INDIAN FERTILITY SOCIETY

IFS Newsletter

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Fertility Preservation

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Challenges and Dilemmas in Counselling for Fertility Preservation: Legal and Ethical Issues

Introduction

The field of fertility preservation has grown exponentially over last 2-3 decades. With the improving life expectancy of cancer survivors following major advancements in chemotherapy and radiotherapy, cancer survivors suffer from variable degree of gonadotoxic effect. These gonadotoxic effects leave these patients with subfertility/infertility. Oncofertility procedures give variable options of preserving fertility potential in young cancer patients. Most important population in need of these procedure are children, adolescents and young adults (CAYA) diagnosed with cancers before they have completed their reproductive carrier. (1).

Therefore in an effort to balance between “saving life” and “saving fertility”, the sub-speciality of onco-fertility was developed for fertility preservation (FP) besides endocrine functions among young cancer patients (2). Providing timely evaluation and treatment for available fertility preservation options without jeopardizing the cancer treatment has become an essential component of modern oncological care (3).

Further there are many benign indications, where either the disease per se or the treatment of the disease jeopardises the gonadal function. The field of fertility preservation is an expanded area covering the fertility preservation in benign and malignant conditions.

Indications for fertility preservation in women

Different scenarios where women need fertility preservation include:

1. **Cancer-** Women of reproductive age group (WRA) and adolescents and young adults (AYA) diagnosed with cancer need to be informed about effect of the cancer per se or its treatment on future fertility. Women with early-stage gynaecological cancers, such as cervical cancer, may opt for fertility-sparing surgery, such as trachelectomy, while those with advanced cancers may need to explore oocyte or embryo cryopreservation.
2. Genetic (Turner/Turner Mosaic)- due to risk of rapid depletion of oocyte pool
3. Immunological diseases with gonadotoxic therapies
4. Benign gynaecological conditions with potential risk of loss of ovarian reserve – endometriosis
5. Transgender men (assigned female at birth) with male partner

Counselling and Psychosocial support

Considering the huge psychosocial impact of cancer treatment related fertility impairment (4), it is important to discuss and offer fertility preservation options to cancer patients in CAYA groups as early as possible before start of therapy. Health care providers involved should address the fertility concerns and refer them to appropriate reproductive specialists, following a “hub and spoke model”, wherein different oncology/haematology/paediatric units can refer patients to fewer, more experienced reproductive specialists. A multidisciplinary team should be involved in counselling and supporting in the decision making to choose fertility preservation option.

Table 1: Factors to be considered during fertility preservation (FP) counselling

Patient factors	Disease/treatment factors
• Age • Ovarian reserve assessment-S.AMH, AFC • Marital status-presence of partner • Medical history • Hereditary conditions • Contraindications to medical or surgical fertility preservation options ❖ Anaesthetic risks ❖ Thrombotic risk ❖ Infection risk ❖ Risk of haemorrhage in patients with haematological malignancies	• Stage of cancer • Type of cancer (prognosis and risk of ovarian metastases) • Urgency of treatment • Type of anticancer treatment planned • Chemotherapy-Regimen, dose • Radiation therapy-Location of RT field, dose and fractionation • Endocrine therapy • Surgery planned • Duration of treatment • Hormone dependence/sensitivity

Fertility Preservation Options

Figure 1 describes the various FP options available for women going for gonadotoxic therapies. Oocyte, embryo, or ovarian tissue cryopreservation are now widely accepted standard FP strategies. Oocyte/embryo cryopreservation takes at least 2–3 weeks, so may not suitable for all women, particularly for those with aggressive malignancies requiring urgent treatment and are not possible for pre-pubertal girls.

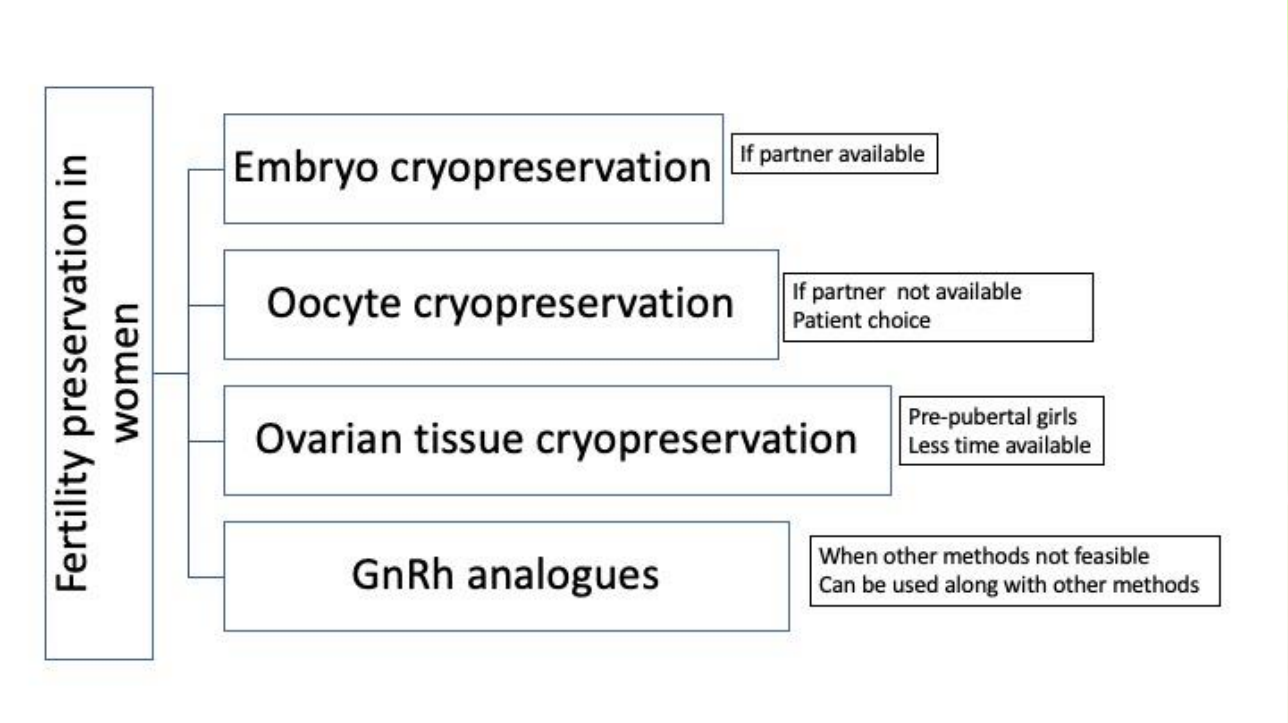

Figure 1- Fertility preservation options for women going for gonadotoxic therapies.

Ethical and legal issues linked with FP

Although FP should be offered to every patient going for gonadotoxic therapy and counselling and discussion should be done about feasible options available, success rates, and real time utility options. But there are few concerns leading to legal and ethical challenges in some situations:

I. Choice of embryo versus oocyte cryopreservation in married women
II. Disposal of embryos/gametes in case of non-utilization.
III. Dilemmas in children and young adolescents, who are not eligible to give valid consent
IV. Oocyte cryopreservation in adolescents
V. Pre-pubertal girls who can't even give assent and not enough mature to understand the procedure
VI. Utility of the gametes/embryos in case of demise of the patient
VII. Duration of freezing

I. Social and ethical issues with oocyte/embryo cryopreservation in married couples

Both are well established methods being used in ART. The choice depends on availability of partner and desire of female to have autonomy over her gametes; oocytes belong to the woman whereas embryos belong to the couple. Considering the legal issues of losing reproductive autonomy that can arise at the time of using vitrified embryos, women with a partner should be offered the option of oocyte cryopreservation, embryo cryopreservation or to split the oocytes for both embryo and oocyte cryopreservation (5). One potential issue is the question of embryo ownership if a couple's relationship dissolves, which blocks the autonomy of the person over her gametes as other partner has equal right over the embryos. She can't use the embryos without consent of the partner which may require legal intervention. In such cases, the embryos could be awarded to one party which becomes difficult due to equal genetic right on the embryos. To avoid this, patient may be counselled and offered the option to cryopreserve unfertilized oocytes or to split the oocytes to attempt both embryo and oocyte cryopreservation (Fgure 2). Legal considerations regarding joint ownership of embryos must be discussed. Table 2 compares the pros and cons of oocyte and embryo cryopreservation.

Table 2-Comparison of embryo cryopreservation and oocyte cryopreservation

Embryo cryopreservation	**Oocyte cryopreservation**
Pros • Higher success/pregnancy rate • Less no. egg retrieval procedures • Better survival on thawing back	**Pros** • No sperm required • Maintains reproductive autonomy and promotes social justice. • Easy to discard
Cons • Loss of autonomy of woman • Controversial procedure in some communities • Difficult to discard	• **Cons** • More fragile and labile to cryopreservation than embryos • More no. of eggs are needed to increase pregnancy rates

II. **Discarding the embryos if not needed**- Discarding embryos might pose a complicated moral dilemma as may not be allowed in certain faiths and in some communities due to religious reasons. However, freezing unfertilized eggs might make the decision to discard them easier, as they won't result in a viable pregnancy unless fertilized. Considering the social and ethical dilemmas related to embryo cryopreservation and problems related to utilisation and discarding, oocyte cryopreservation is preferred over embryo cryopreservation since last few years and is considered as standard procedure for FP in most of the countries for all medical and non- medical indications. In a study by Welle-Butalid et al, cryopreservation of oocytes versus embryos resulted in comparable numbers of used embryos (median of 2) for transfer and comparable live birth rates (33.9% and 34.6%, respectively)(6).

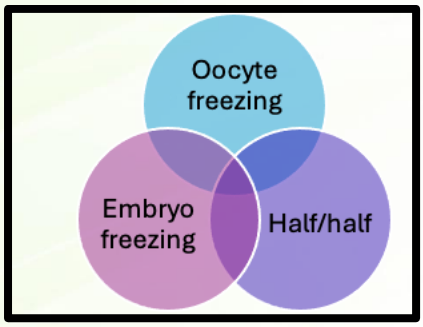

Figure 2- Options available for a woman going for fertility preservation when partner is available.

ESHRE emphasizes the importance of shared decision-making involving a multidisciplinary team, including oncologists, reproductive specialists, and psychologists. The information should be tailored to the individual patient's needs, with specific guidance and counselling provided for adolescents and young adults.

III. Dilemmas in fertility preservation in CAYA with cancer

The term CAYA (children, adolescents and young adults) is used for young patients <25 years who are diagnosed with malignancy and are planned for gonadotoxic therapies which pose

them at risk of gonadal failure. The discussion about FP is must for these patients so that options are discussed about future fertility preservation methods.

Those who are adults (More than 18 years), the options are discussed as mentioned above and oocyte cryopreservation and sperm cryopreservation is done along with valid consent.

But for adolescents and pre-pubertal boys and girls, valid consent is not possible and it is actually difficult to counsel them about the procedure. This leads to significant legal, counselling, and ethical issues. Adolescents (<18 years), who are not eligible for valid consent, but can understand and give permission to participate in research or treatment, can give assent. In pre-pubertal children, even the assent is not possible which leads to issues in this population.

Although ASRM has recommended that ovarian tissue cryopreservation (OTC) is no longer experimental and should be offered to all pre-pubertal girls, adolescents and to adults when time is not sufficient for oocyte cryopreservation, there are challenges in doing this procedure in adolescents and pre-pubertal girls. Only a few countries have developed clear cut guidelines about this procedure and in most of the countries, it is allowed to be done in research setting after ethical committee approval. The issues in pre-pubertal children are :

- Child is not mature enough to understand the FP and its need.
- Opting for FP may purely be interest of the parents/guardian for their wish to become genetic grandparents.
- Child may not be medically fit for the procedure
- Assent and consent are not possible regarding the procedure and utility options

It is advisable that in depth discussion is done with the parents/guardian and decision for FP should not outweigh the treatment for the cancer.

Even if a child cannot assent to the procedure, it is the obligation of the parent or guardian to consent. All eligible children have the right to future fertility because as an adult they would have the capacity to make the autonomous decision whether to procreate.

IV. FP in adolescents (post-pubertal girls)

Although ovarian stimulation and oocyte cryopreservation are possible after puberty is attained in girls, the problems associated with oocyte cryopreservation are:

Oocyte retrieval may require transvaginal ovarian puncture,

- ✓ Considering the invasiveness of procedure, it may be not be acceptable for the child and parents
- ✓ As the retrieval is done vaginally and hymen is ruptured, hymen restoration may be required afterwards.
- ✓ Procedure may not be acceptable due to social or religious issues
- ✓ There is need of meticulous counselling of the child and parents as vaginal intervention may lead to psychological issues

Considering this, OTC may be kept as an alternate and feasible method for young adolescents where vaginal intervention is difficult or the child is not mature enough to understand the procedure and its consequences.

V. Utility of the gametes/embryos in case of demise of the patient

- The decision to use cryopreserved tissue by the surviving spouse or parents or to discard them is another challenging dilemma which depends on the prior consent of the deceased. At the foremost, it is important to choose patient wisely after in depth counselling with oncologist / treating clinician. The patients have to be informed about the options for disposition of genetic materials in future in cases where depositor is unable to consent such as death/incompetency/unavailability . However, there is no clear universal guideline to deal with utility of gametes/tissues after demise of a child. Only few countries , mainly the UK, Sweden and Frnace have established national guidelines for FP procedures in children (table 3)

VI. Duration of freezing:

As per the latest ART Act, the gamete/embryo shall be stored for a period of not >10 years and at the end of such period such gamete or embryo shall be allowed to perish or be donated to a research organisation for research purposes with the consent of the commissioning couple or individual. However, this doesn't apply to FP where it is often required to be cryopreserved for a longer period. This is even more challenging due to increasing demand of fertility preservation in CAYA population.

Overall recommendations and future directions:

The following may be offered to avoid social, legal and ethical dilemmas in FP :

- Counselling the couple and giving option of oocyte /embryo /half-half freezing for maintaining reproductive autonomy

- Decision-making for FP in adolescents- Involve the children to maximum extent possible along with parents and guardian. The discussion may be done with adolescent and parents separately and followed by combined discussion
- Although oncological therapies should take priority over FP strategies, FP should always be discussed and considered where possible
- Need to develop national guidelines about duration of freezing and utility of genetic material in case of child demise or inability to utilize genetic tissue
- Need to develop appropriate legislation to reduce barriers to effective and sufficient funding and payment for oncofertility.

Table 3-Summary of national guidelines for fertility preservation in children

	Sweden (2023)	**France (2022,2023)**	**The UK (2013,2023)**
Consent	From child and both parents	Child & at least one parent	Child & one of the parents 16 yr onwards- consent valid May proceed even without parent consent
Lower age limit			No lower age limit
Decision & responsibility	Treating clinician	Treating clinician (consultation should start within 48 hrs)	Treating clinician
Duration	No time limit		55 years
In case of child death	Donated for research (with parent consent) Destroyed Not allowed for use	Not allowed to use for any purpose Destroyed	Donated for research (with parent consent) Destroyed if not used

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Suggested readings

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