CHAPTER 3

RESEARCH METHODOLOGY

The present study was planned at evaluating the outcomes of pharmacological management of breast cancer in a tertiary care centre in Udupi district of Karnataka, India. An evaluative survey cum interview approach was found to be most suitable for meeting the objectives.

3.1. Study Design

A prospective, observational, follow up study was conducted. An interview cum survey approach was used to collect the demographic details, clinical characteristics and other outcome measures. The schematic representation of the study is presented in figure 3.1.
Fig 3.1 Schematic representation of the research design.
Research Setting

The study was conducted in the wards and day care centre of Shirdi Sai Baba Cancer Hospital and Research Center, a constituent unit of Kasturba Medical College, Manipal University. Kasturba Medical College Hospital Manipal is a 1,600 bedded multidisciplinary hospital, having tertiary referral status with specialized treatment modalities for cancer care. The Shirdi Sai Baba Cancer Hospital and research Center has 285 bed strength and is situated adjacent to Kasturba Medical College Hospital. The hospital has high attendance of cancer patients including breast cancer, making easy availability of subjects for the present study.

3.2. Population and Sample

In this study the population comprised of breast cancer patients from geographical areas of south Karnataka, Goa and Kerala, attending Shirdi Sai Baba Hospital and Research Center, Manipal for treatment. The sample size was estimated based on the concept that the number of observations had to be five to ten times the number of variables in the model for regression analysis techniques to generate reliable estimates. A representative sample, minimum of 300 subjects receiving treatment for breast cancer during July 2009-2011 was planned to be interviewed and surveyed for each outcome measures. Accordingly 303 patients were identified and included in the study. The demographic proforma and disease & treatment details were collected for all subjects.

3.3. Sampling Criteria

Patients primarily diagnosed with breast cancer and undergoing treatment and those who fulfill the inclusion criteria were considered for the study. Daily admission register in wards, day care center, and statistics of records maintained by the medical records department were utilized for finding suitable subjects for the study.
3.4. Inclusion Criteria

- Subjects who were primarily diagnosed for breast cancer
- Women of all age and disease stage who were undergoing breast cancer treatment between July 2009 and 2011
- Subjects who were prescribed with pharmacological treatments, i.e., chemotherapy and/or hormone therapy, were included for the study.
- Subjects who can converse English/Kannada or Malayalam languages and who were willing to participate

3.6. Exclusion Criteria

- Subjects receiving pharmacological treatments in other hospitals completely and subjects who did not receive any pharmacological treatment
- Subjects who were not adherent to the treatments

3.7. Sampling Technique

The present research approach adopted a convenient purposive sampling technique for recruiting study participants.

3.8. Ethical Consideration

- Permission from the Medical superintendent of Kasturba Medical College was obtained.
- Ethical clearance from the institutional ethics committee and the informed consent by the study participants were availed before starting the study. (Vide Ref. No. IEC114 /2009)
- Written informed consent from the subjects
3.9. Data collection technique

The present study was a prospective, observational, follow up study. Structured questionnaire and patient interview along with patients’ record review were adopted to collect data related to background information and quality of life. Information on demographics, diagnostic tests, treatment details and other clinical characteristics were obtained from the patient’s medical record, laboratory reports, histopathology reports, and discharge summaries of individual patients. To measure the quality of life and other outcomes the researcher visited the out patient department and wards where breast cancer patients were admitted for treatment and personally interviewed the subjects. After explaining the study purpose and getting their informed consent, the subjects were included for the study. The questionnaires EORTC-QLQ-C30 and its breast specific module EORTC QLQ BR23 (quality of life measuring tool), were administered. Quality of life was measured further who underwent a minimum of 3 courses of chemotherapy. The difficulty in understanding the questionnaire was clarified and assistance was given to those who required. Repeated follow ups on ADR monitoring, QOL and morbidity were carried out and documented during the courses of therapy. Information regarding the costs was obtained by interviewing the subjects and their relatives regarding costs of prescriptions and other related expenditure. The clinical outcome is summarized by referring the patient’s history/case records for a period of 1-2 year, within the study period. The cost estimation was carried out based on the cost of hospital visit/consultation, diagnostic and other investigations, surgery, pharmacological management, professional and hospitalization and different related charges, radiotherapy charges and total direct cost for breast cancer treatment from the time of diagnosis for 5-8 months according to the completion of preliminary round of treatment.
3.10. Description of Data Collection Tools

3.10.1. Demographic and clinical characteristics data collection form.

As the study was aimed to measure the outcomes of pharmacological management of women with breast cancer with respect to 3 different aspects, namely treatment related economic outcome, clinical outcome and humanistic outcome, data collection form was formulated accordingly. Section 1 (Tool A) consisted of baseline information of the subject with columns and rows including subject identification, demographic information, socio-economic background and clinical characteristics of breast cancer patients with the treatment details.

3.10.2. EORTC-QLQ C 30 version 3 and (EORTC QLQ-BR23)

EORTC-QLQ C 30 version 3 and EORTC QLQ-BR23 is a standardized tool for measuring quality of life of cancer patients and its breast cancer specific module prepared by European Organization for Research and Treatment of Cancer (EORTC) and is validated for internationally, including Indian population. Official permission was obtained from the European Organization for Research and Treatment of Cancer team to use it for the present study. The tool consisted of a total of 53 questions from QLQ C 30 and QLQ BR 23. QLQ C 30 is a questionnaire meant to measure the QOL of cancer patients in general. It covered questions on different health aspects, such as physical, role, emotional, cognitive, social functional scores scoring from 1-4, where one meaning not at all true and 4 meaning very much true. A high score in functional scales meant better quality of life. There were few questions on different symptoms pain, loss of appetite, fatigue, insomnia, dyspnoea, and financial difficulties. A low score in these measured better quality of life. The questionnaire had two questions on global health status, which have a score of 1-7, both ask about the overall health and overall quality of life. The raw scores were calculated first and finally converted to percentage (0-100) using suitable formulas. QLQ BR 23 consisted of 23 questions on different symptoms experienced specifically by breast cancer
patients. Except for body image and future perspectives, for all other symptoms a high number indicates low level of quality of life. Other symptoms measures in this tool were systemic therapy side effects, upset by hair loss, future perspectives, arm symptoms, breast symptoms. There were 3 questions on sexual functioning and sexual enjoyments were not included in analysis as these questions were not relevant to many and many of them did not answer it.

The questionnaires were translated into the local language (Kannada) by language experts employing forward backward translation method and were used for measuring quality of life of breast cancer patients. The content and construct validity of the tool is ensured by first translating to local language and then retranslating to the original language, repeating the process with modifications required. Pretesting of the tool was carried out by giving the tool to few patients admitted in the oncology ward of Kasturba Hospital, Manipal, India, 576104. Reliability of quality of life questionnaire was established by test–retest method (Chronbach alpha 0.76).

3.1. Pilot Study

A pilot study was conducted by administering the tool to 27 patients during July 2009 in Shirdi Sai Baba Cancer Hospital in order to find the feasibility. The study was started after receiving ethical clearance from institutional ethics committee of Kasturba Medical College, Manipal (vide ref. No.IEC 114/2009). The data was analyzed and was found that the study design was feasible.

3.12. Plan for Data Analysis

The data was planned to get analyzed according to the objectives using descriptive and inferential statistics. The treatment related costs were planned to be calculated for different treatment arms and described as costs of consultation, drugs, surgery, investigations, radiotherapy, professional charges and total direct medical costs and cost per quality adjusted life. Clinical outcome of
different groups based on pharmacological management of breast cancer with different drug regimen was planned to get identified by survival analysis by Kaplan Mayer method, and odds ratio by regression analysis. The predictors of adherence to treatment were identified by logistic regression analysis. The humanistic outcomes were planned to describe as functional scales and symptom scales in percentage after different pharmacological treatments using EORTC QLQ C 30 and QLQ BR 23 questionnaire.\textsuperscript{62,63}

**Summary**

This chapter explained the research method and materials adopted for the study. This included description of research approach, research design, setting, population, sample and sampling technique, inclusion and exclusion criteria, description of data collection tools, pilot study, procedure for data collection and plan of data analysis.