

# Research protocol

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## **Introduction:**

Fertility is one of the key aspects of quality of life for young cancer patients and survivors and hence it should be protected and preserved.

Fertility preservation (FP) is receiving increasing attention as an evolving area of reproductive medicine and it aims to protect, preserve, and store gametes and/or reproductive tissue for future use.

There is still a huge lacuna in fertility preservation services and so there is an urgent need for priming, spreading awareness, and educating specialist doctors involved in the treatment of cancer about fertility preservation and its advantages. Currently, not many studies exist in India that question the knowledge and attitude of professionals towards the discussion of fertility preservation with the patients.

Global Cancer Statistics mentioned that there are 19.3 million new instances of cancer worldwide in 2020. Long-term predictions show that, by 2030, there would be a 1.8-fold rise in cancer incidence. According to data from the Saudi Cancer Registry in 2018, the prevalence of cancer among the Saudi Arabia population had been reported to be increasing in both males and females. Despite advancements in chemotherapy drugs that are more effective, their toxicity to reproductive organs results in long-term fertility consequences that are frequently irreversible, such as infertility and sterility, which affect patients' quality of life. Ideal conditions for cancer treatment include early identification, efficient therapy, and rapid posttreatment care.

One of the negative consequences of successful cancer treatment is impaired fertility. Cancer patients' future quality of life is impacted if they are diagnosed before or during their reproductive years. Reproductive endocrinology fertility cryopreservation technologies give hope to cancer survivors for life following cancer treatments.

## **Background: -**

Fertility preservation (FP) refers to the extension of the reproductive window through preservation of gametes and gonadal tissue (oocyte, sperm, embryo, ovarian and testicular tissue). Contemporary advances in assisted reproductive technology allow for safe long-term storage of gametes, permitting their use to achieve pregnancy at a later more convenient time. Initially used in oncofertility, use of FP has now been extended to women at risk of infertility due to decreasing ovarian reserve associated with age, medical disorders or genetic conditions.

The incidence of cancer among children, adolescents and young adults is on the rise and 80% survive. Fertility preservation is not practiced due to lack of knowledge of affects of cancer and its therapy on fertility and the availability of fertility preservation methods. The objective of this study was to assess Knowledge, Attitude and Practice (KAP) of Fertility preservation among parents of adolescents, young adults and among young adults at base line and after intervention of a dedicated health education programme.

Although the prevalence of infertility after cancer treatment and the health of the offspring of survivors have been studied, little information has been available about survivors' attitudes, emotions, and choices with regard to having children.

Improved chemotherapy and radiotherapy treatment protocols, fortunately, increased the rates of cancer survivors over the years. However, these treatments may result in infertility or subfertility. Oncologists are considered the gateway for knowledge about cancer and its treatments' effects. Several studies showed that many oncologists do not discuss fertility preservation with their patients. This study aimed to explore the perspective of oncologists in Oman on fertility preservation.

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## Need of the study:-

The need and importance of FP and oncofertility is underscored by the knowledge of a rising cancer incidence in the young, the damaging effect of cancer treatments on gametes, increasing number of cancer survivors and their desire to live a fulfilled life, which includes having their biological offspring. The global upsurge in cancer has been attributed to rapid industrialization, urbanization, change in lifestyle and an increase in life expectancy.

## Review of literature:-

### Literature related to fertility preservation among cancer patients:

Ha'Aliyah St, Haifa 31096, Israel (2012) The overall increase in cancer prevalence and the significant increase in long-term survival have generated worldwide interest in preserving fertility in young women exposed to gonadotoxic chemo- and radiotherapy. Infertility represents one of the main long-term consequences of combination chemotherapy given for lymphoma, leukemia and other malignancies in young women. The gonadotoxic effect of various chemotherapeutic agents is diverse, may involve a variety of pathophysiologic mechanisms, and is not unequivocally understood. , such as in tissues with high turnover (i.e. bone marrow, gastrointestinal tract and growing ovarian follicles) are more vulnerable to the toxic effect of alkylating agents. These agents may also be cytotoxic to cells at rest, as they are not cell-cycle specific. Alkylating agents, the most gonadotoxic chemotherapeutic medications, cause dose-dependent, direct destruction of oocytes and follicular depletion, and may bring about cortical fibrosis and ovarian blood-vessel damage. The reported rate of premature ovarian failure after various diseases and chemotherapeutic protocols differ enormously, and depend mainly on the chemotherapeutic protocol used and age range of the woman. Several options have been proposed for preserving female fertility, despite gonadotoxic chemotherapy: ovarian transposition, cryopreservation of embryos, unfertilized metaphase-II oocytes and ovarian tissue, and administration of gonadotropin-releasing hormone agonistic analogs in an attempt to decrease the gonadotoxic effects of chemotherapy by simulating a prepubertal hormonal milieu. None of these methods is ideal and none guarantees future fertility in all survivors; therefore, a combination of methods is recommended for maximizing women's chances of future fertility.

Monica Ruggeri o, OMalkahi Abulkhair h (2015) Young patients with breast cancer (BC) are often concerned about treatment-induced infertility and express maternity desire. Conception after BC does not seem to affect outcome, but information in estrogens-receptor positive (ER+) disease is not definitive. From September 2012–March 2013, 212 evaluable patients with ER+ early BC, <37 years at diagnosis, from 5 regions (Europe/US/Canada/Middle-East/Australia) answered a survey about fertility concern maternity desire and interest in a study of endocrine therapy (ET) interruption to allow pregnancy. Overall, 37% of respondents were interested in the study; younger patients ( $\leq 30$  years) reported higher interest (57%). Motivation in younger patients treated >30 months was higher (83%) than in older women (14%), interest was independent of age in patients treated for  $\leq 30$  months. A prospective study in this patient population seems relevant and feasible. The International-Breast-Cancer-Study-Group (IBCSG), within the Breast-International-Group (BIG) – North-American-Breast-Cancer-Groups (NABCG) collaboration, is launching a study (POSITIVE) addressing ET interruption to allow pregnancy.

Boutas I, Kontogeorgi A, (2023) The most suitable treatments for fertility preservation in young patients is the temporary suppression with luteinizing hormone-releasing analogs, while the patient undergoes chemotherapy and cryopreservation. For cryopreservation, the physicians might deem it necessary to either cryopreserve ovarian tissue taken from the patient before any treatment or cryopreserve embryos/oocytes. Cryopreservation of oocytes and/or embryos is the most effective solution for fertility preservation in women of reproductive age, who have a sufficient ovarian reserve and are diagnosed with breast cancer, regardless of the histological type of the tumor. Because approximately 50% of young breast cancer patients are interested in becoming pregnant right after completion of therapy, the evolution and development of fertility preservation techniques promise to be very exciting.

## **Problem statement:**

**"A study to Assess the knowledge and attitude of cancer patients regarding fertility preservation among patients with cancer in a Oncology hospital, Kolkata."**

## **Objectives:**

1. To assess the level of knowledge of cancer patients regarding fertility preservation.
2. To assess the attitude of cancer patients towards fertility preservation.
3. To determine the association between knowledge of cancer patients and selected demographic variables (age, gender, education, marital status, type of cancer, duration of illness, etc.).

## **Variable: -**

**Research variables:** - knowledge and attitude of cancer patient regarding fertility preservation.

## **Operational definition:**

- ❖ **Knowledge:** The level of knowledge score of cancer patients regarding fertility preservation, measured using a structured knowledge questionnaire.
- ❖ **Attitude:** The feelings, beliefs, and perceptions of cancer patients toward fertility preservation, measured using a rating scale.
- ❖ **Fertility Preservation:** Medical techniques used to safeguard reproductive ability before cancer treatment.

**Research design:** A descriptive cross-sectional research design will be used.

**Research setting:** The study will be conducted in the Tata Medical Center in Kolkata. The setting is selected due to the following reasons:

- Availability of study participants.
- Familiarity of the setting.

**Sampling technique:** Non-probability purposive sampling

**Sample size:** - 100

## **Criteria for sample collection:**

**Inclusion criteria :** In this study

- Diagnosed cancer patients
- Age 18 -35 years
- Willing to participate
- Able to understand Bengali/Hindi/English

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**Exclusion criteria:** In this study

- Critically ill patients
- Patients with cognitive impairment

**Data collection tool: -**

Structured knowledge questionnaire

Rating scale for attitude assessment

**Techniques**

Interview method or self-administered questionnaire,

**Steps of Data Collection:-**

1. Obtain permission from hospital authority
2. Select participants based on criteria
3. Explain purpose and obtain written informed consent
4. Administer questionnaire
5. Collect and verify completed data

**Ethical Consideration: -**

- a. Approval from Institutional Ethics Committee
- b. Informed consent from participants
- c. Confidentiality maintained
- d. Right to withdraw ensured
- e. No harm to participants

**Plan of Statistical Analysis: -**

**1. Descriptive statistics:** Frequency, percentage, mean, standard deviation

**2. Inferential statistics:** Chi-square test (To determine the association between knowledge of cancer patients and selected demographic variables)

**References:**

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