

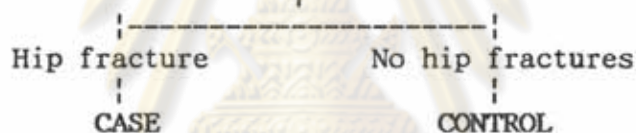
CHAPTER III

RESEARCH METHODOLOGY

DESIGN ARCHITECTURE

It is a case-control study, in which the cases, the eligible patients with hip fracture and the controls, the eligible patients without hip fracture were randomly selected in Chulalongkorn Hospital (see below).

Woman with a fall, aged 45 years old or over

SAMPLE SPECIFICATION

TARGET POPULATION

Elderly female patients with accidental falling present at Department of Orthopedics, Chulalongkorn Hospital were sampled (see below).

	people with hip fracture not presenting to the hospitalmissed
people aged > or =45yr hurt by falling in the community	people with hip fracture presenting to the hospitalCASES
	people without any fractures presenting to the hospitalCONTROLS
	people without any fractures not presenting to the hospitalmissed

A cross-sectional study is needed to reveal the whole view

DISCUSSION OF POPULATION SAMPLED

In both case and control groups, I lost the subjects who did not present to our hospital. In control group, I only selected the patients resulted from falling presenting to the hospital. Probably the ones who came to the hospital had more serious trauma than those who did not come. It is a good point to just select them as controls to see why they did not have fracture even they suffered from stronger force than those who did not come. However, if more time and finance are available, the whole view of a community could be revealed with a cross-sectional study.

SAMPLE SIZE

Alpha=0.05 Beta=0.10

BMD in hip: Group 1 (controls)	mean=1.0 g/cm ²	SD=0.234
Group 2 (hip fractured)	mean=0.7 g/cm ²	SD=0.234

The sample size was calculated by unpaired t-test formula in the computer according to the above data.

Here the minimum total sample size needed is 24 according to the data measured with dual-photon absorptiometry from the previous journals (1, 7).

The difference of BMD between two groups was reduced to 0.2 g/cm², so the minimum total sample size needed was 56 (28 in each group) in order to satisfy the null hypothesis that there is no significant difference of bone mass between the cases and controls.

DATA COLLECTION

1. A structured questionnaire (see Appendix I) was designed which contained demographic items; questions about cigarette smoking, alcohol drinking, milk drinking, body build, physical activity, medical history, drug history, direct causes of fractures; diagnosis; definite location of the hip fracture and BMD result.
2. All subjects were interviewed and the questionnaires were filled in by the authors.
3. Within 4 weeks after falling, all subjects were examined in the defined region of the femoral neck by dual energy X-ray absorptiometry (DEXA), Hologic QDR-2000 (see Appendix II), and all the data of BMD (g/cm^2) were recorded. In hip fracture cases, the contralateral hip was examined. While in controls, the left side was checked.
4. The property of DEXA (such as sensitivity and specificity) remains the same for every subject. The definite area of field size and proper position of the patients during the examination were set and fixed by an assigned technologist.
5. In order to compare DEXA with Singh Index (see Appendix III) which is a measurement for roentgenographs of the proximal femur, Singh gradings have also been assessed. Thus, Singh Index could be evaluated for future studies' use where DEXA is not available. Cases were radiographically examined on the contralateral hip while controls on the left hip. The hip was examined with slightly internal rotation. Singh gradings was assessed by a blinded radiologist. The concordance between Singh Index and DEXA was tested at last.

CONSIDERATION OF ETHICS

Totally the skin dose of X-ray to each subject was about 13 mR, 3 mR of DEXA (once) and 10 mR of conventional plain radiography (one film of both hips) in the study. So It is safe.

CRITERIA OF SELECTING SUBJECTS

INCLUSION CRITERIA

1. Female, aged 45 or over.
2. Hurt by falling on the level, on the slope, while standing up or sitting down, or from a chair or a bed, or from a single step (on the stairs, pavement, etc.).
3. Seeking treatment or admitted to the Department of Orthopedics after fall within 4 weeks from June 1st to February 1st, 1993.
4. Willing to participate.

Case definition:

Patients with hip fracture diagnosed radiographically, including the fracture of head, neck, trochanteric region of the femur. Out of them, those who have been compared with controls (1 case to 2 controls) within three years of age were allocated to age-matched group.

Control definition:

The patients had no hip fracture, but may have trauma in other parts of the body diagnosed radiographically or by a doctor. Out of them, those with closest age within three years compared to cases were allocated to age-matched group.

EXCLUSION CRITERIA

1. those with pathological hip fracture which was diagnosed radiographically or by a doctor.
2. the ones who was unable to walk for 4 weeks or over before presenting to the hospital.
3. the ones who was unable to eat by mouth for 4 weeks or over before presenting to the hospital.
4. the ones who was unable to talk.
5. the ones who had hip fracture in the past.
6. the ones who had fractures on both legs at this time.

DATA PROCESSING AND ANALYSIS

Data was processed and analysed statistically with DBASE4, SPSSPC+, EPI5 and LOGRESS programs.

Totally 45 subjects were recruited during seven months. 10 controls failed to follow-up since they live far away, or were too busy. Eventually, 35 subjects were collected, including 10 cases and 25 controls. This sample size has not satisfied with the designed one which needs 56 in minimum. In Chulalongkorn Hospital, the admitted number of the female patients aged 45 years old or over with hip fracture in each year were just about 30 (30 in 1990, 26 in 1991, from Statistic Department of Chulalongkorn Hospital). Therefore, it was difficult to collect enough eligible samples within seven months.