Post-print of the Group Standard for Technical Specifications of Ovarian Tissue Cryopreservation and Transplantation

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Date: 2023-05-05T00:00:00+00:00

Abstract

[J]. J Oncol Pract, 2018, 14(6): 381-385. DOI: 10.1200/JOP.18.00160.

Full Text

Preamble

ChinaXiv Cooperative Journal · Standard · Specification · Group Standard for Technical Specifications of Ovarian Tissue Cryopreservation and Transplantation

Issuing Organizations: Beijing Obstetrics and Gynecology Hospital, Capital Medical University; Professional Committee on Fertility Protection and Preservation, China Association for the Promotion of Health Science and Technology

Keywords: ovary; ovarian tissue cryopreservation; ovarian tissue transplantation; specification; group standard
Chinese Library Classification: R 322.65
Document Code: A
DOI: 10.12114/j.issn.1007-9572.2023.0237

Citation: Beijing Obstetrics and Gynecology Hospital, Capital Medical University; Professional Committee on Fertility Protection and Preservation, China Association for the Promotion of Health Science and Technology. Group Standard for Technical Specifications of Ovarian Tissue Cryopreservation and Transplantation [J]. Chinese General Practice, 2023. [Epub ahead of print]. DOI: 10.12114/j.issn.1007-9572.2023.0237. [www.chinagp.net]

Scope: This document specifies requirements for medical institutions and personnel management engaged in ovarian tissue cryopreservation and transplantation, as well as requirements for ovarian tissue cryopreservation, thawing, transplantation, transplant risk assessment, and outcome evaluation. This document is applicable to medical institutions conducting ovarian tissue cryopreservation and transplantation.

Funding: This work was supported by the Beijing Research Ward Demonstration Construction Project of Beijing Municipal Health Commission (BCRW202109); Beijing Natural Science Foundation (7202047); Capital Health Development Research Fund (2020-2-2112); "Peak" Program Special Fund of Beijing Hospital Management Center (DFL20181401); Capital Health Development Research Fund (2016-2-2113); Capital Clinical Characteristic Application Research Project of Beijing Municipal Science and Technology Commission (Z161100000516143); and Clinical Medicine Development Special Fund of Beijing Hospital Management Center (XMLX201710).

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Digital Publication Date: 2023-04-28

2 Normative References

The following documents are indispensable for the application of this standard. For dated references, only the dated version applies. For undated references, the latest version (including all amendments) applies.

- GB/T 5458-1997, Liquid nitrogen biological containers
- GB/T 37864-2019, General requirements for the quality and competence of biobanks

3 Terms and Definitions

For the purposes of this document, the following terms and definitions apply.

3.1 Ovarian Tissue Cryopreservation

A female fertility preservation technique in which surgically retrieved ovarian tissue is processed and cooled in cryoprotective agents using slow freezing or vitrification methods, and ultimately stored long-term at ultra-low temperature in liquid nitrogen.

3.2 Slow Freezing

A method that gradually reduces the temperature of ovarian tissue cryopreservation solutions using a predetermined program.

3.3 Vitrification

A cryopreservation technique that uses high concentrations of cryoprotective agents and ultra-rapid cooling to prevent the formation of stable ice nuclei and achieve a glass-like solidification.

3.4 Low Temperature Transport

The process of transferring biological materials from one location to another while maintaining a temperature of 4-8°C in a specific transport solution.

3.5 Ovarian Tissue Transplantation

The surgical procedure of transplanting retrieved ovarian tissue back into the patient, either orthotopically (in the original location) or heterotopically (in a different location).

3.6 Ovarian Tissue Thawing

The process of warming frozen ovarian tissue to restore biological activity after cryopreservation.

4 Requirements for Medical Institutions

4.1 General Requirements for Institutions Conducting Ovarian Tissue Cryopreservation and Transplantation

Medical institutions conducting ovarian tissue cryopreservation and transplantation shall:

a) Have relevant review committees to jointly approve the implementation of ovarian tissue cryopreservation technology, including but not limited to new technology committees, academic committees, and ethics committees;

b) Have obstetrics and gynecology and related professional diagnosis and treatment subjects approved and registered by health administrative departments;

c) Possess corresponding technical capabilities.

4.2 Laboratory Requirements

4.2.1 General Laboratory Requirements 4.2.1.1 When planning the laboratory, medical institutions shall comply with GB/T 37864-2019. The location, design, layout, construction, and maintenance shall meet the requirements for Class I medical facilities, considering the requirements for cryogenic storage (including temperature, humidity, ventilation, and lighting facilities), capacity expansion, and biosafety and biosecurity.

4.2.1.2 Effective separation shall be implemented for adjacent areas conducting incompatible activities. For example, office areas and experimental areas shall be physically separated by walls to avoid cross-contamination. All isolated areas shall be clearly marked.

4.2.1.3 When environmental conditions affect the quality of ovarian tissue samples and related data and/or personnel health and safety, the environmental conditions of infrastructure/venues shall be measured, monitored, controlled, and recorded.

4.2.1.4 Emergency plans shall be formulated to ensure proper response in risky situations.

4.2.2 Facilities and Equipment Requirements

4.2.2.1 General Requirements 4.2.2.1.1 The laboratory shall be equipped with instruments and equipment including ovarian tissue freezing devices, liquid nitrogen storage systems, Class 100 laminar flow hoods, microscopes, incubators, ice machines, balances, and medical refrigerators.

4.2.2.1.2 An archive management system shall be established for laboratory facilities and equipment, including instrument name, serial number, manufacturer, date of use, operation manual, and maintenance records.

4.2.2.1.3 As part of quality control, each instrument shall be regularly tested for function and operation. Important equipment shall obtain formal quality inspection certificates.

4.2.2.2 Ventilation System 4.2.2.2.1 Ventilation systems for areas with incompatible activities shall be independently separated to ensure that air between different areas does not affect each other.

4.2.2.2.2 The laboratory shall maintain positive pressure to ensure airflow from "clean" spaces to "contaminated" spaces, minimizing indoor backflow and vortex. Laboratory air shall be filtered and volatile organic compounds removed.

4.2.2.2.3 Laboratory temperature shall be controlled at 20-24°C, and humidity at 40%-60%.

4.2.2.3 Monitoring System 4.2.2.3.1 Monitoring equipment shall be installed in all laboratory passages, and temperature, humidity, and concentration monitoring devices shall be installed in key areas. Oxygen concentration in liquid nitrogen areas shall be monitored and comply with relevant regulations.

4.2.2.3.2 All monitoring results shall be viewable in real-time with alarm settings. Alarms shall be triggered promptly when values exceed warning ranges.

4.2.2.4 Cryogenic/Ultra-low Temperature Storage Equipment 4.2.2.4.1 Management of liquid nitrogen containers shall comply with GB/T 5458-1997.

4.2.2.4.2 Key equipment such as cryogenic/ultra-low temperature storage devices shall:

a) Be placed in relatively independent spaces with appropriate ventilation, lighting, power supply, and temperature/humidity control;

b) Be operated by users following operation manuals;

c) Have designated personnel responsible for inspection, maintenance, and quality control, with corresponding records maintained.

4.2.2.5 Other Facilities and Equipment Requirements 4.2.2.5.1 Laboratory lighting systems, backup power supplies, access control systems, etc., shall meet normal laboratory operation requirements.

4.2.2.5.2 Designated personnel shall regularly inspect the above equipment and facilities. Any abnormal equipment shall be stopped from use and replaced or repaired promptly.

4.2.3 Laboratory Management Requirements

4.2.3.1 General Requirements 4.2.3.1.1 Laboratories conducting ovarian tissue cryopreservation and transplantation shall achieve GMP Grade A cleanliness. Ovarian tissue processing shall be performed in dedicated rooms with Class 100 laminar flow hoods.

4.2.3.1.2 Laboratories shall have the technical capability to perform ovarian tissue processing, freezing, storage, thawing, and viability testing.

4.2.3.1.3 Laboratories shall have strict data management systems. Data must be entered by two personnel, verified by designated personnel, and patient information must be archived properly. Patient information shall be entered into a unified database and managed centrally.

4.2.3.2 Quality Management Requirements 4.2.3.2.1 The laboratory shall have a quality management manual, management documents, standard operating procedures, and related records.

4.2.3.2.2 Operations shall be standardized to ensure ovarian tissue completes relevant procedures.

4.2.3.2.3 Annual sampling verification of the laboratory shall be conducted.

4.2.3.2.4 Annual quality assessment of the laboratory shall be performed to ensure system effectiveness and timeliness.

4.2.3.3 Information Management Requirements 4.2.3.3.1 The laboratory shall be equipped with a sample information management system that considers future expansion needs.

4.2.3.3.2 Relevant procedures shall be established to ensure the integrity and security of sample information, with backups performed every six months to prevent data loss or damage.

4.2.3.4 Safety Requirements 4.2.3.4.1 A comprehensive safety management system shall be established with clear requirements for samples, personnel, facilities and equipment, environment, operating procedures, and emergency measures.

4.2.3.4.2 Emergency plans shall be in place for fire safety, equipment safety, hazardous materials management, hazard identification, biosafety, biosecurity, information security, and water/electricity/gas accidents.

4.2.3.5 Risk Management A risk assessment mechanism shall be established to regularly identify and assess risks, with timely risk control based on assessment results.

5 Personnel Requirements

5.1 Technical Leader

5.1.1 Qualifications The technical leader shall, in principle, hold an associate senior professional title or above, have a doctoral degree, possess more than 5 years of experience in ovarian tissue cryopreservation and transplantation, have strong clinical and technical expertise, and have the ability to communicate and coordinate with other departments.

5.1.2 Responsibilities The technical leader shall be responsible for: overall oversight of ovarian tissue cryopreservation and transplantation, team building, developing specific workflows and standard procedures, evaluating the quality of all team members' work, and motivating staff enthusiasm and initiative.

5.2 Clinical and Laboratory Personnel

5.2.1 Clinical Personnel 5.2.1.1 Outpatient physicians conducting fertility preservation counseling shall be proficient in the indications and contraindications of ovarian tissue cryopreservation, capable of assessing ovarian function, and hold intermediate professional titles or above.

5.2.1.2 Physicians responsible for ovarian tissue retrieval surgery shall hold associate senior professional titles or above, be proficient in laparoscopic and open surgery, have the ability to manage critical conditions, and have completed at least 5 training sessions on ovarian tissue retrieval surgery with qualified assessment.

5.2.1.3 Physicians responsible for transplantation surgery shall have extensive experience in ovarian tissue transplantation, hold senior professional titles, be proficient in laparoscopic and open surgery, have the ability and experience to manage critical conditions, and have completed at least 5 training sessions on ovarian tissue transplantation surgery with qualified assessment.

5.2.2 Laboratory Personnel 5.2.2.1 Laboratory personnel responsibilities include:

a) Mastering daily laboratory operation procedures and quality control methods, and providing timely feedback to clinical personnel;

b) Conducting daily maintenance and management of various instruments and equipment, and performing timely repairs and troubleshooting;

c) Keeping abreast of disciplinary development trends and assisting the leader in developing laboratory development plans;

d) Developing and revising laboratory rules, regulations, and technical operating procedures under the guidance of the leader;

e) Supervising support technicians to complete laboratory records;

f) Training and guiding support technicians, graduate students, and visiting scholars.

5.2.2.2 Laboratory principal technicians shall:

a) Have completed at least 5 professional training sessions on ovarian tissue cryopreservation and transplantation and passed assessments;

b) Master relevant techniques of ovarian tissue cryopreservation and transplantation and laboratory management methods;

c) Participate in major technical procedures of ovarian tissue cryopreservation and transplantation and complete daily work records.

5.3 Support Technicians

Support technicians shall assist clinical and laboratory personnel in technical operations, complete daily laboratory data recording, coordinate procurement and collection of consumables, reagents, and supplies, and promptly check the accuracy and completeness of various records.

6 Review and Safety Requirements

6.1 Informed Consent, Confidentiality, and Safety

6.1.1 Informed Consent The technical leader and principal technicians shall effectively evaluate risks and benefits to ensure patients or guardians are fully informed about cryopreservation and transplantation information.

6.1.2 Confidentiality Measures Without permission, no party shall disclose any confidential information to third parties. Regardless of whether agreements are terminated, all parties have a permanent confidentiality obligation for confidential information obtained from each other until such information is voluntarily disclosed by the authorized party, or disclosed according to regulations or orders from competent authorities, or with permission from all parties involved.

6.1.3 Safety Protection Patients' infection status shall be confirmed as negative before cryopreservation. High-risk patients such as those with leukemia shall receive treatment before ovarian tissue cryopreservation to reduce cancer-carrying risk in ovarian tissue. If such patients have strong desire for frozen ovarian tissue transplantation, multidisciplinary consultation shall be conducted under full informed consent, with multi-dimensional detection methods employed to carefully assess transplantation risks.

6.2 Review Requirements

Implementation of ovarian tissue cryopreservation and transplantation shall meet the following review requirements:

a) Obtain approval from the ethics committee;
b) Pass scientific review and approval by the academic committee;
c) Pass technical safety and operational standard review by the new technology committee.

7 Technical Procedures

7.1 Basic Requirements

All procedures in ovarian tissue cryopreservation and transplantation shall ensure ovarian tissue viability. Cell survival rate in thawed ovarian tissue shall reach 70% or higher. Ovarian tissue cryopreservation methods include slow freezing and vitrification. Currently, the international standard method for ovarian tissue cryopreservation is slow freezing, and this group standard is primarily developed based on this method.

7.2 Ovarian Tissue Cryopreservation Procedures

7.2.1 General Requirements Ovarian tissue cryopreservation shall strictly adhere to technical operation specifications and diagnosis and treatment guidelines, with strict control of indications and contraindications.

7.2.2 Patient Requirements for Ovarian Tissue Cryopreservation 7.2.2.1 Patients undergoing ovarian tissue cryopreservation shall meet the following requirements:

a) Age $\leq$ 35 years with good ovarian reserve function; age limits may be appropriately relaxed based on ovarian reserve and personal preference; for prepubertal girls, no lower age limit applies;

b) Good prognosis of primary disease;

c) High risk of premature ovarian insufficiency caused by primary disease and its treatment;

d) Ability to tolerate laparoscopic or open ovarian tissue retrieval surgery;

e) At least 3 days before chemoradiotherapy initiation.

7.2.2.2 For patients with ovarian malignant tumors or other malignant tumors with moderate or higher risk of ovarian metastasis, transplantation requires careful and thorough discussion and evaluation. The risk of ovarian metastasis in different malignant tumor types is shown in Table 1.

Table 1 Risk of ovarian metastasis in different types of malignant tumors

- Breast cancer Stage IV, invasive
- Breast cancer Stage I-II, invasive
- Neuroblastoma
- Burkitt's lymphoma
- Cervical adenocarcinoma
- Cervical squamous cell carcinoma
- Hodgkin's lymphoma
- Non-Hodgkin's lymphoma
- Ewing's sarcoma
- Non-genital rhabdomyosarcoma
- Wilms' tumor

7.2.2.3 Ovarian tissue cryopreservation shall be performed with informed consent from the patient or guardian.

7.2.3 Indications Ovarian tissue cryopreservation is applicable for fertility and ovarian endocrine function preservation in patients with malignant and non-malignant diseases. The best indications are prepubertal patients, patients requiring immediate gonadotoxic treatment, and patients with hormone-dependent tumors. Main indications include:

a) Malignant diseases (requiring chemotherapy, radiotherapy, or bone marrow transplantation), including: leukemia, Hodgkin's lymphoma, non-Hodgkin's lymphoma, breast cancer, sarcoma, neuroblastoma, certain pelvic tumors, etc.;

b) Non-malignant diseases, including: immune, metabolic, and hematologic benign diseases requiring bone marrow transplantation, ovarian diseases (such as borderline ovarian tumors, severe or recurrent endometriosis, ovarian torsion, etc.), and high-risk groups for premature ovarian insufficiency

(such as those with family history or genetic testing indicating high risk, Turner syndrome with remaining ovarian function, etc.).

7.2.4 Contraindications Contraindications for ovarian tissue cryopreservation include:

a) Confirmed ovarian metastasis or ovarian malignant tumor;

b) Advanced disease or cachexia unable to tolerate surgery;

c) Confirmed complete ovarian function failure.

7.2.5 Tissue Retrieval Ovarian tissue retrieval may be performed laparoscopically, avoiding corpus luteum and using cold scissors. Ideally, more than 1/2 of the volume of one or both ovaries should be retrieved (individualized based on patient condition). Energy devices shall not contact the ovary to avoid thermal injury, and the integrity of retrieved ovarian tissue shall be ensured. The retrieval procedure shall comply with Appendix A.1.

7.2.6 Transport Surgically retrieved ovarian tissue shall be immediately placed in sterile transport solution provided by the ovarian tissue cryopreservation center, using a dedicated transport box to maintain low temperature at 4-8°C during transport to the cryopreservation center laboratory, with transport time not exceeding 24 hours. To achieve quality control, optimize patient management, and ensure cost-effectiveness, tissue retrieval may be performed locally, while freezing and storage should be centralized. The transport procedure shall comply with Appendix A.2.

7.2.7 Processing Ovarian tissue processing and freezing shall be conducted in qualified laboratories. During processing, sterile scalpels and forceps shall be used to carefully remove medulla while preserving intact cortex. Processed ovarian tissue thickness should be approximately 1 mm, with each piece measuring approximately 4 mm × 8 mm. Processed ovarian tissue pieces shall be immediately placed in cryoprotective solution for pre-cooling equilibrium for 20 minutes, then placed in cryovials containing cryoprotective solution for freezing.

7.2.8 Freezing Slow freezing uses computer-programmed control to gradually cool ovarian tissue to -140°C according to set rates, after which cryovials are stored in liquid nitrogen at -196°C.

7.2.9 Storage Each cryovial shall be labeled with patient name, date of birth, and code, with storage location recorded, and placed in liquid nitrogen tanks.

7.3 Ovarian Tissue Transplantation Procedures

7.3.1 Timing and Indications for Transplantation 7.3.1.1 Transplantation timing should be determined based on the patient's primary disease cure

status and clinical recovery, after full communication with the patient and specialists, according to individual circumstances.

7.3.1.2 Transplantation indications shall meet the following requirements:

a) After primary disease remission, when patients develop menopause-related symptoms such as hot flashes and sweating due to ovarian function decline;

b) Serum follicle-stimulating hormone $\geq$ 25 IU/L, anti-Müllerian hormone $<$ 1.1 ng/mL;

c) At least 3-6 months after completion of gonadotoxic treatment.

7.3.2 Pre-transplant Risk Assessment and Management 7.3.2.1 Pre-transplant Risk Assessment Since transplantation carries the risk of reintroducing primary disease, patients with moderate or higher risk (Table 1) should receive treatment before ovarian tissue cryopreservation to reduce cancer-carrying risk in ovarian tissue. If such patients have strong desire for frozen ovarian tissue transplantation, multidisciplinary consultation shall be conducted under full informed consent, with multi-dimensional detection methods employed to carefully assess transplantation risks.

7.3.2.2 Pre-transplant Management Before and after ovarian tissue transplantation, certain traditional Chinese medicines or patent medicines with proven efficacy may be used to alleviate menopausal symptoms and protect residual follicular function. For non-hormone-dependent tumor patients, such as those with cervical squamous cell carcinoma, hormone therapy may be combined using oral or transdermal natural estrogen, with progesterone added for patients with a uterus. For hormone-dependent tumor patients (such as breast cancer), estrogen is contraindicated, and estrogen-free herbal medicines or traditional Chinese medicines may be used to relieve symptoms.

7.3.2.3 Pre-transplant Viability Assessment Viability testing of tissue survival and follicular activity shall be performed before ovarian tissue cryopreservation and transplantation.

7.3.3 Thawing of Cryopreserved Ovarian Tissue 7.3.3.1 Retrieve the patient's cryovials from the liquid nitrogen tank and verify patient identity by two personnel.

7.3.3.2 Place cryovials in a 37°C water bath, remove immediately when cryoprotective solution is observed to be dissolved.

7.3.3.3 Remove tissue pieces and sequentially place in recovery solutions of different gradient concentrations for 15 minutes each, with shaking.

7.3.3.4 While thawing, prepare the operating room. Thawed ovarian tissue pieces shall be delivered to the operating room within 20 minutes for transplantation back into the patient.

7.3.4 Ovarian Tissue Transplantation Ovarian tissue transplantation is divided into orthotopic transplantation (within the pelvis) and heterotopic transplantation (outside the pelvis). Orthotopic transplantation is preferred; heterotopic transplantation may be considered when orthotopic transplantation is not feasible for various reasons. Orthotopic transplantation may be performed at the original ovary or peritoneal pouch. An incision should be made at a well-vascularized site on the lateral peritoneum to create a peritoneal pouch, into which thawed ovarian tissue pieces are placed.

7.3.5 Post-transplant Follow-up and Monitoring 7.3.5.1 Patients shall be followed up monthly after transplantation to observe and analyze the recovery of ovarian reproductive endocrine function. After ovarian function recovery, follow-up may be conducted every 3-6 months.

7.3.5.2 The following indicators shall be monitored after transplantation:

a) Laboratory endocrine indicators, including follicle-stimulating hormone, anti-Müllerian hormone, luteinizing hormone, estradiol, progesterone, etc.;

b) Menstrual recovery status;

c) Ultrasound monitoring of follicular development in transplanted ovaries;

d) Pregnancy status and outcomes.

7.3.5.3 Generally, ovarian tissue function recovers 3-6 months after transplantation, with menopause-related symptoms significantly alleviated or resolved, and follicle-stimulating hormone < 25 IU/L, which is considered successful transplantation and ovarian function recovery.

8 Special Considerations for Specific Diseases

8.1 Breast Cancer

For low recurrence risk patients requiring adjuvant endocrine therapy, after multidisciplinary evaluation and full communication with patients regarding tumor risk and fertility needs, pregnancy may be cautiously considered after ovarian tissue transplantation following at least 2-3 years of endocrine therapy. Patients should continue endocrine therapy after delivery.

8.2 Hematologic System Diseases

8.2.1 Ovarian tissue cryopreservation and transplantation technology may be applied to women of reproductive age and prepubertal girls requiring urgent chemoradiotherapy for benign or malignant hematologic system diseases.

8.2.2 For benign or malignant hematologic system diseases requiring hematopoietic stem cell transplantation, ovarian tissue cryopreservation should be performed before high-dose chemotherapy.

8.3 Endometriosis

8.3.1 Ovarian tissue cryopreservation and transplantation technology may be applied to ovarian endometriotic cysts.

8.3.2 For patients deciding to undergo ovarian tissue cryopreservation and transplantation, ovarian function should be evaluated before endometriosis surgery, and fertility protection should be considered during surgery, especially for unmarried or nulliparous patients.

8.3.3 For patients who have undergone endometriosis surgery and will undergo ovarian tissue cryopreservation and transplantation, endometriotic lesions and cyst walls should be avoided during ovarian tissue retrieval to avoid affecting cryopreservation quality. For patients with multiple endometriotic lesions, small undetected lesions may exist and should be carefully identified.

8.4 Cervical Cancer

For cervical cancer patients requiring pelvic radiotherapy, in addition to ovarian transposition, ovarian tissue cryopreservation may be used to protect patients' fertility and ovarian endocrine function.

Appendix A (Normative Appendix)

"Ovarian Tissue Retrieval and Transport Procedures and Requirements" - Please scan the QR code on the title page.

Principal Drafting Organizations and Personnel

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(Received: 2023-04-25)
(Editor: Zhao Yuecui)

Note: Figure translations are in progress. See original paper for figures.