CHAPTER 2

RESEARCH DESIGN

Research Questions

1. Primary research question

Can intraperitoneal lidocaine or intramuscular morphine or both effectively lower the mean pain scores of intraoperative pain of postpartum tubal ligation from the control group by 30% ?

N.B. pain score = Numerical Rating Scale (NRS), 0→ 10

(when 0 means no pain at all and 10 means the most severe.pain)

2. Secondary research questions

2.1 Can intraperitoneal lidocaine or intramuscular morphine or both decrease the percent of the patients in grade 3 ?

Patients who require no additional analgesic (success group) = grade 1

Patients who require only fentanyl (accepted group) = grade 2

Patients who require fentanyl plus ketamine = grade 3

or General anesthesia (failure group)

2.2 What are the plasma lidocaine levels ? Do they reach the plasma toxic levels (9-10 μgm/ml)[23]?

2.3 Are there any differences in adverse effects such as hemodynamic changes, nausea, vomiting, urinary retention, ileus or others?

Objective

The objective of this study is to determine whether intraperitoneal lidocaine, intramuscular morphine or their combination can effectively decrease intraoperative pain from postpartum tubal ligation as compared to only local skin infiltration.

Hypothesis

Intraperitoneal lidocaine, intramuscular morphine or their combination will help relieve intraoperative and postoperative pain and decrease the requirement of narcotics, ketamine or general anesthesia in postpartum tubal ligation. This will decrease suffering from pain and avoid the side effects or complications of intravenous narcotics, ketamine or general anesthesia. It will help reduce the intraoperative time which will result in the availability of the operating room for other operations and will cost less compared to the control group. Plasma lidocaine level and hemodynamics changes will be low and safe enough to be used by any doctors and even the paramedics.

Research design

This study will be carried out as a randomized double blind controlled factorial design to compare among the four groups which are the control group, morphine group, lidocaine group and morphine plus lidocaine group.