# CHAPTER VI


## OUTCOMES MEASUREMENTS


Outcomes measurements of this study were sensitivity, specificity, predictive values of colposcopy in diagnosis of cervical neoplasia in abnormal Pap smear women in Gynecology Unit of Bhumipol Hospital. The essential two measurements for the calculation of those results were "the definitive diagnosis of colposcopy" and "the final histopathology of cervix". The definitions and the criteria of the two diagnostic results were described in the former chapters. This chapter will emphasize the two diagnostic results in terms of how to collect the results and summarize for the further analysis.

All of the eligible patients who were willing to participate in the study were attend the Colposcopy Clinic. The colposcopists asked the patients about symptoms of their illness. Personal data were collected by the researcher before performing colposcopy. The researcher used the data collection forms to guide the interview and record the data immediately. All of the personal data were kept. The researcher used the code to identify the patients rather than using the patients' name to maintain confidentiality. After that colposcopy was

performed in the colposcopy room. The sites of lesions, colposcopic impressions of the cervical lesions and the colposcopic directed biopsy sites were recorded and coded in the record forms.

All tissues gained from the colposcopic directed biopsy were preserved immediately by Formalin solution. The tissues were sent to the Pathology Unit without the information of the patients. Only name and hospital number were recorded for prevention of tissues missing during transportation. The tissue containers and the pathology requests were labeled with the stickers. The pathologists and laboratory staff could know that these tissues were in the research project. The researcher had made the agreement with the pathologists and laboratory staff. They accepted that these tissues should have no clinical data or provisional diagnosis of the physicians. Because the researcher wanted to "Blind" the interpreters (the pathologists) to prevent bias.

The tissues were pass through the process of histopathologic preparation in the laboratory. The tissues were fixed with liquid Paraffin, then cut into microslides and stained by Hematoxiline and Eosine method (H. and E. stain). The tissue slides were coded with code numbers rather than coded with hospital numbers. Because the researcher wanted to "Blind"the pathologists from connecting the results of colposcopic directed biopsy with the conization results in the same patients. This could prevent possible bias. The histopathology results of colposcopic directed biopsy and conization results were coded in the pathologic reports. The

results of all pathologic slides were rechecked by another pathologist who did not know the results of these tissues before. The slides which were in disagreement between two pathologists would be discussed in the pathology conference. The conference committee composed of three experienced pathologists (two were pathologists who had read the slides and the third was the head of the Pathology Unit). The agreements of the committee would be the histopathology results of the problem slides.

## Colposcopy

Diagnostic result of the colposcopy were

A. Cervicographic description of cervix (map).

B. Impression of the staging of diseases by the colposcopist using colposcopic criteria.

C. Histopathology of tissue obtained from biopsy under colposcope using pathologic criteria.

Definitive diagnostic result of colposcopy was based on the histopathology of tissue obtained from colposcopic directed biopsy.

## Conization

Each cone biopsy specimen was cut into 12 to 24 blocks and step sections were made. Each slide was examined for grade and extent of the lesion.

Diagnostic result of conization was the histopathology result of tissue obtained from conization.

## Final Histopathology

Final histopathology was the most severe histopathology result of the cervix obtained from patients by various methods (combination of colposcopic directed biopsy, conization and other definitive surgery ).

All histologic material was classified by the pathologists without clinical history or knowledge of which biopsies correlated with which conizations.

## Histopathology Criteria

The pathological terms used were those defined by Boyes et Al. (1981).

The histological diagnosed were:

A. Physiological Epithelium  - CIN 0

B. Dysplasia

    Mild dysplasia        - CIN I

    Moderate dysplasia    - CIN II

    Severe dysplasia      - CIN III

C. Carcinoma In Situ     - CIN III

D. Microinvasion or Invasive Squamous Carcinoma.

                           - CIV

**Summarization of Data**

The data was summarized in the form of counting number. The results of colposcopy were compared with final histopathology by 5 x 5 table. To analyse this table ,the varieties of disease stages would be grouped to the two big categories.

Grouped the five categories into the two mains categories, depending on the clinical application of colposcopy to separate "the non dysplasia cases" from "dysplasia cases" (non disease cases from disease cases). This application of colposcopy could help the physicians to diagnose the patiens who had high tendency to have cervical neoplasia (dysplasia cases-disease cases). These patients needed further diagnostic procedure. The physicians could also omit unnecessary diagnostic procedure in the patients, who were unlikely to have the disease (non dysplasia cases-non disease cases). From the definition, the patients whose final histopathology diagnoses were read as normal epithelium were grouped as the non dysplasia cases. And the patients with more severe lesions than normal epithelium were grouped as the dysplasia cases (disease cases).

The data were analyzed for specificity, sensitivity and predictive value of the test using standard methods.

Sensitivity was defined as the accuracy of the colposcopists in the detection of histologically confirmed "CIN" lesions. If all histologically confirmed "CIN" lesions were recognized colposcopically, a sensitivity of 100% for

sensitivity would be achieved.

Specificity was defined as the accuracy in determining that no lesions was present when none was present histologically. A specificity of 100% would indicate that no lesions was visualized colposcopically when none was present histologically.