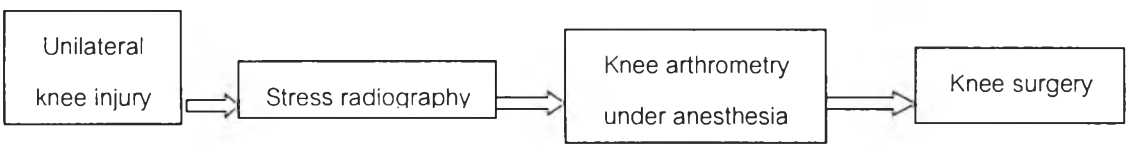
CHAPTER 4

RESEARCH METHODOLOGY

4.1 RESEARCH DESIGN

This is a hospital-based prospective cross sectional diagnostic test study with a consecutive sampling of unilateral knee injury patients who are planned for surgery.



4.2 POPULATION

Target population

Adult patients with soft tissue injury of the knee in Thailand.

Sample population

Hospital-based patients with soft tissue injury of the knee and planned for knee surgery

Eligible criteria

Adult patients, aged 18 years old or more with history of acute or chronic unilateral knee injury planned for knee surgery at Siriraj Hospital.

Inclusion criteria

1. Agree to participate in this study
2. Obtained written informed consent

Exclusion criteria

1. Patients with associated bony lesions of the knee
2. Patients with opened knee injury
3. Patient with wounds that applying stress on would be contraindicated
4. Patient who could not position laterally on both sides

Sampling technique

Consecutive sampling was used on patients diagnosed knee injuries at Siriraj Hospital. Every patient who fulfills the eligible criteria was selected for stress radiography and knee arthrometry prior to surgery until the number of patient is enough

Sample size calculation

In this diagnostic test study, a sensitivity of simplified stress radiography was anticipated to be 90%. A precision was specified as 95% confidence interval. An absolute precision required on either side of the proportion was 81% to 99%. Then the sample size for one population proportion with specified absolute precision is given by

$$N= Z_{\alpha/2}^2 P.Q/d^2$$

Estimated sensitivity of stress radiography is 90%

Acceptable error = 10% of expected sensitivity

α = 0.05

$Z_{\alpha/2}$ = 1.96

P = 0.9

Q = 0.1

d = 0.09

N = 43 for cases

Assumed incidence of torn ACL in hemarthrosis knee = 70%

Total subjects = 43/0.7 = 62

4.3 INTERVENTION

Each eligible subject was informed in detail about this study and written informed consent was requested.

These subjects underwent stress radiographic investigation immediately prior to surgery. Radiographic technicians executed a procedure of positioning, applied the device and took a radiograph on each knee. Then, the radiographs were sent to two radiologists for measurement of anterior tibial displacement. In order to control a measurement bias, both of them measured independently without any patient clinical details.

A research assistant performed knee arthrometry under anesthesia prior to surgery.

Arthroscopic knee surgery was performed.

Two radiologists who were blinded in arthrometric and surgical findings performed a radiographic measurement independently.

4.4 OBSERVATION AND OUTCOME MEASUREMENT

Radiographic measurement (Figure 4)

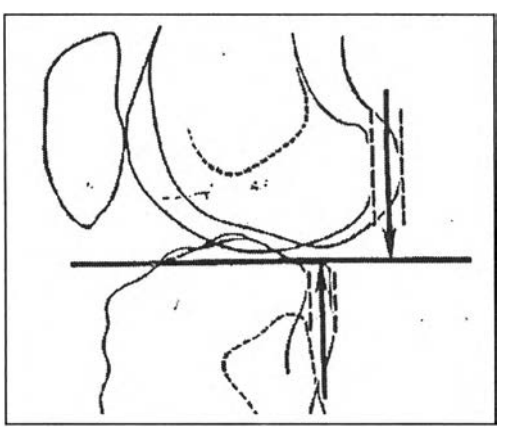


Figure 4 Diagram of knee shows a method to measure anterior tibial displacement

1. Identification of anatomical landmarks

The posteriormost of both femoral condyles were identified.

The posteromedial tibial condyle was identified by following the subchondral bone of medial tibial plateau posteriorly. The posteromedial tibial plateau outline was sharply turn posteriorly even though there was some rotation.

The posterolateral tibial plateau outline was identified by following the lateral intercondylar spine posteriorly. The posterolateral tibial plateau outline turned smoothly and corresponded with the tip of fibulae. (Figure 5)

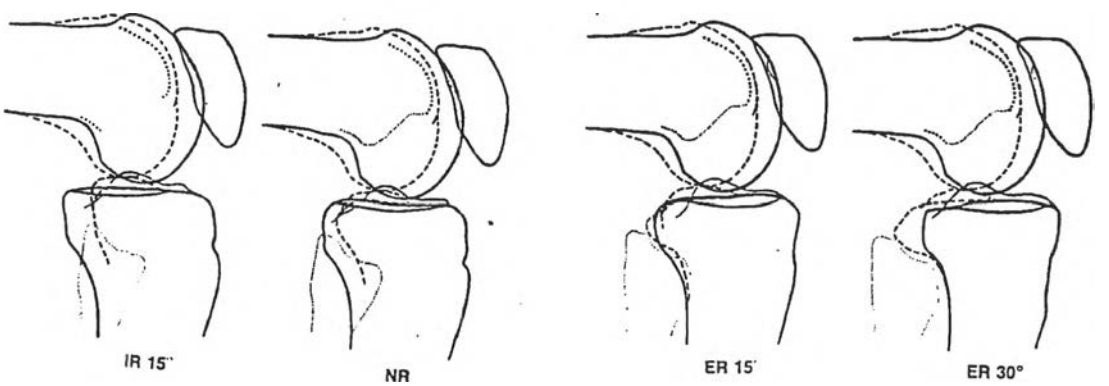


Figure 5 Outline of knee joint in different tibial rotation views. Dot line is lateral femoral and tibial condyles; rigid line is medial femoral and tibial condyles. IR = internal rotation, NR = normal rotation, ER = external rotation

2. Draw the lines

A first line (tibial plateau line) was drawn tangentially to the subchondral bone of medial tibial plateau by identifying the point anteriormost and posteriormost on this line first and drawing.

The tangents to the posterior contours of the tibial condyles and femoral condyles were drawn perpendicular to the tibial plateau line.

3. Distance measurement

The distance between the two midpoints of the posterior aspects of the tibial and femoral condyles on a tibial plateau line were measured.

Two radiologists who were blinded in arthrometric and surgical findings performed a measurement independently.

4. Interpretation

The side to side measurement difference of more than or equal to 3 mm was considered torn ACL.

Arthrometry

KT-1000 arthrometry (Figure 3) was used. After each subject was anesthetized, a research assistant used the thigh support to position both knees in 20 to30 degrees of flexion and the foot support to hold both feet 15 degrees from midline with the hips in lateral rotation. The examiner secured the arthrometer over the anterior leg with the force handle located 10 cm distal to the joint line of the knee, then adjusted and positioned the patellar sensor pad over the patella. The examiner applied a downward pressure to the patellar sensor pad until no further deflection of the dial needle was seen. This amount of pressure was held constant throughout the test. Th examiners then applied a posterior force to the force handle until an audible "beep" was heard. Then the examiner released the posterior force and adjusted the dial needle to zero. Finally, the examiner applied an anterior force on the force handle until another audible "beep" was heard, which indicated that a force of 20 lb. was reached. The examiner then read the anterior laxity from the dial to the nearest 0.5 mm.

The difference in anterior laxity between both knees was recorded.

Surgery

A surgeon who was blinded in prior measurement results executed arthroscopic knee surgery. Pathology of cruciate ligaments and menisci and cartilage were recorded. ACL was palpated from femoral to tibial insertion thoroughly, any discontinuity or detachments of ACL from normal insertions were considered as torn ACL.

4.5 DATA COLLECTION

The following variables were recorded :

1. Administrative variables
   Name, address, identification number
2. Zero state variables
   Age, sex, weight and height
   Duration of injury,
   Cause of injury
3. Outcome variables
   Radiographic measurement results

Arthrometric results

Surgical findings

4.6 DATA ANALYSIS

The surgical and radiographic results were categorized into two groups: ACL deficiency or not. The surgical findings and the results of the first radiologist were analyzed for the indices of the performance of the stress radiography. The results were filled up in the 2 by 2 table for calculations. Sensitivity, specificity, predictive value, and likelihood ratio were calculated. 95%CI was calculated by Wilson's method. The results of the second radiologist were compared to the results of the first radiologist. The inter-observer reliability study of the test was calculated with Kappa statistic.

Subgroup analyses was done by stratified subjects into 4 subgroups according to the results of knee arthrometry. The criterion to classified were a difference in anterior knee laxity between both knees that were less than 3 mm., 3 to 6 mm., more than 6 mm. to 9 mm., and more than 9 mm. Sensitivity and specificity of each group were calculated and 95% confidence interval (95% CI) was calculated by Wilson's method (35).

Wilson's method for confidence interval calculation

r = the observed number of subjects with some feature in a sample of size n

n = a sample size

$p = r/n$

$q = 1-p$

z = 1.96 for 95% confidence interval (from the standard Normal distribution)

$A = 2r + z^2$; $B = z\sqrt{z^2 + 4rq}$; and $C = 2(n + z^2)$

The confidence interval for the population proportion is given by

$$(A-B)/C \quad \text{to} \quad (A+B)/C$$

4.7 ETHICAL CONSIDERATIONS

Plain lateral knee radiography was one of preoperative routine investigations at present in Siriraj Hospital. Knee arthrometry was noninvasive study and was used routinely to monitoring the joint laxity pre and post-operation in many sports medicine centers.

In this study, patients were exposed to X-rays radiation in addition to only one plain lateral radiograph of normal knee. This radiation caused no further harm to the subject. According to our pilot study, the stress force that we provided caused no pain or discomfort and any further injuries to the subjects.

Patients were completely free to refuse to participate at any time without prejudice to patient management. Written informed consent was asked from the patients.

4.8 LIMITATIONS

The setting of this study was in a medical school hospital, and subjects were all surgical patients. Patients' characters might be different from those in community hospitals, where this technique of stress radiography was intended to use. However, severity of knee laxity or temporal character was not a key factor to indicate surgical need.

Because there were some knee injuries from traffic accidents in Siriraj Hospital, the prevalence of ACL injury might be different from the one that we cited from sport medicine centers in USA. This might affect a sample size calculation result.

4.9 BENEFITS OF THE STUDY

We modified the technique of stress radiography to detect ACL injury. This study determined diagnostic values of simplified stress radiography in diagnosis of ACL injury. We expected that this technique would decrease diagnostic uncertainty of inexperience clinicians in clinical approach of knee injuries. This procedure is inexpensive as compared to MRI and can be performed in every hospital in Thailand. This will save a lot of money spent in sophisticated diagnostic procedure and incorrect diagnosis and treatment will be limited.

4.10 OBSTACLES

There were four X-rays technicians who worked in rotation for a year. We had to re-orientate and teach the positioning procedure with fixed technical parameters. We

monitored all technicians to follow our protocol in term of positioning technique, point of focus, distance of an x-rays tube to a cassette, and machine set up.