Analogue Scale (VAS) was recorded for evaluation of pain before, during, and after reduction by the Junior Resident of Orthopaedics on duty (J_3) blinded to the anesthesia technique used for manipulation of the fracture. Vital parameters like pulse rate, respiratory rate, blood pressure and Oxygen saturation were recorded before, during and after manipulation. Patients requiring rescue analgesics would be labeled as failures.

Quality of reduction was assessed by X- Ray (Roentgenogram) immediate post reduction. The acceptability of the reduction was evaluated by the Consultant surgeon on call blinded to the anesthesia technique used. The radiological criteria were based on Modified Sarmiento Criteria for the post reduction acceptability varying from Perfect, Acceptable and Unacceptable. According to which Perfect reduction consists of Excellent and Good results, Acceptable reduction consists of Fair result; and Unacceptable consists of Poor results. Criteria of radiological assessment are given in table form Table 1.

Figure 1

Table 1: Criteria for anatomical result

Result	Criteria		Modified Criteria	
Excellent	No or significant deformity	Dorsal angulation ≤0 ⁰ Shortening <3mm Loss of radial deviation<4 ⁰	PERFECT	
Good	Slight deformity	Dorsal angulation 1-10 ⁰ Shortening 3-6mm Loss of radial deviation 5-9 ⁰	REDUCTION	
Fair	Moderate deformity	Dorsal angulation 11-14 ⁰ Shortening 7-11mm Loss of radial deviation 10- 14 ⁰	ACCEPTABLE REDUCTION	
Poor	Severe deformity	Dorsal angulation >15 ⁰ Shortening ≥12mm Loss of Radial deviation>15 ⁰	UNACCEPTABL E	

Patients were followed up in next day post reduction for neurovascular assessment. Follow up in $10^{\text{ th}}$ day, $4^{\text{ th}}$ week and $6^{\text{ th}}$ week was done to evaluate the post reduction complications.

OBSERVATIONS AND RESULTS

The clinical and demographic characteristics of the study population of two groups separately are reported in Table 2.

Figure 2

Table 2: Demographic characteristics of the study population

Characteristics	BPB Group(n=50)	HB Group(n=50)	P value	
Age in years	43.58±18.68	44.96±18.39	0.710	
Sex Male: Female	22:28	24:26		
Handedness L: R	2:48	1:49		
Side of fracture L: R	26:24	28:22		
Fracture Duration (hrs)	7.56±7.32	11.86±12.12	0.0351	
Displacement D:MD	39:11	38:12		

During the study, it was found that there was different mode of injury to the distal end of the radius like fall from Bicycle, fall from height, fall from ladder, fall from tree etc. Among them, trivial trauma was the commonest mode of injury occurring Colles' fracture.

The mean duration of injury is 7.54±7.32 hrs in the BPB group and 11.86±12.12 hrs in the HB group. Most of the BPB group patients were not splinted at the time of presentation at the Emergency Room (ER) or the

Orthopaedics OPD. 65 patients out of 100 were not splinted among them 38 in the BPB group and 27 in the HB group.

In the study, all the patients receiving analgesics within 8 hrs of the time of reduction under the BPB or HB were excluded. But the analgesics (oral or injectables) taken beyond 8 hrs or more were included. Total of 75 patients did not take any form of analgesic prior to the reduction where as 25 patients took analgesic 8 hrs prior to the reduction. Among them, 43 in the BPB and 32 in the HB did not take any form of analgesic prior to the reduction. After making radiological diagnosis, the fracture at the lower end of radius was divided into displaced and minimally displaced. Undisplaced fractures were not included in the study. Displaced and minimally displaced fractures were equally distributed in both the groups showing 39 and 38 displaced fractures, and 11 and 12 minimally displaced fractures in the BPB and the HB group respectively.

The table (3) shows the VAS before the reduction of the fractures in both the groups. It was 7.60±1.32 and 7.68±1.16 in the BPB group and the HB group respectively. Therefore VAS before reduction of fracture was comparable.

Figure 3

Table 3: Visual Analogue Scale Before and After reduction

VAS at different stages of reduction	BPB	HB	P- value	K-W test
VAS Before reduction	7.60±1.32	7.68±1.16	0.7495	0.6048
VAS after 5 min	2.9±0.80	2.9±0.90	0.9075	0.7210
VAS after 10 min	1.78±0.73	2.02±0.65	0.0881	0.1239
VAS during procedure	1.70±0.64	2.08±0.85	0.0137	0.0161
VAS after procedure	0.72±0.49	0.92±0.633	0.0821	0.1107

The table (3) also depicts the Visual Analogue Scale (VAS) recorded in various stages of procedure viz. VAS after 5 min and 10 min of the block, and VAS during the reduction and after reduction.

The table (4) shows the post reduction fracture configuration in each group of patients after taking anteroposterior and lateral view radiographs. 32 out of 50 reductions were perfectly reduced in the HB group whereas 17 out of 50 that in the BPB group.

Figure 4

Table 4: Post Reduction fracture configuration and Significant P-value showing acceptability of reduction in the HB group

	BPB	HB	Total	
Perfect	17	32	51	
Acceptable	33	18	49	
	Odd	Lower	Upper	P
	Ratio			value
Acceptability				
of reduction	3.45	1.52	7.85	0.0051

The acceptability of fracture reduction in HB is odds of 3.45 times odds of the acceptability of fracture reduction in BPB. The 95% CI of odds ratio not included one thereby meaning the chances of the perfect reduction in HB is three times higher than that of reduction in BPB. Therefore it is highly significant in this study.

Table (5) shows various complications encountered during the study from time of reduction to the 6 $^{\text{th}}$ week of post reduction.

Figure 5

Table 5: Complications encountered in both the groups

Complications	BPB (n=5 0)	%	HB (n=5 0)	%
 Swelling of Hand post reduction requiring cast splitting and re application of cast 	2	4%	2	4%
 Displaced and re-manipulation needed in 10th day of reduction 	1	2%	1	2%
3. Bronchial spasm and needed Intubation soon after the Block	1	2%	-	-
 Infection at the block site at 10th day 	-		1	2%
 Minimally displacement of reduction on 4th week of post reduction. 	-		1	2%

DISCUSSION

The popularity of the hematoma block in reducing Colles' fracture was studied by Kendall J M $_{13}$ in which an increasing awareness of cost and time with the National Health Service contributes to a marked change in the anesthetic management of Colles' fractures, and demonstrates the increasing popularity of the hematoma block compared with 5 years ago (7% in 1989 vs. 33% in 1994), at the expense of the general anesthetic (44% in 1989 vs. 24% in 1994). Local and regional anesthetic techniques

can be safely performed by Accident & Emergency doctors, with appropriate monitoring, and this has beneficial resource implications for the anesthetic department and the hospital. AU Handoll et al. ²¹ reviewed in Cochrane Database of Systemic Reviews regarding anesthesia for treating distal radial fractures in adults. The 18 included studies involved at least 1200, mainly female and older, patients with fractures of the distal radius. All studies had serious methodological limitations, notably in the frequent failure to assess clinically important and longer term outcomes.

The pain relief during reduction measured by Visual analogue scale, the acceptability of reduction in terms of post reduction radiographic configuration and complications associated with the type of anesthesia used are three main basic subjects of interest of this study and are now, will be discussed.

THE PAIN RELIEF DURING REDUCTION MEASURED BY VISUAL ANALOGUE SCALE

In the present study Visual Analogue Score during manipulation in the both groups were comparable i.e., 1.7 in the Brachial Plexus group and 2.08 in the Hematoma group. Considering the risk of BPB, HB is much safer and can be done easily in Emergency or OPD with less resources. Singh et al. 11 studied about analgesia for reduction of Colles' fracture by Double Blind RCT between Conventional sedation and Hematoma Group. Sixty six out of 80 consecutive cases with the fracture were studied. Singh et al concluded that pain scores during reduction in the Xylocaine group (i.e. Hematoma Group) were acceptably low, that is < 3 (median = 1.8) as compared to the unacceptably high, that is > 3 pain scores in the conventionally practiced sedation group (median =8.7), at a very high level of clinical and statistical significance. Therefore they concluded that hematoma block by local anesthesia is a safe and effective alternative to sedation in reduction of Colles' fracture. This sole study favors the hematoma block for the reduction in distal radial fractures. The study done by Furia et al. 17 is also comparable with the present study. Results demonstrated pain differential score of 2.7 and 0.8 for the HB group and NHB group. The VAS is 2.7 in this study where as in the present study it is 2.08. In Kendall et al's 18 study 72 patients in Bier's block group and 70 patients in the hematoma block group were included. There was no difference in pain score on fracture manipulation as 1.5 in the Bier's Block group and 2.8 in the Hematoma group. But the value of visual analogue scale in their study and the present study is comparable

showed in Table 6.

THE ACCEPTABILITY OF REDUCTION IN TERMS OF POST REDUCTION RADIOGRAPHIC CONFIGURATION

In the present study, the reduction done under the Hematoma block have high chance of excellent reduction than the Brachial Plexus block as shown by the post reduction radiograph. There were 32 excellent reduction in the HB group and 17 that of in the BPB group, whereas acceptable reduction were 18 and 33 in the HB and the BPB group respectively. In Kendall et al's 18 study, more manipulations were required in the hematoma block group (17/70 v 4/72;P=0.003). Therefore his study favors the Bier's Block group for the perfect reduction than the Hematoma Block group. Ogunlade et al. 22 showed, in his study in 35 patients, significant reduction of the pain following infiltration of 10ml of 2% Xylocaine at the fracture site and all the patients had satisfactory reduction of the fracture. This study also favors the present study. Funk et al. 16 in his prospective trial to compare hematoma blocks alone and hematoma block with sedation with general anesthesia for the reduction of distal radius fractures in adult patients regarding radiological position after reduction showed that "Radiological correction was as good in those patients receiving a hematoma block with or without sedation as in a general anesthesia group". The waiting and manipulation times and resources costs were greater in those receiving a general anesthesia. The study done by Case R D 3 showed that there was no significant difference in the number requiring re manipulation between three methods employed in his study: Hematoma block, Bier's Block or General Anesthesia, thereby concluded that hematoma block is a safe method of reducing Colles' fracture.

POST REDUCTION COMPLICATIONS

Regarding complications, the current study shows infection in one case (2%) and post reduction swelling equally in both the groups i.e., 2 in each group comprising 4% overall. The only dreadful complication in the BPB group was sudden bronchial spasm in the elderly lady soon after the injection Xylocaine was administered in the supraclavicular region, requiring intubation and ICU care. But the patient recovered after 12 hrs of ICU care and had spontaneous breathing after 6 hrs and discharged next day. In Singh et al. 11 study, there was no incidence of infection or significant drug toxicity in the Hematoma block group. Furia et al. 17 in his study showed no complications associated with any of the procedure. Based on these three parameters they also concluded that the hematoma block is an effective and safe method for fracture reduction in closed, isolated fractures in selected patients. In Kendall et al's 18 study also there were no complications in either group viz. Bier's block group and Hematoma group. Johnson PQ et al 's 10 results revealed no incidence of infection in both group, Hematoma block group and Intravenous Regional Anesthesia (IVRA) group. They concluded that if appropriated precautions are taken, Hematoma Block does not increase the risk of infection. Hennrikus et al 14 in this study showed that there were no complications such as vomiting, respiratory depression, a change in the oxygen saturation level, infection, or nerve injury in 100 children with closed fractures of forearm reduced under nitrous oxide combined with a hematoma block. Funk et al. 16 in his prospective trial comparing three anesthetic technique used for reduction of fracture distal radius showed no complications relates to any of anesthetic methods like hematoma block alone and hematoma block with sedation and general anesthesia.

By discussing and analyzing the study comparing with all the literatures available till date favors the effectiveness and safety of the Hematoma Block in the reduction of the distal forearm fractures. In terms of pain relief, quality of reduction and post reduction complications, it is very feasible in the setting like ours. Therefore "the Hematoma Block" is to be encouraged in our set up for the reduction of the distal forearm fractures.

Finally, the technique developed is of use to surgeons required to reduce the distal forearm fractures especially Colles' fracture in places with scarce anesthesia facilities. This situation is frequent in orthopedic and trauma units in most densely populated developing countries. After appropriate research the technique may become generalizable to other fracture easily infiltrated percutaneously. The study may result in therapy policy change with regard to the use of IV sedation, or the Brachial Plexus Block, or the Bier's Block in such fracture reduction.

CORRESPONDENCE TO

Dr Suraj Bajracharya, MBBS, MS (orthopaedics) Department of orthopaedics B P Loirala institute of health sciences Dharan Bepal Ph no: 977-25-525555 ext 3100 (res), 2016 (off) E-mail: drsurajbajra@yahoo.com

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Author Information

Suraj Bajracharya, MBBS, MS (Orthopaedics)

Assistant professor, Department of orthopaedics, B P Koirala Institute Of Health Sciences

Sudhir Singh, MBBS, MS (Orthopaedics)

Ex-associate professor, Department of orthopaedics, B P Koirala Institute Of Health Sciences

Girish Kumar Singh, MBBS, MS (Orthopaedics), FICS, DNB (Physical and Medical Rehabilitation) Professor of Orthopaedics, Department of orthopaedics, King George Medcial College

Mahipal Singh, MBBS, MS (Orthopaedics)

Head of Department, Department of orthopaedics, B P Koirala Institute Of Health Sciences

Tamanna Bajracharya, MBBS, MD (Anesthesiology and Critical Care Medicine)

Department of Anesthesiology and Critical Care Medicine, Kist Medical College