CHAPTER III

RESEARCH METHODOLOGY

This chapter deals with the design architecture, the study sample, the selection of the sample and to which population the results of this study may be generalized.

Design Architecture

Study design

This research is a cross-sectional study, which aim to study the association of postterm pregnancy and the unfavorable fetal outcomes.

Justification of study design

The best designs to study the association is the longitudinal study that are cohort study or case-control study.

We have no way to apply the cohort study in this special case because of the ethical problem. We cannot let the subjects get the harm due to our study. If we follow the subject we could not let them pass the term without any intervention.

In the case of case-control study, it is similar to the cross-sectional study that was applied. The diagnosis of fetal growth retardation, the outcome of the study, is based on the gestational age that is considered as the risk factor. It means that at the same time we have to access both, outcome and exposure.

Sample Specification

Target population

The target population is the population to which the researcher want to be able to apply the results of the study. In this study, the target population includes the newborn infants who are born at TUDU OB/GYN Hospital in HCM city - Vietnam .

Sampled population

The sampled population is the population that is selected from the target population for studying and making conclusion. The sampled population in this study included the newborn infants who are born to post term pregnancy and term pregnancy at TUDU hospital.

Sample

The sample is the newborn infants who fit the selection criteria.

Selection Criteria

Inclusion criteria

The newborn infants are born to the pregnant women who remember the date of the onset of the last normal menstrual period.

Exclusion criteria

The newborn infants are born to the pregnant women with the gestational age, which are less than 38 weeks.

The newborn infants with the congenital malformation.

The newborn infants are born to the multiple pregnancies.

The newborn infants are born to the pregnant women with the serious medical illness or use of drugs that effect on the fetal growth.

The newborn infants are born to the pregnancies with complications (Obstetrical, surgical, and internal complication . . .).

Justification of the selection criteria

Up to now, the diagnosis of the gestational age has been mainly based on the last normal menstrual period. It is different from the developed country where the diagnosis is based on the last normal menstrual period and the confirmation of the early second-trimester uHxrasound, which have been considered as the standard method to determine the gestational age. Hence, we have used the LNMP as the criteria to determine the GA without the confirmation of the early second-trimester ultrasound. That criteria is most suitable and most feasible in Vietnam today. That is the rationale we have chosen the inclusion criteria as the infants born by the pregnant women who remember the date of LNMP. With that inclusion criteria, the sample is the representative for the target population. It means that the generalizability is considerably increased.

The purpose of this study has just been to study the newborn infants without the congenital malformation, the multiple pregnancy, the maternal serious illness, the maternal drug use. Another reason is that we want to find out the true association between the postdate pregnancy and the bad obstetric outcome. Therefore, we need to rule out the factors that confound the fetal growth instead of the gestational age only. These are the rationale we have used the exclusion criteria as mentioned above.

Sample size calculation

The applied equation

$$n/gr = \frac{[Z_{\alpha}\sqrt{2pq} + Z_{\beta}\sqrt{P_1[1+R-P_1(1+R^2)]}]^2}{[P_1(1-R)]^2}$$

Where

Confidence of test: 95%
Alpha error: 0.05 - Za = 1.65 (One-tailed)
Power of test: 90%
Beta error: 0.10 - Zb = 1.28 (One-tailed)
R: Expected relative risk.
P1: Probability of event in the postterm group.
p = (1/2)P1(1 + R).
q = 1 - p.

There are two figures we have to estimate, that is the expected relative risk and probability of fetal growth retardation in the postterm group.

Firstly, we did the pilot study in order to obtain the main figures to calculate the sample size. We spent nearly first month of data collection period to enroll 150 subjects that consist of 75 postterm pregnancies and 75 term pregnancies. After that, we calculated the probability of fetal growth retardation in postterm group

and in term group. The results are 7 cases of FGR in group of postterm pregnancy and 5 cases of FGR in group of term pregnancy. In other words, the proportion of FGR in postterm group and in term group are 9.3% and 6.7 per cent, respectively. The odds ratio we get from the pilot sample was 1.46 with the 95% confident interval falls within 0.38 - 6.13 (Epi-Info, version 5.0). Using the odds ratio to estimate the relative risk, we can estimate that the population relative risk also falls within 0.38 - 6.13. We have expected that the real relative risk is approximately about 2. Using the expected relative risk equal to 2 and the probability of fetal growth retardation in postterm group equal to 0.09 to apply in the formula. Finally, we get the sample size that has at least 488 subjects, totally. Otherwise, it must have at least 244 subjects in each group.

Justification of sample size calculation

Because we want to know the association between the postterm pregnancy and unfavorable fetal outcomes, whereas, the best measurement is the relative risk. So, we need the formula that uses the relative risk as the figure to calculate the sample size in order to get the reliable result. That is the reason of using that formula.

Data collection

Data collection period lasted from June 1st,1992 to November 15th, 1992 at TUDU OB/GY hospital in Hochiminh city. Data collection was mainly carried out by researcher with co-operation of health personnel of the Tudu hospital. The instrument of data collection was the form, which had been written by researcher. All of the needed data were included in the data collection form in which the data collector had to fill (see appendices).

When the delivery of a pregnant woman began at the delivery room or the operating room. The pregnant women were accessed whether she was eligible to enroll. Subject selection was based on the gestational age, which was determined from the date of the last normal menstrual period (LNMP), from the recorded at the first prenatal examination or from direct interview of the pregnant women directly. The pregnant women with period of time from 266 days until 293 days of gestation were considered as the term pregnancy. Similarly, the pregnant women with 294 days of gestation or above 294 days were considered as the postterm pregnancy.

The pregnant women with gestational age of 38 weeks or above 38 wks of gestation were included for selection. Then, they were checked the health by interview and clinical examination. We had to know whether they had gotten a serious medical illness in this

period or chronic disease the condition of the fetus by direct interview, clinical examination. The pregnant women with serious medical illness or chronic disease such as hypertension, diabetes, heart diseases or obstetrical diseases were excluded. The pregnant woman with multiple fetuses or fetal malformation was also excluded. Finally, only the pregnant women with normal status during the period of child bearing was selected as the real sample.

Data processing

Data was entered from the data collection form into the coding forms and the verification was done, using DBase III Plus. Verification of the data in the diskettes with the coding also operated.

Data processing was computerized with a personal computer using the Epi-Info version 5.0 and Statistic Package for Social Science (SPSS-PC +) version 4.0.