Australasian Gynaecological Endoscopy & Surgery Society Limited

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists
Excellence in Women's Health

Tissue Extraction at Minimally Invasive Procedures

This statement has been developed by the AGES Society and reviewed by the Endoscopic Surgery Advisory Committee (RANZCOG/AGES) and Women's Health Committee and approved by the RANZCOG Board and Council.

A list of Women's Health Committee and Endoscopic Surgery Advisory Committee Members can be found in Appendix A.

Disclosure statements have been received from all members of this committee.

Disclaimer This information is intended to provide general advice to practitioners. This information should not be relied on as a substitute for proper assessment with respect to the particular circumstances of each case and the needs of any patient. This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. The document has been prepared having regard to general circumstances.

First endorsed by RANZCOG: June 2014 Current: March 2017
Review due: March 2020

Objectives: To provide advice on the use of mechanical morcellators for removal of tissues.

Target audience: Health professionals who use mechanical morcellators, and patients undergoing procedures that use mechanical morcellators.

Values: The evidence was reviewed, and applied to local factors relating to Australia and New Zealand.

Background: This statement was first developed by the AGES Society and ratified by the AGES Board in May 2014 and most recently reviewed by in March 2017.

Funding: The development and review of this statement was funded by the AGES Society and RANZCOG.

Contents

1. Patient summary

At times, organs or tissues that are to be taken out during surgery need to be broken up in order to allow removal through small incisions or the birth canal. This statement provides guidance for specialists to reduce the risk of injury to patients or the spread of unrecognised abnormalities.

2. Introduction

Minimally invasive surgery, including endoscopic and vaginal procedures, offer patients the benefits of improved recovery, less postoperative pain, lower risk of postoperative complications (reduction of inherent risks of laparotomy). Furthermore, less invasive procedures, such as myomectomies, have also allowed for uterine preservation in settings that traditionally would have resulted in a hysterectomy and loss of fertility.

By their nature, these minimally invasive procedures may at times require the morcellation, drainage or deflation of abdominal or pelvic masses to permit extraction through the vagina or other access points. Morcellation may be defined as the division of a large specimen into smaller fragments to permit removal from the peritoneal cavity. Morcellation may be performed manually with the use of a scalpel in techniques such as bivalving or coring, or electromechanically, utilising devices specifically designed for this purpose, such as a morcellator.

As such, gynaecologists recognise that tissue extraction by morcellation may be associated with a number of risks:

1. Patient injury: other tissue, such as bowel, other pelvic organs intended to stay in the body or blood vessels may be inadvertently injured during the morcellation process. The efficiency of electromechanical morcellation poses a specific hazard in this setting.
2. Dissemination: fragments of tissue generated by the morcellation process may disseminate throughout the peritoneal cavity. This has been reported for both benign disease (fibroids, endometriosis) and malignancy where this may have a detrimental effect on prognosis and / or increase the need for adjuvant treatment. Concerns have been expressed that electromechanical morcellators may increase the risk of dissemination by creating a larger volume of smaller fragments.
3. Pathology: the size of the fragments and, at times, the loss of anatomical relationships, may complicate the diagnosis by the pathologist. Concerns have been expressed that electromechanical morcellation may yield a large volume of small and dissociated fragments, which may further complicate analysis.

3. Discussion and recommendations

3.1 Risks of Tissue Extraction

This statement addresses each of the defined risks of tissue extraction as follows:

3.1.1 Patient Injury

Manual morcellation is a core gynaecological technique that is acquired during membership and fellowship training. However, electromechanical morcellation is an advanced surgical technique. Local credentialing bodies need to be satisfied that specialists using such devices have received appropriate training and education in the use of such devices. In general, the use of such devices is restricted to practitioners at AGES-RANZCOG Level 5 and above.

The following precautions should be applied when using a morcellator:

1. No suspicion of malignancy on preoperative or intraoperative assessment
2. Maintain the tip of the instrument in view at all times
3. Maintain control of the specimen at all times
4. Feed the specimen into the morcellator in a controlled manner
6. Minimise spillage of specimen fragments wherever possible
7. Post-morcellation retrieval of all macroscopic fragments

3.1.2 Dissemination

The dissemination of both benign and malignant disease cannot be completely prevented if a decision is made to morcellate a specimen. However, appropriate steps may be taken to minimise this risk:

3.1.2.1 Case Selection

Patients requiring a hysterectomy or removal of an abdominopelvic mass represent a heterogeneous group, each with inherent risk factors. As such, it is not possible to distil the assessment of any patient to a simple decision matrix. This assessment is inherent to the core knowledge of a specialist in obstetrics and gynaecology.

3.1.2.1 Preoperative Assessment

Patients should have an appropriate history and examination performed, specifically to assess the risk of malignancy. Routine preoperative investigations should include a Pap smear and an ultrasound. Further investigations must be targeted to the type of pathology and may include blood tests, such as tumour markers, endometrial sampling and/or extended imaging.

3.1.2.3 Consent

Patients must be engaged in the discussion of the risks and benefits of the route of any proposed surgical procedure, including the mechanism of tissue extraction. This discussion should include the risks, benefits and likely outcomes of alternative management options.

3.1.2.4 Intraoperative Assessment

Clinical intraoperative assessment of a pelvic mass is difficult and inaccurate. If gynaecologists unexpectedly encounter suspicious pathology, it may be appropriate to abandon the procedure, seek the advice of a gynaecological oncologist intraoperatively or avoid techniques that may increase the risk of dissemination, such as morcellation. Consider options to minimize the potential risks of tumour spread, such as mini-laparotomy or extraction with an endopouch.

3.2 Pathological assessment

The postoperative histopathological diagnosis of a morcellated specimen may be compromised. It is recommended that members seek the opinion of a gynaecological oncologist and specialised pathologist in the diagnosis of any gynaecological malignancy, whether expected or unexpected.

3.3 Specific Consideration: Leiomyosarcoma

In April 2014, the United States Food and Drug Administration (FDA) issued an FDA Safety Communication regarding power morcellation in hysterectomy and myomectomy, followed shortly by a Safety Alert on laparoscopic power morcellators from the Australian Therapeutic Goods Administration (TGA). These alerts

reacted to reports of adverse patient outcomes in patients with fibroids related to the potential for the devices to spread malignant cells in patients with previously undetected malignancy.

The specific problem posed by the diagnosis of uterine sarcoma, is that there are no reliable preoperative diagnostic tools to differentiate malignant mesenchymal tumours of the uterus from their benign counterparts.

Local gynaecological units are encouraged to develop their own guidelines, based on the availability of local resources and expertise.

The incidence of leiomyosarcoma (LMS) has been variably quoted at between 0.02 to 0.3%, depending on the study population. The difficulty in attaining an exact incidence relates to both case capture and the determination of an appropriate denominator.

Reported demographic risk factors for LMS include:

- Age (mean age of diagnosis: 60)
- Menopausal status
- African American ethnic background
- Current or prior tamoxifen exposure
- History of pelvic Irradiation
- Hereditary Leiomyomatosis and Renal Cell Carcinoma (HLRCC) syndrome
- Survivors of childhood retinoblastoma

In the clinical assessment, practitioners should be alert to the possibility of malignancy, if:

- Rapidly expanding mass
- Postmenopausal bleeding or variants of abnormal uterine bleeding, in premenopausal women with an unusual pattern
- Ascites
- Lymphadenopathy
- Evidence of secondary spread

A cervical screening test should be taken and endometrial assessment be performed by imaging and / or endometrial sampling prior to engaging in any invasive procedure if there is a history of abnormal uterine bleeding.
Patients should have preoperative imaging by ultrasound or MRI, with reference to local guidelines. Risk factors for LMS include:

- Large size or large interval growth
- Tissue signal heterogeneity
- Central necrosis
- Ill-defined margins
- Ascites
- Metastases

With the exception of the last two elements, it is recognised that these features have a significant overlap with degenerating fibroids. There are no established tumour markers for LMS, though there may be an elevation in LDH, related to an increased cell turnover.

Recommendation 1	Grade
Patients must be engaged in the discussion of the method of tissue extraction. This discussion should include the risks and benefits of alternative management options.	Consensus-based recommendation
Recommendation 2	**Grade**
Morcellation of a fibroid or uterus should only be performed in the absence of a suspicion of malignancy.	Consensus-based recommendation
Recommendation 3	**Grade**
Practitioner should be credentialed for the use of an electromechanical morcellator by the local credentialing committee.	Consensus-based recommendation

4. Conclusion

It is recognised that these measures will not completely preclude the occurrence of an unsuspected malignancy at myomectomy or hysterectomy. If the diagnosis is made postoperatively, early consultation with a gynaecological oncologist is mandatory.

5. Other suggested reading

1. American College of Obstetricans and Gynecologists. Power Morcellation and Occult Malignancy in Gynecologic Surgery. May 2014.
2. AAGL Advancing Minimally Invasive Gynecology Worldwide. AAGL Tissue Extraction Task Force Report. May 2014.
3. Use of Electric Power Morcellation and Prevalence of Underlying Cancer in Women Who Undergo Myomectomy.[Erratum appears in JAMA Oncol. 2015 Apr;1(1):110; PMID: 26182314] Wright JD; Tergas AI; Cui R; Burke WM; Hou JY; Ananth CV; Chen L; Richards C; Neugut AI; Hershman DL. JAMA Oncology. 1(1):69-77, 2015 Apr.
4. Trends in Use and Outcomes of Women Undergoing Hysterectomy With Electric Power Morcellation. Wright JD; Chen L; Burke WM; Hou JY; Tergas AI; Ananth CV; Hershman DL. JAMA. 316(8):877-8, 2016 Aug 23-30.
5. What is the Future of Open Intraperitoneal Power-Morcellation of Fibroids?. [Review] Parker WH; Pritts EA; Olive DL. Clinical Obstetrics & Gynecology. 59(1):73-84, 2016 May.

6. Appendices

Appendix A Women's Health Committee Membership

Name	Position on Committee
Professor Yee Leung	Chair
Dr Joseph Sgroi	Deputy Chair, Gynaecology
Associate Professor Lisa Hui	Member
Associate Professor Ian Pettigrew	EAC Representative
Associate Professor Rosalie Grivell	TAC Representative
Dr Tal Jacobson	Member
Dr Ian Page	Member
Dr John Regan	Member
Dr Craig Skidmore	Member
Associate Professor Janet Vaughan	Member
Dr Bernadette White	Member
Dr Scott White	Member
Associate Professor Kirsten Black	Member
Dr Greg Fox	College Medical Officer
Dr Marilyn Clarke	Chair of the ATSI WHC
Dr Martin Byrne	GPOAC Representative
Ms Catherine Whitby	Community Representative
Ms Sherryn Elworthy	Midwifery Representative
Dr Amelia Ryan	Trainee Representative

Endoscopic Surgery Advisory Committee (RANZCOG/AGES) Membership

Name	Position on Committee
Dr Stephen Lyons	Chair, Representative AGES
Professor Michael Permezel	Deputy Chair, Representative RANZCOG
Dr James Tsaltas	Representative AGES
Professor Ian Symonds	Representative RANZCOG
Dr John Tait	Representative RANZCOG
Associate Professor Jason Abbott	Representative AGES
Associate Professor Anusch Yazdani	President AGES
Professor Steve Robson	President RANZCOG

Appendix B Overview of the development and review process for this statement

i. Steps in developing and updating this statement

This statement was originally developed in June 2014 by AGES and was most recently reviewed in March 2017. The Endoscopic Surgery Advisory Committee (RANZCOG/AGES) carried out the following steps in reviewing this statement:

- Declarations of interest were sought from all writers prior to developing this statement.
- Declarations of interest were sought from all members prior to developing this statement.
- An updated literature search to answer the clinical questions was undertaken.
- At the March 2017 face-to-face committee meeting, the existing consensus-based recommendations were reviewed and updated (where appropriate) based on the available body of evidence and clinical expertise. Recommendations were graded as set out below in Appendix B part iii)

ii. Declaration of interest process and management

Declaring interests is essential in order to prevent any potential conflict between the private interests of members, and their duties part of the Endoscopic Surgery Advisory Committee (RANZCOG/AGES).

A declaration of interest form specific to guidelines and statements was developed by RANZCOG and approved by the RANZCOG Board in September 2012. The Endoscopic Surgery Advisory Committee (RANZCOG/AGES) members were required to declare their relevant interests in writing on this form prior to participating in the review of this statement.

Members were required to update their information as soon as they become aware of any changes to their interests and there was also a standing agenda item at each meeting where declarations of interest were called for and recorded as part of the meeting minutes.

There were no significant real or perceived conflicts of interest that required management during the process of development of this statement.

iii. Grading of recommendations

Each recommendation in this College statement is given an overall grade as per the table below, based on the National Health and Medical Research Council (NHMRC) Levels of Evidence and Grades of Recommendations for Developers of Guidelines.17 Where no robust evidence was available but there was sufficient consensus within the Endoscopic Surgery Advisory Committee (RANZCOG/AGES), consensus-based recommendations were developed or existing ones updated and are identifiable as such. Consensus-based recommendations were agreed to by the entire committee. Good Practice Notes are highlighted throughout and provide practical guidance to facilitate implementation. These were also developed through consensus of the entire committee.

Recommendation category		Description
Evidence-based	A	Body of evidence can be trusted to guide practice
	B	Body of evidence can be trusted to guide practice in most situations
	C	Body of evidence provides some support for recommendation(s) but care should be taken in its application
	D	The body of evidence is weak and the recommendation must be applied with caution
Consensus-based		Recommendation based on clinical opinion and expertise as insufficient evidence available
Good Practice Note		Practical advice and information based on clinical opinion and expertise

Appendix D Full Disclaimer

This information is intended to provide general advice to practitioners, and should not be relied on as a substitute for proper assessment with respect to the particular circumstances of each case and the needs of any patient.

This information has been prepared having regard to general circumstances. It is the responsibility of each practitioner to have regard to the particular circumstances of each case. Clinical management should be responsive to the needs of the individual patient and the particular circumstances of each case.

This information has been prepared having regard to the information available at the time of its preparation, and each practitioner should have regard to relevant information, research or material which may have been published or become available subsequently.

Whilst the College endeavours to ensure that information is accurate and current at the time of preparation, it takes no responsibility for matters arising from changed circumstances or information or material that may have become subsequently available.