A Study on Assessment of the Quality of Life and Associated Factors among Patients with Gynecological Cancers Undergoing Gyneco-Oncological Therapy in a Selected Tertiary Care Hospital in Kolkata

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"Life is a culmination of the past, an awareness of the present, an indication of a future beyond knowledge, the quality that gives a touch of divinity to matter."

- Charles Lindbergh

Abstract: ***Introduction: Quality of life is a comprehensive sense of wellbeing which gets afflicted due to disease condition like gynecological cancers. The matter of concern comprises impact of gynecological cancer and treatment on QOL of patient, family care giver and its association with socio-demographic milieu. Rather limited is recognized about the influencers of QOL. Aim of study is assessment of QOL and associated factors among patients with gynecological cancers undergoing gyneco-oncological therapy. Materials and methods: A non-experimental cross-sectional study was conducted on 200 patients with gynecological cancers undergoing gyneco-oncological therapy attending OPD in a tertiary care setting of Kolkata. Health related quality life questionnaire was administered to patients and responses were analyzed. Identified QOL, associated factors and established association between them. Results: Most of the patients were between 55-64 years of age, unemployed, married, parous, living in joint families and belonged to low income group. Majority were diagnosed as carcinoma cervix and nearly half suffered from stage II cancer. Most of them had undergone radiation onco-therapy. Respondents had an average level QOL mean scores (64.7 ±15.2) and high functional status. Patients had better role, physical, cognitive, and social functions. However, majority experienced financial difficulties. QOL was found significantly associated with age, occupation, parity, type of family and cancer stage of respondents. Conclusion: Study findings suggest average QOL and high level of functional status post treatment. Nurses might plan support strategies to reduce emotional distress, anxiety and fear related to disease and cure among gynecological cancer patients.***

Keywords: Quality of life, associated factors, Gynecological cancer patients

1. Introduction

Just as beauty is not an area of reality however its aspect, so too is quality in reference to life. This is further asserted by WHO which defines QOL as "an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, personal beliefs, social relationships and their relationship to salient features of their environment."QOL is a complete sense of wellbeing and a mix of objective and subjective individual feelings and it is known that in case of a disease condition like gynecological cancers, this sense of wellbeing is markedly affected.[1] [2]

Gynecological cancers are an umbrella term used to describe any cancer of the female reproductive tract, including those originating in the cervix, ovaries, endometrium, vagina or vulva, fallopian tubes. Modern management of gynecological cancers follows a comprehensive approach which includes treating the disease condition as well as taking care of psychological and social aspects of the individual. Especially when a woman gets diagnosed with a gynecological cancer there is a marked impact on her QOL. Understanding these impacts has the potential to improve approaches to care, modify therapies and provide supportive care for the duration of the illness. [3]

However to assess or measure QOL is a complex task, given the subjective nature of it. QOL is an upcoming holistic concept which reflects the physical, social, emotional attitudes and behaviors of an individual. It is becoming increasingly recognized as an outcome and predictor for cancer patients. [4]

2. Background of the Study

As explained by American Cancer Society gynecological cancer is a leading cause of death worldwide among women in both low and middle-income countries and it is expanding due to the growth and aging of the population. [5]

According to GLOBOCAN 2012, an estimated 14.1 million new cancer cases and 8.2 million cancer related deaths occurred in 2012. With 1,085,900 new cases and 417,600 deaths yearly, gynecological cancers are affecting women worldwide and are most notable in sub Saharan Africa.[6] The most frequent reported unmet need is help in dealing and living with the fear of recurrence. It seems that psychosocial status at time of diagnosis is determining for QOL and well-being in the long term. Association has been found between coping style and QOL, risk of depression, and anxiety in the long term after gynecological cancer. [7]

American cancer society (2018) states that cancer accounts for about 1 in every 7 deaths worldwide which is more than

HIV/AIDS, tuberculosis and malaria combined. Gynecological cancers alone contribute to 107,470 estimated new cases and 31,600 estimated deaths yearly. The global cancer burden is growing at an alarming pace and this burden is increasing due to adoption of unhealthy behaviors, lifestyles and changes in reproductive patterns (e.g. fewer children, later age at first child birth).The main treatments proposed for this type of cancer are radiotherapy, surgery, chemotherapy or a combination of these. Despite great developments in diagnostic and therapeutic methods, disease and the effects of its treatment still bring important consequences for the lives of these women, possibly compromising, in many ways, their well-being and QOL. [8]

South and South East Asian countries have also reported 175,000 new cases of gynecological cancers yearly and 94,000 related deaths which constitutes more than one-third of the global burden. Maximum disease related morbidity and mortality has been found to be present in India. [6]

In India, Ovarian and Cervical cancers are the most common gynecological cancers affecting women. Cervical cancer is on a declining trend, but remains the second most common cancer in women after breast cancer. Every year in India, 123,000 women are diagnosed with cervical cancer and 67,000 die from this disease. In fact, almost 90% of cervical deaths in the world occur in developing countries, with India alone accounting for 25% of the total cases. [6]

According to Indian Council of Medical Research data on site specific cancer burden, the gynecologic cancers contribute about 30% of total cancers among women in India. Among these, carcinoma cervix followed by carcinoma ovary and corpus uteri are the major contributors.[9] Moreover, according to Cancer Foundation of India, the maximum rate of gynecological cancer has been found in Barshi i.e. 40%. In Delhi 25.4%, Mumbai 22.6%, Chennai 23.7% and in Kolkata 25.8%. In addition to this the peak age of occurrence of cervical cancer in India is between 55 and 59 years.[10] Mortality statistics and trends in cervical cancer are lacking due to inadequate and incomplete information on deaths. [11]

It has been found that various factors contribute to changes in the QOL of women with gynecological cancer i.e. functional damage secondary to treatments such as pelvic surgery involving the removal of parts of the female genital anatomy and radiation, which damages the vaginal mucosa and epithelium; side effects of chemotherapy, which in part are common to radiotherapy, such as nausea, vomiting, diarrhea, constipation, mucositis, weight changes and hormonal changes, psychological factors, including erroneous beliefs about the origin of cancer, changes in self-image, low self-esteem, marital tensions, fears and worries, sleep quality disturbance. [8]

Complications of disease and treatment can have negative influences on QOL. However few evidences report the magnitude of stress, anxiety, and sleep disturbance on QOL. [12]

2.1 Need of the Study

The issues of concern not only include the impact of gynecological cancer on QOL of the patient and family care giver but also the relationship with socio-demographic variables, side effects of treatment, stage of cancer. Relatively very less is identified about the determinants of QOL. Also it is not known to what extent attitudes and coping styles contribute to individual perception of QOL and their ability to tolerate the treatment after diagnosis of gynecological cancers.

Ample literature is published on cancer and various treatment strategies in Kolkata but very less evidence is found about the QOL of gynecological cancer patients and ways to improve the care.

This study aims to explore the less investigated categorical domains of QOL namely functional, physiological, psychological, sexual and social, in an effort to analyze a comprehensive picture for an intense understanding of different dimensions affecting QOL of gyneconcological patients.

2.2 Scope of the Study

Advances in the early detection and treatment of gynecological cancers have provided gains in patient survival time. However, these gains are often accompanied by a variety of treatment associated toxicities that diminish the patient’s QOL during and after treatment.[13] Addressing this burden is particularly important not only for health impact, but to increase the level of awareness of patients and monitoring of therapeutic interventions from patients perspective.

The study has great relevance in present scenario as it provides supplementary information about the burden and impact of the disease on the QOL which can be helpful in planning, modifying the healing approaches toward patients for improved supportive care for the duration of illness.

QOL assessment as an outcome and predictor for cancer patients is an upcoming concept. It is helpful to nurses who are in constant interaction with the patients and can better address the needs of the patients. QOL as an indicator can be included in day to day practice by the nurses, so as to compliment medicalonco-therapy.

By the virtue of spending relatively increased duration of patients contact, nurses may be better equipped to assess patient as well as care takers regarding issues of QOL.

2.3 Statement of the problem

“A study on assessment of the QOL and associated factors among patients with gynecological cancers undergoing gyneco-oncological therapy in a selected tertiary care hospital in Kolkata.”

2.4 Aim of the study

Assess the QOL and associated factors among patients with gynecological cancers undergoing gyneco-oncological therapy.

2.5 Objectives

1) To identify the QOL and associated factors in patients with gynecological cancers.
2) To identify the association between QOL and selected variables such as socio demographic and clinical data.

2.6 Assumptions

1) Women affected with gynecological cancers may have varied levels of quality of life.
2) Various associated factors such as socio-demographic and clinical characteristic might be associated with the quality of life in gynecological cancer patients.

Research variables

1) QOL
2) Associated factors

2.7 Operational definitions

1) QOL: It is the general perception of an individual about the overall status of her health and life inclusive of its major domains such as physical, role, emotional, cognitive and social functioning.
2) Associated factors: Those factors that may affect the QOL such as socio-demographic (age, education, occupation, marital status, parity, type of family, individual and family income) and clinical characteristics (diagnosis, stage and treatment of cancer).
3) Gynecological cancers: Cancers of female reproductive organs (ovarian cancer, uterine cancer, cervical cancer, vaginal cancer, vulvar cancer, fallopian tube cancer).
4) Undergoing gyneco-oncological therapy: Respondents who have already undergone onco-therapies like radiation therapy, chemotherapy, surgery, immunotherapy, hormonal therapy, brachytherapy etc. to treat the gynecological cancers prior one week to one month.
5) Patients: Outpatients diagnosed with gynecological cancers attending gyne-onco OPD and undergoing gyneco-oncological therapy in tertiary level hospital of Kolkata.

2.8 Delimitations

1) The study is restricted to only one hospital.
2) It is limited to the patients of age group 25-65 yearswho have been diagnosed with gynecological cancer.
3) Patients who have undergone gyneco-oncological therapy for a period of minimum one week and maximum one month.
4) Patients who are available in the OPD during the period of data collection and willing to participate in the study

3. Conceptual Framework

A framework in QOL research is an important aspect as it promotes the selection of appropriate measurement variables and identifies potential links between variables within the complex construct of QOL. Wilson and Cleary published their conceptual model of QOL in JAMA in 1995 which was later revised by Ferrans et al, 2005.

This model was developed in order to help explain the relationships of clinical variables that relate to QOL. The authors of the model present it as taxonomy of patient outcomes that link the characteristics of the individual to the characteristics of the environment. The model proposes causal linkages between five different types of patient outcome measurements.

In this research study the basic model of QOL by Wilson and Cleary is described as follows: -

3.1 Major Concepts

1) Characteristics of individuals: In this study patients with gynecological cancer undergoing gyneco-oncological therapy had been selected to identify the QOL.
2) Biological and physiological variables: This is the most basic concept that includes the gender, disease condition, and its stage and physiological response to treatment.

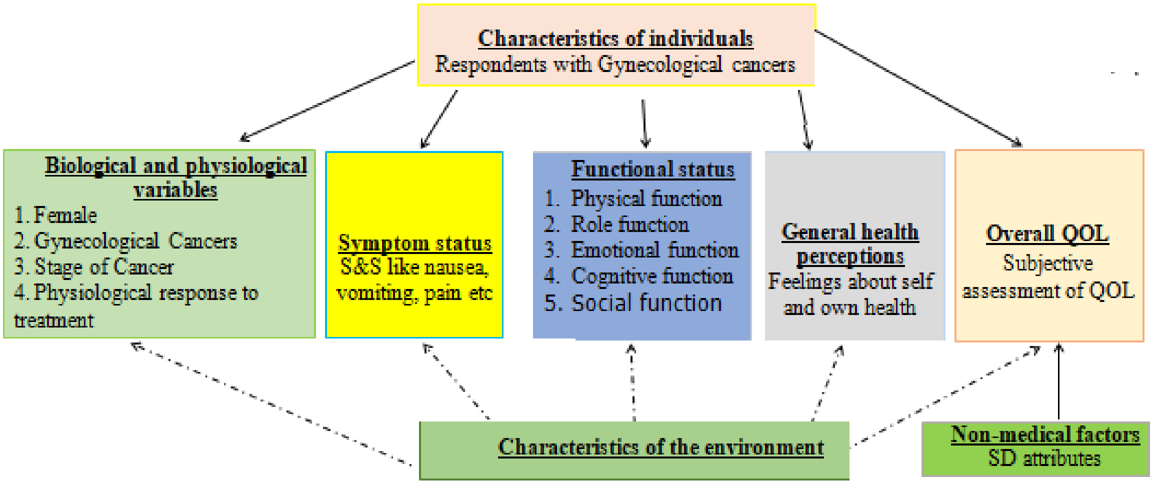

Figure 1.1: Conceptual framework - QOL Model (Wilson and Cleary)

3) Symptom status: It consists of signs and symptoms that are subjectively experienced by the patient.
4) Functional status: It refers to the patient's ability to perform certain tasks which are measured in terms of physical, role, emotional, cognitive, and social functioning.
5) General health perceptions: It refers to the general perception of individual about self and own health.
6) Overall QOL: It is the patient's overall satisfaction with life or subjective assessment of QOL.
7) Non-medical factors: These are the socio-demographic attributes that may have effect on the overall QOL.

The arrows represent dominant causal relationships between the major concepts. Relationship between the concepts and characteristics of environment are not explored in this study and are represented by dotted arrows.

3.2 Ethical aspects

The study plan was thoroughly scrutinized by the institutional ethical committee and approved by the Board of members of West Bengal University of Health Sciences, Kolkata. The ethical principles applied for this research study were as follows:

Privacy: No revelation of any information identifying the participant or the study setting was mentioned in the tool. Their names were represented as codes in the compiled data sheet. Anonymity of all the participants and confidentiality of the information conveyed was ensured throughout the study.

Consent: The participants were given the full right of self-determination as to whether or not to participate in the study. Participant's right to privacy was maintained. Informed consent was taken from each subject after explaining the purpose of the research. The principles were not violated and emphasis was given to the sensitive aspects of human behavior.

Rewards/Promises: There were no rewards or promises offered to the participants. However, informational and technical assistance and support was extended to all the participants by the investigator during their period of association with hospital.

Protection: The respondents were not subjected to any kind of physical or psychological harm. The study proceedings did not overlap the participants turn for oncological consultation or aid. No subjects were forced into the study. Lastly the gathered information about the respondents was not misused in any form to exploit the participants.

Information: The participants were informed as to how their participation in the study might prove beneficial to initiate practices and measures for improving QOL in gynecological cancer patients undergoing gyneco-oncological therapy. While explaining the research process researcher ensured that the information provided would create awareness only and not produce anxiety in them.

Debriefing: The complete research design was not briefed to the participants since it was difficult to meet the participants after they left from OPD.

Approval: The study proposal was scrutinized thoroughly by the subject experts to exclude violation of human rights and was agreed upon by the ethical committee board of the institution and the university.

Permission: The investigator had obtained formal permission to conduct the research study from the administrative authorities of the tertiary care hospital mentioned in the study. Permission to undertake this research was obtained from the Director of the hospital. The concerned medical authorities of the oncology department of the hospital were briefly informed about the study.

Publication: The research was conducted and certified as a requirement of partial fulfilment for the degree of Master of Science in Nursing and was for onward submission to the West Bengal University of Health Sciences.

3.3 Summary

QOL is a comprehensive sense of wellbeing which gets afflicted in disease conditions like gynecological cancer whichis the leading cause of mortality among women is amplifying due to growth and aging of population. Complications of disease and treatment may adversely influence the QOL. QOL issues in gynecological cancer care have rarely been tested in a place like Kolkata where a rising incidence of gynecological cancers has been noted. Researcher strongly feels that it would be an ideal place to assess the QOL issues highlighted above, with a view to examine unexplored determinants of QOL in gynecological cancers to deliver comprehensive health care. The study is designed to fill the gaps and will add more knowledge to the existing database on QOL of patients with gynecological cancers.

4. Review of Literature

4.1 Introduction

A systematic review of literature was carried out of published literature that contained information on gynecological cancers and its magnitude in health with a purpose to identify the QOL in gynecological cancer patients undergoing gyneco-oncological therapy and various associated factors. This chapter integrates the related literature into the following sections:

- Overview of gynecological cancers
- Impact of gynecological cancers and its treatment on QOL
- Determinants of QOL
- Measurement of QOL

1) Overview of gynecological cancer burden

There is ample of literature and scientific articles that unveils vital facts related to gynecological cancers. This section aims to highlight the burden of gynecological cancers globally as well as nationallyand what are the major concerns of the affected population.

Center for Disease Control (2010) reports on gynecological cancers reveal that approximately 71,500 women get diagnosed with gynecological cancers and approximately 26,500 die from it each year. Further, similar findings have been reported in other global health statistics that estimates the heavy burden of gynecological cancers. [14]

Likewise, GLOBOCAN (2015) also estimated 14.1 million new cancer cases and 8.2 million cancer related mortality occurring in 2012. Gynecological cancers are afflicting women worldwide and are most notable in Sub Saharan Africa with nearly 1,085,900 new cases and 417,600 deaths yearly. Cervical cancer is the fourth most common cancer in women, with an estimated 528,000 new cases and 266,000 deaths. [6]

American Cancer Society (2018) states that now a days cancer accounts for about 1 in every 7 deaths globally which is more than HIV/AIDS, TB, and malaria combined. More than 60% of cancer deaths occurred in low- and middle-income countries. By 2030, the global burden is predicted to reach 21.6 million new cancer cases and 13.0 million cancer deaths exclusively owing to the expansion and aging of the population. [5]

Additionally South and South East Asian countries constitutes more than one-third of the global burden. Maximum disease related morbidity and mortality has been found to be present in India.In India Ovarian and Cervical cancers are the most common gynecological cancers affecting women. Every year in India, 123,000 women are diagnosed with cervical cancer and 67,000 die from it. In fact, almost 90% of cervical deaths in the world occur in developing countries, with India alone accounting for 25% of the total cases. [6]

Daily Excelsior (2/11/2014) in its publication on cancer scenario in India reports that India contributes about one-fifth of the global burden annually. In South India, cancer cervix is the most common cancer among females. The gynecologic cancers are contributing about 30% of total cancers among women in India. Among these carcinoma cervix followed by carcinoma ovary and corpus uteri are the major contributors.[9]

According to Cancer Foundation of India the maximum rate of gynecological cancer has been found within Barshi i.e. 40%. In Delhi 25.4%, Mumbai 22.6%, Chennai 23.7% and in Kolkata 25.8%.The peak age of occurrence of cervical cancer in India is between 55 and 59 years. Mortality statistics and trends in cervical cancer are lacking due to inadequate and incomplete information on deaths.[10]

Maheshwari A et al (2016),has reviewed the literature on gynecological cancers in India and states that as a result of lack of awareness programs and formal screening programs, majority of whom have conferred with the advanced stages of cervical cancer. However, with the advent of visual inspection screening which may be done by primary health workers and better screening programs, the incidence of cervical cancer has been declining in the country. Endometrial cancer is the most common gynecological malignancy in the West, however in India, the incidence rates are low. Most of these cancers present at an early stage and are associated with a good prognosis. Also decreasing trends of vulvar cancer had been reported over past many years. [15]

A review by Mallath Mohandas K et al (2014) on cancer burden in India states that nationally, no written account exists that has comprehensive cancer incidence or mortality data. However, the National Cancer Registry provides population-based data and information supplied is quite reliable. The ensuing estimates may have many limitations. They might be more representative of urban and south Indian populations than rest of the country. Under-recording of cancer cases and mortality, particularly among older folks, is another drawback that reduces accuracy. [16]

A publication by Ernst and Young Global Limited (2015) on Expanding cancer care in India predicted prevalence of cancer to be 3.9 million with reportable incidence of 1.1 million in 2015. However, actual incidence is estimated to be 1.5 to 2 times higher as suggested by data from large screening studies and low coverage of Indian cancer registries. This gap between reported and real incidence might be attributed to under-diagnosis of cancer, which gets manifestedrelatively in the late stage. The contributory factors might be lack of awareness of cancer and screening for disease. Further, late detection impact bothsurvival rates and treatment cost. Cervical cancer being the second commonest along with other cancers represent >60% of the incidence burden which is nearly three times the incidence of US and China.[17]

A survey conducted by Sreedevi A et al (2015) on epidemiology of cervical cancer from 8 community based and 6 hospital based studies in Indiastates that 86% of mortality related to cervical cancer in developing countries indicates health inequities. Additionally India has the highest age standardized incidence of cervical cancer as compared to neighboring countries. However, old folk is at the highest risk of developing cancer but are least likely to undergo screening. The study results showed HPV prevalence of 87.8% – 96.67% among women with cervical cancer. It has been found that the incidence is greater among women of lower classes, those less educated, and with large number of children. [11]

It is inferred from the above data that the global burden of gynecological cancer is quite high. It continues to be a major health problem in India in-spite of the evidences that it is preventable and if treated at early stage, it might significantly reduce the mortality and morbidity.

2) Impact of gynecological cancers and its treatment on QOL

QOL is an individual perception about health and life which may be greatly influenced due to disease condition and its treatment. This section specifically deals in detail about the impact of gynecological cancers and its treatment on the QOL.

Cancer Support Community of America reports that having a potentially life-threatening illness like cancer often leads people to examine their lives and look for meaning and this search for meaning has a positive influence on life. The fear of death that affects most people when they are diagnosed with cancer, often leads to think about what they leave behind and what would they like to do with the time they have left. It can make one feel like it’s the QOL and not just the quantity that matters most.[18]

A meta-analysis based on four studies by L Wenzel et al. (2003) on QOL in patients receiving treatment for gynecological malignancies focuses on a number of treatment associated toxicities and conditions that might lead to impairments in QOL. Managing QOL in such patients may need careful consideration of varied issues such as side effects of onco-therapy andillness related factors. Major toxicities and symptoms can be pain, emotional distress, surgery related impairments, sexual dysfunction, nausea and vomiting, treatment related toxicities, neurotoxicity, alopecia, anemia and fatigue.[13]

A cross-sectional study done by Nanjaiah R et al. (2017) to assess the QOL among 131 gynecological cancer patients in Mysore city showed that the diagnosis of cancer affects patients and their families physically, financially and emotionally. The stigma related to cancer and its consequences adds to the negativity towards the disease. Various contributing factors that cause change in QOL might be functional damage secondary to treatment such as pelvic surgery, chemotherapy and radiation therapy. Treatment associated problems experienced by the patients can be nausea, vomiting, diarrhea, constipation, mucositis, weight changes, hormonal changes. QOL may be affected by various psychological factors such as erroneous beliefs about the origin of cancer, change in self-image and self-esteem, martial tensions, fears and worries. [2]

The cancer.net editorial board (07/2017)gives an overview of best known treatments for cervical cancer. It states that women with cervical cancer may have sexual and fertility concerns. Various side effects of surgery may be bleeding, infection, damage to urinary and intestinal systems, poor sexual health. Radiation therapy is another treatment modality that may have side effects like fatigue, skin reactions, stomach upsets, loose motions, bowel obstruction, abdominal pain, decreased vaginal elasticity, infertility. While chemotherapy drugs may have side effects like fatigue, risk of infection, nausea and vomiting, hair loss, loss of appetite, diarrhea. Relieving a woman’s symptoms and side effects by supporting with her physical, emotional and social needs is an important part of cancer care. [19]

A meta-analysis by Duska Linda R et al (2017) on approach towards cervical cancer survivors reports that 70% of the global burden occurs in resource-poor countries, with more than one-fifth of these diagnosed in India. It is found that gynecological cancers mostly affects younger women, with a mean age at diagnosis of 49 years who will face years of potential treatment-related side effects, concerns regarding fertility preservation, more family and work responsibilities which will impact their survivorship. [20]

A descriptive study conducted by D Arunachalam et.al (2011) to evaluate QOL among 120 patients cancer survivors with disfigurement due to cancer and its treatments in Coimbatore, Kerala, revealed that 51.7% of the patients were facing minor difficulties in socializing after the appearance was altered. There were feelings of loss of self-confidence, low self-esteem, and heightened self-consciousness in people affected by hair loss. It was stated that living with cancer can lead to emotional stress, fear related to treatment side effects and relapse, and generalized distress, significant social maladjustment, elevated anxiety and depression, and lowered QOL that results from living with the day-to-day physical problems.[21]

An observational prospective study conducted by Bisht M et.al. (2010) to assess QOL as an outcome variable in the management of advanced cancer among 100 patients in Uttarakhand, revealed significant improvement in the QOL scores after receiving palliative drug therapy. A high correlation was found between the average change of pain intensity and QOL scores. This study emphasized the significance of palliative care and pain management in improving the QOL of advanced cancer patient. [22]

A survey carried out by Colombo Nicoletta et.al (2017), to identify impact of recurrence of ovarian cancer on QOL and outlook for the future among 173 women in tertiary care hospital in Italy, out of which 116 were with relapse and 57 without, undergoing follow-up in a routine clinical setting. An ad hoc questionnaire was used to compare changes in health perceptions, burden of disease, and expectations for the future QOL in women. Substantial differences were seen in self-assessed health status between women with and without recurrence with 33.6% and 82.4% of women with and without recurrence rated their health as good to excellent, respectively. From this survey, it is clear that relapse of disease has a negative psychological and physical impact, highlighting the need for effective treatment in the long term. [23]

An observational study carried out by Omichi Chiaki et.al. (2017) to correlate influence of adverse effects on QOL among 75 survivors of gynecologic cancer before and after treatment in a tertiary hospital in Japan, revealed that patients with 02 adverse effects had poorer QOL in the domains of physical and emotional wellbeing. It was recommended to consider the effects of radical therapy not only on survival but also on the QOL of survivors. [24]

A randomized control drug trial conducted by Bezjak A et al. (2004) to assess the QOL among 152 ovarian cancer patients in Canada explored that there was deterioration in the QOL domains immediately after chemotherapy followed by clinical improvements in global QOL, emotional function, social function, fatigue, pain, sleep, constipation, appetite, abdominal swelling, and abdominal cramps. It was suggested that QOL data could provide useful information on the experience of symptoms and their time course, which might help patients and physicians in their anticipated effects of therapy. [25]

A review carried out by Izycki D et al. (2016) in Poland, on consequences of gynecological cancers in patients and their partners revealed that such patients are at risk of developing sexual and psychological problems. Sexual concerns may include decreased libido, feelings of being unwanted and unattractive and fear of restarting sexual activity. Partners of cancer patients may experience varied levels of distress followed by depression, anxiety, hopelessness, low QOL. It is suggested that social support might buffer against the occurrence of cancer associated distress.[26]

It is can be affirmed from the above data that diagnosis of gynecological cancer and its treatment might have distressing effects on the overall health and QOL of the patients and their family members. Patients may face sexual dysfunction, physical symptoms, psychological problems due to the cancer and its treatment. It is evident from the previous studies that it is more prevalent among women of reproductive age group which is also the most productive time period in the life of a young lady that further might have an impact on families and society as well as cost of treatment.

3) Determinants of QOL

Modern management of gynecological cancers not only includes the treatment but other aspects too, such as physical, cognitive, emotional, social, emotional functioning with a view to improve the overall quality of life. It has been identified from the previous research studies that there may be many factors which may be directly or indirectly associated with QOL. This section discusses various associated factors in relation to the quality of life.

A randomized control drug trial was carried out by Gruenigen VE von et al. (2010)in Florida, among 324 patients with stage III/IV ovarian cancer who underwent surgery followed by adjuvant chemotherapy. The study findings revealed that ovarian cancer patients had decreased QOL in physical, functional, and emotional domains. It was suggested that a clinical intervention in the physical and functional wellbeing subscales might have a positive effect on the emotional or social wellbeing scales and/or improve global QOL. [27]

A prospective cohort study was conducted by Vaz Ana Francisca et.al (2011) in Brazil, to evaluate the QOL and adverse events after radiotherapy among 95 gynecological cancer survivors. The study findings revealed symptoms experienced by women were pain (64.2%) and dyspareunia (45.9%) that were negatively associated with the physical, psychological and social relationship domains. However, there was significant improvement in QOL scores in the psychological domain, general health and overall QOL. It was suggested that QOL might be positively influenced by higher family income whereas, adverse events of treatment can have negative impact on it. [28]

A comprehensive literature review of MEDLINE databases was conducted by Del Pup L et al. (2017)on sexual dysfunction in gynecologic cancer patients related to onco-therapies. The review explored that various onco-therapies may impact sexual dysfunction with different mechanisms. Interventions for gynecological cancer can cause vaginal dryness, reduced flexibility, and shortening of the vagina. It was suggested that giving information and active hearing about sexual issues might not resolve organic sexual dysfunctions but improves the QOL as the patient who feels understood. [29]

A cross-sectional descriptive study was carried out by Khalil J et.al (2015) in Morocco, to assess the impact of cervical cancer on QOL among 110 cervical cancer survivors. The study finding revealed that the long term cervical cancer survivors had a good global QOL. However, they were experiencing less sexual functioning and enjoyment and less satisfaction with their body image when compared to 80 healthy controls. It was suggested that a better understanding of the relationship between QOL and cervical cancer sequelae in one hand and socio-demographic factors in the other hand might be necessary to improve QOL among cervical cancer survivors. So it becomes important for health care professionals to recognize those aspects of cancer survivorship that require attention and specific follow-up care.[30]

An integrative literature review carried out by Muliira Rhoda Suubi et.al (2017) to assess QOL among female cancer survivors in Africa suggested various factors affecting QOL. The socio-demographic factors identified were age, education, employment, income and residence. Similarly illness-related factors were having advanced cancer and multiple symptoms and treatment-related factors were associated with surgery and radiotherapy such as pain, sexual dysfunction, hormonal & body image changes. Various psychosocial factors such as support, depression and anxiety; and cultural factors including fatalism and bewitching were also identified. It was suggested that nurses and healthcare providers must increase their awareness of the potential impacts of these factors on QOL. [31]

A descriptive study was conducted by Ogoncho Isaac Machuki et.al (2015) to identified determinants of QOL among 108 gynecological cancer patients in Kenya between 18 to 72 years of age. The study revealed that the socio-demographic factors significantly associated with QOL scores, were age, level of education, marital status, occupation and monthly income whereas clinical characteristics significantly associated were type of cancer and cancer treatment, duration of illness and palliative care services. Among them vulnerable patients were those who were less educated, peasant farmers or casual workers, had a long duration of illness and underwent combined therapy. It was suggested that sufficient attention should be given to the more vulnerable patients in identifying and addressing their specific needs by the healthcare providers.[32]

A descriptive cross-sectional study conducted by Ustundaq S et.al (2015) to identify factors affecting the QOL among 352 cancer patients undergoing chemotherapy of an Outpatient Chemotherapy Unit in a state hospital of Turkey. The major findings of the study revealed that women had worse physical and social well-being then men. It was found that singles had worse psychological and general well-being whereas housewives had the worst physical and social well-being. It was suggested advanced studies on individual QOL factors affecting cancer would empower nurses for better personal care techniques and patients for easily overcoming the disease.[33]

A cross-sectional comparative study was carried out by H Pradjatmo et al.(2017) to assess the QOL of cervical cancer patient with support from nuclear family and extended family during chemotherapy in Dr. Sardjito general hospital, Yogyakarta Indonesia among 30 respondents for nuclear and 32 for extended family groups respectively. Major findings of the study were that nearly all cervical cancer patients in nuclear and extended families had supportive family. It was suggested that the strong bond in the family might influence strong cooperation among family members. Family member may be considered as the first one who provides social support for the other members with severe disease or problem. [34]

A descriptive cross-sectional study was conducted by I Gungor et al. (2017) to identify QOL and fatigue levels among 154 gynecologic cancer patients of polyclinic in Istanbul, Turkey. The mean score of total QOL was low. Physical and emotional states were found to be mostly affected, whereas fatigue scores found to be high in metastatic cancer. It was analyzed that most important factor affecting QOL is economic condition. It was suggested that QOL in such patients might be affected by factors such as cancer type, cancer diagnosis, stage and spread of the cancer. [35]

A correlational study was conducted by Yoo S H et al. (2013) to assess the correlates of unemployment and its association with QOL among 858 cancer survivors in South Korea. Major findings revealed that survivors with lower income, unemployed and with other comorbidities were highly associated with an impaired QOL, physical functioning and role functioning. It was suggested that there is a need to secure the financial status of cervical cancer survivors. [36]

A cross-sectional study was conducted by Teng Flora F et al. (2014) among 102 ovarian cancer survivors in an OPD setting in Vancouver, Canada. The study findings revealed that majority of the participants reported low global QOL scores. It was found that older patients were more affected by chemotherapy and had greater peripheral neuropathy. Additionally, emotional functioning and fatigue were associated with disease stage. Patients undergoing active treatment had low QOL scores. It was suggested that psychosocial factors have a greater effect on QOL then the physical sequel of cancer. [37]

It can be understood from the above data that QOL of gynecological cancer patients might be determined by various factors. It may be influenced by socio-demographic factors such as age, education, occupation, marital status, parity and economic status. Additionally, influencing clinical characteristics might include diagnosis of cancer, stage, and onco-therapy. Few studies have documented QOL among cancer patients in Kolkata as the socio-demographic factors and clinical practices may influence QOL differently in different regions.

4) Measurement of QOL

Measurement of QOL is a complex task being subjective and abstract in nature. Every individual might have a different perception about their life and health which makes it more complex to measure. This section discusses the previous research studies done to measure QOL in different settings.

A very unique study by Anderson B & Lutgendorf S (1997) in Lowa, US on QOL in gynecologic cancer survivors states that QOL is influenced by outside forces and intrinsic capabilities. The enormous adaptability of human beings help them to manage and appreciate those life circumstances which were once unacceptable to them. This incredible adaptability makes life precious and so measuring its quality becomes difficult. The cancer experience greatly changes major concerns of an individual in a unique way. This is why measurements tools for QOL must reflect these changes. It identifies the need to focus on individual meaning of QOL thereby introducing many variables in making investigations related to QOL difficult. It suggests the idol QOL treatment addresses all the major domains such as physical, psychological, social, spiritual, global, and positive influences. [38]

A cross-sectional study was conducted by Wu Shu-Fen et al. (2017) to explore QOL and the influencing factors among 167 gynecological cancer patients recruited from a district hospital in Southern Taiwan. The instruments used to measure QOL was EORTC QLQ C-30 Version 3.0 in Chinese language which evaluated physical, emotional, role, cognitive, social functioning, and global health status. Additionally, the tool also measured symptoms experienced by the patients. [39]

A cross-sectional study was carried out by Tripathi S et al. (2015) to evaluate the validity of Euro QOL 5D and identified its use to assess QOL and health status among 305 cancer patients in Eastern India. It states that EQ5D is a versatile QOL instrument with five dimensions inclusive of mobility, self-care, usual activities, pain/discomfort, anxiety/depression and a visual analog scale. This tool can be used to calculate quality adjusted life years as cancer treatment in India still focuses largely on longevity due to scarcity of resources. The major findings revealed that Odia version of EQ5D had good reliability and validity for QOL measurements in oncology and OPD patients and can be used in similar clinical scenario. [40]

A prospective study by Kannan Gopal et al. (2011) on assessment of QOL among 32 cancer patients in a tertiary care hospital of South India showed use of a validated questionnaire to measure QOL. The QOL questionnaire was designed and validated by Vidhubala E et al. which consisted of 10 factors inclusive of psychological well-being, self-adequacy, physical well-being, confidence in self-ability, external support, extent of pain experienced, mobility of the patients, optimism and belief, IPR, self-sufficiency, and independence. The instrument extensively described various domains of QOL and enabled the researcher to monitor and evaluate effects of treatment or disease condition from patient's perspective. [41]

A study published by Stephen Hicks, National Statistics; UK highlights some new approaches to measure QOL through household and social statistics. It focuses on inclusion of subjective well-being measurements and engagement with citizens about what matters to them and how they think statistical agencies should measure well-being and QOL in a nation. [42]

A theoretical paper regarding the definition and measurement of QOL by Theofilou P (2013) of Kinesiology Department, Trikala, Greece, explored that QOL being subjective in nature is difficult to measure and define. QOL may be viewed as a multidimensional concept stressing upon the self-perceptions of an individual’s current state of mind. HRQOL has been understood in many different ways and so has been measured using a variety of instruments. Some instruments used to measure QOL are generic, to be used in general population while others are disease specific. The choice of instrument might depend upon the reason for measurement and primary concepts of instruments or its utilization in a practice setting. It is evident that benefits of QOL instruments in general practice settings needs further research. [43]

A research conducted by Ruzevicius J (2014) to define the conception of QOL and its component identified that there is no universal quality of life determination as it can be influenced by an individual’s physical and mental health, the degree of independence, the social relationship with the environment, and other factors. Additionally, evaluation of QOL depends upon individual’s value system and his cultural environment. It states that while analyzing QOL, it should be kept in mind this concept is wider than the issues of an individual’s health. QOL might be identified according to nine major indicators such as material welfare, health, political stability and safety, family life, social life, climate and geographical location, employment, political and gender freedom. [44]

An international field study by Aaronson N K et al (1993) was conducted to establish the practicality, reliability (Cronbach’s α coefficient ≥0.70), and validity of the EORTC QLQ-C30, the quality life core questionnaire among 305 patients with non-resectable lung cancer from various centers in 13 countries. The questionnaire was administered before and after treatment and it was found that inter-scale correlations were statistically significant. Additionally, the scale was found to be highly valid and reliable. [45]

A study was conducted by Bjordal K et al (2000) to test the reliability and validity of EORTC health related quality life questionnaire among 622 head and neck cancer patients from 12 countries. The study findings revealed that quality life core questionnaire seems to be reliable, valid and applicable to broad multicultural samples. [46]

A survey by Kim M K et al. (2016) to investigate the prognostic indicators of HRQOL among 860 cervical cancer survivors from 6 Korean cancer hospitals explored that HRQOL is an important clinical outcome. Measures of overall well-being and functional scale might be used as complementary monitoring tool in routine follow-up of cancer survivors. The HRQOL instrument used in study included EORTC QLQ-C30 and QLQ-CX24 which assessed major domains of QOL inclusive of physical, emotional, role and social functioning, global health status and symptoms experienced by the patients. The socio-demographic and clinical variables identified were age, stage, time since diagnosis, marital status, income level, employment status, physical activity. [47]

A validation study conducted by Hua C H et al (2013) among 115 OPD patients in China, investigated and statistically analyzed EORTC QLQ-CX24 to be patient friendly. It was evident by the study that most patients welcomed the opportunity to report their health and illness experiences in detail. There are two optional scales – sexual/vaginal functioning and sexual enjoyment – that can be skipped if the woman considers herself to have been not sexually active during the past 4 weeks. It is evident from the study that quite a few researches is published related to QOL of gynecological cancer patients. [48]

It is inferred from the above data that various tools might be helpful in measurement of HRQOL. The HRQOL instrument should include generic questionnaire along with disease specific questionnaire which might describe QOL intensively. Additionally these questionnaire may be helpful in day to day practice.

Summary

Review describes the huge burden of gynecological cancers globally as well as within the nation. It also discusses the impact of gynecological cancers and its treatment on overall wellbeing of patients. It is evident that very few databases have documented QOL among gynecological cancer patients undergoing gyneco-oncological therapy in Kolkata. QOL is identified as an essential predictor of health and need more exhaustive research on it. Equally, no specific study has identified individual income of a patient as determinant of QOL that might be an important one. Research gap exists on the QOL of gynecological cancer patients in Kolkata. More research needs to be done to assess the QOL and associated factors that might bring something new to the existing body of knowledge.

5. Methodology

“It is important to get results from experiments but the most important is the process in getting those results.”

-Dr. Nik Ahmed Nizam

A research methodology is a systematic plan for obtaining and organizing the data for conducting rigorous research. It is the general research strategy that outlines the way in which research is to be undertaken and identifies the methods to be used in it. This chapter deals with the brief description of the methodology adopted for the study and it includes the research approach, research designs, setting, sample, sampling technique, tools, data collection technique, pilot study, procedure for data collection and plan for data analysis.

Research approach refers to the approach that has been adopted to conduct study. It basically involves the selection of research questions, the conceptual framework that has to be adopted, and the selection of appropriate research methods. In view of the problem selected and the objectives to be achieved, the approach used is a non-experimental approach which is used to observe, document and describe a phenomenon that examine relationships among variables but involve no manipulation or control. In this study assessment of QOL and associated factors were done for the patients having gynecological cancer undergoing gyneco-oncological therapy without any manipulation.

Research design is used to describe, observe and document aspects of a situation, phenomena or population and studies the relationship between variables or subjects. The study has adopted a descriptive, cross-sectional research design. The purpose of descriptive research is to observe, describe and document aspects of a situation as it naturally occurs and cross-sectional study examines the phenomenon only at one point of time. In the present study the QOL and associated factors are assessed only at one occasion in the gyneco-oncology OPD and data is recorded.

Research setting refers to the place where the research was conducted in order to collect the data. Pilot study and main study was conducted in the gyneco-oncology OPD of a tertiary care hospital of Kolkata.

Research Variables are qualities, properties or characteristics of persons, things or situations that change or vary. An attribute that varies, takes on different values. Research variables in this study are

1) QOL
2) Associated factors (socio-demographic and clinical characteristics): Socio-demographic characteristics under study are age, education, occupation, marital status, type of family, parity, individual income, and family income. Moreover, clinical characteristics are diagnosis and stage of gynecological cancers, gyneco-oncological therapy

Population is the entire set of individual or objects having some common characteristics.

Identification of target and accessible population: Target population is the entire set of unit for which the research data is used to make inference where accessible population is subset of target population from where samples are drawn. The target population selected for this study comprised of patients with gynecological cancers undergoing gyneco-oncological therapy. The accessible population of interest was patients with gynecological cancer undergoing treatment that were attending gyne-onco OPD at the tertiary care hospital of Kolkata, and available during period of study.

Sample is the selected proportion of the defined populations. It is the set of elements that make up the population and an element is the most basic unit about which information is collected. In this study, sample consists of 200 cases of gynecological cancers that were undergoing gyneco-oncological therapy and attending gynae-onco OPD at selected tertiary care hospital in Kolkata and available during the period of data collection.

Sample size was calculated by using the standard formula by Yamane Tore (1967) for a cross sectional study for a known population size. (Ogoncho Isaac Machuki et al, 2015) Where: n=sample size of adjusted population; N=population size; e =accepted level of error taking alpha as 0.05. The approximate number of gynecological cancer patients seen at the gyneco-oncological OPD of the tertiary level hospital as illustrated by the OPD records. After putting values into the formula a sample size of 200 was obtained as shown below. Calculation of sample size:

$$n = \frac{N}{1 + N\,(e)2}$$

$$n = \frac{400}{1 + 400\ (0.05)2}$$

$$n = \frac{400}{1 + 400\ (0.0025)}$$

$$n = \frac{400}{1+1}$$

$$n = \frac{400}{2} = 200 \text{ samples}$$

Sampling technique is the process of selecting a portion of the population to represent the entire population so that inference about the population can be made. In this study a non-probability purposive sampling is used to select the sample. Purposive sampling is selection of sample or subjects as participants in a study with a specific purpose in mind. The target population was identified and from them the eligible samples were selected as per inclusion and exclusion criteria. 200 samples selected for final study and the data was analyzed.

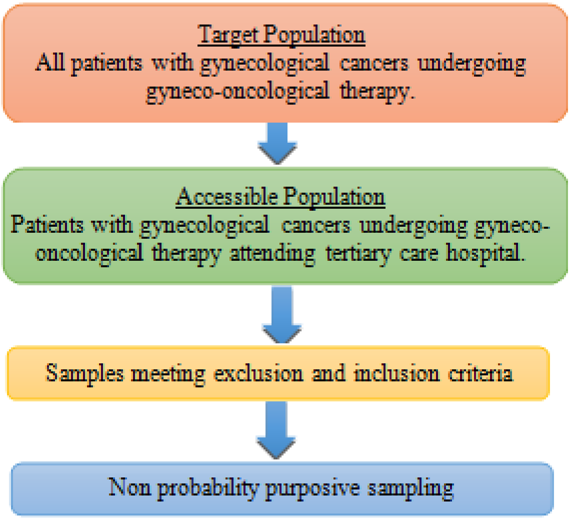

Figure 3.1: Schematic representation of sampling procedure

Inclusion Criteria
1) The study is limited to the patients of age group 25-65 years who have been diagnosed with gynecological cancer.
2) Patients who have undergone gyneco-oncological therapy for a period of minimum one week and maximum one month
3) Patients who are available in the OPD during the period of data collection and willing to participate in the study.
4) Patients who are able to read /and understand Hindi.

Exclusion Criteria
1) Patients with any co-morbidity other than gynecological cancer.
2) Patients with gynecological cancer not undergoing any treatment.
3) Patients who have undergone gyneco-oncological therapy for a period of more than one month.
4) Patients with poor treatment compliance.

Development and description of the tool

Data collection tools are the instruments used by the investigators to observe or measure the key variables in the research problems. When data are collected in a structured fashion, researchers must develop a data collection instrument, which is a formal written document used to collect and record information. Hence a valid, reliable and feasible tool or instrument to measure the variables is important. Based on the objectives of the study the following data collection tools were used in order to obtain necessary information. The Standard tool by European Organization for Research and Treatment Center has been used namely:

1) Quality Life Core Questionnaire-30 (generic scale)
2) Quality Life Questionnaire (disease specific scales): Cervix-24, Ovary-28, Endometrium-24.

Preparation of self-structured questionnaire: To elicit data for the present study the researcher had developed questionnaire comprising of clinical details and demographic profile.

Preparation of blue print: The various dimensions of the problem were considered and a blue print of the instruments was developed after consultation with the experts. It depicted in brief the name of the tools used, the number of items present and the scoring pattern. In-depth search of ROL from books, journals and published dissertations related to the topic were then searched to decide and select upon the structured tool to be used for the study. Hence the final tool applied was as follows:

Section A – Socio-demographic questionnaire with clinical details comprised of clinical details such as diagnosis and stage of gynecological cancer, type of onco-therapy and socio demographic profile consisted of items such as age, education, occupation, marital status, parity, family income, and individual income.

Section B- EORTC QLQ-C30 is a 30-item self-reporting questionnaire developed to assess the QOL of cancer patients. It was first published and field tested in a cross-cultural sample of lung cancer patients in 13 countries to establish reliability and to evaluate validity **(Aaronson et al, 1993; EORTC scoring manual; Fayers P et al, 2002).** It is a copyrighted instrument, which has been translated and validated into 81 languages and is used in more than 3,000 studies worldwide. Additionally it is supplemented by disease specific modules e.g. cervix, ovarian, endometrium, all which are distributed from the data center. Presently the QLQ-C30 version 3.0 is the most recent that has also been tested among 622 head & neck cancer patients from 12 countries with reliability quotient of 0.83 (**Bjordal et al, 2000;EORTC scoring manual).**

Section C- EORTC QLQ (Disease specific scale) is an essential component of the EORTC QLQ supplementary questionnaire modules which, when employed in conjunction with the QLQ-C30 provides more detailed information relevant to evaluating the QOL in specific patient populations. It assesses symptoms related to a specific tumor site (e.g. Cervix, Ovary, and endometrium), side effects associated with a given treatment (e.g Chemotherapy – induced neuropathy), additional QOL domains affected by the disease or treatment (e.g. sexuality, body image, fear of diseases recurrence, etc.) **(Fayers P et al, 2002; EORTC scoring manual).** The following scales have been used in the current study:

Cervical Cancer – QLQ-CX24
Ovarian Cancer – QLQ-OV28
Endometrial Cancer –QLQ-EN24

Validity & Reliability of the tool

Validity is the degree to which an instrument measures what it is supposed to measure whereas Reliability refers to the accuracy and consistency of the measuring tool. EORTC QLQ core questionnaire and disease specific questionnaire were standardized tools, and hence validity and reliability were established.

The socio demographic tool underwent several reforms and many omissions and alterations before adopting its final form. The content validity of the socio demographic tool was established by experts who were requested to give their opinions and suggestions in the criteria checklist. The experts were from the department of Obstetrics and gynecology, Nursing, Education, Research and Statistics. Suggestions from the experts were incorporated in the final draft and then was translated to Hindi by translation expert for which translation certificate is obtained.

Description of Scoring: The QLQ-C30, CX-24, EN-24, and OV-28 is composed of multi item scales and single item measures. All of the scales and single item measures range in score from 0 to 100. A high scale score represents a higher response level. Thus a high score for a functional scale represents a high/healthy level of functioning; a high score for the global health status/ QOL represents a high QOL, but a high score for a symptom scale/ item represents a high level of symptomatology/ problems. The principle for scoring these scales is the same in all cases. First estimate the average of the items that contribute to the scale; this is the raw score. Followed by use of linear transformation to standardize the raw score, so that scores from 0 to 100; a higher score represents a higher (“better”) level of functioning, or a higher (“worse”) level of symptoms.

Respondents were defined with problematic functioning as those who scored <33.3 while subjects in good condition scored >66.7. For symptom scales, respondents scoring < 33.3 were considered as having less severe symptoms, while those scoring >66.7 described as having more severe symptoms. [49] [50] [51] [52]

Feasibility of the study

Feasibility was determined during the pilot study period by assessing the adequacy of study methods and procedures, appropriateness and quality of instruments, availability of subjects during the data collection period, time duration for administration of tool, facilities needed for maintaining the privacy of the study samples and cost for budgeting purposes. Availability of the subjects under study, cooperation from the OPD staff were some of the aspects addressed while determining the feasibility of the study. A formal permission through proper channel was obtained prior to study.

Ethical considerations

Research proposal was submitted to the institutional ethical committee and approval was taken. Ethical clearance and institutional approval for the study is enclosed. Privacy and anonymity of subjects was ensured by using codenumbers to identify the samples. The principle of veracity, autonomy and justice was ensured by obtaining written informed consent from each patient. Respondents were explained about their individual right to take the independent decision regarding participating and continuing in the project in the language they understand. Selection process and purpose of the study were explained to each sample before enrolling. Only willing samples were included in the study. Researcher treated every participant equally, respecting their beliefs, habits, life style and culture. Samples were protected from physical and psychological harm. No probing was done and participants were also assured that the information they provided will not be misused in any manner.

Pilot study

Pilot study is a small scale version or trial run done in preparation for a major study. It is conducted to check the feasibility of the study and to foresee the problem which may arise during the study.

After obtaining the institutional ethical committee clearance and the permission from the concerned authority the pilot study was carried out w.e.f. 01 Nov to 07 Nov among 20 participants at gynae-oncology OPD of a tertiary care hospital in Kolkata. Also the permission to use the standard tool was obtained from the EORTC through the mail.

The aim, objectives, and nature of the study was explained to the respondents, before taking a written consent from them. The sample was selected by purposive sampling. The purpose of the study was to establish the feasibility of conducting the study, familiarizing with the administration of tool, analyze the suitability of the tool, improving the tool and to decide the plan for analysis. The findings of the pilot study revealed that there was statistically significant association between QOL and socio demographic variables at 0.05 level of significance. Overall QOL scores proved to be good in majority of respondents. However, illiterate respondents could not read the questionnaire hence interview technique was used to collect data. Additionally the study setting changed from service hospital to another tertiary care hospital as all the respondents were dependents on their spouses and their individual income could not be assessed. The study was found feasible and the investigator proceeded for the final study with inclusion of desired changes in study setting and administration of tool. Data analysis was done with use of descriptive statistics like mean, standard deviation, percentage, and inferential statistics Pearson's Chi Square test.

Data collection procedure

After obtaining the formal permission from the concerned hospital authorities the data collection period commenced w.e.f. 16 Dec 2017-15 Jan 2017. The OPD authorities were approached and explained the nature of help and cooperation required for conducting the research. Self-introduction was given and then rapport was established with the respondents. They were taken to a room in Gyne-OPD where they were comfortably seated. Daily 6-8 respondents were interviewed on an average. The purposive sampling procedure was used to enrol subjects into the study. Informed written consent was obtained from the willing and eligible participants of the study. Separate code numbers were used for each respondent. Care was taken that there is no contamination of the sample by keeping adequate distance between the respondents before the administration of questionnaire. Respondents were interviewed about their socio-demographic details and their clinical details were retrieved from their medical documents. The data was collected through self-reporting by the respondents in response to the EORTC QLQ-C30 and QLQ CX-24, OV-28, and EN-24 as applicable.

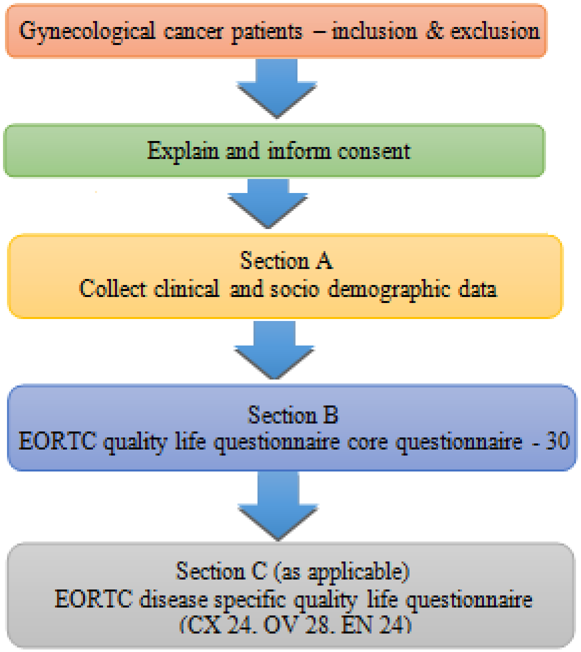

Figure 3.2: Diagram showing plan of data collection

Plan for data analysis

The researcher planned a number of steps to analyze the data in the following manner. Initially all data from the socio-demographic, clinical details and quality life questionnaires were entered into an MS Excel database. Before being entered into a data file, data were verified by a second individual to minimize error. Data were analyzed using the Statistical Package for social science (SPSS) windows release 20.0. Descriptive statistics, including means, standard deviations, range of scores, frequencies, and percentage, were used to describe the characteristics of subjects and provide initial description of study variables. The demographic variables and clinical data were also described in frequency in percentages. QOL scores were described using mean and standard deviations. The association of QOL scores with research variables under study were inferred using Pearson's Chi Square test along with the test of significance taken out through p values. Experts from the field of biostatistics were consulted for data analysis.

Summary

This chapter has explicitly described the sequence in which the research was conducted. It has also discussed the issues faced and remedial measures undertaken to reduce the effect on external and internal validity. QOL questionnaires were found to be appropriate to use for gynecological cancer patients through a pilot study. Difficulty in administration of tool was noted in the pilot study due to high illiteracy rate among majority of patients. As a result the method of administration of questionnaire was changed from self-administration to the reported structured interview method. Additionally, the study setting was also changed in view of getting more representative population. Overall, the pilot study indicated that the data collection method in the study was feasible, though time consuming.

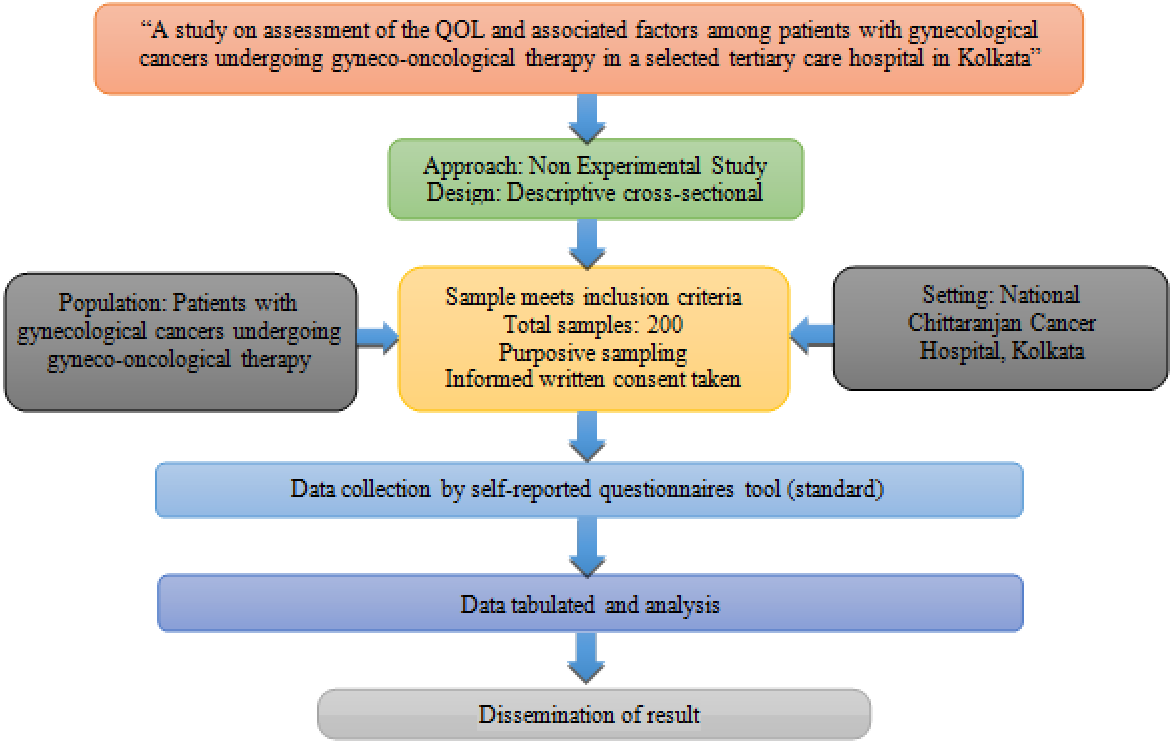

Figure 3.3: Schematic representation of research methodology

6. Analysis & Interpretation of Data

Analysis and interpretation of data is the most important phase of the research process. It is a process of organizing and synthesizing the data so as to answer research question and test hypothesis. Analysis and interpretation of data includes compilation and editing, coding, classification and presentation of data. This chapter deals with description of samples as per their demographic data, analysis and interpretation of the data collected from 200 samples in a tertiary care center as per the objectives. A descriptive approach with cross-sectional design was incorporated in the study. The samples were selected by purposive sampling technique for sample selection. The samples were subjected to the standard tool and data was collected and coded, and organized, tabulated, analyzed and interpreted using descriptive statistics like frequency, mean and standard deviation and with inferential statistics like Chi square test. The data has been analyzed and interpreted as per the objectives of the study. The objectives of the study were to identify the QOL and associated factors in patients with gynecological cancers and to identify the association between QOL and selected research variables. The data analyzed were presented under the following sections:

Section I – Analysis of data according to Socio demographic characteristics of respondents

Clinical characteristics of respondents

Section II Analysis of QOL

Section III Association of QOL with selected research variables such as socio demographic and clinical data

Section I

Part A-Socio demographic characteristics of respondents

Table 4.1.1: Distribution of respondents according to their socio-demographic data, n=200

Socio demographic data	*Category*	*F*	*%*
Age in years	25-34	Nil	0
	35-44	42	21
	45-54	77	38.5
	55-64	81	40.5
Educational Status	Illiterate	102	51
	Primary	57	28.5
	Secondary	19	9.5
	Senior Secondary	13	6.5
	Graduation and above	9	4.5
Occupation	Unemployed	176	88
	Employed	24	12
Marital Status	Unmarried	5	2.5
	Married	195	97.5

The data in Table 4.1.1 shows that among 200 gynecological cancer patients whose QOL was assessed, it was found that majority of them i.e. 81 (40.5%) were in the age group of

55-64 years and only 42 (21%) were in the age group of 35-44 years. In this study more than half of the patients i.e. 102 (51%) women were illiterate and only 9 (4.5%) were graduate and above. Majority of them i.e. 176 (88%) were unemployed and only 24 (12%) were employed. Only 5 (2.5%) women were unmarried and the rest 195 (97.5%) were married.

Table 4.1.2: Distribution of respondents according to their socio-demographic data, n=200

Socio demographic data	*Category*	*f*	*%*
Parity	Nullipara	15	7.5
	Parous (1-2)	90	45
	Parous (3-4)	69	34.5
	Grandmultiparous (>4)	26	13
Type of Family	Nuclear	65	32.5
	Joint	107	53.5
	Extended	28	14
Individual income (monthly)	≤2000/nil	188	94
	2001-6000	6	3
	6001-10000	0	0
	10001-20000	6	3
	20001-50000	0	0
	50001-100000	0	0
Family Income (monthly)	≤20000	194	97
	20,001-40,000	6	3

The data in Table 4.1.2 shows that most of the women had parity of 1-2 (45%) or 3-4 (34.5%) whereas only 15 (7.5%) were nulliparous. Majority of them i.e. 107 (53.5%) hailed from joint families and the rest belonged to nuclear and extended families i.e. 65 (32.5%) and 28 (14%) respectively. Most of them i.e. 188 (94%) had individual income less than 2000 while only 12 (6%) women were earning income more than Rs.2000. majority of them i.e. 194 (97%) belonged to the family with the monthly income less than 20,000, while others 6 (3%) earned an income of Rs.20,000-40,000.

Part B-Clinical characteristics of respondents

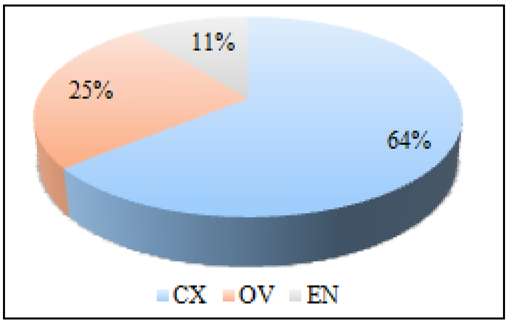

Figure 4.1: Distribution of respondents as per the diagnosis of gynecological cancer, n=200

Figure 4.1shows that among 200 respondents, almost more than half 128 (64%) were diagnosed as a case of carcinoma cervix and the rest were diagnosed as carcinoma ovary and carcinoma endometrium i.e. 50 (25%) and 22 (11%) respectively.

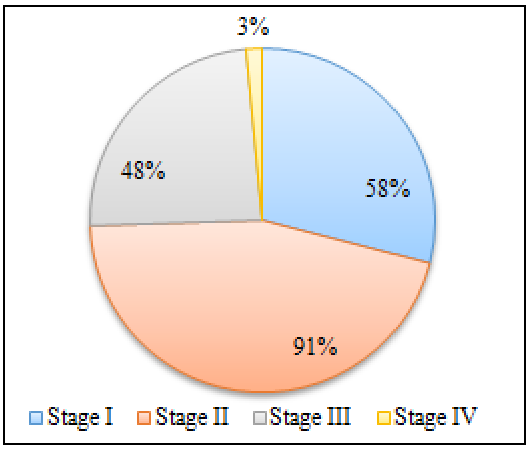

Figure 4.2: Distribution of respondents as per the stage of gynecological cancer, n=200

Figure 4.2 depicts that among 200 respondents, majority91 (45.5%) were suffering from stage II of the cancer and only 3 (1.5%) suffered from stage IV. Rest of the respondents were suffering from stage I and stage III i.e. 58 (29%) and 48 (24%) respectively.

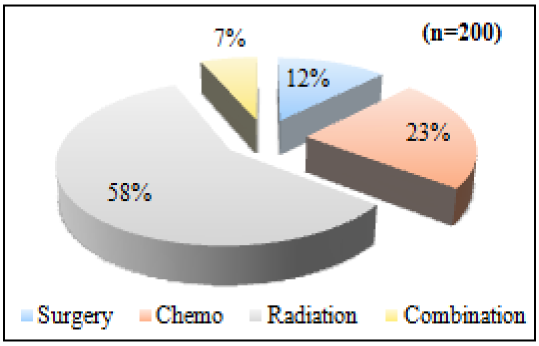

Figure 4.3 Distribution of respondents as per the gyneco-oncological therapy

Figure 4.3 shows that among 200 respondents, more than half116 (58%) had undergone radiation therapy as the treatment modality and only 14 (7%) were treated with the combination of onco-therapies. Chemotherapy was used to treat 46 (23%) respondents and surgery was performed among 24 (12%) respondents.

Analysis of QOL

This section deals with assessment of Global Health Status/QOL score, along with its predictors such as physical functioning, role functioning, emotional functioning, cognitive functioning, social functioning and sexual functioning and various symptoms experienced by the respondents.

Table 4.2: Level of QOL and Functional status of the respondents, n=200

EORTC QLQ- C30 Variables	f/%	Level of QOL perceived			Mean Scores	(±) SD
		Good	Average	Poor		
		≥66.7	33.3-66.6	≤33.3		
Global Health Status/QOL	f	6	121	73	64.7	15.2
	%	3%	60.5%	36.5%		
Functional Scales						
Physical Functioning	f	157	40	3	78.9	15.2
	%	78.5%	20%	1.5%		
Role Functioning	f	162	35	3	89.6	18.1
	%	81%	17.5%	1.5%		
Emotional Functioning	f	52	97	51	49.1	28.8
	%	26%	48.5%	25.5%		
Cognitive Functioning	f	100	97	3	75.5	19.9
	%	50%	48.5%	1.5%		
Social Functioning	f	88	100	12	68.8	22.6
	%	44%	50%	6%		

Figure 4.2 shows that among 200 respondents, more than half 121 (60.5%) had an average level of QOL whereas only 6 (3%) respondents had good QOL. Respondents had good level of role (89.6 ±18.1), physical (78.9 ±15.2), cognitive (75.5 ±19.9), and social functioning (68.8 ±22.6) with high mean scores ≥ 66.7 whereas they had an average level of emotional functioning (49.1 ±28.8) with mean score between 33.3- 66.6.

Table 4.3: Symptoms/ Difficulties experienced by the respondents, n=200

EORTC QLQ- C30 Variables	f / %	Level of QOL perceived			Mean Scores	(±) SD
		Good	Average	Poor		
		≥66.7	33.3-66.6	≤33.3		
Symptom Scales						
Fatigue	F	22	111	67	39.4	23.9
	%	11%	55.5%	33.5%		
Nausea/ Vomiting	F	3	21	176	8.0	16.1
	%	1.5%	10.5%	88%		
Pain	F	10	85	105	28.0	24.8
	%	5%	42.5%	52.5%		
Dyspnea	F	3	45	152	10.0	20.0
	%	1.5%	22.5%	76%		
Insomnia	F	15	67	118	23.5	33.5
	%	7.5%	33.5%	59%		
Appetite Loss	f	3	97	100	25.8	29.0
	%	1.5%	48.5%	50%		
Constipation	f	36	88	76	40.6	38.8
	%	18%	44%	38%		
Diarrhea	f	0	15	185	2.5	8.8
	%	0%	7.5%	92.5%		
Financial Difficulties	f	98	68	34	70.5	40.4
	%	49%	34%	17%		

Table 4.3 reveals that among 200 respondents major problem experienced was financial difficulty (70.5 ±40.4). However respondents scored low on most of the symptoms (mean score <33.3) except constipation (40.6 ±38.8) and fatigue (39.4 ±23.9).

Table 4.4: Level of functioning and symptoms experienced by respondents who had carcinoma cervix n1=128

EORTC QLQ-CX24 Variables	*f* / %	Level of QOL perceived			Mean Scores	(±) SD
		Good	Average	Poor		
		≥66.7	33.3-66.6	≤33.3		
Functional Scales						
Body Image	*f*	81	47	0	84.54	15.2
	%	63.3%	36.7%	0%		
Sexual Functioning	*f*	89	36	3	85.17	26.3
	%	69.5%	28%	2.3%		
Symptom Scale						
Symptom Experience	*f*	3	35	90	23.5	15.8
	%	2.3%	27.3%	70.3%		
Lymphedema	*f*	0	68	60	20.8	21.7
	%	0%	53.1%	46.9%		
Peripheral Neuropathy	*f*	3	77	48	29.6	27.5
	%	2.3%	60.2%	37.5%		
Menopausal symptoms	*f*	0	97	31	33.3	23.2
	%	0%	75.8%	24.2%		

Table 4.4 reveals that 128, out of 200 respondents who suffered from carcinoma cervix had good level of sexual functioning (85.17 ±26.3) and body image perception (84.54 ±15.2) whereas low level of symptoms were experienced by them with mean scores less than 33.3.

Table 4.5: Level of functioning and symptoms experienced by respondents who had carcinoma ovary

EORTC QLQ-OV28 Variables	*f* / %	Level of QOL perceived			Mean Scores	(±) SD
		Good	Average	Poor		
		≥66.7	33.3-66.6	≤33.3		
Functional Scales						
Body Image	*f*	25	26	0	82.35	16.4
	%	49%	51%	0%		
Sexual Functioning	*f*	43	8	0	91.8	15.04
	%	84%	16%	0%		
Symptom Scale						
Attitude towards disease	*f*	3	40	8	43.5	20.2
	%	6%	78%	16%		
Abdominal/GI symptoms	*f*	0	17	34	25.3	16.7
	%	0%	33%	67%		
Peripheral neuropathy	*f*	2	38	11	40.5	17.8
	%	4%	74.5%	21.5%		
Hormonal/Menopausal Symptoms	*f*	0	29	22	28.10	19.8
	%	0%	57%	43%		
Other Chemotherapy Side Effects	*f*	0	14	37	23.7	18.6
	%	0%	27.5%	72.5%		
Hair Loss	*f*	0	0	0	0	0

Table 4.5 exhibits that 51, out of 200 respondents who suffered from carcinoma ovary had good level of sexual functioning (91.8 ±15.0) and body image perception (82.35 ±16.4) whereas average level of mean scores were found in peripheral neuropathy (40.5 ±17.8) and attitude towards disease (43.5 ±20.2). However other symptoms were not experienced by the respondents to much extent with low mean scores less than 33.3.

Table 4.6: Level of functioning and symptoms experienced by respondents who had carcinoma endometrium

EORTC QLQ-EN24 Variables	*f* / %	Level of QOL perceived			Mean Scores	(±) SD
		Good	Average	Poor		
		≥66.7	33.3-66.6	≤33.3		
Functional Scales						
Body Image	*f*	9	12	0	76.19	23.9
	%	43%	57%	0%		
Sexual Functioning	*F*	21	0	0	94.4	9.1
	%	100%	0%	0%		
Symptom Scale						
Lymphedema	*f*	0	18	3	40.4	22.0
	%	0%	85.7%	14.3%		
Urological Symptoms	*f*	0	3	18	5.9	14.9
	%	0%	14.3%			
Gastrointestinal symptoms	*f*	0	9	12	24.7	11.3
	%	0%	43%	57%		
Pain in back & pelvis	*f*	6	9	6	52.3	40.2
	%	28.5%	43%	28.5%		
Tingling/ numbness	*f*	0	21	0	52.3	16.9
	%	0%	100%	0%		
Muscular Pain	*f*	6	15	0	61.9	28.4
	%	28.5%	71.5	0%		
Hair Loss	*f*	6	12	3	61.9	33.8
	%	28.7%	57%	14.3%		
Taste Change	*f*	0	9	12	14.2	16.9
	%	0%	43%	57%		

Table 4.6 reveals that 21 out of 200 patients who suffered from carcinoma endometrium had good level of sexual functioning (94.4 ±9.1) and body image perception (76.19 ±23.9) whereas average level of symptoms experienced were muscular pain (61.9 ±28.4), hair loss (61.9 ±33.8), tingling/numbness (52.3 ±16.9), pain in back and pelvis (61.9 ±40.2), and lymphedema(40.4 ±22.0). However rest of the symptoms were not experienced by the respondents to much extent with mean scores less than 33.3.

Section III

Association between QOL with selected variables

Table 4.7: Association between QOL and age of the respondents, n = 200

QOL Score	*f* / %	Age			Total	χ^2	p value
		35-44	45-54	55-64			
Poor	*f*	0	0	6	6	11.370	<0.023*
	%	0%	0%	7.4%	3%		
Average	*f*	29	50	42	121		
	%	69%	64.9%	51.9%	60.5%		
Good	*f*	13	27	33	73		
	%	31%	35.1%	40.7%	36.5%		
Total	*f*	42	77	81	200		

Table Value = 9.488, df = 4, *p<0.05

Table 4.7 shows that among 200 respondents, 81 in the age group of 55-64 years 40.7% had good QOL whereas 42 respondents in the age group of 35-44years, only 31% had good QOL. An association between QOL mean scores and age of the respondents by using Pearson's Chi Square elicited the computed χ2value (11.370) greater than table value (9.488) at df 2 with a p value of <0.023. As the p value is < 0.05it is concluded that there is an association between QOL and age.

Table 4.8: Association between QOL and education of the respondents, n = 200

QOL Score	*f* / %	Education					Total	χ^2	p value
		Illiterate	Primary	Secondary	Senior secondary	Graduation & above			
Poor	*f*	3	3	0	0	0	6	12.52	0.129
	%	2.9%	5.3%	0%	0%	0%	3%		
Average	*f*	69	27	12	10	3	121		
	%	67.6%	47.4%	63.2%	76.9%	33.3%	60.5%		
Good	*f*	30	27	7	3	6	73		
	%	29.4%	47.4%	36.8%	23.1%	66.7%	36.5%		
Total	*f*	102	57	19	13	9	200		

Table Value = 15.507, df = 8, *p<0.05

Table 4.8 reveals that out of 200 respondents, 102 were illiterate but 67.6% out of them had average QOL. However among 9 respondents who were graduate more than half (66.7%) had good QOL. An association between QOL mean scores and education of the respondents by using Pearson's Chi Square elicited the computed χ2value (12.52)lesser than table value (15.507) at df 8 with a p value of 0.129. As the p value is > 0.05it is concluded that there is no association between QOL and education.

Table 4.9: Association between QOL and occupation of the respondents, n = 200

QOL Score	*f* / %	Occupation		Total	χ^2	p value
		Unemployed	Employed			
Poor	*f*	6	0	6	17.575	<0.001*
	%	3.4%	0%	3%		
Average	*f*	115	6	121		
	%	65.3%	25%	60.5%		
Good	*f*	55	18	73		
	%	31.3%	75%	36.5%		
Total	*f*	176	24	200		

Table Value = 5.991, df = 2, *p<0.05

Table 4.9 reveals that out of 200 respondents, 176 were unemployed but only less than half (31.3%) had good QOL whereas among 24 employed respondents 75% had good QOL. An association between QOL mean scores and occupation of the respondents by using Pearson's Chi Square elicited the computed χ2value (17.575) greater than table value (5.991) at df 2 with a p value of <0.001. As the p value is <0.05it is concluded that there is a strong association between QOL and occupation.

Table 4.10: Association between QOL and marital status of the respondents, n = 200

QOL Score	*f* / %	Marital status		Total	χ^2	p value
		unmarried	Married			
Poor	*f*	0	6	6	1.286	0.526
	%	0%	3.1%	3%		
Average	*f*	2	119	121		
	%	40%	61%	60.5%		
Good	*f*	3	70	73		
	%	60%	35.9%	36.5%		
Total	*f*	5	195	200		

Table Value =5.991, df = 1, *p<0.05

Table 4.10 reveals that among 200 respondents, 195 were married and less than half (36.5%) among them had good QOL whereas among 5 unmarried respondents more than half (60%) had good QOL. An association between QOL mean scores and marital status of the respondents by using Pearson's Chi Square elicited the computed χ2value (1.286)lesser than table value (5.991) at df 1 with a p value of 0.526. As the p value is <0.05it is concluded that there is no association between QOL and marital status.

Table 4.11: Association between QOL and parity of the respondents, n = 200

QOL Score	*f* / %	Parity				Total	χ^2	*p* value
		Nullipara	Parous (1-2)	Parous (3-4)	Grandmultiparous (>4)			
Poor	*f*	0	0	0	6	6	44.170	<0.001*
	%	0%	0%	0%	23.1%	3%		
Average	*f*	9	60	38	14	121		
	%	60%	66.7%	55.1%	53.8%	60.5%		
Good	*f*	6	30	31	6	73		
	%	40%	33.3%	44.9%	23.1%	36.5%		
Total		15	90	69	26	200		

Table Value =12.592, df = 6, *p<0.05

Table 4.11shows that among 200 respondents, 69 were with pariy of 3-4 and 44.9% among them had good QOL. Moreover among 15 nulliparous 40% had good QOL. However among 26 grand-multipara a very few (23.1%) had good QOL. An association between QOL mean scores and parity of the respondents by using Pearson's Chi Square elicited the computed χ2value (44.170)greater than table value (12.592) at df 6 with a p value of <0.001. As the p value is <0.05it is concluded that there is strong association between QOL and parity.

Table 4.12: Association between QOL and type of family of the respondents, n = 200

QOL Score	f / %	Type of family			Total	χ2	P value
		Nuclear	Joint	Extended			
Poor	*f*	0	6	0	6	23.644	<0.001*
	%	0%	5.6%	0%	0%		
Average	*f*	52	59	10	121		
	%	80%	55.1%	35.7%	60.5%		
Good	*f*	13	42	18	73		
	%	20%	39.3%	64.3%	36.5%		
Total	*f*	65	107	28	200		

Table Value =9.488, df = 4, *p<0.05

Table 4.12shows that among 200 respondents, 28 were living in extended family and more than half (64.3%) among them had good QOL. However among 65 respondents living in nuclear family a very few had good QOL. An association between QOL mean scores and type of family of the respondents by using Pearson's Chi Square elicited the computed χ2value (23.644) greater than table value (9.488) at df 4 with a p value of <0.001. As the p value is <0.05it is concluded that there is strong association between QOL and type of family.

Table 4.13: Association between QOL and individual income of the respondents, n = 200

QOL Score	f / %	Individual Income			Total	χ^2	*p* value
		<2000	2001-6000	10001-20000			
Poor	f	6	0	0	6	1.253	0.869
	%	3.2%	0%	0%	3%		
Average	f	115	3	3	121		
	%	61.2%	50%	50%	60.5%		
Good	f	67	3	3	73		
	%	35.6%	50%	50%	36.5%		
Total	f	188	06	06	200		

Table Value =9.488, df = 4, *p <0.05

Table 4.13 shows that among 200 respondents, 06 were earning Rs. ≥2000 – 20,000 monthly and half of them (50%) had good QOL whereas among 188 respondents earning ≤ Rs. 2000 less than half (35.6%) had good QOL. An association between QOL mean scores and individual income of the respondents by using Pearson's Chi Square elicited the computed χ2value (1.253) lesser than table value (9.488) at df 4 with a p value of 0.869. As the p value is >0.05it is concluded that there no association between QOL and individual income.

Table 4.14: Association between QOL and family-income of the respondents, n = 200

QOL Score	*f* / %	Family-income		Total	χ^2	*p* value
		<20,000	20,001-40,000			
Poor	*f*	6	0	6	0.607	0.738
	%	3.1%	0.0%	3%		
Average	*f*	118	3	121		
	%	60.8%	50.0%	60.5%		
Good	*f*	70	3	73		
	%	36.1%	50.0%	36.5%		
Total	*f*	194	06	200		

Table Value =5.991, df = 2, *p <0.05

Table 4.14 shows that among 200 respondents, 06 were earning Rs.20,000 – 40,000 monthly and half of them (50%) had good QOL whereas among 194 respondents earning ≤ Rs. 20,000 less than half (36.1%) had good QOL. An association between QOL mean scores and family income of the respondents by using Pearson's Chi Square elicited the computed χ2value (0.607) lesser than table value (5.991) at df 2 with a p value of 0.738. As the p value is >0.05it is concluded that there no association between QOL and family income.

Table 4.15: Association between QOL and diagnosis of cancer, n = 200

QOL Score	f / %	Diagnosis			Total	χ^2	***p* value**
		CX	OV	EN			
Poor	f	103	38	12	153	8.788	0.067
	%	80.5%	74.5%	57.1%	76.5%		
Average	f	22	13	9	44		
	%	17.2%	25.5%	42.9%	22%		
Good	f	3	0	0	3		
	%	2.3%	0%	0%	0%		
Total	f	128	51	21	200		

Table Value =9.488, df = 4, *p <0.05

Table 4.14 shows that among 200 respondents, 128 suffered from carcinoma cervix and a very few (3%) had good QOL whereas none of the respondents suffering from carcinoma ovary and endometrium had good QOL. An association between QOL mean scores and cancer diagnosis of the respondents by using Pearson's Chi Square elicited the computed χ2value (8.788) lesser than table value (9.488) at df 4 with a p value of 0.067. As the p value is >0.05it is concluded that there no association between QOL and cancer diagnosis.

Table 4.16: Association between QOL and stage of cancer, n = 200

QOL Score	f / %		Stage of cancer			Total	χ^2	*p* value
		Stage I	Stage II	Stage III	Stage IV			
Poor	f	46	67	40	0	153	15.350	0.018*
	%	79.3%	73.6%	83.3%	0%	76.5%		
Average	f	12	21	8	3	44		
	%	20.7%	23.1%	16.7%	100%	22%		
Good	f	0	3	0	0	3		
	%	0%	3.3%	0%	0%	1.5%		
Total	f	58	91	48	3	200		

Table Value =12.592, df = 6, *p<0.05

Table 4.16shows that among 200 respondents, 91 were in advanced stage II of cancer and a very few among them (3.3%) had QOL whereas none of the respondents in other stages of cancer had good QOL. An association between QOL mean scores and type of family of the respondents by using Pearson's Chi Square elicited the computed χ2value (15.350) greater than table value (12.592) at df 6 with a p value of 0.018. As the p value is <0.05it is concluded that there is strong association between QOL and stage of cancer.

Table 4.17: Association between QOL and treatment of cancer, n = 200

QOL Score	*f / %*	Treatment of cancer				Total	χ^2	*p* value
		Surgery	Chemo	Radiation	Combination			
Poor	*f*	19	33	91	10	153	3.725	0.714
	%	76%	71.7%	78.4%	76.9%	76.5%		
Average	*f*	6	13	22	3	44		
	%	24%	28.3%	19%	23.1%	22%		
Good	*f*	0	0	3	0	3		
	%	0%	0%	2.6%	0%	1.5%		
Total	*f*	25	46	116	13	200		

Table Value =12.502, df = 6, *p <0.05

Table 4.17 shows that among 200 respondents, 116 had undergone radiation therapy and only a very few of them (2.6%) had good QOL whereas none of the respondents who underwent other treatment modalities had good QOL. An association between QOL mean scores and cancer treatment of the respondents by using Pearson's Chi Square elicited the computed χ2value (3.725) lesser than table value (12.502) at df 6 with a p value of 0.714. As the p value is >0.05it is concluded that there no association between QOL and cancer treatment.

Major findings of the study

The main findings of the study reveals that the 200 respondents with gynecological cancer undergoing gynec-oncological therapy had an average level of QOL with mean scores 64.7 (±15.2). Moreover, the role (89.6 ±18.1), physical (78.9 ±15.2), cognitive (75.5 ±19.9), and social functioning (68.8 ±22.6) of the respondents were high. However, the respondents scored low on symptom scale except constipation (40.6 ±38.8) and fatigue (39.4 ±23.9) which implies that they were not very symptomatic.

Among specific gynecological cancers almost all the respondents scored high on sexual functioning and body image perception. Carcinoma cervix respondents scored low on symptom scale (<33.3). However, menopausal symptoms were the most common problem experienced by the respondents. Moreover, carcinoma ovary respondents experienced peripheral neuropathy, and their attitude toward disease was affected at an average level whereas other symptoms scored low on scale which is supported by the fact that neuropathy is significantly co-related with female hormones. [53] Similarly, carcinoma endometrium respondents also scored moderate level on symptom scale except urological symptoms (5.9 ±14.9) and taste change (14.2 ±16.9).

The association of QOL mean scores with selected research variablesreveals that QOL is associated with age, occupation, parity, type of family and cancer stage of respondents. However association of QOL mean scores with education, marital status, individual income, family income, diagnosis and cancer treatment could not be established.

7.1 Summary

This chapter dealt with the analysis and interpretation of data collected from gynecological cancer patients undergoing gynec-oncological therapy. Descriptive and inferential statistics were used for analysis. The sample characteristics were described using frequency and percentage. The assessment of quality of life is done on the basis of mean and SD whereas association between QOL scores and research variables was done by using Pearson Chi Square test. Most of the respondents had an average level of QOL with mean score of 64.7. Respondents had higher functional scores than symptom scores suggestive of better QOL. In addition to this, QOL mean score found to be significantly associated with the age, occupation, parity, type of family and cancer stage of respondents. However, association of QOL mean score with education, marital status, individual, and family income, diagnosis and cancer treatment could not be established.

7. Discussion

Discussion in research aids in interpreting and describing the significance of study findings in light of what is already known about the research problem under investigation and explain any fresh insights about it after considering the current research findings. This non experimental descriptive cross-sectional study was undertaken to assess the QOL and associated factors among patients with gynecological cancer undergoing gyneco-oncological therapy in a selected tertiary care hospital in Kolkata, wherein 200 patients were the sample size. This research provided data relevant to the existing knowledge about QOL and associated factors. The data was collected from 15 Dec 2017 to 16 Jan 2018. The sampling technique followed was purposive sampling. The data regarding QOL was collected using EORTC quality life questionnaire, a standardized tool. The objectives of the study were to assess the QOL and associated factors in patients with gynecological cancers and to identify the association between QOL and selected variables such as socio demographic and clinical characteristics. The main findings relating to the objectives of the study are discussed below.

8. Major Findings of the Study

The main findings of the study reveals that the 200 respondents with gynecological cancer undergoing gynec-oncological therapy had an average level of QOL with mean scores 64.7 (±15.2). Moreover, the role (89.6 ±18.1), physical (78.9 ±15.2), cognitive (75.5 ±19.9), and social functioning (68.8 ±22.6) of the respondents were high. However, the respondents scored low on symptom scale except constipation (40.6 ±38.8) and fatigue (39.4 ±23.9) which implies that they were not very symptomatic.

Among specific gynecological cancers almost all the respondents scored high on sexual functioning and body image perception. Carcinoma cervix respondents scored low on symptom scale (<33.3). However, menopausal symptoms were the most common problem experienced by the respondents. Moreover, carcinoma ovary respondents experienced peripheral neuropathy, and their attitude toward disease was affected at an average level whereas other symptoms scored low on scale which might be due to the chemotherapy induced side effects which are seen more in patients with carcinoma ovary. Similarly, carcinoma endometrium respondents also scored moderate level on symptom scale except urological symptoms (5.9 ±14.9) and taste change (14.2 ±16.9).

The association of QOL mean scores with selected research variables reveals that QOL is associated with age, occupation, parity, type of family and cancer stage of respondents. However association of QOL mean scores with education, marital status, individual income, family income, diagnosis and cancer treatment could not be established.

8.1 Distribution of the respondents as per their socio-demographic profile under study

Analyzing the demographic data of 200 respondents whose QOL was assessed, it was seen majority (79%) belonged to the age group 45-64 years. More than half (51%) were illiterate and only a few (4.5%) were graduates and above. Maximum respondents (88%) were unemployed and housewives. Majority of the respondents (97.5%) were married and only 2.5% were unmarried. Similarly, majority (92.5%) were parous and the rest (7.5%) were nulliparous. Many of them (67.5%) hailed from joint or extended families and the rest belonged to nuclear families. Majority of the respondents (94%) had self- income less than Rs. 2000/- monthly and large part of them (97%) belonged to low socioeconomic group with a monthly family income less than Rs. 20,000. These figures are consistent with the previous research work carried out in various regions of India which is suggestive of the homogeneity and high representativeness of the selected population (Nanjaiah R et al, 2017; Satwe S et al, 2014; Verma A et al, 2017; Thulaseedharan JV et al, 2012). [2] [53] [54] [55] None of the studies in the past stressed upon individual income of the women and its association with QOL. However researcher strongly believes that individual income might be closely associated to QOL as it gives a sense of economic independence to the individual (Stephen Hicks, National Statistics, UK). [42]

8.2 Distribution of the respondents as per theirclinical characteristics under study

Among 200 patients who were assessed for their QOL, many of the (64%) respondents were diagnosed with carcinoma cervix and nearly quarter (25.5%) of them with carcinoma ovary and a few (10.5%) with carcinoma endometrium. Many (69.5%) of the respondents were in advanced stage II/III of the gynecological cancer and a very few (1.5%) were in late stage IV. More than half (58%) of the respondents had undergone radiation therapy as the treatment modality whereas for the rest it was surgery, chemotherapy or a combination of treatment modalities that were used. These clinical characteristics are similar to the statistics given by American Cancer Society, 2018[5] and are also found to be consistent with the previous research work carried out nationally and globally on gynecological cancer patients (Daily Excelsior, 2014; CFI cancer statistics, Kolkata; Sharma DC et al, 2016; Dahiya N et al, 2017).[9] [10] [56] [57] However, slight difference in the clinical characteristics is reported in a study by Chagani P et al, 2017, on quality of life and its determinants among gynecological cancer patients in Pakistan that reported carcinoma ovary as the most prevalent cancer and chemotherapy as the commonest treatment modality used there.[58]

8.3 Discussion as per objectives in relation to other studies

1) Assessment of the QOL and associated factors

Assessment of 200 gynecological cancer respondents undergoing gynec-oncological therapy was done and it was found that many of the respondents (60.5%) perceived an average level of QOL whereas less than half (36.5%) perceived poor QOL and a very few (3%) perceived good QOL. The mean scores of QOL found to be 64.7 which is consistent with the average level QOL mean scores after 4th week of radiation therapy among 16 gynecological cancer patients (Satwe S et al, 2014).[53] However, QOL mean scores in the present study are better in comparison to a previous study by Hossain N et al, 2016 where poor QOL was reported with mean score of 45.[59] Moreover, study results are also found to be consistent with previous studies where improved QOL had been reported regardless of the treatment related side-effects which could be due to relief from acute symptoms of cancer (Pasek et al, 2013; Vaz AF et al, 2011). [28][60]

In addition to this, the respondents had high functional mean scores in comparison to the mean scores on symptoms scale which justifies the moderate level of QOL among most of the (60.5%) respondents. This can be explained on the basis of previous studies (Bjordal K et al, 2000; Fayers P et al, 2002; EORTC scoring manual, 2010) which states that higher functional status leads to overall better QOL.[45] [46] [61] Moreover, good level of role, physical, cognitive and social functioning might be contributed to the relief from acute symptoms of cancer immediately after one month of treatment as suggested by the previous study (Bisht M et al, 2010)[22] whereas high social functioning could be because of strong family support (Pradjatmo H et al, 2017).[34] However, emotional functioning had average mean scores (49.1 ±28.8) which is consistent with the findings of previous studies where emotional problems have been found to be the most unmet need (Pearman T, 2003)[62] and high level of emotional distress had been contributed to the avoidant coping mechanisms and pessimism (Pearman T, 2003; M Kristen, 2008).[62] [63]

However major problem faced by the respondents was financial difficulty which might be contributed to their poor socio-economic status. Moreover, among symptoms experienced by the respondents, most common were constipation and fatigue which might be because of unwanted side-effects of the onco-therapies (Ustundag S et al, 2015).[33]

Additionally, assessment of QOL among specific gynecological cancer patients revealed that the respondents had good level of sexual functioning and body image perception which might be due to good level of role, physical, cognitive and social functioning. This finding is supported by previous study where body image is found to be significantly associated with mental, physical and sexual health (T Jessica et al, 2007).[64] Moreover, this can be contributed to the concept of sexual self-schema defined as cognitive generalizations about sexual aspects of oneself. Respondent's positive sexual self-schema must have helped respondents to counteract the effects of cancer and its treatment. All the more, sexual satisfaction have been found to be more strongly associated with the intimate and sensual aspects rather than with the act of coitus (I Juraskova et al, 2002). [65]

The symptom status of the respondents suffering from carcinoma cervix was found to be low in the present study whereas the respondents who suffered from carcinoma ovary experienced an average level of peripheral neuropathy and their attitude towards disease was also affected in moderate amount. However, respondents with carcinoma endometrium experienced multiple symptoms such as lymphedema, GI symptoms, pain in back & pelvis, tingling/numbness, muscular pain and hair loss. These findings suggest that respondents with carcinoma endometrium were experiencing more symptoms which might be contributed to the advanced stage of the cancer. This is supported by the evidence from previous study where it has been suggested that prognosis of endometrial cancer is poor in advanced stages (I Gungor et al, 2017). [35] In addition to this increased morbidity has been observed in carcinoma ovary and endometrium post treatment. (Temkin Sarah M et al, 2016).[66] However, none of the respondents who suffered from carcinoma ovary, were facing problem of hair loss which could be justified as it is a temporary condition which get reversed on cessation of treatment, additionally interval between hair loss and cessation of treatment is unpredictable (Von Gruenigen VE et al, 2010).[27]

2) Association between QOL with selected research variables such as socio demographic and clinical data

The association of QOL mean scores with selected socio-demographic variables and clinical characteristics was done by applying Pearson's Chi Square Test. The results were considered to be significant with p-value less than 0.05 and at confidence interval of 95%.

There was significant association of QOL mean scores with age of the respondents ($p = 0.023$) suggestive of a strong relationship between age and QOL. The results of the current study reveals that percentage of good quality of life increased with increasing age. This finding is supported by many research evidences which have suggested that younger patients' QOL was affected more negatively and cancer specific distress was significantly higher in them whereas older patients more effectively managed their stress related to cancer diagnosis (Yoo SH et al, 2013; Nipp RD et al, 2016; Pfaendler KS et al, 2015). [36] [67] [68] However, in contrast to this few studies have also suggested that elderly people commonly get affected because of cancer and its treatment thus reduced global QOL among patients older than 40 years of age (Damodar G et al, 2014; Nipp RD et al, 2016). [67] [69]

No statistically significant relationship was found between QOL score and education of the patient ($p = 0.129$). However the trend in the current study revealed that QOL score was maximum in patients with education level of graduation or above which is consistent with the previous studies where it has been reported that QOL worsened when education level was low. Also, patients had worse physical, social, and role functions and experienced more side effects in the poorly educated group which might be because of their poor health seeking behavior (Ustundag S et al, 2015; I Gungor et al, 2017; Knight SJ et al, 2007; Ayana Birhanu A et al, 2018). [33] [35] [70] [71]

However, a strong statistically significant association was found between QOL score and occupation of the respondents (p =<0.001). The findings of current study gives a clear picture that percentage of good QOL was more among employed respondents as compared to the unemployed ones. This is consistent with the previous studies where worse physical and social wellbeing have been observed among housewives than other occupations. Lower QOL levels in housewives might be because of the lack of social life and their poor social support whereas good QOL in employed patients is found to be associated with good social support and economic stability (Ustundag S et al, 2015; Ogoncho Isaac Machuki et.al, 2015).[32] [33]

No statistically significant relationship could be established between QOL score and marital status of the patients (p = 0.526). Yet it is revealed by the findings of the current study that unmarried patients had better QOL as compared to married patients. This is not in favor with the findings of a previous study according to which married or partnered women had high level of social support and so better QOL. So current findings can be justified as marriage might not be an important factor but social support could have led to an effect on QOL (Knight SJ et al, 2007).[70] Additionally females are identified with household work, childbearing and rearing. Women happily adapt to these roles, however disturbances in these roles due to disease or treatment might greatly affect QOL (Chagani P et al, 2017).[58]

Association of QOL scores was found to be highly significant with parity of the patients (p = <0.001). The trend of the current study revealed that nulliparous and the parous respondents with parity of 3-4 had good QOL whereas grand-multiparous had poor QOL. This is consistent with findings of previous study which states that pregnancy being an important event for reproductive-age women, changes during this period might significantly decline the health status during and after pregnancy thus responsible for poor QOL (Singh S et al, 2015).[72] However, good QOL among respondents with 3-4 parity is supported with an evidence from the previous study by Oliveira M F De et al, 2015 which states that having more than one child is associated with high QOL because maternal memory and responsiveness increases with each child thus increasing their adaptability.[73]
A statistically significant association was found between QOL and the type of family (p= <0.001). Moreover, good QOL was observed more among extended families. This could be justified as positive effect of family support is observed on the social functioning of the cancer patients thus enhancing QOL. Family support has been identified as an enhancing factor for QOL of an individual against a life threatening disease condition or treatment (Banovcinova L et al, 2016; Ustundag S et al, 2015). [33] [74] Contrary to this, in a study by H Pradjatmo et al, 2017 on QOL among 62 cervical cancer patients in Indonesia revealed no significant association between QOL and the type of family in which they were living.[34]

Moreover, no statistically significant association could be established between the QOL scores and individual income of the respondents (p =0.869). However, the findings of the study revealed that good QOL was seen in all the patients who were earning a monthly income more than Rs. 2001/-. This finding is supported in a previous study by Banovcinova L et al, 2016 which suggests that high income leads to better social networks thus enhancing QOL among cancer patients.[74] Additionally, more income allow an individual to satisfy his preferences leading to improved QOL (Stephen Hicks, National statistics, UK). [42]

Similarly, association between QOL and the family income was not found to be statistically significant (p =0.738). However, the trend in current study revealed better QOL among patients earning a monthly income Rs. 20,000. This finding is consistent with other studies where it had been suggested that low income leads to poor resources, thereby reducing the level of QOL (I Gungor et al, 2017). [35] Moreover, patients facing financial difficulties had significant negative association with QOL (Chagani P et al, 2017). [58] On the contrary, no association of QOL with family income might be due to strong social support and better coping strategies.

Moreover, no significant association was found between the QOL scores and the diagnosis of cancer (p =0.067). However the trend of current study findings revealed that respondents suffering from carcinoma cervix had more poor level of QOL as compared to carcinoma ovary and endometrium. This finding is consistent with other studies where patients with carcinoma endometrium had better QOL scores in comparison to the other gynecological cancers. This could be due to the fact that when diagnosed early tends to have better prognosis, slow growth rate and late metastasis thereby leading to high QOL (Goker A et al, 2011; Ogoncho I M et.al, 2015). [32] [75] However, women with cervical and ovarian cancer receive radiation and/or chemotherapy, thus leading to a strong impact on their QOL (Sekse RJ et al, 2015). [76]

The current study revealed a strong and statistically significant association between the QOL and the stage of cancer (p = 0.0180). Moreover, most of the respondents were in advanced stage of cancer and poorest level of quality was observed in stage III. These findings are consistent with previous studies which have reported deterioration of role functioning with increasing stage of the disease condition (Ainuddin HA et al, 2016). [77] Moreover, extensive treatment in later stages of gynecological cancer might significantly contribute to decrements in quality of life due to the treatment complications (Hengrasmee P et al, 2004). [78]

However, no statistically significant association was found between the QOL scores and the treatment modality used for the patients (p =0.714). This is consistent with findings of previous research work that states QOL scores were not affected with different treatments (Goncalves V et al, 2013). [79] It has been suggested that treatment modality of disease might not affect the QOL. (Hossain N et al, 2016). [59] As per the current study findings respondents who underwent radiation therapy had the poorest level of QOL in comparison to other treatment modalities which might be due to more adverse effects of radiation therapy (Pfaendler KS et al, 2015). [68]

Summary

The present research study provides data relevant to the existing knowledge about QOL among gynecological cancer patients undergoing gynec-oncological therapies. Major findings revealed that respondents had an average level of QOL whereas they had high level of functional status. However, respondents experienced low levels of symptoms which was contributed to the treatment modalities used in them. Good level of role, physical, cognitive, and social functioning was contributed to the treatment and strong family support whereas average emotional functioning was explained on the basis of individual coping mechanism and pessimism.

Moreover, major problem among respondents was found to be financial difficulty as majority of the respondents belonged to the poor socio-economic status. In addition to this, good level of sexual functioning brought fresh insights about the concept of sexual self-schema and role of intimacy and sensuality in improving sexual satisfaction. Also no hair loss among carcinoma ovary patients post treatment was a new finding in current study.

Additionally increased age, occupation, increased parity, type of family and advanced stage of cancer seemed to be significantly associated with the QOL score. However, no significant association could be established between QOL and education, marital status, individual as well as family income, diagnosis and treatment modality used among respondents.

9. Limitations

1) The present study has the following limitations:
2) The study was restricted to the gynecological cancer patients undergoing gyneco-oncological therapy in a selected tertiary care hospital which limits its generalization.
3) The cross-sectional design of the study led to decreased interaction with the respondents related to their sexuality issues.
4) The non-probable purposive sampling technique that led to chance of sampling bias.
5) No control on extraneous variables like previous experiences or any exposure to such interviews or interactive session from family members, mass and print media.

Nursing Implications

Women are strong pillar to the growth and success of any country so their welfare is a need of the hour. It is important to find ways to improve QOL of women so as to achieve the nation's wealth. The findings of this study have several implications for the nursing profession such as in nursing practice, nursing education, nursing research and nursing administration.

Nursing practice: Indian women have a poor health seeking behavior which might be due to many reasons such as poor socio-economic status, more responsible position in family, and being considered as the weaker sex in the community. They come to the health care settings at an advanced stage of disease which presents as a big challenge to the health professionals. A nurse midwife practitioner can strive for improvement in her knowledge and skills in assessment of QOL. She can consider the use of QOL questionnaires in her day to day practice as detailed history taking instruments. Health related tools can be used by midwives in assessment of the impact of onco-therapies on the general health of patients which can be further utilized in planning effective nursing care and modifying therapies. QOL tools can be used by midwives in improving her communication and interaction with the patients thus providing psychological support to them. Role of nurse midwife practitioner can be expanded as counsellor for patients and their families in hospital as well as in OPD.

Nursing education: Nursing students of today will be the future nurses of tomorrow so it becomes important in the present era that nurses do not leave the healing touch at the cost of technology. Such studies might prove to be as basis for their theoretical knowledge. Implementation of health related questionnaire in their clinical experience can help nursing students in improving their practical skills of assessment, history taking, early identification of signs and symptoms in such patients. Moreover, students can plan nursing care, nursing theories, new models of caring for cancer patients. In addition to this nursing students can improve their communication skills. Use of health related QOL questionnaires in their day to day practice serves as a platform for enhancing their knowledge in psychological aspects of the patients. Further, such research studies help student in understanding the determinants of QOL. Nursing students can plan and conduct various IEC activities in their clinical practice about the prevention, early screening and diagnosis of gynecological cancer. Students may be sensitized about the expanded role of nurse as a comprehensive care provider.

Nursing administration: Nurse Administrator has great responsibility on their shoulders, therefore such studies and QOL tools can be used to educate and screen the public, and staff through various IEC activities at wider community level. She can liaison for the conduct of various programs on enhancement of QOL for gynecological cancer patients. She can conduct various screening programs where associated factors of QOL can be more prioritized. Nurse Manager in the obstetrics and gynecology department can undertake or direct the nurses working under her to include QOL as a care aspect and may facilitate change. She can bring change in the counselling environment for the affected patients and their families by providing counselling rooms, rest rooms, rehabilitation hall, etc.

Nursing research: As a researcher there is lot of scope in this area to explore many unknown determinants of QOL for which further research can be continued. Various coping strategies to enhance the QOL can be researched upon. The current study emphasizes the need for more research relate to the sexuality and sexual issues. Further, research should be undertaken to assess use the coping strategies by patients at the time of diagnosis, and during their survival years after treatment. This should also examine the women's attitude towards their disease condition and treatment. This would lay foundation for better midwifery services keeping in view the Indian value, cultural beliefs, and social available to these patients.

10. Suggestions and Recommendations

Keeping in view the findings of the current study, the following recommendations rae drawn for future practice and research:

Support strategies to decrease the emotional distress, anxiety, fear related to the disease and treatment among gynecological cancer patients may be planned at hospital and OPD level.

Counselling sessions for gynecological cancer patient as well as for their family members may be conducted on regular basis by the nurse midwifery practitioner so as to deal with their concerns and worries on day to day basis.

A nurse specialized in cancer care may be posted in cancer clinics who will be responsible for providing education to the patients and their families regarding management of disease condition and side effects related to onco-therapy.

Public awareness campaigns can be organized at community level which will encourage patients for screening and thereby in providing detection of cancer in early stages.

The post of counselor may be created in the cancer clinics for providing to the patient and their families at the time of diagnosis, start and end of treatment and at the time of discharge.

A study may be planned to develop a structural QOL questionnaire that can be easily applied to the Indian population. Similar studies may be replicated on large samples to examine more closely the level of quality and its associated factors among gynecological cancer patients.

A longitudinal research study may be conducted to identify the incidence of psychological problems among gynecological cancer patients and their correlation with QOL.

11. Conclusion

The research study "A study on assessment of the quality of life and associated factors among patients with gynecological cancers undergoing gyneco-oncological therapy in a selected tertiary care hospital in Kolkata" was conducted following all the steps of the quantitative research study. This descriptive non-experimental cross-sectional study was conducted from December 2017-January 2018 among 200 gynecological cancer patients undergoing gyneco-oncological therapy with an aim to assess QOL and associated factors. As per the inclusion criteria, samples were selected by the purposive sampling. Ethical clearance from the institution was accomplished, consent was taken and privacy of the samples were maintained. The tool for data collection consisted demographic and clinical data. A standardized tool by EORTC was used to assess QOL and association between QOL and associated factors was established. SPSS 20 was used for data analysis.

The data was analyzed by descriptive (mean, frequency, percentage) and inferential (Pearson Chi Square test) statistics. The study results revealed an average level of QOL and high level of role, physical, cognitive, and social functioning. In addition to this, QOL was found significantly associated with age, occupation, parity, type of family, and cancer stage. The findings from the study contributed deep understanding of QOL and its determinants. It also provides suggestions for future research.

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