METHODOLOGY

The present study was undertaken with the main objective of assessing the "Nutritional status of postmenopausal women" the methodology followed in conducting the study is furnished under the following heads

3.1 Selection of area
3.2 Selection of sample
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3.4.7.4 Estimation of Lipid profile
3.4.7.5 Comparison with control group
3.4.8 Imparting Diet counseling and assessing its impact
3.1 Selection of area: The area selected for the present study is Thiruvananthapuram district. Thiruvananthapuram district was selected for the study because of their closer proximity, availability of adequate number of subjects and presence of all types of income groups. It also enables accessibility to the study area since the indepth study need constant and frequent contacts with the subjects. In Thiruvananthapuram district Chirayinkeezhu (Rural) and Thiruvananthapuram taluk (Urban) were selected by purposive sampling method. According to Sotirious (1998) Purposive sampling is a sampling technique in which the researchers purposely choose subjects who in their opinion are thought to be relevant to the research topic. In this case, the judgement of the investigator is more important than obtaining a probability sample.

Under Chirayinkeezhu taluk Kilimanoor block which includes Pyakunnilmeil, Kilimanoor, Nagaroor, Pulimath Panchayat were chosen. In Thiruvananthapuram taluk Nemom block which includes Karakamandapam, Papanamcode, Vellayani, Koliyakode panchayat were the areas undertaken for the study. The flow chart indicating the selection of area is given in fig:3.1(1)
3.2 Selection of Sample: - According to Funk (1995) A sample is a portion or a subset of a larger group called a population. The population is the universe to be sampled. For this purpose the voters list both from the Corporation office and Panchayat were collected. From the list, women between the age 45-55 years were identified as the menopause usually occurs at this period. Post menopausal women who had completed minimum one year after their last mensus and also not more than two years after the attainment of menopause were carefully selected from the identified women. Door to door survey was carried out to locate the subjects who fulfilled the criteria for selection.
Out of the 2450 households identified in urban area 1507 women had not attained menopause, 643 were hystectomy cases and 300 women had attained natural menopause. 75 women subjects who had attained menopause naturally were taken from each of the four panchayat by random sampling. Kothari (2004) has defined random sampling one in which every item of the universe has an equal chance of inclusion in the sample. Hence a total of 300 post menopausal women who had attained menopause naturally were taken as experimental group in urban area. Of the 1507 women who had not attained menopause 100 women subjects of the same socio-economic background and same mean age were taken at random as the control group for the purpose of comparison with experimental group. (fig 3.2 [2])

In rural area out of the 3142 households surveyed 2382 women had not attained menopause, 460 women had undergone hystectomy and 300 women had attained natural menopause. 75 women subjects who had attained menopause naturally was taken from each of the four panchayat by random sampling. Hence a total of 300 post menopausal women who had attained menopause naturally were taken as experimental group in rural area. Of the 2382 women who had not attained menopause 100 women of the same socio-economic background and same mean age were taken at random as the control group for the purpose of comparison with experimental group.

A subsample of 120 post menopausal women 60 each from rural and urban area were selected at random to conduct the indepth study. The indepth study was also conducted among 40 pre-menopausal women of the same socio-economic background and same mean age (control). Fig 3.2 (2) indicates the mode of selection of subjects.
3.3 Methods and Tools used: - Survey method was used for collecting data. Surveys are one of the most frequently employed methods in social research all surveys are characterized by the collection of data from large or even very large, numbers of people. All surveys aim to describe or explain the characteristics or opinions of population through the use of a representative sample (May, 2001). Yates (2004) states that structured interview format are short specific questions, read questions exactly as on the schedule. Respondent is therefore constrained in their replies it deliberately limits what can be talked about.

Accordingly an Interview schedule and checklist were formulated by the investigator for the collection of data. The interview schedule was pretested and standardized among subject experts, doctors and adult women. This schedule included details on background information of selected subjects, lifestyle pattern, health history, medical history and nutritional profile. Face to face interview was conducted for collection of data since unlike the other methods there is a visual interaction component between interviewer and interviewee. Interview schedule formulated is presented in Appendix I.

Checklist was formulated to assess the knowledge of the selected women regarding post menopause and nutritional disorders. The check list are presented in Appendix II

3.4 Conduct of the Study

3.4.1 Pilot Study :- The reliability and validity of the interview schedule and checklist was tested using sixty Post menopausal women from rural and urban areas of Thiruvanathapuram district. The pretest revealed that certain questions were irrelevant
and confusing. Repetitions were avoided and confusing questions were suitably modified and the questions were then finalized.

3.4.2 Personal characteristics of the subjects

Information regarding the age of the postmenopausal women, age of attainment of menopause, the mode of attainment of menopause, educational status of the selected subjects, the employment status of the women, also about the income status of the family, the family composition of the selected postmenopausal women were elicited using the interview schedule.

3.4.3 Life style pattern and health history of Postmenopausal women

To understand the lifestyle pattern details regarding time spent in occupation was collected the subjects habit of chewing pan, drinking tea / coffee, the frequency of consumption, the exercise pattern of the subjects and time spent for exercising, the habit of sharing thoughts and feelings, their stress were elicited

To elicit details on health history information regarding the birth order of the respondent, the age of attainment of menarche, premenstrual symptoms the age of marriage, pregnancy and child birth, nature of delivery and practice of family planning were collected. Data was also collected on the symptoms at menopause such as presence of fibroid, irregular menstrual flow, abdominal pain etc and symptoms after menopause such as hot flushes, fatigue, night sweats, joint pain, knee pain etc were also collected.

3.4.4 Nutritional Profile of the subjects

Assessment of nutritional status of community is one of the first steps in the formulation of any public health strategy to combat malnutrition. The principal aim of such an assessment is to determine the type, magnitude and distribution of
malnutrition in different geographic areas, to identify the at-risk groups and to
determine the contributory factors. In addition, factual evidence of the exact magnitude
of malnutrition is essential to sensitize administrators and politicians to obtain
allocation of material and human resources and to plan appropriate intervention

The nutritional status of the selected Post menopausal women was assessed
through Anthropometric Measurements, diet survey, Biochemical estimations and
clinical examination using standard techniques.

3.4.4.1 Anthropometric Measurements

According to Garrow et al (2000) anthropometry is a method in which many
attempts have been made to derive equations by which the fat and fat free mass of the
body can be estimated from the measurements of selected length and circumferences.

The Height, weight, waist and hip circumference were recorded and the
corresponding Body Mass Index and Waist Hip Ratio were computed for the
experimental (N=600) and control group (N= 200).

(i) Measurement of Height :- The subjects were asked to stand against a wall
with barefoot and with heels, buttocks, shoulders and back of the head touching the
wall. The head was held comfortably erect with the arms hanging freely at the sides in
a natural manner. The height of the subject was assessed using a non-stretchable
measuring tape. The scale was kept perpendicular to the wall and then a mark was
made on the wall after which a non-stretchable measuring tape was used to measure
the height of the sample.
(ii) Measurement of weight: - Weight of the selected subjects was recorded using a bathroom scale. The subjects were asked to stand on the weighing scale, barefoot without touching anything, knees not bent, head straight and looking forward. The readings were carefully viewed and recorded nearest to 0.5Kg.

(iii) Measurement of Body Mass Index: - The Body Mass Index was computed by dividing the individuals weight in kilogram by the square of the height in metres.

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\text{Body Mass Index} = \frac{\text{Weight in KG}}{\text{Height in M}^2}
\]

Park and Park (2000)

(iv) Measurement of Waist and Hip circumferences: -

According to Boyle (1993) the waist circumference should be taken at the narrowest circumference between ribs and hip. Mahan (2000) stated that hip circumference is defined as the largest circumference between waist and knees. The waist and hip circumferences were accurately measured and Waist Hip Ratio was computed by the formula given by National Institute of Nutrition (1999).

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\text{Waist Hip Ratio} = \frac{\text{Waist circumference (cm)}}{\text{Hip circumference (cm)}}
\]

3.4.4.2 Diet survey

The value of nutritional assessment is greatly enhanced when it is supplemented by an assessment of food consumption. Direct assessment of food consumption involves dietary surveys which may be household enquires or individual food consumption surveys. The nutrient intakes of all the subjects were assessed by 24 hour dietary recall method. Subjects were asked to recall the specific food item they ate during the previous day describing the nature and amount of each food (Williams, 1993) Standard cups and spoons were used to facilitate the subjects to quantify the amount of food intake. From this the raw food equivalents were calculated using the
food composition table published by Indian council of Medical Research (Gopalan et al 2004). Performa used for dietary assessment by 24 hour recall method is given in appendix III.

3.4.4.3 Biochemical Parameters

Biochemical parameters such as blood pressure and blood haemoglobin were estimated for all the subjects (N=600).

**Blood Pressure:** The blood pressure was measured using sphygmomanometer with stethoscope placed over the artery in front of the elbow just below the armlet, while gradually the pressure is reduced by opening the valve. As the air pressure falls and allows the blood to escape and fill the artery below, faint tapping sounds synchronous with the heart beats are heard. The reading of the manometer at which the sounds are first heard is taken as systolic pressure. The sounds become progressively louder as the air pressure is reduced later the sounds acquire soft - muffled quality and the manometer at which this occurs is diastolic pressure.

**Blood Haemoglobin:** Blood Haemoglobin was estimated using cyanomethemoglobin method (NIN 2003).

Detailed procedure is given in Appendix IV

3.4.4.4 Clinical Examination

Clinical examination is an essential feature of all nutritional surveys since their ultimate objectives is to assess levels of health of individuals or of population groups in relation to the food they consume. It is also the simplest and most practical method of ascertaining the nutritional status of group of individuals. There are a number of physical signs some specific and many non specific known to be associated with states
of malnutrition. When two or more clinical signs characteristic of a deficiency disease are present simultaneously their diagnostic significance is greatly enhanced (Park and Park 2000)

Using the score card evolved by the Nutrition Advisory committee of the ICMR clinical assessment was carried out for all the Post menopausal women (Appendix V).

3.4.5 Developing Nutritional Status Index

NSI is an indicator of social well being of a community (Sreenath, 1988). In the present study nutrient intake (calcium, phosphorus, iron), Body Mass Index, waist-Hip Ratio and hemoglobin level were taken into consideration for the computation of this Index. NSI was computed for 600 postmenopausal women and 200 pre-menopausal women.

Let there be ‘n’ random variables $x_1, x_2, \ldots, x$ which are considered to be determinants of the nutritional status of an individual. Let ‘m’ observation be taken on there variables (or let there be ‘m’ respondents)

Thus if $x_{ij} ; I \leq I \leq m, I \leq j \leq n$ be the observation matrix, then an index ‘$p_j$’ is defined for each individual, $I \leq I \leq m$ as follows

$$p_i = \sum_{j=1}^{n} w_j \cdot x_{ij}$$

Where $w_j = 1/s_j^2$ being the sample variance of $x_{ij}$. This index $p_1$ is defined as the NSI.

3.4.6 Comparison with control group

Certain factors such as the nutrient intake Body Mass Index, Waist Hip Ratio, nutrient intake, blood haemoglobin level, monthly income and Nutritional Status Index
of the selected Post menopausal women (N = 600) was compared with control group pre-menopausal women (N = 200) of the same age group to find out whether there is any significant difference between these groups and whether the post menopausal condition has any influence on the nutritional profile.

3.4.7 Indepth study on subsample

An indepth study was carried out on subsample of 120 Post menopausal women and 40 pre-menopausal women of the same age group. In depth study included determination of food and nutrient intake (weighment method), Bone Mineral Density, serum calcium and phosphorus and estimation of lipid profile.

3. 4.7.1 Assessment of food and nutrient intake-

Food weighment method was carried out for subsample of 120 postmenopausal women and 40 pre-menopausal women. Weighment method is most reliable one. But it is time consuming. (Swaminathan, 2001)

Food weighs with accurate balance. Before the actual cooking edible portion of raw food is weighed. Information regarding actual food intake for one day was conducted by weighment method. The nutrient intake were calculated using food composition table published by ICMR (Gopalan et al. 2004). Performa used for food weighment survey is given in Appendix VI.
3.4.7.2 Assessment of Bone Mineral Density

The Bone Mineral Density was estimated using DXA – Dual energy X-ray absorptiometry. A bone density system that uses two X-ray energies to measure bone density with a low patient exposure and fast scan time. It replaces DPA Dual photon absorptiometer the first dual energy clinical densitometer that was capable of measuring the spine and hip using a radioactive source such as Gd 153.

Scan sites :- The scan areas that provide the most information about patterns of bone loss include

Lumbar spine
Proximal Femur
Forearm
Whole body

Lumbar Spine :- The spine consists of number of vertebrae categorized as cervical (upper column) thoracic (mid column) Lumbar (mid to lower) and sacrum and coccyx (to the end) significant bone loss due to aging or osteoporosis is often observed in the vertebrae and particularly in the lumbar area.

The AP Lumbar spine is the most widely used anatomical site for the evaluation of osteoporosis. The vertebral bodies L1, through L4 contain approximately 40% cortical and 60% trabecular bone.

The high amount of trabecular bone and the relative ease of reproducibility of positioning of the spine provide an important source of base line bone density data.

Reference Data Base :- Reference data base represents the average results as a function of age, sex and ethnicity for a matched population. Reference curves specify
average BMD and standard deviation as a function of age. Each curve applies to a specific scan type, analysis type, bone region, patient sex and ethnic group.

Reference data base reports use these reference curves for a graphic display and for the calculation of Z and T scores. Each of these curves compares a patient scan or a series of patient’s scan with the reference data base.

Based on the WHO Criteria the subject were grouped as normal, osteopenia and osteoporosis.

WHO Criteria

This is based on the measurements of BMD and establishing T- scores and Z scores.

T-Score: It is the deviation of the subject’s BMD value from the mean BMD for a young healthy adult population in units of the population standard deviation (SD). A normal T-Score is arbitrarily set at zero, plus or minus one standard deviation. In other words, any T-score above minus 1 is considered normal.

Z-score: The reference values are those of healthy, age matched population. It expresses how many SDs a subject’s BMD differs from the mean values for the age, sex and race matched population.

Normal: A value of BMD above -1 SD of the young adult reference mean (T-score >1)

Osteopenia: Diagnosis of osteopenia is made when the BMD is between -1SD and -2.5 SD of the young normal adult value (T-score -1 to -2.5) (osteopenia refers to BMD that is lower than normal peak BMD but not low enough to be classified as osteoporosis.)

Osteoporosis: A BMD of <-2.5 SD of the young adults is diagnostic of osteoporosis (T-score <-2.5)

Sample of scan information is given in appendix VII.
3.4.7.3 Estimation of Serum calcium and phosphorus

Serum calcium was estimated for post menopausal women using the method of Clark and clip (Appendix-VIII)

Serum phosphorus was estimated for post menopausal women using the method of fisk and subarea. (Appendix- IX)

3.4.7.4 Estimation of Lipid profile

Lipid profile of the subjects which included total cholesterol, VLDL, HDL, and LDL level of 120 randomly selected post menopausal women and 40 pre-menopausal women were analysed by standard method (Appendix -X )

3.4.7.5 Comparison with the control group

The indepth study conducted on determination of food and nutrient intake (weighment method), Bone Mineral Density, serum calcium and phosphorus and estimation of lipid profile in experimental group (N= 120) was compared with control group of 40 pre-menopausal women of the same age group.

3.4.8 Imparting of Diet counseling and assessing its impact

Diet counseling was imparted to 120 subjects. The knowledge of the selected subjects was tested using a check list scores were given for every correct answer. Irrespective of the scores obtained appropriate diet counseling was provided for illnesses and diseases commonly occurring after menopause. Picture, charts pamphlets and booklets were used for counseling. They contained details on risk factors, symptoms of diseases, nutrient rich food, and food to be avoided and included in disease condition. Diet counseling also laid emphasis on the modification of present diet. The aids used in counseling are presented in Appendix -XI.
The impact of diet counseling was studied by administering the same checklist after one month. The answers were again scored and the difference in scores obtained indicated the retention of knowledge and impact of diet counseling.

Hypothesis framed for the study:

1. Nutritional status of postmenopausal women is not better than pre-menopausal women.
2. There will not be significant relationship between the Bone Mineral Density and menopausal status of women in both rural and urban area.
3. Dietary counseling will not have influence upon the dietary knowledge of postmenopausal women.

Statistical Analysis

The data collected were coded, tabulated and statistically analysed. Coding is the purpose of converting the quantitative data in the questionnaire to numerical form and presenting it on the coding material. (Sharma, 1994). The purpose of tabulation is to simplify the presentation and facilitate comparisons. A table is a systematic arrangement of statistical data in columns and rows. (Ghosh, 1995). Suitable statistical tools were used to analyse the data collected. According to Koul (1992) analysis of data means studying the organized material in order to discover inherent facts. The data were studied from as many angles as possible to explore the new facts. Analysis requires a alert, flexible and open mind. It is worthwhile to prepare a plan of analysis before the actual collection of data.
The data collected in the above procedure was analysed using the following statistical procedures as shown below:

Mean, Percentage : For finding out frequency distribution
Chi Square : For determining dependency between variables.
Analysis of Varience : For finding significant difference between the experimental and control group.
Test for proportions : For finding out significant difference between pre and post tests with respect to knowledge.
Selection of Area

Chirayinkeezhu Taluk
- Rural
- Urban
Kilimanoor Block

Pyakkunnilmel
Nagaroor
Kilimanoor
Pulimath
Karakanandapam
Vellayani Papanamacode
Koliyakode

Selection of Sample (N = 800)

Experimental
- Postmenopausal Women (N = 600)
  - Rural (N = 300)
  - Urban (N = 300)
  - Socio-economic background lifestyle pattern and health history
  - Nutritional Assessment of the subjects
    - Anthropometry
      - BMI
      - W:H ratio
    - Biochemical Analysis
      - Hb
      - BP
    - Clinical Examination
    - Dietary Intake
      - Nutrient intake
  - Comparison of Experimental and control group
    - (W:H ratio, BMI, Nutrient intake)
    - Food expenditure, NSI

Control
- Premenopausal women (N = 200)
  - Rural (N = 100)
  - Urban (N = 100)
  - Assessment of BMI, Hb, Nutrient intake
  - Developing NSI (N = 800)
    - (BMI, W:H ratio, Hb, Nutrient intake)
    - Ca, P, Fe

Selection of Sub Sample (N = 160)

Experimental
- (N = 120)

Control
- (N = 40)

Dietary Counselling to the Women

Final Evaluation

Statistical Analysis

Indepth Study

- BMD
- Serum Calcium & Phosphorus
- Lipid Profile
- Dietary Intake

Comparison of exp and control

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