CHAPTER IV
RESEARCH METHODOLOGY

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4.1 INTRODUCTION

Research methodology is a way to systematically solve the research problem (Kotheri 1990)

According to Sharma (1990) research methodology involves the systematic procedures by which the researcher starts from the initial identification of the problem to the final conclusions. The role of methodology is to carry on the research work in a scientific and valid manner. The methodology consists of procedures and techniques for conducting a study.

The title of the present study was effect of educational intervention on the prevention of specific post operative complications in patients who undergo valve replacement surgery.

4.2 OBJECTIVES OF THE STUDY

This is designed with the following objectives.

1. To administer an educational intervention before the surgical intervention with a view to improve the KAP knowledge of patient about the surgical process, its possible complication and measures to prevent specific post operative complications.
2. To compare the effect of educational intervention in the test group and control group.

4.3. RESEARCH APPROACH

In this study experimental research approach is utilized.

The cause and effect relationship can be established only through an experimental study. That is, the relationship between the independent and dependent variables can be established only through an experimental approach.

According to David. J. Fox, (1996) experimental research approach is used by researcher who believes that the data needed to answer her research questions do not exist. Therefore the researcher needs to experiment and seem answers to these questions. Only then can the researcher make a generalized prediction on a wider application of the experimental condition.

The study is a quasi experimental design applied one. Here the investigator intended to assess the effect of educational intervention on the prevention of specific post operative complications in patients who undergo heart valve replacement surgery.
4.4 RESEARCH DESIGN

Research design is the researcher's overall plan for obtaining answers to the research question or for testing the research hypothesis.

The design adopted is a quasi experimental design. Here all factors are not under the investigator's control.

The research design is the conceptual structure within which the research is conducted. It constitutes the blueprint for the collection, measurement and analysis of data (Kothari, 1993).

The research design adopted for this study is the pre test, post test, non equivalent control group design. The pretest, post test, non equivalent control group design is exactly like the true experimental, except that the subjects are not randomly assigned to groups.

The research design can be diagrammatically represented as

\[ 0_1 \times 0_2 \]
\[ 0_1 \text{Co}_2 \]

Where \( 0_1 \) is pre test
\( 0_2 \) is post test
\( x \) experimental intervention
\( C \) is control
In this study the independent variable was the educational interventions. The dependent variable was specific post operative complications which are measured in terms of increase in awareness level, development of attitude and practice related to the disease, peri-operative preparations, structure of heart, valvular abnormalities, measures to be followed perioperatively to prevent specific post operative complications among the study population.

4.5 SETTING OF THE STUDY

Since 1980, open heart surgeries have been performed in Medical College Hospital, Thiruvananthapuram which renders services to the Kerala and Tamil Nadu states patients.

The related Medical College Hospital, Thiruvananthapuram has been doing valve replacement surgeries from 1981 onwards. Medical College Hospital, Thiruvananthapuram has a bed strength of 1444. It is a teaching and referral hospital. It has all medical and surgical departments as well as specialized departments.

The cardiothoracic surgical unit (Thoracic surgery) is functioning in the main hospital complex. 32 beds excluding PCU (Progressive patient care unit) and ICU are present. The OPD and progressive patient care unit are in the ground floor. Wards and ICU are in the 2nd floor.
This department was managed by one professor and head of department. Apart of him there was one more professor (The department was functioning as 2 functional units with the OPD days on Mondays and Thursdays. All days open heart surgeries were carried out except public holidays. Apart from Professors and Associated Professor, one Assistant professor, one lecturer, MCH students, and MS students in rotation were present to manage this unit.

273 open heart surgeries were performed by this unit during the year 2001.

In scheduled outpatient days patients are seen in the outpatient departments and are admitted according to the availability of beds in the wards and the patients fitness. Patients are admitted approximately 7 days prior to surgery.

Female patients were admitted in ward 8 and 19. Male patients were admitted in Ward 5.

In the 2nd post admission day patients were seen and an appointment was taken for an interview. The data were collected with the help of interview schedule on the same day. A pre test was also carried out on the same day. Question related to knowledge, attitude and practice component were present in the pre test / post test.
For experimental group pre operative teaching was carried out.

Post operatively patients were kept in ICU for 2-3 days and then in ward 8 or 7. Patients who can afford payment will be kept either in progressive care unit or paywards.

Both experimental and control groups were observed for any specific complications till discharge. In the 6th PO day a post test will be done.

Patients will be discharged from ward 8-12 days post operatively.

For the experimental group patients teaching regarding anatomy and physiology of heart, valvular anomaly she or he is suffering from, signs and symptoms, outline of surgery, specific post operative complications, how to prevent these complications, activities which have to be carried out perioperatively were taught.

Demonstrated procedures like steam inhalation, deep breathing and coughing, turning, extremity and ambulation exercises. Post operatively the experimental group patients were looked for to see that they were carrying out the activities to prevent specific complications. Procedures like steam inhalation deep breathing and coughing before coughing out sputum were carried out. Nurses will do percussion and vibration of the chest to mobilize the secretion.
This will prevent lower respiratory tract infection and pleural cavity infection. Turning, extremity and ambulation exercises prevent deep vein thrombosis. That also were stressed.

An ICU orientation was given preferably on the previous day of the surgery, location, staff, equipments, environment how they will be in the ICU by showing a patient lying in the ICU and also visiting time were told. Time of giving fluids after extubation will be told. Introduced the staff, oriented to the equipments like ventilator, monitors, I/V infusion pump, other things like closed chest drainage systems, I/V line, arterial line, catheter, chest leads. In the environment other facilities like calendar, calling bell, light switch and clock were shown. This will, with other factors will give you orientation to the ICU when you open your eyes after the effect of anesthesia. This will prevent sensory deprivation. Noises in the ICU due to use of ventilators and monitors is common. Do not get frightened by hearing that these all were stressed. This will prevent sensory overload. This will prevent psychological maladjustments then these patients will be transferred to PCU or ward.

4.6 POPULATION

The population selected for the study were the patients who underwent single or double valve replacement as per inclusion criteria.
4.7 SAMPLE

20 patients in the control group and 20 patients in the experimental group were selected as per inclusion criteria. Thus 40 patient were selected. They were divided for control and experimental group as per the availability of the sample. The first 20 cases were considered in the control group.

4.8 CRITERIA FOR SAMPLE SELECTION

Inclusion criteria

1. Age between 15 and 65 years.

2. Not more than 2 valve replacements

(Single and double)

Exclusion criteria

1. Pregnant women were excluded.

2. Patients with complications like lower respiratory tract infection, pleural cavity infection, psychological maladjustment, wound infection, deep vein thrombosis and subacute bacterial endocarditis were excluded.

3. Patients below 15 yrs and above 65 yrs were excluded.
The above exclusion criteria were selected as they might affect the outcome of the study unless both control and experimental were equivalent. For eg; age and their understanding.

4.9 TIME AND DURATION OF THE STUDY

The data collection period was 20-06-2001 to 14-08-2002.

4.10 RESEARCH TOOL AND TECHNIQUES

The methods and procedures employed for the collection of data are called techniques and the instruments used are called tools.

In this study, structured interview and structured observation were the techniques used by the investigator for the collection of data.

In a structured interview questions were asked orally in either a face-to-face or telephone format by using an interview schedule (Polit and Hungler 1995).

A structured observation is characterized by careful definition of the units to be observed, the style of recording of the observed information, standardized condition of observation and selection of pertinent data of observation (Kothari, C.R. 1993).
Tool

Consists of structured interview schedule, with 28 items. These items are both vital statistics data providing clinical data, providing data of whole assessment of the patient by history, physical examination, laboratory investigations, and related literature viz NYHA dyspnoea functional class (New York Heart Association).

Vital Statistics : Include name, age, sex, IP No., religion, marital status, education, income and habits.

Clinical data : Include NYHA functional class, date of admission, date of surgery, date of discharge, date of re-surgery, name of re-surgery, weight, blood group, Rh and physical examination findings, and habits.

Structured observation check list

The investigator made use of an observation check list to determine 6 specific complications under this study. The investigator went through different process to finalise the observation check list. Through review of literature it was possible to identify the various parameters used in determining those 6 specific complications.
The observation check list of this study consists of 6 sections.

1. Check list to determine lower respiratory tract infection.

2. Check list to determine pleural cavity infection

3. Check list to determine psychological mal adjustment

4. Check list to determine the deep vein thrombosis

5. Check list to determine the wound infection

6. Check list to determine the subacute bacterial endocarditis

1. The investigator has made use of a model by name weighted level of pulmonary infection tool, which was used by a doctoral candidate at New York city for her study to assess the pulmonary infection. The parameters used are consistent with that shown in the literature. In order to suit the present study, certain modification in this tool was made because the sample consists of only open heart patients. In open heart surgery patient, change in body temperature, WBC count, neutrophils, eosinophils post operatively are due to release of complement due to stress associated with surgery. Therefore these parameters could not be included to assess the lower respiratory tract infection. The other parameter blood culture couldn’t be observed
because of the practical difficulty routinely but when there was a doubt it was carried out.

**Scoring**

In order to do a quantitative analysis it was necessary to find out a method, then a score value computation was used for finding out the lower respiratory tract infection.

Score model for lower respiratory tract infection consists of clinical and laboratory findings. If all the clinical parameters were positive, a total of six mark were given for eg. If the sputum colour was of significant yellow, brown or red three marks. If the sputum viscosity is increased, one mark and if there is adventitious breath sounds on auscultation, two marks. A total of five marks was given if all the laboratory findings were positive like chest X-ray lung fields showing signs of infiltrate or effusions – one mark, collapse or non aerated portions of the lung – one mark, sputum culture showing presence of pathogenic organism – three marks.

Since some of the criteria were omitted, a corresponding reduction on the total score value was made for the purpose of scoring the lower respiratory tract infection. Respiratory infection scores were computed for each patient based on each indicator. A score more than 6 is positive.
2. The investigator has made use of an observation check list to determine the pleural cavity infection. It also consisted of clinical signs and laboratory findings. A total of 15 scores.

A weighed score model where the clinical signs like tachypnoea and dyspnoea for which two marks each and also fever and tachycardia for which three marks each.

Laboratory findings where if the blood total count was more than 11,000/cmm two marks and x-ray chest showed signs of pleural effusion – three marks.

A total of more than 8 scores was considered as a positive pleural cavity infection.

3. An observation check list to determine the psychological maladjustment

From the anxiety depression and sleepness scale of American Psychiatric hospital. The grading tool was prepared.

Depression level was graded under 4 grades. No depression – grade zero, sad – grade one, Weeping – grade two, frequent weeping – grade three,
always weeping, not taking food, keep aloof, not interested in anything – grade four.

. Level of sleeplessness was graded under 4 grades. Sleep normal – grade zero, sleep disturbed – grade one, no sleep at all – grade two, sleep after medicine – grade three, daily sleeps partially with drugs - grade four.

Anxiety level was graded under 4 grades. Not anxious – zero grade, restlessness – grade one, irritability, fear of night/darkness – grade two, tension, extreme fear, cannot hear – grade three and sound insomnia – grade four.

3. Deep vein thrombosis was determined by making use of a weighted score model. This includes clinical signs like pain, a score of one, pain and tenderness of local area over involved vein a score of two, erythema a score of one, warmth a score of one, swelling a score of two, of atleast three scores, are present out of 7 scores. USS of calf to rule out thrombosis.

Asymmetry in size, temperature, colour of legs and impaired neurovascular status one score each. Dilated superficial veins 2 scores. Hofman’s sign two scores. If over 8 points out of 15 do USS of calf, which is 100% confirmatory.
4. Wound infection to determine a weighted score model of twelve score was utilized. This included both clinical signs and laboratory findings. Clinical signs temperature and redness one score and swelling at the site of wound two scores. Laboratory findings blood total count more than 11,000/cmm two scores. A score of above 6 is positive. If pus culture is positive it is 100% confirmatory.

5. A score model of 25 scores was utilized for determining subacute bacterial endocarditis. Fever, a score of three marks, weakness, loss of appetite, palpitation a score of two marks each, haemorrhage and clubbing, a score of three marks each and signs of embolism for a score of ten marks. A score of 14 or above was positive. Blood culture is 100 % confirmatory.

Validity and Reliability of the tool

In order to ensure validity and reliability of the interview schedule, pre test and post test, observation check list, the investigator sought the expert opinion of the staff in the concerned field.

The structured interview schedule and structured observation schedule prepared were checked for content validity and reliability by subject experts and statistical experts.
Moreover through the review of literature the researcher could identify the areas where observation was required. The tool was tested by pilot study, by taking 12 patients, 6 control and 6 experimental.

Technique

By introducing the investigator herself, she took an appointment for an interview. In that day she interviewed and physical examination were carried out. For this history format and clinical profile were utilized to collect data. Other data of investigations related were also collected from results. Pre test and post test were carried out by asking 24 questions and eliciting answers for each one. Thus the techniques utilized were interview, observation and measurement.

By interview patient’s demographic data, viz (1) name of the patient, (2) address (3) phone number if any, (4) age, (5) IP no. (6) sex, (7) religion, (8) marital status, (9) education, (10) occupation, (11) monthly income, were collected.

By interview, observation and measurement the following clinical data were also collected. Surgery, date of admission, date of surgery, date of discharge, date of re-surgery, name of re-surgery, weight, blood group, Rh factor, general appearance, psychological status, past history of any disease or
surgery, family history of any disease, menstrual history, habits, physical examination findings, clinical class and functional class.

By interview the pre test - post test were carried out. It elicited answers regarding the structure, function and diseases of the heart valve, deep breathing and coughing exercises, how to prevent lower respiratory tract infection, Pleural cavity infection, Psychological maladjustment, deep vein thrombosis, wound infection, and subacute bacterial endocarditis and also daily activities.

By observation the six specific complications were observed post operatively. A check list for each complication is utilized for this purpose. To identify lower respiratory tract infection sputum colour, smell, viscosity, chest x-ray findings, adventious breath sounds and sputum culture and sensitivity were observed.

By observation of tachypnoea, dyspnoea, Increased temperature, tachycardia increased blood count, presence of pleural effusions, we could identify pleural cavity infection.

By observation of the following psychological mal adjustment could be identified. Presence of sad, weeping, frequent weeping, always weeping, not taking food, keeping aloof, not interested in anything, sleep disturbed, no sleep at all, sleep after with medicine, daily sleeps partially with drugs, restlessness,
irritability, fear of darkness, oesophagia, palpitation and distension of abdomen, tension, extreme fear, cannot hear and sound insomnia.

Deep vein thrombosis could be identified by observing clinical signs as pain, tenderness over involved vein, erythemia, warmth, swelling, asymmetry in size, dilated superficial veins.

Wound infection could be identified by observation method. This was by observing the following, temperature, redness, discharge from wound, pain, swelling at the site of wound, blood total count and pus culture.

Sub acute bacterial endocarditis could be identified by observation method. Which includes fever, weakness, loss of appetite, palpitation, haemorrhage, clubbing, signs of embolism and blood culture.

4.11. PILOT STUDY

According to Polit and Hungler (1995) pilot study is a small scale version, or trial run of the major study. The function of the pilot study is to obtain information for improving the project or for assessing its feasibility.

After planning the educational interventions, structured interview and structured observation check list, with the help of subject specialists and statistical experts, the educational interventions and tool were tested on a
sample of 12 patients (6 control and 6 experimental) to establish the reliability and validity of the tool and to test the feasibility and practicability of the whole research design. The period of pilot study was from 20-06-2001 to 02-11-01.

The data for pilot study was started from 20th June 2001. On the 2nd post admission day the patient was seen individually and self introduced. Then an appointment for an interview was obtained. On that fixed day, data by the interview schedule were collected. A pre test was administered. To the experimental group planned educational interventions were taught and return demonstration were asked to show on the next days. An intensive care unit orientation was given preferably on the previous day of surgery.

On the 2nd post operative day when the patient was fully conscious and awake after auscultation of chest she or he was asked to spit out the sputum. Before spitting they were asked to take deep breathing and coughing exercise. Presence of yellow, brown, red, green, foul smelling and increased viscosity were observed. Sputum was collected and sent for sputum culture and sensitivity. Breath sounds were auscultated. X-ray chest findings were noted. Based on the findings of these the presence of lower respiratory tract infection was identified.
Blood culture and wound pus culture were not carried out for all patients, as these were not included in the daily routine. Wherever there is suspicion it was checked.

An ICU orientation was given to patients in the experimental group.

A post test was carried out to both the groups post operatively on the 6th Post Operative day.

4.12. DATA COLLECTION PROCESS

In order to collect data, the period of data collection was planned from 20-06-2001 to 14-08-2002. Since the collection of data for the study required maximum cooperation on the part of the cardiac surgeon and the nursing staff, necessary permission from the concerned authority was obtained before the data collection process. All the data were collected during the period 20.06.2001 to 14-08-2002.

In the preoperative ward

On the 2nd day after admission the patient was seen individually. After self introduction and expressing her purpose of the visit an appointment was taken to interview them. On that fixed day patients were met and good interpersonal relationship established by enquiring about the personal problems.
Moreover enquiries regarding demographic data, clinical data needed to make sure that there were no evidence of any complications like lower respiratory tract infection, pleural cavity infection, psychological mal adjustment, deep vein thrombosis, wound infection and sub acute bacterial endocarditis. This clinical data included were the functional class of dyspnoea according to New York Heart Association, history of any disease or surgery, weight, blood group and Rh, general appearance, psychological status, past history of any disease or surgery, family history of any disease, habits, diet, alcohol consumption, smoking, sleeping, bowel and bladder movements, physical examination findings functional and clinical classes. It also include name of surgery, date of surgery, name and data of re surgery.

After this a pretest, which consists of 24 questions, each carrying one mark under five headings viz. heart structure and function, regarding deep breathing and expectoration of sputum, how to prevent wound infection how to prevent endocarditis, daily activities were administered.

To the experimental group the planned educational intervention individually which consisting information related to heart structure and function, valvular disease, outline of surgery, how to prevent specific complications post operatively like how to prevent lower respiratory tract infection by deep
breathing and coughing exercise, how to prevent psychological mal adjustment by good faith in God, being optimistic, giving, a systematic orientation to ICU, meeting previous patient who have undergone valve replacement successfully, how to prevent deep vein thrombosis by early ambulation, exercise and bandaging. Moreover by avoiding pillows below the knee, how to prevent wound infection, by avoiding any sort of contamination in the wound and do not touch the wound with bare hands, prevention of sub acute bacterial endocarditis by preventing foci of infection in the body especially by undergoing dental check up and ENT checkup preoperatively.

In this study ICU orientation was carried out on the previous day of surgery. Then deep breathing, steam inhalation and coughing exercises were asked to do as return demonstration.

**In the ICU and post operative wards**

All patients were observed for any presence of the specific complications under study. For this sputum is observed for its colour, smell, viscosity and any presence of adventious breath sounds, in the X-ray chest for any presence of infection, sputum was collected and sent for culture and sensitivity.

Temperature, respiratory rate, pulse rate, total blood count, X-ray chest for pleural effusion were checked to see pleural cavity infection.
Psychological mal adjustment was observed by noting the changes in depression, sleep and anxiety levels.

Deep vein thrombosis was observed by pain and tenderness over involved vein, erythemia, warmth, swelling, asymmetry in size, temperature, colour changes of legs, improved neuromuscular system, and dilated superficial vein.

4. Wound infection:- By observing temperature, redness, discharge from wound either blood, pain, swelling at the site of wound, blood total count and culture.

5. Sub acute bacterial endocarditis:- By observing Fever, weakness, loss of appetite, palpitation, haemorrhage, clubbing, and signs of embolism. Moreover all the procedure showed to them prevent these specific complication were carried out in ICU and post operative wards in the experimental group. All these observation were also continued till the time of discharge for all those patients. Some of the daily activities to be carried out perioperatively also were told to them, which had some relation for specific complications.
4.13. PROCEDURE FOR DATA ANALYSIS

The data were tabulated, and analyzed to test null hypothesis

1. It was put under frequency distribution and percentage

2. Testing of hypothesis was done by student chi-square

3. Students t test was done to test the difference between mean of both groups.

4. SPSS (Statistical Package for Social Science) was utilized for analysis.

4.14. SUMMARY

This chapter included research methodology under different heading viz introduction, objectives, research approach, research design, setting of the study, population sample, criteria for sample selection, time and duration of the study, research tool and techniques, pilot study, data collection process and procedure for data analysis.