

CHAPTER III

RESEARCH QUESTION AND DESIGN OVERVIEW

Cervical cancer is an important health problem in Thailand, leading to undue morbidity and mortality to many of the Thai women. By using Pap smear as a screening method, the mortality and morbidity can be reduced. Recently, there have been an increasing number of younger patients with abnormal Pap smears. The clinical problem needs a diagnostic procedure to confirm the disease. Diagnostic conization has been accepted to be the gold standard for many decades. But it can cause some morbidity to patients, especially fertility problems, which is an unwanted side effect in younger patients.

Colposcope is widely used to diagnose cervical cancer because of its high accuracy and less complications. But the diagnostic performance of the test should be evaluated with a gold standard before being used in clinical practice.

Bhumipol Hospital has had a campaign for cervical cancer screening for many years. Physicians can detect about 90 patients who have abnormal Pap smear per year. These are considered high risk patients. The diagnostic procedures which will be appropriate for the patients are being considered, Colposcope is one of the choices.

RESEARCH QUESTION

1. Primary Research Question

Can colposcopic directed biopsy diagnose cervical neoplasia with a sensitivity of 93 % compared with the final histopathology?

2. Secondary Research Questions

a) what is the specificity, predictive values of colposcopic directed biopsy in the diagnosis of cervical neoplasia compared with final histopathology?

b) what is the false positive rate of Pap smear evaluated by the Cytology unit at Bhumipol Hospital?

c) what is the incidence of cervical neoplasia in women who have abnormal Pap smear in Gynecology Unit of Bhumipol Hospital?

OBJECTIVES

1. To find the sensitivity, specificity, predictive values of colposcopic directed biopsy (new test) in the diagnosis of cervical neoplasia in women with abnormal Pap smear in Gynecology Unit at Bhumipol Hospital compared with final histopathology (gold standard).

2. To develop a guideline for colposcopic directed biopsy in the diagnosis of cervical neoplasia in women who have abnormal Pap smear.

3. To determine the incidence of cervical neoplasia in Bhumipol Hospital and the false positive rate of Pap smear.

STUDY DESIGN

This design is a prospective descriptive study for a diagnostic test, to study the performance of a new test (colposcopic directed biopsy) compared with the gold standard (final histopathology).

LIMITATION

This study is the study of performance of diagnostic test, the result can benefit the Colposcopic clinic of the Gynecology Unit of Bhumipol Hospital. Generalization to the Colposcope Clinic and other levels of experienced colposcopists in other hospitals is not appropriate without further study.

BENEFIT

The results of this study can be applied to the routine works of the Gynecology Unit in screening and diagnosis of cervical neoplasia, and can lead to the improvement of the facilities of the Gynecology Unit which may subsequently lead to the patients' benefit.

1. If the performance of the colposcopic directed biopsy is in the generally accepted standard, physicians can rely on this procedure to bring more beneficial treatments to the patients.

2. The country may also gain benefits from this result

a) First, government can save money in the diagnosis of cervical neoplasia because of its low cost.

b) Second, Bhumipol Hospital can be the training centre for colposcopy, providing appropriate technology to the country health care system.

3. If the colposcope directed biopsy turns out to be inaccurate, it will be imperative to search for possible reasons and adopt the appropriate corrective measures.