CHAPTER VII

DETAIL OF ANALYTIC PROCESS

Data summary and analysis depends on the questions being posed and the study design. This chapter deals with the summarization and the analysis of the data to answer the primary and secondary questions.

Summarization of Data

The primary outcome was the sensitivity of colposcopic directed biopsy in the diagnosis of cervical neoplasia among abnormal Pap smear women. This outcome was summarized by using the descriptive statistics for the diagnostic test. Definition of sensitivity and other outcome measurement will be discussed later. The data were collected in the form of 5 by 5 table. The table compared the outcome of colposcopic directed biopsy with final histopathology. Outcomes of colposcopic directed biopsy were the histopathology of tissues gained from colposcopy. Final histopathology outcomes were the most severe histopathology of all the cervical tissues gained from various methods. Data were collected in the ordinal scale (CIN 0, CIN

I, CIN II, CIN III, CIV). The 5 by 5 table compared colposcopy outcome with final histopathology. Both outcomes were compared scale by scale. To calculate the primary outcome, the researcher change the 5 by 5 table into the 2 by 2 table. As mentioned in the last chapter, five ordinal scales can be grouped into two ordinal scales. The sensitivity can be calculated in the simple form of 2 by 2 table.

The secondary outcomes could be calculated when the 2 by 2 table was created. We could also calculate the 95 % confidence interval of specificity, predictive values of the colposcopy. The calculation will be described later.

False positive rate of Pap smear was the result of number of abnormal Pap smear patients, whose final histopathology revealed that the patients were disease free, divided by total number of patients who participated in this study.

The incidence of cervical neoplasia in abnormal Pap smear women was the result of number of abnormal Pap smear women, whose final histopathology confirmed the disease, divided by total number of patients who participated in this study. Although this figure was not the real incidence rate of cervical neoplasia in Bhumipol Hospital because some patients did not agree to participate. But this figure could estimate the burden of disease in Bhumipol Hospital.

The personal data about age were summarized by descriptive statistics using mean, standard error and 95 % confidence interval.

Statistics Used

Statistics used was descriptive statistics to show the sensitivity of colposcopic directed biopsy (new test) in diagnosis of cervical neoplasia, compared with final histopathology (gold standard). The sensitivity was compared with the accepted standard value (from literature review and expertise opinions).

Statistics Definition

The new test - The new tissue sampling method was the **colposcopic directed biopsy** by a colposcopist at Bhumipol Hospital. The result of new test was the report from histopathologic examination of the cervical tissue obtained from colposcopic directed biopsy.

The gold standard - **Final histopathology** was the combination result of various tissue sampling methods including direct biopsy, colposcopic directed biopsy, conization, hysterectomy.

Final histopathology was the most serious histopathology result of cervical tissues obtained from patient by various tissue sampling methods.

Sensitivity of the new test was defined as the probability of detecting cervical neoplasia cases (cervical intraepithelial neoplasia and invasive cancer) by colposcopic directed biopsy from total cervical neoplasia cases confirmed by final histopathology.

Negative predictive value was the probability of patients being free from disease if the colposcopic results were negative.

Positive predictive value was the probability of patients to have the disease if the colposcopic results were positive.

Prevalence of disease was the percentage of disease cases from total abnormal pap smear cases examined.

Disease cases are the patients who had abnormal pap smear (Abnormal cytology) and had histopathology diagnosis of cervical neoplasia (cervical intra epithelial neoplasia and invasive cancer).

Non disease cases were the patients who had abnormal pap smear (abnormal cytology) and had histopathology diagnosis negative for cervical neoplasia. (For example - normal cervix, cervicitis, condyloma, etc.)

Test positive cases were the patients who had abnormal pap smear and have histopathology result of tissue gained from colposcopic directed biopsy revealing cervical neoplasia (cervical intraepithelial neoplasia or invasive cancer).

Test negative cases were the patients who had abnormal pap smear and have histopathology result confirming the absence of any neoplastic tissue (no cervical intraepithelial neoplasia or no invasive cancer) in the specimens obtained from colposcopic directed biopsy.