




# Quality care guidelines for uterine artery embolisation in women with symptomatic uterine fibroids in Australia and New Zealand: According to the AGREE-II checklist and endorsed by the Interventional Radiology Society of Australasia

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## Objective

This guideline defines recommendations for quality care in women being treated with UAE for symptomatic uterine fibroids in Australia and New Zealand. The guideline has been developed according to the AGREE-II checklist for reporting of guidelines, with more detailed responses in Appendices S1 and S2. Recommendations have been made according to the available level of evidence with a focus on local data where applicable, and the types of recommendations are detailed in Table 1.

## Target audience

Patients seeking and receiving treatment for uterine fibroids by embolisation, with comparison to alternative treatments including hysterectomy and myomectomy where relevant.

## Target users

Medical practitioners providing care for women with symptomatic uterine fibroids in Australia and New Zealand including general practitioners, gynaecologists, and interventional radiologists. This guideline can be used to inform clinical and governance decisions on standards of care.

## Search methods

Data were derived from a search of MEDLINE, EMBASE, and Google Scholar from 1 January 1995 to 1 January 2022. Data collection was performed using the PICO format including the following search terms: women, uterine, fibroid, embolisation, UAE, UFE, hysterectomy, myomectomy, quality, bleeding, infection, and complications.

## Evidence selection

Peer-reviewed evidence has been assessed according to study design with a preference for higher-level evidence were available including systematic reviews of

prospective randomised controlled trials. However, evidence levels may include smaller cohort studies and case-control studies for emerging topics including pregnancy after UAE, or rarer topics such as complications. For some topics there exists a lack of evidence and case series or expert commentary may need to be considered.

## Formulation of recommendations

This guideline was developed through a modified version of the Delphi technique using an electronic process with a single facilitator combining responses. The contents of each of the 10 guideline topics were discussed in 4 rounds before a final guideline was reached. At the conclusion, a consensus was reached for 8 out of the 10 topics based on existing high-quality evidence. A statement of lack of consensus was discussed for the remaining 2 topics including the necessity of pre-operative MRI (with its local funding challenges in Australia) and pre-operative intra-uterine device removal, with the direction given for the need for more evidence.

## Updating procedure

The guideline will be updated within 5 years of 1 January 2022, and will be updated according to the AGREE-CheckUp process.

## Funding and competing interests

The contributors declare no funding was received for this guideline, and the authors declare no competing interests either financial or other.

## Summary recommendations

- Uterine artery embolisation (UAE) is a safe and effective treatment for symptomatic uterine leiomyomata (fibroids). Recommendation: A
- Treatment should be performed in women with the appropriate symptoms, in the absence of contraindications, as an alternative to surgery. Recommendation: A
- UAE is typically associated with quicker recovery, shorter hospitalisation and fewer major complications compared to surgery. Recommendation: A
- Women seeking treatment or advice for symptomatic fibroids should be informed of all treatment options, including UAE. Recommendation: A
- Women referred for consideration of UAE should be evaluated by an interventional radiologist in an appropriate clinic setting where clinical history, examination, and imaging assessment can be conducted. The pros and cons of UAE compared with other treatments should be discussed. Recommendation: C
- Where future pregnancy is actively desired and where surgery is an option, myomectomy is currently the preferred option. If myomectomy is deemed

**Table 1.** Recommendations and relationship to the level of evidence

Recommendation level	Highest level of evidence available
A	Level I or II evidence. e.g., systematic review, randomised controlled trial, prospective cohort study
B	Level III or IV evidence. e.g., case-control study, retrospective cohort study, case series
C	Level V evidence. e.g., case report or consensus of opinion of the authors

technically difficult then UAE may be offered as an alternative. Although successful pregnancy is possible after UAE, women need to be counselled regarding potential pregnancy complications due to fibroids and its treatment. Further studies are still needed in this area. Recommendation: B

- The risk of unrecognised incidental leiomyosarcoma is approximately 0.3%, and can be minimised by screening with MRI and lactate dehydrogenase isoenzymes, although MRI prior to UAE is not currently publicly funded in Australia. Careful post-UAE follow-up with attention to fibroid regrowth or failure to respond to UAE despite a technically successful procedure should prompt consideration of an underlying leiomyosarcoma. Recommendation: C
- Embolisation should be ideally performed in pre-menopausal women. Careful assessment with consideration of other pathologies is advised in post-menopausal women not on hormonal replacement therapy. Recommendation: B
- Planned follow-up should be undertaken by the interventional radiologist who performed the procedure, and they should be contactable by the patient, GP, or gynaecologist when required. Recommendation: C
- Interventional radiologists are the medical specialist group with suitable training and expertise to perform UAE in Australia and New Zealand. Recommendation: C

## Background

Leiomyomata, also known as fibroids, are a benign mesenchymal tumour of the uterus and are one of the most common diseases, affecting up to 70% of women in their lifetime.<sup>1</sup> Symptoms may include heavy menstrual bleeding, dysmenorrhoea, and mass effect.<sup>1,2</sup> Adenomyosis is the presence of ectopic endometrial tissue in the myometrium, and often co-exists with leiomyomata.<sup>3</sup>

Small fibroids in asymptomatic patients do not require active treatment. When symptomatic, treatment options vary based on the patient's disease burden and effect on the quality of life. Medical therapy includes non-hormonal medications or oral/injectable hormonal agents, and is effective in many patients with small fibroids.<sup>4</sup> Invasive or minimally invasive therapy may be required in those with large fibroids, diffuse disease, or those in which medical therapy has failed.

Hysterectomy, myomectomy, and endometrial ablation are surgical options that have been performed as treatments for uterine fibroids for many years. Hysterectomy is the most definitive option for women when fertility is no longer a consideration but carries significant direct and indirect morbidity.<sup>4</sup> Myomectomy is another surgical option that may be performed via laparoscopic, hysteroscopic, or open surgical techniques.<sup>4</sup> It is offered to women who wish to conserve their uterus and preserve fertility. Endometrial ablation is a hysteroscopic,

minimally invasive treatment for menorrhagia, but may not be feasible or effective if the endometrial cavity is distorted by fibroids.

## Embolisation as an effective treatment for fibroids

Uterine artery embolisation (UAE), also known as uterine fibroid embolisation, is a minimally invasive uterine-sparing alternative to traditional surgical techniques.<sup>5-7</sup>

A recent systematic review concluded that there was a similar overall symptom improvement between UAE and surgery (75% surgery vs. 60% UAE,  $P > 0.05$ ), and that UAE resulted in shorter hospitalisation by 2.9 days ( $P < 0.05$ ), earlier recovery by 19 days ( $P < 0.05$ ), and fewer major complications (7.5% vs. 4.4%,  $P < 0.05$ ).<sup>7</sup> A review by Popovic *et al.* showed that treatment of co-existent adenomyosis and leiomyomata by UAE led to short-term symptom improvement in up to 92.9% of patients and up to 82.4% long term<sup>8</sup> which is supported by the systematic review from de Bruijn *et al.*<sup>9</sup> A 2018 retrospective review of 117 Australian patients with MRI-confirmed fibroids and adenomyosis who underwent UAE for heavy menstrual bleeding or dysmenorrhoea, reported clinical success in 89% at a mean follow-up of 22.5 months, with significant improvements in both symptoms and quality of life.<sup>3</sup> The FEMME trial was a multi-centre prospective study comparing UAE and myomectomy in 254 women with fibroids who declined hysterectomy. The study showed significant improvement in health-related quality of life scores for both myomectomy and UAE, although there was a greater mean difference in the myomectomy group (8.0 points,  $P = 0.001$ , 95%CI 1.8 to 14.1).<sup>10</sup> The study also showed that, compared with myomectomy, UAE resulted in fewer complications (myomectomy 29%, UAE 24%) and shorter median hospital stay (myomectomy 4 days [IQR 3–5], UAE 2 days [IQR 2–3]). In addition, 9 women (8%) reported pregnancy after UAE with 6 live births, and 5 women (4%) in the myomectomy group resulted in 4 live births.<sup>10</sup>

The HOPEFUL study assessed the economic impact of UAE and hysterectomy, showing a reduced cost with UAE even when recurrent symptoms are taken into consideration.<sup>11</sup> This is supported by Australian data.<sup>12</sup>

### Recommendation: A

## Indications

Interventional treatment should be considered for a refractory, recurrent, or severe disease that impacts the patient's quality of life.<sup>1,13</sup> Patients should be offered treatment after clinical consultation which includes a review of the clinical history (including past and future fertility considerations) and examination. Symptoms include:

- Heavy menstrual bleeding
- Dysmenorrhoea
- Symptoms of local mass effects such as pelvic pressure, bloating or fullness, urinary frequency, nocturia, urinary retention, or hydronephrosis
- Dyspareunia

Investigations with pelvic ultrasound or contrast-enhanced MRI are required to confirm the diagnosis and exclude alternative differential diagnoses. The size, number, and location of fibroids should be determined, and/or the presence of adenomyosis reviewed. Patients' treatment preferences should be assessed regarding minimally invasive versus surgical treatments.

### Recommendation: A

## Contraindications

Absolute contraindications to UAE include:

- Active viable pregnancy
- Suspected pelvic malignancy
- Active or subacute pelvic infection

Patients should be counselled about increased risks associated with embolisation procedures in some patients with the following co-morbidities, with additional details below.

- Contrast allergy
- Severe cardiopulmonary disease
- Morbid obesity
- Bleeding diathesis

Mild contrast allergy can be managed with oral corticosteroid pre-medication.<sup>14</sup> In patients with a severe allergy, alternative contrast agents including carbon dioxide or gadolinium may be used.<sup>14</sup>

Many patients are suitable for intravenous conscious sedation prescribed by an interventional radiologist and administered by an appropriately trained radiology nurse in co-ordination with guidelines for sedation from the Australian and New Zealand College of Anaesthetists.<sup>15</sup> For those with severe cardiopulmonary disease or morbid obesity, a dedicated anaesthetic assessment may be required on a case-by-case basis including performing the procedure in conjunction with a trained anaesthetist. These are recognised risk factors for all interventional and surgical procedures, and are not a contraindication to UAE. Some technical limitations such as morbid obesity and/or bleeding diathesis can be obviated with ultrasound-guided access, trans-radial access, and/or the use of vascular closure devices.

The presence of an intra-uterine device (IUD) and the risk of post-UAE infection remain uncertain, but recent studies suggest that IUD's may not need to be routinely removed pre-procedure.<sup>16</sup> Additionally, many women

may not need the IUD after UAE if the indication was for heavy bleeding, and higher-level studies are needed to expand this evidence base.

The presence of a pedunculated subserosal fibroid should no longer be considered a contraindication to treatment as rates of torsion and intra-peritoneal detachment are small and subsequent studies have shown treatment success in these groups.<sup>17</sup>

### Recommendation: C

## Consent

Informed, written consent should be obtained prior to any fibroid intervention. This should include a thorough assessment of all treatment options, potential benefits, and possible risks. For patients interested in pursuing UAE, counselling should include procedural complications such as uterine infection, the possibility of requiring future treatment, the small risk of an incidental diagnosis of leiomyosarcoma, and the rare potential for salvage hysterectomy. Patients should be informed of the risk of passage of fibroid or fibroid products after UAE with rates quoted between 4% and 15%.<sup>18</sup> The risk may increase when there is <25% attachment of the fibroid to the underlying myometrium and can be assessed on pre-procedure MRI. It generally presents in the first 2–4 weeks, is associated with post-procedure endometritis, and is an important reason for ongoing gynaecologist collaboration in the event of requiring post-procedure curettage.<sup>19</sup> Post-embolisation syndrome should also be discussed.

Any invasive intervention, including surgery or UAE, should not be performed without considering the full spectrum of treatment options. Ideally, this should include an assessment by both a gynaecologist and an interventional radiologist. Patients should be offered information leaflets or access to electronic resources to aid their understanding of the UAE. This includes those prepared by professional societies such as Inside Radiology (RANZCR), Interventional Radiology Society of Australasia, and/or Cardiovascular and Interventional Radiology Society of Europe. It is recommended that consent is performed in an outpatient clinic setting so that adequate time can be allowed for patients to consider the procedure and seek alternative advice if necessary.

### Recommendation: A

## Future pregnancy

Historical advice suggested UAE should be avoided in women desiring future fertility due to concerns around causing subfertility. A number of early case reports linked embolisation to early miscarriage, placental insufficiency, and premature ovarian failure.<sup>20</sup> However, many studies have since shown that successful pregnancy after

UAE is possible. A systematic review published in 2018, comprising 989 patients from 17 studies, including 1 randomised controlled trial, 2 case-control studies, and several case series, showed that there was a slightly higher miscarriage rate for UAE (45–60%) than myomectomy (20–38%) and slightly lower pregnancy rates in UAE (51–69%) than myomectomy (47–78%).<sup>21</sup> The FEMME trial showed that pregnancy was achievable after both myomectomy and UAE.<sup>10</sup>

Recently, Serres-Cousine *et al.* retrospectively assessed the rate of successful pregnancy in 398 women after UAE; inclusion criteria were <43 years of age, single fibroid >5 cm, multifibroid disease, and/or adenomyosis. Although there was a high loss of follow-up, they reported 148 successful pregnancies and 109 live births including 74 at term.<sup>22</sup>

Patients' levels of interest in future pregnancy should be thoroughly explored and considered on an individual basis, with informed consent including advice that the potential for future pregnancy after UAE is currently uncertain. For women who experience subfertility due to fibroids, desire pregnancy, and where surgery is a safe and feasible option, myomectomy may be preferred. In those who have had myomectomy previously or are poor surgical candidates, UAE may be performed with appropriate counselling regarding fertility. Only 1 randomised controlled trial on this topic has reported results, and prospective studies are now needed on this topic.<sup>21</sup>

#### Recommendation: B

### Consideration of Malignancy

The incidence of incidental uterine leiomyosarcoma increases with age, particularly over 50 years.<sup>23,24</sup> Treatment of women where histology of fibroids is not assessed should include counselling that the risk of uterine leiomyosarcoma is 1 in 200 to 1 in 500<sup>23–25</sup> and may be potentially undetected at the time of treatment; this may lead to a delayed diagnosis. This holds true for embolisation as it does for all non-surgical fibroid treatments. It is recommended that patients who are post-menopausal, or in whom fibroids continue to enlarge post-treatment, have dedicated surveillance with MRI.

There may be a role for pre-procedure screening for malignancy using MRI with diffusion-weighted sequences and the use of lactate dehydrogenase isoenzyme levels. Tong *et al.* assessed the incidence of leiomyosarcoma within 1960 patients who underwent MRI screening pre-uterine fibroid resection, identifying 10 with leiomyosarcoma (0.5%) with a sensitivity of 100% and specificity of 97%. However, there was a high false-positive rate in their study (59 patients or 3%). The incremental cost-effectiveness from MRI assessment was USD\$9326 per gained life-year based on their analysis.<sup>24</sup> Currently, MRI is not Medicare-funded for this indication in

Australia and patients incur an out-of-pocket cost for this investigation.<sup>12</sup>

Treatment of fibroids without MRI is the same consideration for all non-surgical treatments including hormonal agents for smaller fibroids. The balance in recommending MRI needs to be based on the available evidence, and include the sensitivity, cost, and leiomyosarcoma incidence. Recommendations must also consider women who would rather choose no treatment rather than hysterectomy, and thus where definitive histology is not possible. An 0.3% incidence of leiomyosarcoma should not justify a "surgery first" approach, especially in pre-menopausal women.

Given the level of evidence is low, and the high false-positive rate, the use of routine MRI may depend on individual patient circumstances (including age and economic situation) and could form a part of the pre-procedure counselling process.

There was no consensus on the necessity of routine MRI from the authors. However, there was agreement that increased advocacy is needed towards expanding the Medicare Benefits Schedule to allow access for Australian women with fibroids in the future.

#### Recommendation: C

### Periprocedural considerations

Embolisation may be performed as a day case or with hospital admission, depending on local circumstances and patient preferences. A regional local anaesthetic block to the superior hypogastric nerve may be considered to reduce the requirement for post-operative opioid analgesia, however, a recent randomised controlled trial of UAE day-procedures did not show any difference in the rate of readmission for pain, and its use may help to confine UAE procedures to a day-admission.<sup>25</sup> Intra-arterial lidocaine has also been reported to result in reduced post-procedure analgesic requirements.<sup>26,27</sup> More data on efficacy for both these techniques are required before they can be recommended as a routine procedural adjunct.

The role of antibiotic prophylaxis in minimising infectious complications after UAE is controversial.<sup>28</sup> The Royal College of Obstetricians and Gynaecologists and the Society of Interventional Radiology both recommend a single dose of periprocedural antibiotic prophylaxis targeted at skin flora<sup>28</sup> and this is supported based on the available evidence and consensus. There was no consensus on the role of post-procedure prophylactic oral antibiotic use.

#### Recommendation: C

### Potential procedural complications

Immediate complications include access site (haematoma, pseudoaneurysm, and infection) or procedure-related (contrast allergy, non-target embolisation, and

dissection). Later or delayed complications can include vaginal discharge (approximately 15%), expulsion per vagina of fibroid tissue (10%), and infection (<1%).<sup>17,29</sup> These are usually related to submucosal or transmural fibroids that need to be proactively and collaboratively managed with gynaecologists, including GnRHa pre-treatment, planned same day or delayed hysteroscopic resection, a contingency plan for unexpected endocavitary migration and cervical obstruction. Post-embolisation syndrome should be regarded as an expected sequela of treatment in most patients and is of variable severity.<sup>17</sup> Symptoms may include fever, abdominal pain, nausea, and vomiting. Interventional radiologists who perform UAE should be competent in the detection and management of procedural and post-procedural complications, and when it is appropriate to seek additional treatment including referral to a relevant gynaecologist.

#### Recommendation: A

### Follow-up

Technical success should be expected in 90–100% of patients at completion of UAE.<sup>7,19</sup> It may take months for uterine volume to reduce and it is anticipated that a volume of reduction of 40–60% is achievable, however, symptom improvement is often much sooner for women with heavy menstrual bleeding or dysmenorrhoea.<sup>7,19</sup> It was estimated from the FIBROID registry that 14% of patients may need some form of additional uterine treatment again at 3 years<sup>29</sup> and repeat UAE is an option in addition to surgical treatments.

Overall patient satisfaction and monitoring of symptom improvement and complications remain the responsibility of the treating interventional radiologist. Planned follow-up within 3-months of the procedure should be arranged with the patient and the interventional radiologist should be available for contact in the event the patient, GP, or gynaecologist requires in the future.

#### Recommendation: A

### Who should perform embolisation

UAE procedures should be performed by those who have undergone appropriate training and experience, ideally including credentialing from a relevant specialist college as well as local hospital accreditation for performing advanced embolisation procedures. In addition, training and credentialing should include competency in the use of microcatheters and advanced embolisation techniques with particulate embolic material. Procedures should be monitored by a local quality assurance program that may include logbook, appropriate follow-up, and quality improvement meetings. In Australia and New Zealand, interventional radiologists are the only specialist group who currently meet these criteria.<sup>30</sup>

#### Recommendation: C

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### Data availability statement

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

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## Supporting Information

Additional Supporting Information may be found in the online version of this article at the publisher's web-site:

**Appendix S1.** Summary of the AGREEII reporting checklist.

**Appendix S2.** AGREEII reporting checklist.