CHAPTER 5
ETHICAL CONSIDERATION

GENERAL CONSIDERATION

This study was conducted in accordance with the ethical principles stated in the most recent version of the Declaration of Helsinki. This study was approved by the ethical committee of Faculty of Medicine, Siriraj Hospital and the ethical committee of Faculty of Medicine, Chulalongkorn University.

Prior to recruitment into this study, the patients were thoroughly informed about the following items:

1. Objectives and methods of the study,
2. Treatment outcomes and anticipating side effects,
3. The patients' right to refuse to participate in this study or to withdraw from the study at any time, without affecting their proper medical care.

A signed informed consent was obtained from the patient without enforcement. (For consent form, see APPENDIX IV).

SPECIFIC CONSIDERATION

The major concerns of PCB and IUA include:

Lidocaine hypersensitivity and intoxication

Although there is evidence that PCB can reduce pain during F/C, PCB is not routinely used because of its potential risk from systemic absorption of lidocaine causing serious adverse events such as convulsion or cardiopulmonary arrest.[34, 35] To reduce the risk in this study, the following measures were applied

- Standard safety measure includes continuous monitoring of vital signs and the accessibility of CPR instruments.

- Anesthesia provider was an experienced gynecologist using careful technique, i.e. needle aspiration must be performed before injection of the local anesthesia to avoid accidental intravascular injection.

- The maximum dosage of lidociane was 200 mg. This dosage should not lead to toxic blood level. The dosage as high as 550 mg of intraperitoneal lidocaine in Thai parturients caused maximal blood level of only 3 µg/ml, which was much less than the toxic level of 8.7 µg/ml.[36]

Spreading of malignant cell from uterine cavity

The instillation of 5 ml solution into the uterine cavity during IUA application may cause discomfort to the patient. This discomfort can be at negligent level because the instillation is performed after PCB. The potential risk of intrauterine instillation is the spillage of fluid into peritoneal cavity, consequently spreading malignant cells if the patient has endometrial cancer as a cause of abnormal uterine bleeding. This theoretical risk has been of concern for various intrauterine procedures. However, there is no evidence of such consequence from these procedures. Hysteroscopy is an example of the procedures that need instillation of distention media into uterine cavity. Now-a-day hysteroscopy is a standard diagnostic procedure for AUB in the developed countries. If such risk should exist, hysteroscopy would not have reached this level of acceptance. Comparing with hysteroscopy, the volume and pressure of solution used in this study is much lower. Therefore the risk should be very low, if there is any.