

CHAPTER III

RESEARCH METHODOLOGY

RESEARCH DESIGN

The design this study is an experimental, blind evaluator, randomized controlled trial.

POPULATION AND SAMPLE SELECTION

Target population

All children with closed totally displaced supracondylar humeral fracture.

Sample population

Any of target population who come to Siriraj hospital, Bangkok, Thailand during study period.

Sample selection

Inclusion criteria

Children less than 13 years old with closed totally displaced supracondylar humeral fractures.

Exclusion criteria

1. Open supracondylar fracture.
2. Fracture with vascular injury.
3. Non displaced or minimal displaced fracture
4. Children with skeletal dysplasia, abnormal growth and development, abnormal healing of bone.
5. Bilateral fracture or segmented fracture of the humerus.
6. Fracture more than 1 week.
7. Compartmental syndrome.

Sampling technique

By block randomization, patients are randomized into 2 groups.

1. Group A : treated by closed reduction and pinning.
2. Group B : treated by open reduction and pinning.

By block randomization, the sample from both group will be equal. It is the advantage compared with simple randomization especially when the sample size is small.

Sample Size Calculation

Compare two independent means.

Formula

$$n_{\text{group}} = \frac{2\sigma^2}{\Delta^2} \left[Z_{\frac{\alpha}{2}} + Z_{\beta} \right]^2$$

$Z_{\frac{\alpha}{2}}$ = The value of the standard normal distribution cutting off probability $\frac{\alpha}{2}$ in each tail = 1.96 for $\alpha = 0.05$ 2 - tailed)

Z_{β} = The value of the standard normal distribution cutting off probability in B the upper for right hand-tail = 2.33 for 99% power.

σ = The standard deviation of the difference angle between deformity angle A of group A and deformity angle B of Group B = 3°

Δ = The maximum acceptance of the difference between deformity angle A in group A and deformity angle B in group B = 5°

$$\begin{aligned}n_{\text{group}} &= \frac{2\sigma^2}{\Delta^2} \left[Z_{\frac{\alpha}{2}} + Z\beta \right]^2 \\ &= \frac{2 \times 9(1.96 + 2.33)^2}{25} \\ &= 13.25\end{aligned}$$

If drop out = 10%

n_{group} = 15 cases

total = 30 cases

OBSERVATION AND MEASUREMENT

Operational definition

1. The Baumann's angle is the angle formed between the line of the humeral shaft and the plane of the physis of the capitellum. It is measured on an anteroposterior (AP) radiograph of the lower humerus when the X-ray beam is perpendicular to the humerus

(Fig. 1).

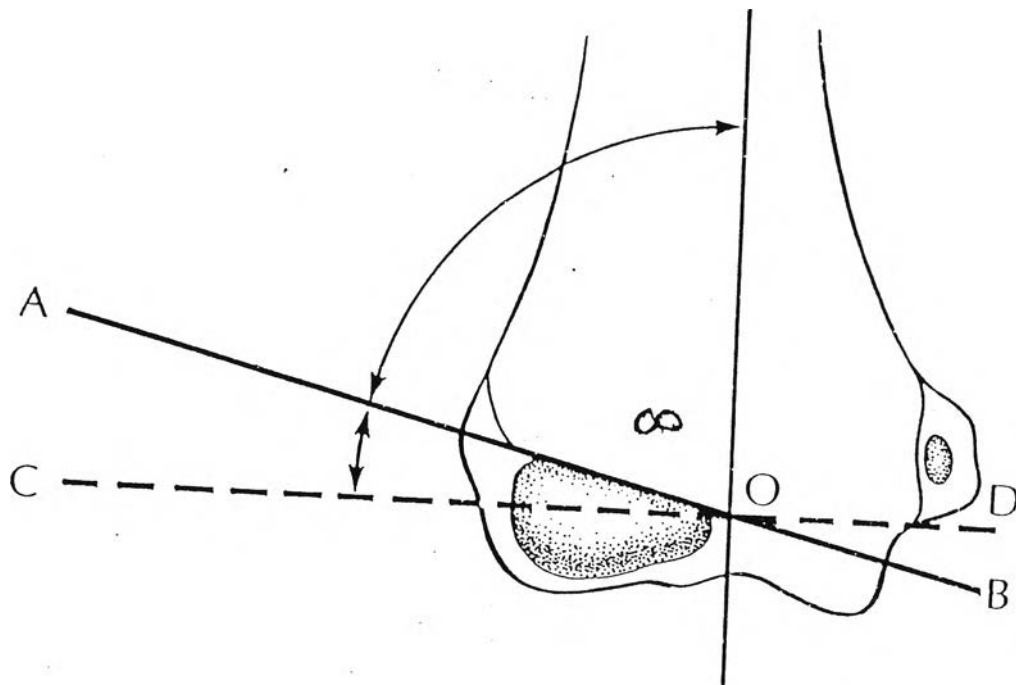


Fig 1. Anteroposterior X-ray of the elbow α = The Baumann's angle

Methods of the study

After the children less than 13 years old with closed totally displaced supracondylar humeral fracture without exclusion criteria were in Siriraj hospital, the parents and children were explained about the diagnosis, the prognosis, the complications, the method of treatments and the details of the study. A written informed consent was obtained from every parent or relatives.

The children were assigned into 2 groups by block randomization to get equal number of patients, **group A**, patients had closed reduction under fluoroscopy and pinning under general anesthesia in the operating room. The reduction was done by longitudinal traction in supination and extension of the elbow until the length and alignment were corrected, the elbow was then flexed. At the same time, a posteriorly directed force was applied to the anterior portion of the arm over the proximal fragment and an anteriorly directed force was applied posteriorly over the distal fragment. The forearm was always held in full pronation, Three Kirschner wires were inserted laterally by two wires in upward direction and one wire medially in upward direction.

All the described steps were done percutaneously and were let the wire protrude the skin. Patients were admitted into the hospital for one day after casting. After four weeks in cast, the wires and cast were removed in outpatient clinic without anesthesia. The patients would receive home programme teaching for physical therapy.

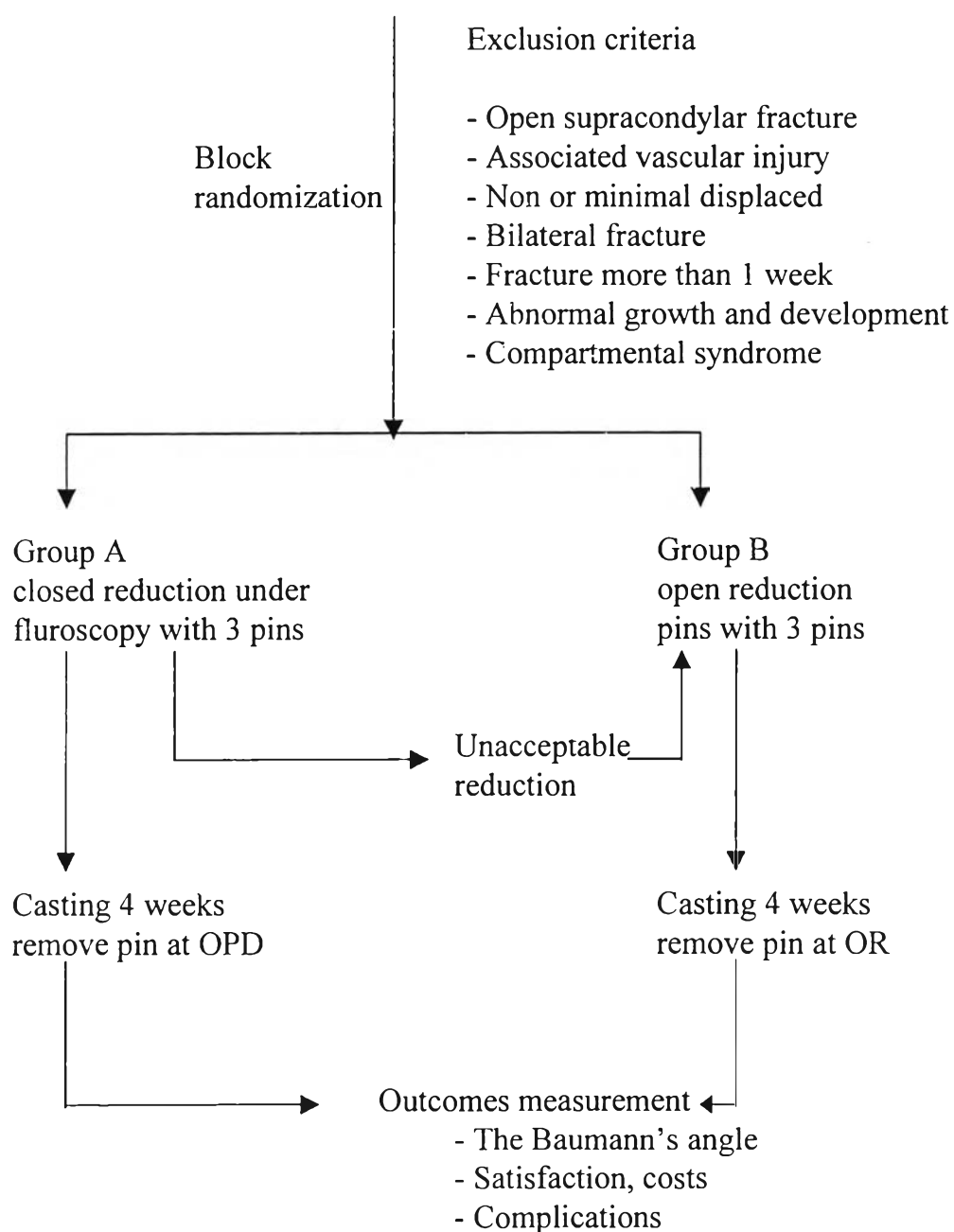
Acceptable reduction. The Baumann's angle of the injured side should be not more than plus or minus five degrees compared to the uninjured side.

Group B. Patients had open reduction and pinning under general anesthesia. After the skin was draped, lateral skin incision was made. The

fracture site were approached , the reduction was performed anatomically and the fracture was fixed with three Kirschner wires. Patients were admitted in the hospital for 1-2 days. After four weeks of casting, the cast and Kirschner wire were removed in the operating room under general anesthesia with one day admission, then proceed with home program physical therapy.

Research Framework

Children < 13 years old with totally displaced supracondylar humeral fracture



DATA COLLECTION

1. Administrative Variables : name, address, ID

2. Zero state variables

2.1 Age

2.2 Sex

2.3 Side of injury (left, right)

2.4 Displacement

- Posteromedial
- Posterolateral

2.5 Nerve injury after fracture, before the treatment

- ulnar nerve
- anterior interosseous nerve
- radial nerve

3. Outcome Variables

3.1 Baumann's angle

- X-rays AP (antero posterior) position of the humerus
- Using goniometer to measure the angle after remove the pin
- Blind evaluator measure the angle without knowing the types

of operation performed

3.2 The satisfaction score

- When the range of motion of the elbow is within 10° between injured and uninjured side (good result).

- Two persons evaluated the cosmetic appearance of the extended elbow compared between injured and uninjured side, one was the parents, the other one was blind evaluator. The question is “What is your opinion about the cosmetic result of the child’s elbow after treatment compared between both sides.

- Instrument was visual analog scale which scale from 0 to 10.

3.3 The costs (provider and parents’ perspective)

3.3.1 Provider’s perspective

Total cost = Direct medical costs : labor cost, fluoroscopy, operating room, drug, hospitalization, casting, instrument, laboratory, material.

3.3.2 Parents’ perspective

Total cost = Direct cost in operative cost, hospitalization, instrument, drug, transportation, plus indirect cost in the loss of work of parents.

3.4 The range of motion

3.5 The union rate of the fracture

3.6 The infection rate

3.7 The nerve injury after the operation

DATA ANALYSIS AND STATISTIC USED

Analysis of zero state variable

Variable	Descriptive statistics
1. Age	mean \pm standard deviation, 95 % CI
2. Sex (male, female)	percentage
3. Side of injury (right, left)	percentage
4. Displacement	percentage
- Posteromedial	
- Posterolateral	
5. Nerve injury before treatment	percentage

Comparison between group A and group B by unpaired t-test for mean, and chi square for percentage (proportion) to confirm the similarity of two groups.

Analysis of outcome variables

1. The Baumann's angle difference compared injured side and uninjured side
 - in group A (deformity angle A) mean difference \pm SD
 - in group B (deformity angle B) mean difference \pm SD
 - Compared between two groups unpaired t test, 95% CI

2. The satisfaction score

2.1 Parents

group A mean \pm SD

group B mean \pm SD

Compared between two groups unpaired t test, 95% CI

2.2 Blind evaluator

group A mean \pm SD

group B mean \pm SD

Compared between two groups unpaired t test, 95% CI

3. Total cost

3.1 Providers perspective

group A mean \pm SD

group B mean \pm SD

Compared between two groups unpaired t test, 95% CI

3.2 Parents' perspective

group A mean \pm SD

group B mean \pm SD

Compared between two groups unpaired t test, 95% CI

4. The range of motion (ROM) difference compared injured side and uninjured side

Group A mean difference of flexion and extension \pm SD

Group B mean difference of flexion and extension \pm SD

Comparison between group A and B by unpaired t-test, 95% CI

5. The union rate of the fracture

Group A percentage of union in group A

Group B percentage of union in group B

Comparison between group A and B by Chi square

6. The infection rate

Group A percentage of infection in group A

Group B percentage of infection in group B

Comparison between group A and B by Chi square

7. The nerve injury after the operation, all variables are in proportion and will be compared by chi square test

Test of normality by Komolgorov-Smirnov, if it is not in normal distribution, nonparametric analysis will be used to compare between groups.

Intention to treat analysis to all variables in closed and open reduction groups. Even in the failure of closed reduction, the variables will be analysed in the closed reduction group in the same package.

ETHICAL CONSIDERATION

Because both treatments are standard and give good and excellent outcomes in more than 85% of cases. Prior to the study, the research proposal was submitted and approved by Siriraj ethical committee, Faculty of medicine Siriraj hospital. Every parent was explained about the detail of the study. Written informed consent was obtained from every parent.

LIMITATION

Number of the cases

There were 20 cases in this study because of low incidence of new cases in Siriraj hospital but it is enough to show the difference in cost minimization analysis. By using the real S.D found during study, the real sample size calculation was also equal to 20, and it was enough of sample size in this study.