Chapter III RESEARCH

METHODOLOGY

“Thinking well is wise; planning well is wiser, doing well is best of all”

(Oscar Wilde)

This chapter deals with the methodology selected by the investigator to study the effectiveness of aromatherapy and biofeedback in reduction of labour pain and duration of labour among primigravida women admitted in selected hospitals at Kanyakumari district, Tamilnadu.

Research methodology is a systematic way of conducting a research study to solve a problem. It comprises of research design, setting of the study, variables population, sample size, sampling technique, and sample selection criteria, description of the tool, content validity, reliability, pilot study, method of data collection and plan for data analysis.

3.1 Research approach;

A quantitative research approach has been adopted for this study. Quantitative research refers to the systematic empirical investigation of social phenomena via statistical, mathematical or numerical data or computational techniques

3.2 Research Design

The research design used for this study was Post test only experimental design, where a pre test is not possible because Normally pain intensity varies widely and generally increases as labor progresses. Three groups true experimental research design was adopted in this study. The researcher will have 3 groups for experimental study. 200 parturient for Biofeedback, 200 parturient for Aromatherapy, 200 parturient for control group, Outcome of labour measured by visual pain analogue scale, Partograph and individual review.
FIGURE NO 3.2

TENTATIVE SCHEMATIC REPRESENTATION OF STUDY DESIGN

Quantitative Approach

True experimental research design

Study setting: Selected Hospitals in Kanyakumari District, TN

Target Population: Parturient who got admitted in Selected Hospitals in Kanyakumari District TN.

Accessible population: Primi Parturient who were in first stage of labour with inclusion criteria

Sampling technique: Simple Random sampling technique

Sample size: 200 for Biofeedback, and 200 for Aromatherapy, & 200 for control group

Routine interventions (n=200)

Aromatherapy (n=200)

Biofeedback (n=200)

- Partograph
- Numeric pain intensity scale
- Duration of Labour
- Use of Analgesics
- Self Opinionnaire about Aromatherapy and biofeedback.

Data Analysis: Descriptive and inferential statistics

Study findings
3.3 Variables

Variables are concepts at different levels of abstraction that are concisely defined to promote their measurement and manipulation within a study.

Variability in the dependant variable is presumed to depend on the variability in the independent variable. In this study the variables are:

Independent Variables

✓ Routine Interventions
✓ Biofeedback
✓ Aromatherapy

Dependent Variables

✓ perception of labour pain
✓ Duration of First stage of labour
✓ Use of analgesics

Influencing Variables

✓ Age
✓ Occupation and Type of Family
✓ Age at menarche
✓ Gravidity and Parity
✓ Nature of conception
✓ Nature of onset of labour pain
✓ Analgesics given during labour

Extraneous Variables:

✓ Hospital settings and Treatment given during first stage of labour
✓ Psychological status of the mother
✓ Previous knowledge about the labour pain
Figure 3.3 RELATIONSHIPS BETWEEN VARIABLES

- **Influencing Variables**
  - Age
  - Occupation
  - Type of family
  - Gravidity
  - Parity
  - Nature of conception
  - Analgesia given during labour

- **Dependent Variable**
  - Perception of labour pain
  - Duration of labour
  - Experience towards childbirth

- **Independent Variable**
  - Routine intervention
  - Aromatherapy
  - Biofeedback therapy

- **Extraneous Variables**
  - Hospital settings and Treatment given during first stage of labour
  - Psychological status of the mother
  - Previous knowledge about the labour pain
3.4 Setting of the Study

The location for conducting the research is referred to as setting. (Polit H, 1999)

The study was conducted in selected hospitals at Kanyakumari district, Tamil Nadu. The hospitals are renowned for its excellent medical expertise, nursing care and quality of diagnostic services. The obstetrics and Gynecology Department of this Hospital is well staffed with chief gynecologists, duty doctors and staff nurse with 24 hours obstetrical services and emergency care. It offers advanced and affordable health care to the people. All the facilities were provided for conducting normal and instrumental delivery. The facilities include maternity wards, outpatient departments, well equipped labour rooms, and neonatal unit with ICU and operation department for emergency management. There are about 1000 cases attending the outpatient department per month and nearly 400 deliveries are conducted per month. The hospital details are as follows:

Table 3.4.1 shows the number of samples selected from each hospital

<table>
<thead>
<tr>
<th>Sl.no</th>
<th>Hospital names</th>
<th>Samples taken for aromatherapy</th>
<th>Samples taken for Biofeedback therapy</th>
<th>Samples taken for control group</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Carmel Hospital</td>
<td>67</td>
<td>72</td>
<td>70</td>
</tr>
<tr>
<td>2</td>
<td>Dennis hospital</td>
<td>42</td>
<td>37</td>
<td>40</td>
</tr>
<tr>
<td>3</td>
<td>M. Nsg home</td>
<td>13</td>
<td>08</td>
<td>11</td>
</tr>
<tr>
<td>4</td>
<td>Nirmala Nsg, Home</td>
<td>18</td>
<td>12</td>
<td>17</td>
</tr>
<tr>
<td>5</td>
<td>Joseph Hospital</td>
<td>60</td>
<td>71</td>
<td>62</td>
</tr>
<tr>
<td></td>
<td>Total samples</td>
<td>200</td>
<td>200</td>
<td>200</td>
</tr>
</tbody>
</table>
3.5 Population

Population is the total number of people, who meet the criteria that the researcher has established for a study from whom subjects will be selected and with whom the findings will be generalized.

The population of this study comprised of primigravida women who had singleton normal pregnancy and were admitted before 4cm dilatation of cervix assessed by vaginal examination.

3.6 Sampling size

A sample size is a portion of the population that has been selected to represent the population of interest.

The sample in this study consisted of 600 primigravida women who met the eligibility criteria. Simple Random sampling technique was used in selecting the sample. They were randomly assigned into three groups. (GroupI-200, GroupII-200 and GroupIII-200)

**Group I (Experimental group):** 200 primigravida women in labour who received aromatherapy application with regular treatment for pain relief.

**Group II (Experimental group):** 200 primigravida women in labour who received biofeedback therapy application with regular treatment for pain relief.

**Group III (Control group):** 200 primigravida women in labour who received only regular routine treatment for pain relief.

3.7 Sampling

Simple Random sampling was adopted in this study.

**Simple random Sampling** is possible when it makes sense to partition the population into groups based on a factor that may influence the variable that is being measured.
3.7 SAMPLING PROCESS

Simple Random sampling is a method of selecting the study when it makes sense to partition the population into groups based on a factor that may influence the variable that is being measured.

The researcher has selected 5 hospitals from Kanyakumari Dist, Tamilnadu, South India. The hospitals were well equipped with all the care given to the mothers routinely and in case of emergency. Among these five two hospitals were the nursing home and the number of subjects also less. The investigator maintained good rapport with the hospital staffs to get timely information about the arrival of participants. The participants were assessed thoroughly before the entry of study to screen for complications. Thorough head to foot assessment including abdominal and vaginal examination was done before starting data collection. The participants those who met the eligibility criteria were informed about the purpose of study and its procedure detail. The researcher has randomly selected the samples and the interventions applied for them.

3.8 CRITERIA FOR SAMPLE SELECTION

**Inclusion Criteria**

- The parturient who are primigravidas.
- Parturient who are not having any obstetrical complications.
- Parturient who are having normal lie and position of the fetus.
- Parturient who are able to understand English or Tamil.
- Parturient who are having singleton pregnancy.
- The parturient who are willing to participate in this study.
- Parturient who are not having any medical problems associated with pregnancy.
Exclusion Criteria

✓ Parturient who are having abnormal lie presentation and position.
✓ Parturient who are having multiple pregnancy.
✓ Parturient who are having obstetrical complication.
✓ Parturient who are deviating from normal vaginal delivery.
✓ The parturient who are not willing to participate in this study.
✓ Parturient who are not able to understand English or Tamil.
✓ Parturient who are multigravida
✓ Parturient who are having medical complications associated with pregnancy.

3.9 DESCRIPTION OF TOOL

The researcher has developed the tool on the basis of the objectives of the study. The following steps were adopted prior to the development of the tool. Review of literature provided adequate content for the tool presentation. Personal experience of the investigator in the clinical field and expert opinion from the teachers of maternity department and gynecologists were of extreme help in devising this tool. The tool was developed in English and translated into Tamil.

The following tools included in the study.

1. Demographic and obstetrical profile of the women
2. Visual Pain Analogue Scale
3. Partograph
4. Opinionnaire about aromatherapy/ Biofeedback

TOOL I: Demographic and obstetrical profile of the women

Section 1: It comprised of demographic characteristics of parturient women such as Age, education, occupation, family monthly income, religion, residential area, family birth order, and type of family. Totally it has eight items.
Section 2: It consist of obstetrical profile of the women such as age at menarche, age at marriage, type of marriage, gravidity, parity, Last Menstrual Period (LMP), Expected date delivery (EDD), onset of uterine contraction, time of cervical dilatation, uterine contraction, Body Mass Index, duration of first stage of labour etc.:

TOOL II: Visual Pain Analogue Scale

It is a Standardized pain scale, which consisted of 10 points. It was used to assess the perception of pain during first stage of labour. The women with true labour pain were asked to choose the appropriate pain perception level in the 10 points visual pain analogue scale. The pain perception was assessed in latent phase, active phase and transitional phase.

The pain perception was categorized as follows:

TOOL III: MODIFIED WHO PARTOGRAPH

It is a usual procedure according to hospital policy. Partograph data were not included in the present study. It is a composite graphical record of labour events on a single sheet of paper. The components of Partogram are time, fetal heart rate, state of membrane, cervical dilatation, drugs, vital signs, uterine contractions, temperature. It was used to assess the labour events for every ½ an hour during first stage of labour.
TOOL V: OPINIONNAIRE ABOUT AROMATHERAPY/ BIOFEEDBACK

The investigator formulated self designed opinion format. It was given to the mother next day of delivery to assess the effectiveness of expectant father’s presence during the first stage of labour. This format consists of 7 items. The possible range of score is 7-28. It was obtained from the experimental groups.

3.10 Content validity of the tool

Content validity refers to the extent to which measuring instrument provides adequate coverage of the main study.

A criterion rating scale for the validation of the tools was developed. It had columns like agree, disagree and remarks/suggestion from the experts for each item regarding accuracy, relevance and appropriateness of content. The prepared tools along with objective and criteria were submitted to 7 experts in the field of obstetrics and gynecology department 2 experts from Medical department and 5 from nursing department. Experts were asked to give their opinion and suggestions about the content of the tool.

Suggestions were given by the experts to change certain terminologies into simpler forms. Modifications were made as per the expert’s opinion. These modifications were incorporated in the final preparation of the tool.

3.11 Pretesting of the tool

Pretesting is the process of measuring the effectiveness of an instrument. The purpose is to reveal problems relating to answering, completing, and returning the instrument and to point out weakness in the administration, organization and distribution of the instrument. Pretesting was done in the labour room. The tools were tested on 60 primigravid women in labour. The women marked the intensity of pain using visual pain analogue scale and their responses were found to be appropriate.
3.12 Reliability of the tool

Reliability is defined as the ability of the instrument to create reproducible results. The tools were tested on 60 primigravida women in labour room of selected hospitals. Inter rater reliability was used to find out the reliability of Opinionnaire.

The correlation was computed using Karl Pearson's co efficient of correlation formula. The reliability of the tool was found to be 0.9 which indicated that the tool was reliable.

3.13 Pilot study

A pilot study is defined as a small scale version or a trial run of the major study. Its function is to obtain information for improving the project or for assessing its feasibility. The principal focus is on the assessment of the adequacy of measurement.

The pilot study was conducted in labour room of selected hospitals. The investigator obtained written permission from the concerned authority prior to the study. The study was conducted on 60 primigravida women 20 in each group (GroupI-200, GroupII-20 and GroupIII-20) who met the inclusion criteria. The purpose of the study was explained to the respondents prior to the data collection to get their co operation.

Analysis of the data was done using descriptive and inferential statistics. The experimental groups (GroupI-200 and GroupII-200) were happy with the treatments given by the investigator. Analysis of the data showed that aromatherapy/biofeedback was effective in reducing pain and duration of labour. Therefore the investigator decided to get the opinion of the respondents regarding the use of aromatherapy/biofeedback an Opinionnaire consist of 7 items was formulated by the investigator after the pilot study.

The tool was found to be feasible and practicable. No further changes were made after the pilot study in the tool. After the pilot study the investigator proceeded for the main study.
3.14 Data collection process

Data collection was done for a period of 16 months in selected hospitals of Kanyakumari Dist. A formal written permission was obtained to conduct the study from human ethical committee of selected hospitals in Kanyakumari, Tamil Nadu. Concerned obstetrician and gynecologist were informed of the purpose of the study and their co-operation was obtained. Confidentiality was assured to the respondents. The therapy was administered for the following reasons: to reduce anxiety, alleviate pain or to reduce the maternal & perinatal morbidity. The two methods of application were explained as follows:

Method: 1

Modes of Aromatherapy application: The oil used for aromatherapy is lavender oil. The most common application of aromatherapy during labour is by massage used with lavender oil. Essential oils are concentrated substances and in some cases can cause skin irritations; conducting a patch test on the skin can check for allergies. Aromatherapy application was done over the back & abdomen with a slight massage. The massage was continued till the end of first stage of labour. The pain was assessed in 4 periods of intervals, the first at 4cm dilatation, 6 cm dilatation, 8 cm & the last at full dilatation of cervix. The routine intrapartum care also given for the mother. Finally a structured and self designed questionnaire was administered to get the opinion of the mother about aromatherapy application.

Method: 2

Mode of Biofeedback Application:

The investigator personally explained the purpose of the study with the participants individually. The electronic mode used for biofeedback is cardiotocograph. The mother asked to experience the fetal heart sound & also the variation in her uterine contractions. It helps her to consciously regulate both psychological and physical processes, such as pain, that are not usually under conscious control. The pain was assessed in 4 periods of intervals, the first at
4cm dilatation, 6 cm dilatation, 8 cm & the last at full dilatation of cervix. The routine intrapartum care also given for the mother. Finally a structured questionnaire will be administered to assess the opinion of the mother.

3.15 Application of Therapies

**Group 1: Aromatherapy application:**

- **Before therapy:** written consent was obtained from the study samples. The investigator personally explained the purpose of study. Before the therapy, skin allergies were checked by conducting a patch test on the skin. After 10 mts the patient was asked for any itching or numbness, redness over the area. If there was no complaint the participant was selected for the study. Undress the area where the massage was done. Ask the mother to lie in left lateral position.

- **During therapy:** Created a relaxed environment to the mother. Room temperature also maintained comfortably warm. Warm up the hands and applied diluted lavender oil over the back. Fingers were spread apart like a scrape. Hands were moved from the middle of back towards the sacrum in a rotator movement. One hand was racked towards down and the other towards up. The next step of massage was done in a circular movement with the flat hand. Continuing that fan stroke massage was done by pressing from the middle of spine towards peripheral area. Last step of massage was done by Petrissage, it is the method of massage with grabbing and squeezing of skin.
**After therapy:** No special attention is needed after therapy.

**Group 1: Biofeedback application**

**Before therapy:** The investigator personally explained the purpose of study. A gel applied over the skin. After assessing the position of fetus an its heart sound, two electrodes placed on the abdomen to get the fetal heart sound and contraction of uterus

**During therapy:** A broad belt with the electrode move around till the heart sound heard. The mother was asked to hear the fetal heart rate and the variations in her uterine contractions.

**After the procedure:** no special attention is needed after the procedure.

### 3.16 Plan for data analysis

Data analysis was done based on the information collected from the participants. Analysis is the systematic organization and synthesis of research data and the testing of research hypothesis using those data.

A master sheet was prepared by the investigator to organize and compute the data. The data obtained was analyzed by using descriptive and inferential statistics on the basis of objectives and hypothesis of the study.

- Descriptive statistics was used to analyze the frequency, percentage of demographic and obstetrical variables of the parturient.
- Inferential statistics was used to determine the relationship and association in control and experimental group.
- Assessed the effectiveness of Aroma therapy & Biofeedback during first stage of labour in experimental group was by ‘t’ test.
- Association of the findings with selected obstetrical variables and demographic variables was by $\chi^2$.
- Individual review was analyzed by using RR interval
Summary

This chapter dealt with the research methodology of the study. It included research design, setting of the study, variables population, sample size, sampling technique, and sample selection criteria, description of the tool, content validity, reliability, pilot study, method of data collection and plan for data analysis. The analysis and results of the study are presented in the following chapter.