

CHAPTER VIII

ETHICAL CONSIDERATION

Evaluation of Risk and Benefit

There should not be any significant risk resulting from the proposed intervention since colposcopic directed biopsy selected for use have been proven beneficial in other studies. Further, the prevalence of unnecessary conization was expected to be high if no conservative measure was being contemplated, many patients would have to suffer from the complications.

The possible benefit from this intervention could be substantial. If this study could show the performance of colposcopic directed biopsy was in accepted standard it would benefit both the patients and health care facilities.

A. Patients' benefit

1. Decrease morbidity and mortality from surgery
2. Decrease hospital stay
3. Less expenditures on medication and hospital costs
4. Decrease risk to miss diagnose cervical cancer

B. Hospital and Health Care System

1. Decrease hospital expenditure in diagnostic procedure of cervical cancer

2. Be able to give service to more patients as a result of the shorter hospital stay of patients and more convention performed procedure.

3. Improve quality of care of hospital and personnel in diagnostic procedure of cervical cancer.

C. Risk of the Study

Eligibility criteria were used to protect patients from risks of the study. The risks of the study came from the diagnostic procedure: colposcopy and conization.

The conization brought high risk to many patients. Eligibility criteria would excluded the patients who had potential risk with this procedure. In addition, the researcher set other criteria to give a chance for patients to avoid unnecessary conization.

In the patients for whom diagnostic conization was necessary. The conization was performed under safety precautions that mentioned in the previous chapters. The patients had their own right to refuse operation if they wanted to. The judgements were depended on the patients, the physicians only gave the information or some suggestions.

By these reasons, the patients would be protected from the potential risks of conization as much as possible.

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Colposcopy had no serious complication. It was unnecessary to use anaesthesia. Bleeding was also minimal, equal to punch biopsy.

The study performed colposcopy in the patients for whom diagnostic conization was necessary. In the ordinary treatment, if the colposcopy had not been presented, the diagnostic conization would have been the choice. So this study was not increase the additional risk to the patients.

Protection of Subjects

This study should not do more harm than good for both patients and the health personnel included in the study. patients should not get any further complication due to colposcopic biopsy apart form those of their own ordinary diagnostic procedure. They should be better protected from surgery complications and hospital associated infections. The human rights of patients should be preserved conscientiously by health care providers although the patients had signed the informed consents for the diagnosis and treatment in the hospital.

The application of the colposcope directed biopsy to abnormal pap smear patients was a putative intervention which certainly did very little harm to the patients.

In conclusion, this study had no ethical problems. Furthermore, the benefit from this study was expected to be high.