# CHAPTER III

## RESEARCH DESIGN AND METHODOLOGY

**Research question:**

Can the amount of radiographic dorsal angulation of Colles' type of fracture, at the end of short arm cast immobilization, be predicted from the size of dorsal cortical bone defect, radioulnar index difference, and patients' age and gender immediately after reduction?

**Objectives:**

1. to predict the amount of redisplacement of dorsal tilt angle of Colles' fracture at the end of immobilization with the size of dorsal cortical bone defect after reduction, radioulnar index difference between before and after reduction, age and patients' gender
2. to validate the predicting equation for redisplacement of dorsal tilt angle of Colles' fracture at the end of immobilization
3. to construct a normogram for prediction redisplacement of dorsal tilt angle of Colles' fracture at the end of immobilization according to size of dorsal cortical bone defect, radioulnar index difference, and patients' age and gender

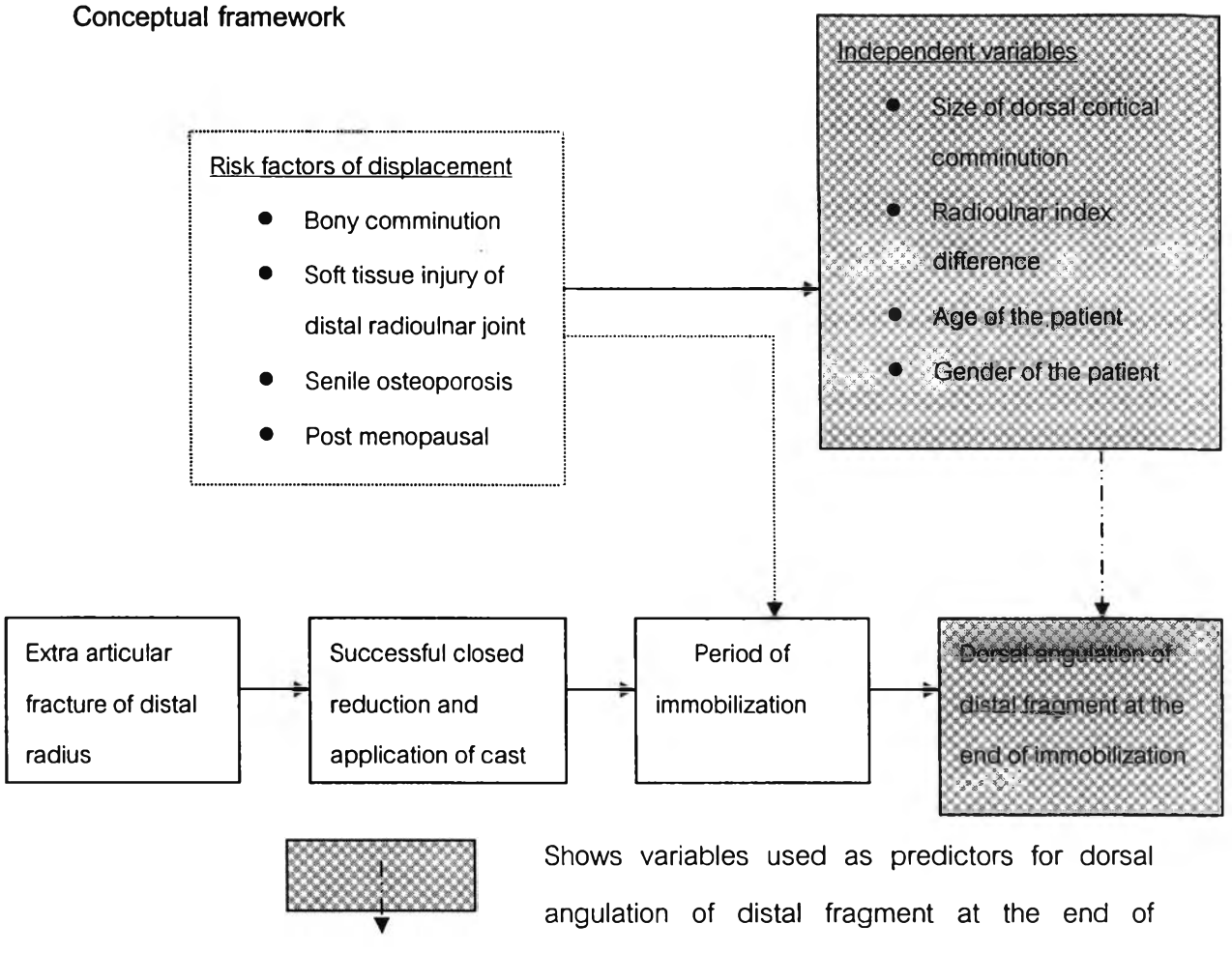
**Operational definitions**

**Colles' fracture** is the practical term to describe the extra articular fracture of distal end of radius without ulna bone fracture (except for minor fracture of ulnar styloid tip) with an apex of angulation volarly.

**Dorsal tilt angle** is the practical term to describe the radiographic deformity caused by hyperextension of distal bone fragment, with apex of angulation volarly , measured in degrees of deviation of distal articular surface of the radius from the line perpendicular to the axis of the radial bone.

**Radioulnar index** is the method of measurement used to measure the difference in level between the distal ulnar surface and the ulnar part of the distal radial surface, with the positive value described as the ulna that projects more distally than the radius[3]

## Conceptual framework




**Keywords**

Colles' fracture, instability, multiple regression

**Research design**

Descriptive, retrospective study

**Research methodology**

**Target population**

Colles' fracture completely treated with closed reduction and short arm cast

**Inclusion criteria**

1. Colles' fracture
2. Dorsal tilt angle after reduction equal to or less than 15 degrees[18, 20]
3. Fracture was immobilized in short arm cast for 4-6 weeks.
4. Wrist radiographic pictures were available for evaluation (before and after reduction, and at the end of the immobilization)
5. Complete hospital record
6. Acceptable radiographic techniques
7.

**Exclusion criteria**

1. Intra articular fracture
2. Diagnosis of failure immobilization and required surgical intervention

**Statistic analysis**

**Part I Multiple regression analysis**

To predict the amount of redisplacement of dorsal tilt angle from multiple independent variables: size of cortical defect , radioulnar index difference, age and patients' gender, a multiple regression analysis was used in our study.

Formula of regression analysis for estimating the change of dependent variable y, from the change of multiple independent variables $x_i$, is;

$$y = a + b_1 x_1 + b_2 x_2 + b_3 x_3 + b_4 x_4$$

where:

y = redisplacement of dorsal tilt angle of Colles' fracture at the end of immobilization, measured by dorsal tilt angle at the end of the immobilization – dorsal tilt angle after reduction

$x_1$ = dorsal cortical bone defect size

$x_2$ = radioulnar index difference

$x_3$ = patients' age

$x_4$ = patients' gender

**Measuring the strength of relationship**

Strength of relationship between dependent variables - redisplacement of dorsal tilt angle, and multiple independent variables - dorsal cortical bone defect size, radioulnar index difference, age and patients' gender, was determined by $R^2$ where $R^2$ = SSR/SST

**Part II descriptive analysis**

Descriptive statistical analysis was used to determine mean $\pm$standard deviation of the size of the dorsal cortical bone defect, dorsal tilt angle, radioulnar index, patients' age. Student t-test, paired t-test and non parametric were used to compare means of dorsal tilt angle and radioulnar index, before and after reduction, between male and female patients.

**Sample size determination**

By Calculation method: to our knowledge, there was no study of this type before, so we had to perform a pilot study to estimate the Pearson correlation coefficient to be used to calculate sample size from the equation[35]:

$$n = (Z_{1-\alpha/2} + Z_{1-\beta})^2 / C(r)^2 + 3$$

where $C(r) = 1/2\log((1+r)/(1-r))$

$\alpha = 0.05$, $\beta = 0.9$

Pearson correlation from pilot study for maximum sample size was 0.365

then $n_1 = 53$ cases

for our study of p independent variables $n_p = n_1/(1- \rho^2_{1,2,3,4})$

then $n_4 = 62$ cases

**Sampling technique**

We used a single database from our institution (Rajavithi Hospital, Bangkok, THAILAND) to identify all patients with distal radius fractures over the last 3 years who fulfilled the following technical inclusion criteria:1) all films were required to be taken at the study institution 2) both films had anteroposterior and lateral views with forearm in neutral rotation 3) standard x-ray tube to film of 40 inches without magnification

The search results of studied population of Colles' fracture from January 2004 to December 2006 is shown below. (Table 1)

Table 1

| Searching index | | No. of cases |
|---|---|---|
| S 52.5[1] | | 790 |
| exclusion | S 78.1-3[2]<br>S 79.3-3[3] | 59 |
| Total | | 731 |

1 Colles' fracture, Smith's fracture, close fracture type

International Classification of Disease, 10th revision, WHO Geneva, 1994

2 application of external fixation device - wrist

3 open reduction of fracture with internal fixation - wrist

International Classification of Disease, 9th revision, Clinical Modification 5th Edition, 2000

Computer generated random sampling (Linear System Sampling) was used to select the studied sample population plus 10% drop out or until the desired number was reached. The research assistance checked the inclusion and exclusion criteria of each selected patient.

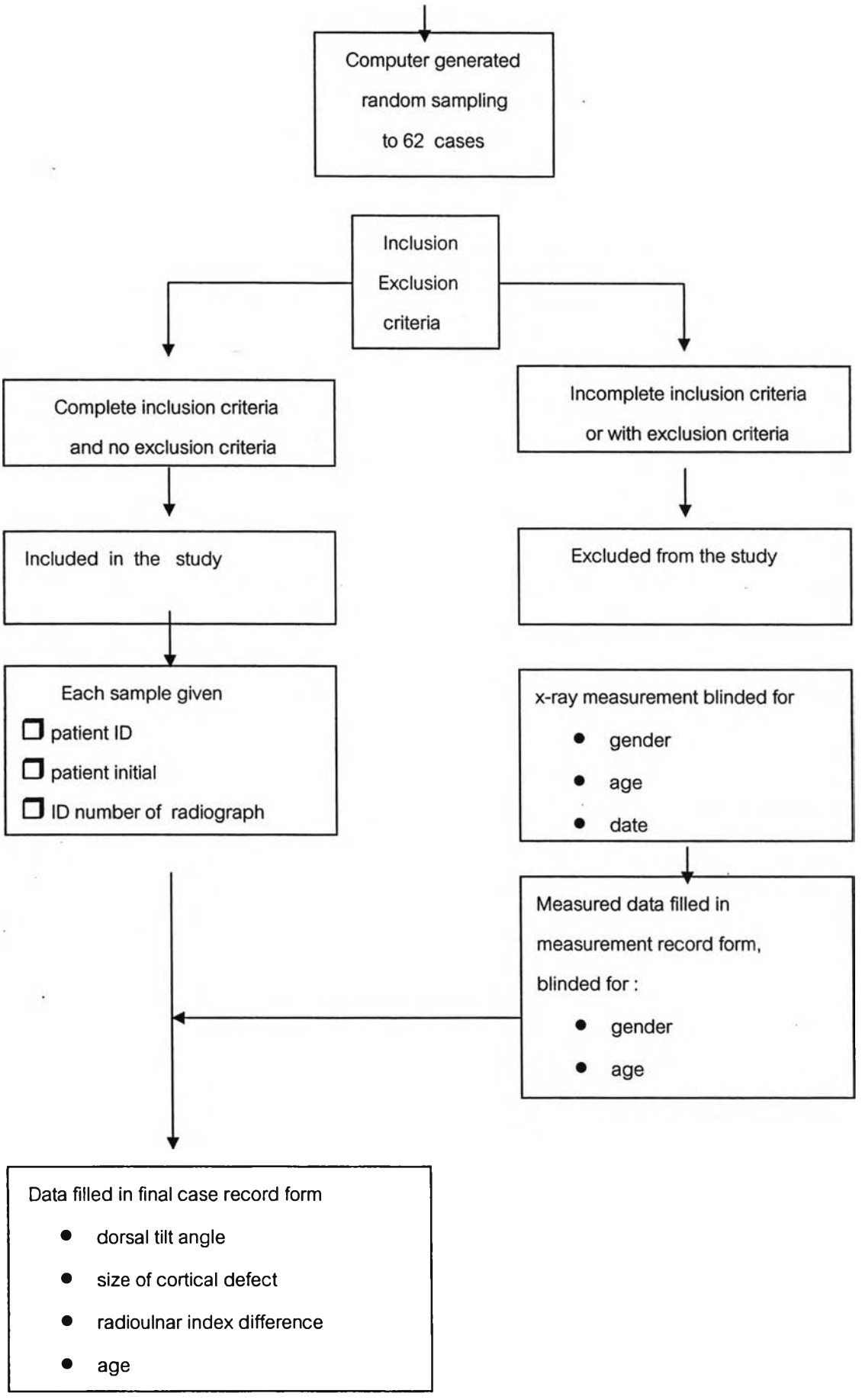
Reasons for drop out and number of cases are shown in the table below (Table 2)

Table 2

| Condition | | No of cases |
|---|---|---|
| Computer generated random sampling result | | 356 |
| Condition for exclusion | Intra articular fracture | 13 |
| | Incomplete record | 15 |
| | Incomplete x-ray | 121 |
| | irreducible | 2 |
| | Wrong diagnosis | 95 |
| | Lost to follow up | - |
| | Misc. | 10 |
| Total excluded cases from study | | 294 |

For patients who met the inclusion criteria, their wrist radiographs were blinded for age, gender and date for the assessor. The wrist radiographs of each patient were randomly labeled in numbers 1, 2 and 3 and then sent to the assessor one at a time for measurement. The assessor was assigned to measure all three radiographic indeces on every radiograph to avoid measurement bias. The measured numbers of dorsal angulation, size of dorsal cortical defect, radioulnar index difference were filled in measurement record forms according to patients' ID numbers without adding age and gender. The data of patients' age and gender were filled separately in the final case record forms (see appendix).

Protocol flow chart



**Radiographic measurement**

**1. Size of dorsal cortical bone defect**

In this study, we used our practical and economical method, which is generally used in our institute, for measuring the size of dorsal cortical bone defect. The size was measured in degrees of angle between the lines joining dorsal and volar fracture edges of distal and proximal bony fragments. The size of dorsal cortical bone defect was measured from the lateral radiographic picture in post reduction of Colles' fracture. A angle in Fig.1)

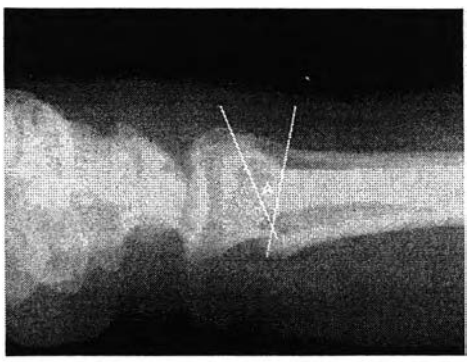


Fig.1

**2. Radioulnar index difference**

In this study, we used the difference between radioulnar index that was measured before and after reduction of Colles' fracture. (Fig.2)

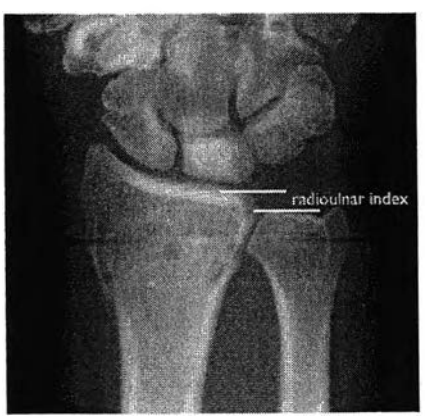



Fig.2

3. Dorsal tilt angle

Dorsal tilt angle is the angle between a perpendicular to the long axis of the radial shaft and a line connecting the dorsal and volar pole of the articular surface. [36] (B angle in Fig.3)

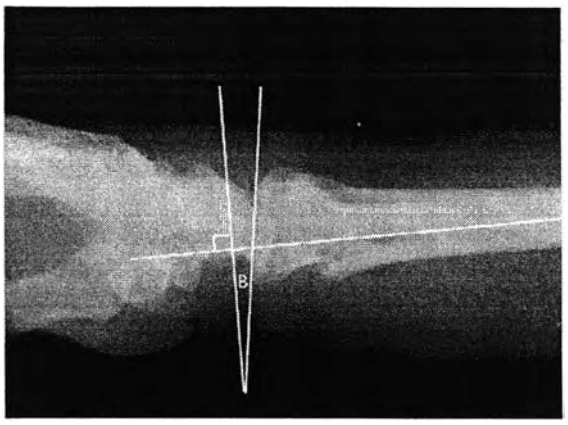



Fig.3

Training data set

The size of dorsal cortical bone defect was measured from the lateral radiograph only after reduction of Colles' fracture.

The dorsal tilt angle was measured at three intervals, before reduction, after reduction and at the end of immobilization. The dorsal tilt angle measured at the end of immobilization was used as a dependent variable in the study. The radioulnar index was measured at three intervals, before reduction, after reduction and at the end of immobilization. The difference between the former two measurements was used as an independent variable and the last one was for descriptive analysis only. Patients demographic data recorded were gender and age groups of under 60 years old or 60 years old or more [27]

Validating data set

To validate the predicting equation: $y = a + b_1 x_1 + b_2 x_2 + b_3 x_3 + b_4 x_4$ from our study, we randomized another set of Colles' fracture patients. Every selected patient was checked for inclusion and exclusion criteria and was not from the same group of Colles' fracture patients in the training data set. The method used in measurement and analysis of data was the same method as previously described. We compared the

calculated degree of dorsal tilt angle with the measured degree of dorsal tilt angle of Colles' fracture from the same validating data set using paired t-test.

**Expected benefit from this study**

If all of our objectives were met, all of the following could be expected

1. Predictable amount of radiographic redisplacement of dorsal tilt angle of Colles' fracture at the end of immobilization from the size of dorsal cortical bone defect, radioulnar index difference, and patients' age and gender since the beginning of the treatment
2. Standard normogram used to predict the amount of radiographic redisplacement of dorsal tilt angle of Colles' fracture at the end of the immobilization from the size of dorsal cortical bone defect, radioulnar index difference, and patients' age and gender since the beginning of the treatment

**Limitation**

According to the method used in our study, multiple regression analysis, the constructed normogram could not be used to predict any Colles' fracture patients other than those within the same age range and same size range of dorsal cortical bone defect.