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UTERINE FIBROID EMBOLIZATION (UFE)

These guidelines are jointly produced by the Society of Obstetricians and Gynaecologists of Canada (SOGC), the Canadian Association of Radiologists (CAR), and the Canadian Interventional Radiology Association (CIRA).

This document has also been reviewed by the Clinical Practice Gynaecology Committee and approved by the Executive and Council of the Society of Obstetricians and Gynaecologists of Canada.

We recommend that these guidelines be reviewed and updated on a regular basis by a joint committee of the SOGC, CAR, and CIRA. They should be made widely available to physicians and patients contemplating uterine fibroid embolization.

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Abstract

Objective: To help direct the organized and effective implementation of uterine fibroid embolization into clinical practice in Canada.

Options: This document is restricted to the management of uterine fibroid embolization as performed by the radiologists utilizing a trans-femoral artery approach with arteriography followed by vessel embolization.

Outcomes: Uterine fibroid embolization has been evaluated in terms of patient satisfaction, risks of complications, risks in subsequent pregnancy and rate of hysterectomy within a few months of the procedure. As the procedure is relatively new, data on long-term outcomes are not available.

Evidence: Published opinions of experts, supplemented by evidence from clinical trials where appropriate.

Values: The quality of the evidence is rated using the criteria described by the Canadian Task Force on the Periodic Health Examination.

Benefits, Harms, and Costs: For women presenting with symptomatic uterine fibroids who are candidates for UFE, there is often a benefit to avoiding an abdominal surgery. The risks of the UFE procedure, possible complications, and short- and long-term prognosis must be measured on an individual basis against the well-studied surgical alternatives. Patient preference is an important component of this evaluation. The non-material costs of ongoing symptoms from the fibroids are difficult to measure and use comparatively against the cost of hospitalization and treatment. In evaluating costs of UFE, the calculations should take into consideration the cost of managing occasional complications including subsequent hysterectomy. The cost of myomectomy or hysterectomy will vary largely depending on technique used and length of hospital stay.

Recommendations:

1. Women considering treatment of fibroids should be counselled that while the early results of uterine artery embolization are encouraging, no long-term data exist. (II-2-B)
2. UFE should only be considered for women with symptomatic or problematic fibroids who might otherwise be advised to have surgical treatment. (III-A)
3. UFE as a treatment for fibroids in patients wishing to preserve their fertility should be undertaken with full disclosure to the patient about the limitations of such a procedure and the lack of existing data regarding future fertility and pregnancy outcomes. (III-C)
4. UFE is contraindicated in women who have evidence of current genitourinary infection and/or malignancy. (II-2-B)
5. Women who choose UFE as an alternative to hysterectomy should be counselled regarding the risk of major complications

Key Words

Uterine artery embolization, uterine myomas, uterine fibroids, leiomyoma, hysterectomy, myomectomy, interventional radiology, menometrorrhagia, dysfunctional uterine bleeding

of UFE where hysterectomy may be urgently required and potentially lifesaving. In view of this small but important risk, UFE is relatively contraindicated in women who are unwilling to have a hysterectomy under any circumstances. (III-C)

6. Genitourinary infection is the predominant cause of serious morbidity and mortality. Further research on the utility of prophylactic antibiotic therapy and the value of pretreatment screening for infection is needed. (II-2-B)
7. A gynaecologist who is familiar with UFE should evaluate all patients considered for UFE before the procedure is booked and a consensus on the suitability of the procedure achieved between the gynaecologist and radiologist. (III-C)
8. Only radiologists with specialized embolization experience and techniques should perform UFE. (III-C)
9. The particular responsibilities of both gynaecologist and radiologist should be established prior to treatment and be set out in a relevant hospital protocol. A particular physician must be responsible for the patient at all times. (III-C)
10. A Canadian national registry of numbers, indications, outcomes, complications, and successful pregnancies associated with UFE should be created and jointly administered and funded by the SOGC, CAR, and CIRA. (III-C)

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INTRODUCTION

Leiomyomata are the most common tumours in women. The Society of Obstetricians and Gynaecologist of Canada published guidelines on the management of fibroids in 2003, which reviewed the available evidence for diagnosis and management both medical and surgical.[1]

Uterine artery embolization has been used during the last 2 decades in a variety of clinical settings including postpartum hemorrhage, bleeding after Caesarean section, and bleeding following gynaecological surgery.[2] The technique was extended in later years to include the management of arterial venous malformations of the genital tract as well as gestational trophoblastic disease. Ravina first used arterial embolization to treat fibroids in 1991, publishing his first series in 1995.[3] Since that time, many thousands of uterine artery embolizations have been performed worldwide and there is increasing public awareness of the availability of this new technology. The Royal College of Radiologists and the Royal College of Obstetricians and Gynaecologists in the United Kingdom recognized the importance of interdisciplinary collaboration and published a joint guideline for the management of women who choose uterine fibroid embolization (UFE).[4] As the procedure increases in popularity and with the apparent efficacy of this technique, the Society of Obstetricians and Gynaecologists of Canada (SOGC), the Canadian Association of Radiologists (CAR), and the Canadian Interventional Radiology Association (CIRA) formed committees to prepare this guideline within a Canadian perspective.

Ischemia of uterine fibroids may be achieved by a variety of techniques. Laparoscopic uterine artery occlusion has been shown to yield equivalent results to UFE in the short term utilizing bipolar coagulation[5,6] or clips.[7] Furthermore, a procedure of temporary bilateral uterine occlusion performed with intravaginal, "incisionless" application of a paracervical clamp with integrated audible Doppler ultrasound to treat uterine fibroids has been reported.[8] Discussion of the alternative treatments including medical and surgical options for uterine fibroids is presented elsewhere and will not be covered in this document.[1]

The quality of evidence reported in these guidelines has been described using the Evaluation of Evidence criteria outlined in the Report of the Canadian Task Force on the Periodic Health Exam (Table).[9]

ADVANTAGES AND RISKS OF UFE

UFE is emerging as an effective alternative to hysterectomy and

Table.

Quality of Evidence Assessment[9]	Classification of Recommendations[9]
The quality of evidence reported in these guidelines has been described using the Evaluation of Evidence criteria outlined in the Report of the Canadian Task Force on the Periodic Health Exam.	Recommendations included in these guidelines have been adapted from the ranking method described in the Classification of Recommendations found in the Report of the Canadian Task Force on the Periodic Health Exam.
I: Evidence obtained from at least one properly randomized controlled trial.	A. There is good evidence to support the recommendation that the condition be specifically considered in a periodic health examination.
II-1: Evidence from well-designed controlled trials without randomization.	B. There is fair evidence to support the recommendation that the condition be specifically considered in a periodic health examination.
II-2: Evidence from well-designed cohort (prospective or retrospective) or case-control studies, preferably from more than one center or research group.	C. There is poor evidence regarding the inclusion or exclusion of the condition in a periodic health examination, but recommendations may be made on other grounds.
II-3: Evidence obtained from comparisons between times or places with or without intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940s) could also be included in this category.	D. There is fair evidence to support the recommendation that the condition not be considered in a periodic health examination.
III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.	E. There is good evidence to support the recommendation that the condition be excluded from consideration in a periodic health examination.

myomectomy for symptomatic fibroids. Although early results are encouraging, there are no long-term data available. The initial report of UFE was published in 1995 by Ravina *et al.*[3] The same group subsequently reported excellent results with a larger series of 88 patients who were followed up to 5 years.[10] Mean fibroid volume reduction (largely ultrasound assessed) was reported at 69% with procedural success reported at 89% (although their definition of "success" was not stated). Nine patients (10%) in this series underwent hysterectomy; 8 for pain and 1 for bleeding associated with a sub-mucous fibroid. Since then it is estimated that 40 000 women have been treated worldwide. Numerous case series have been published.

Pron *et al.*[11] reported on the Ontario Uterine Fibroid Embolization Trial, which enrolled 555 women. The median follow-up was 8.9 months. Menorrhagia improved in 83% of women following the procedure, dysmenorrhea improved in 77%, and urinary frequency improved in 86% of women. The mean fibroid volume reduction for the dominant fibroid was 33% at 3 months. Amenorrhea occurred in 8% of women (3% of women under 40 and 41% of women over age 50). The complication-related hysterectomy rate in the Ontario UFE Trial was 1.5% within 3 months of the embolization.[12] Of the 8 procedures, 2 were for infection, 4 for persistent post-embolization pain, 1 for a 10 cm prolapsed leiomyoma, and 1 for persistent vaginal bleeding.

Walker and Pelage[13] reported on 400 patients with an average follow-up of 16.7 months. Menstrual bleeding improved in 84% and dysmenorrhea improved in 79%. Seven percent of women experienced amenorrhea and 3.5% of women expelled fibroids per the vagina. Three patients (1%) developed endometritis requiring hysterectomy. Twenty-six women (6%) had clinical failure, meaning that their symptoms did not resolve.

The first quality-of-life assessment was reported by Worthington-Kirsch in 1998.[14] This series has recently been upgraded and is now the largest in the literature, with 305 patients entered.[15] Follow-up was restricted to 3 months. There were 6 hysterectomies in the series but none for infectious complications. Average fibroid volume reduction was not stated; but the success rate—defined as improvement in menorrhagia, pain, and pressure, as well as overall patient satisfaction—was reported as 92%. Thirteen fibroid expulsions were reported in this series, all without complication. Quality-of-life was also addressed by Spies *et al.*[16] Health-related quality of life was improved in all 50 cases at 3 months. Mean change scores were statistically significant for all domains up to 3 months ($P<0.01$) and up to 6 months ($P<0.05$), other than backache ($P = 0.12$).

Spies *et al.*[17] reported on 200 women with a mean follow-up of 21 months. At 1 year post-UFE, menorrhagia was improved in 90% of women and bulk symptoms improved in 91%. Complications after 400 consecutive UFE cases were reported by this group. Peri-procedural complications (defined as complication within 30 days of the procedure) occurred in 34 patients (8.5%). Ten women (2.5%) passed fibroids. Two women developed endometritis. One woman had a pulmonary embolus 3 days after the procedure. Another patient developed bilateral iliac artery thrombosis. Two women had hysterectomies —1 for a uterine infection 10 weeks after embolization, and 1 required hysteroscopic myomectomy for incomplete expulsion of a fibroid with associated menorrhagia.

Having reviewed these published series, it appears that menorrhagia and bulk or pressure symptoms are alleviated in 80 to 90% of patients by 1 year. Mean fibroid volume reduction at 1 year range from 50 to 60%. Hysterectomy or myomectomy for complications occurred in 1% of patients. Readmission for infections occurred in 1%. Infections can occur several months after the procedure. Delayed post-procedural pain should raise suspicion of uterine infarction. This complication can lead to infection and always results in hysterectomy in the women studied.

At least 5 deaths have been reported after UFE. The first reported case involved septic shock secondary to *Escherichia coli* in the United Kingdom.[18] The patient was thought to have an asymptomatic urinary tract infection at UFE. In the second case, a 60-year old Italian woman with known breast cancer underwent UFE for fibroid disease. After several days of inpatient treatment she developed a pulmonary embolus and died.[19] Another death from septic shock after embolization was reported by de Blok *et al.* in the Netherlands.[20] At autopsy, there was extensive ischemic necrosis of the uterus. Cultures revealed group A streptococcus.[20] In the United States, 2 deaths following UFE were reported by Robert Worthington-Kirsch at the 31st Annual Meeting of the American Association of the Gynecologic Laparoscopists held November 20 to 24, 2002 in Miami Beach, Florida (personal communication with Worthington-Kirsch, Society of Interventional Radiology UFE Task Force member).

RECOMMENDATIONS

1. **Women considering treatment of fibroids should be counselled that while the early results of uterine artery embolization are encouraging, no long-term data exist. (II-2-B)**
2. **UFE should only be considered for women with symptomatic or problematic fibroids who might otherwise be advised to have surgical treatment. (III-A)**

PATIENT ASSESSMENT

While safety and efficacy of the technique are being established, we believe that UFE should only be recommended to women with symptomatic fibroids who might otherwise be advised to have surgical treatment. Symptoms might include menorrhagia, dysmenorrhoea, dyspareunia, and other pressure effects of

the fibroid on the urinary or gastrointestinal tract. Patients should be informed of the limitations of UFE. Women who are infertile (or who may wish to become pregnant subsequently) present particular problems. Women who have medical conditions contraindicating surgery, who are unwilling to receive a blood transfusion (e.g., Jehovah's Witnesses), or who have had previous unsuccessful fibroid surgery may find UFE an acceptable method of treatment. Patients must however recognize that complications of the procedure may require hysterectomy.

INDICATIONS FOR UFE

Accurate pre-treatment diagnosis is essential and should be made by the referring gynaecologist. Any patient with demonstrated fibroids where the potential for symptomatic relief overrides the potential for complications and where there is no contraindication, would be a candidate for UFE. Appropriate steps should be taken to ensure that presenting complaints relate to fibroids and are not due to unrelated pathology. The uterine cavity should be carefully evaluated and abnormal uterine bleeding should be appropriately investigated prior to contemplating UFE. If the fibroids are sub-mucous, consideration should be given to hysteroscopic management.[1,21]

Magnetic resonance imaging (MRI) is superior to ultrasound (US) in delineating fibroids and is more likely to permit recognition of adenomyosis if present, however MRI is not readily accessible across the country. The value of UFE in adenomyosis is unproven but may be indicated when fibroids and adenomyosis coexist. It should be noted that UFE is almost always performed without a tissue diagnosis of the fibroids to be treated. The radiologist undertaking the procedure should watch for atypical imaging findings that are not characteristic of fibroids. There have been several cases of presumed fibroids, which did not respond to UFE and later proved to be sarcomas.[22-25]

UFE will not be the preferred method of treatment in all instances, and evaluation by both gynaecologist and radiologist will be necessary to determine appropriate selection.

At present, there are insufficient data to advocate UFE as a means of preserving fertility in those who require relief from symptomatic fibroids; and, likewise, there is not sufficient evidence yet to recommend UFE as a means of treating suspected fibroid-induced infertility.

CONTRAINDICATIONS

While some fibroids (large or pedunculated or very numerous) may not respond as well to UFE, there is insufficient evidence to prescribe UFE based solely on size or number of fibroids. The decision to proceed with UFE should be individualized in the context of predicted risks and benefits as compared with other available modalities of treatment. Absolute contraindications to UFE include active genitourinary infection and/or malignancy, reduced immune status, severe vascular disease limiting access, radiographic contrast media allergy, and impaired renal function which contrast medium may worsen. The relative contraindications related to fibroid morphology (or presence of adenomyosis) need to be weighed against the anticipated benefit of UFE and the relative risks of surgery. Sub-mucosal and pedunculated fibroids may be considered relative contraindications as are previous internal iliac or uterine artery occlusion or recent GnRH analogue administration.

INFERTILE PATIENTS AND THOSE CONTEMPLATING A SUBSEQUENT PREGNANCY

Reports of successful term pregnancies following UFE for a variety of indications have been summarized by Goldberg *et al.*[26] who reported 34 pregnancies after UFE. The spontaneous abortion rate was 32%, the postpartum hemorrhage rate was 9%, the premature delivery rate was 22%, the malpresentation rate was 22%, and there was a 65% rate of Caesarean delivery.

In the Ontario UFE multicentre trial,[12] 555 women with symptomatic fibroids were embolized from June 1998 to November 2000; of these women, 164 (30%) desired future fertility. Seventeen women achieved pregnancy, 2 of them twice and 18 of 19 pregnancies were achieved spontaneously. The pregnancy outcome following UFE were 14 live births (8 term, 6 preterm), 4 spontaneous abortions (15.8%), and 1 therapeutic abortion. Eight were Caesarean deliveries, 2 for placenta previa. There were 2 placenta accretas and 1 membranous placenta. In view of this high risk of placental complications, it may be prudent to follow pregnancies after UFE in a special pregnancy clinic with access to ultrasound with capabilities for early placental studies looking for placenta accreta, which may result from implantation over an area denuded of endometrium.[27]

Patients expressing interest in embolization as a means of restoring fertility must be made aware of the potential complications of the procedure, and cautioned that restoration of fertility is not yet a recognized indication for the procedure. In addition, the potential for adverse effects to a subsequent pregnancy have not yet been determined.[27]

Notwithstanding these limitations, the patient, gynaecologist, and radiologist must evaluate the risks and benefits of such a procedure on an individual basis. Women who elect to undergo UFE for the more accepted gynaecological indications should be told that the effects of the procedure on pregnancy and delivery are uncertain as there are insufficient data on this subject. Infertility and recurrent miscarriage should not currently be regarded as a usual indication for UFE until a controlled clinical trial with appropriate approval by an ethics committee has determined the safety and efficacy. It is recommended that the above advice be included in the written information given to the patient before initial meetings with the radiologist and/or gynaecologist and that a written consent form should be devised that clearly records that the patient understands these risks. Pregnancies will continue to occur following fibroid embolization. It is very important to collect, evaluate,

and disseminate information on these pregnancies.

Myomectomy remains an acceptable option for some women wishing pregnancy.[1]

RECOMMENDATIONS

3. **UFE as a treatment for fibroids in patients wishing to preserve their fertility should be undertaken with full disclosure to the patient about the limitations of such a procedure and the lack of existing data regarding future fertility and pregnancy outcomes. (III-C)**
4. **UFE is contraindicated in women who have evidence of current genitourinary infection and/or malignancy. (II-2-B)**
5. **Women who choose UFE as an alternative to hysterectomy should be counselled regarding the risk of major complications of UFE where hysterectomy may be urgently required and potentially lifesaving. In view of this small but important risk, UFE is relatively contraindicated in women who are unwilling to have a hysterectomy under any circumstances. (III-C)**

CONSENT

As for any procedural consent, time should be allowed for due consideration by the patient. Following a complete evaluation by the gynaecologist, patients who wish to go ahead with UFE, should discuss this with the radiologist responsible and, again, take time for sufficient consideration before the procedure is undertaken. Full consent will include a disclosure of options and potential complications. An example of a suitable consent form is included as Appendix 1 and a typical patient information leaflet as Appendix 2. General practitioners and referring physicians must be kept aware of the details of this new procedure and of its risks. An example of one such information leaflet is provided as Appendix 3.

Every effort should be made to avoid fibroid embolization procedures in the presence of an early pregnancy. While embolization can be carried out at any stage of menstruation if the radiologist is confident that the patient has taken adequate contraceptive precautions, UFE should only be performed in the early to mid-follicular phase of the cycle if adequate contraception has not been used. Patients who present for the procedure later in the cycle should be offered a repeat appointment after menses and this should be documented in the hospital notes.

THE PROCEDURE AND PERIOPERATIVE OPTIMIZATION

Urinary tract infection, if present, should be eradicated. An intrauterine contraceptive device, if present, should be removed prior to the procedure.

Adequate pre-procedural imaging of the fibroids with MRI or US should be available and reviewed prior to the procedure. The menstrual history should be carefully checked and a pregnancy test done to exclude pregnancy, if appropriate. Appropriate consent will have been obtained following the consultation process.

Interventional radiologists may perform the procedure on an inpatient or outpatient basis. Performing the procedure early in the day improves the opportunity for better control of post-procedural pain. Hospital protocols should be available and should include a protocol on peri-procedural sedation and pain relief. UFE should only be carried out in a specialized angiographic suite equipped with digital subtraction angiography. The equipment should be such that multi-angulation is possible, allowing oblique views to be achieved and radiation dosage to be minimized.[28] Equipment with pulsed fluoroscopic capability can be helpful in this respect. Prior to the procedure, intravenous access will be established, allowing intravenous sedation and analgesia to be given during the procedure. Patient-controlled analgesia may be instituted following the procedure. Appropriate monitoring is mandatory, including pulse oximetry.[29] The existing CAR standards for interventional radiology should apply.

The objective of UFE for fibroid disease is to sufficiently reduce flow in both uterine arteries with particulate emboli that will produce ischemic necrosis of the more susceptible uterine fibroids but have no permanent adverse effect on the otherwise normal uterus.

A standard percutaneous transfemoral approach (usually right-sided) is used to access both internal iliac arteries. Occasionally left-sided or bilateral puncture(s) may be used. Having confirmed the position of the catheter in the internal iliac artery, a guide wire is manipulated into the uterine artery and the catheter advanced over the wire. Contrast is injected to confirm satisfactory catheter position within the uterine artery. Arteriography is performed at this stage documenting the vascularity and size of the fibroid uterus as well as satisfactory positioning of the catheter. Embolization is then performed.

The most commonly used agent is polyvinyl alcohol, a well-established non-biodegradable agent available in a variety of sizes, although experience is being accumulated with newer agents. The embolic agent is mixed with contrast as it is injected in order to monitor particle location as well as the progress of embolization. Frequent test injections of contrast may also be used. As the particles obstruct the arterial tree, the speed of contrast clearance will decrease until it reaches a point of stasis or even reflux within the uterine artery. This may serve as an end-point for embolization. A more conservative procedure is used by some radiologists with the end point a *slow* rather than *absent* flow in the uterine artery. The efficacy and difference in complication rates between these 2 approaches require further assessment.

Adequate patient monitoring and pain control is essential in the post-procedural period. There are numerous published approaches to pain management, including narcotics orally or

by patient-controlled analgesia, anti-emetics, and, more recently, regional or epidural administration. Consultation between radiology, gynaecology, and possibly anesthesia in some centres may be required.

Once the patient has been determined to be a candidate for embolization, the procedural technique is in the hands of the radiologist. After the procedure, the patient is jointly in the care of radiologist and gynaecologist (and possibly the anesthesiologist). The single most important element in the continuing care of the patient is that the patient should have rapid access to a named qualified health provider who will be in a position to allay any anxieties relating to expected sequelae and also to act immediately if there is any question of the development of a serious problem.

Radiologists may take principal medical responsibility for the care of a patient for part or all of the hospital stay on the same basis as any other registered medical practitioner, provided that their skills, training, and available facilities are sufficient to ensure appropriate care until responsibility is reassumed by the referring medical practitioner. Where radiologists are working in a hospital without a gynaecological unit, agreed upon procedures for communication between clinicians to allow rapid recourse to the appropriate specialist are essential. As the gynaecologist, radiologist, and sometimes anesthetist and primary care provider are involved in the management of the patient, it is important that these individuals undertake a team approach to potential complications to ensure that the patient receives appropriate care when required.

RECOMMENDATIONS

6. **Genitourinary infection is the predominant cause of serious morbidity and mortality. Further research on the utility of prophylactic antibiotic therapy and the value of pretreatment screening for infection is needed. (II-2-B)**
7. **A gynaecologist who is familiar with UFE should evaluate all patients considered for UFE before the procedure is booked and a consensus on the suitability of the procedure achieved between the gynaecologist and radiologist. (III-C)**
8. **Only radiologists with specialized embolization experience and techniques should perform UFE. (III-C)**

SIDE EFFECTS AND COMPLICATIONS

Perioperative risks and complications include infection, bleeding, and hematomas at the groin femoral artery puncture site; allergic or anaphylactic reactions to the iodinated contrast dye; and incomplete uterine artery occlusion as well as misembolization of non-target organs.[30-33] Such complications occur in approximately 1% to 2% of procedures. Puncture-site hematomas often occur but are unlikely to have significant consequence. Serious adverse reactions to the contrast medium are rare and, in non-diabetic women with normal renal function, it is unusual for problems to arise with typical dosage of contrast. Spasm in the uterine artery, if excessive, can be minimized with an intra-arterial vasodilator or micro-catheter techniques, although arterial dissection or occlusion may prevent effective embolization of that artery.

A. EARLY OR ACUTE ABDOMINAL PELVIC PAIN

Virtually all women experience some degree of acute pain, often requiring hospitalization with intensive pain management protocols and monitoring. No correlation has been established between uterine size, myoma number or size, duration of procedure, quantity of polyvinyl alcohol particles used, or clinical outcome of the treatment.[2] The pain is thought to be due to non-specific ischemia of the uterus and fibroids, and responds to pain control including opiates and non-steroidal anti-inflammatory drugs (NSAIDS).[2]

B. POST-EMBOLIZATION SYNDROME

Up to 40% of women experience a constellation of signs and symptoms including diffuse abdominal pain, generalized malaise, anorexia, nausea, vomiting, low-grade fever, and leukocytosis.[32] The syndrome is self-limiting and usually resolves within 48 hours with conservative and supportive therapy, consisting of intravenous fluids and adequate pain control, including NSAIDS.

C. INFECTION

The incidence of febrile morbidity and sepsis following embolization has been reported to be between 1.0% and 1.8%.[30-33] The infections have included pyometria with endomyometritis, bilateral chronic salpingitis, tubo-ovarian abscess, and infected myomas. The most frequent pathogen isolated has been *Escherichia coli*.[33] Some women have responded to antibiotic therapy but others have required prolonged hospitalization, intensive therapy, and hysterectomy. One woman died following uterine artery embolization, despite an abdominal hysterectomy performed 17 days after embolization and intensive therapy. Prophylactic antibiotics have not been shown to be effective and their use should be reserved for women at higher risk of infection, according to established guidelines.[34]

D. PERSISTENT OR CHRONIC PAIN

In 5% to 10% of women, the pain persists over 2 weeks. When it lasts longer than 2 to 3 months, persistent pain in the absence of infection does not resolve spontaneously, and it may require surgical intervention. Hysterectomy for post-embolization pain has been reported in up to 2% of women within 6 months of the embolization.[31,32,35]

E. OVARIAN DYSFUNCTION

Transient and permanent symptoms indicative of ovarian failure have been reported by up to 10% of women after uterine

artery embolization. Underlying factors leading to ovarian dysfunction are unknown, but the evidence indicates that women over the age of 45 are more likely to experience post-embolization ovarian failure.[30,36] Ovarian failure is of great consequence when preservation of fertility is desired.

F. MENSTRUAL DYSFUNCTION

Improvement in menstrual bleeding in up to 90% of women following uterine artery embolization has been reported.[11,12] The menstrual improvement is age dependent, the highest being after age 50. Transient and permanent amenorrhea has been reported in 15% and 3% of women, respectively.[16,31,37] Amenorrhea after embolotherapy is also highly age dependent and is reported to be related to waning ovarian function.

G. TRANSCERVICAL MYOMA EXPULSION

Following artery embolization, spontaneous expulsion of myomas through the cervix has been reported to occur in approximately 5% to 10% of women.[32,38,39] Sixty percent of women with submucous myomas, confirmed by hysteroscopy, passed myomas vaginally, following uterine artery embolization.[39]

H. UTERINE WALL INTEGRITY

The physical characteristics, integrity, and the histopathologic features of the uterine wall after uterine artery embolization remain unknown. Uterine wall defects,[40] uterine fistula,[41] and 1 case of diffuse uterine necrosis[42] following uterine artery embolization have been reported. Although normal pregnancies and deliveries following uterine artery occlusion have been reported, there is insufficient long-term data regarding reproductive outcome following this procedure and it would be prudent to reserve embolization for women who will not wish pregnancy.[26,27,43]

I. HYSTERECTOMY

The number of women who proceed to hysterectomy following uterine artery embolization has been used as an indicator for the measurement of treatment failure.[11,12] The rate of hysterectomy within 6 months of embolization has been reported to be 1% to 2%, and the indications have included infection, persistent bleeding, persistent pain, fibroid prolapse, and uterine malignancies.[12,13,30,38]

K. MORTALITY

Please see the section "Advantages and Risks of UFE" earlier in these guidelines.

PROFESSIONAL RESPONSIBILITY

It is the responsibility of the gynaecologist referring a patient for UFE and of the radiologist to have adequate understanding of the procedure, and a willingness to work together to guarantee proper patient selection, appropriate follow-up, and treatment of complications. The gynaecologist must be able to intervene with a surgical remedy should a complication necessitate this. The radiologist must have extensive experience with selective arterial embolization and thorough knowledge of the anatomy and risks of the procedure, and/or have formalized training on the techniques of UFE.

RECOMMENDATION

9. **The particular responsibilities of both gynaecologist and radiologist should be established prior to treatment and be set out in a relevant hospital protocol. A particular physician must be responsible for the patient at all times. (III-C)**

CENTRALIZED CANADIAN NATIONAL REGISTRY FOR UFE

The concept of a national registry has been increasingly employed as new procedures or treatment methods are introduced throughout the world. Examples are the European registry for aortic stent grafting, and the recent UFE and Legs for Life registries in the United States. The registry affords an opportunity to continuously monitor the frequency and success of the procedure, particularly as newer and older approaches are debated.

Data would be collected from gynaecologists, radiologists, and patients. Registry forms, patient information sheets, and consent forms would be sent out to radiologists and gynaecologists in a manner and using resources yet to be determined by a joint SOCG/CAR/CIRA committee.

A standardized SOGC/CAR/CIRA-approved patient information sheet could form the basis of informed consent. The patient's consent for telephone follow-up would also be obtained prior to the procedure. A series of simple forms should be sufficient to collect patient information and clinical and procedural data.

This data should become part of a national database. The aim of the registry should be to determine the periprocedural and late complication rates of UFE as well as the clinical outcomes and "treatment satisfaction." Every 12 months, the patient would be contacted directly and a further telephone questionnaire completed.

RECOMMENDATION

10. **A Canadian national registry of numbers, indications, outcomes, complications, and successful pregnancies associated with UFE should be created and jointly administered and funded by the SOGC, CAR, and CIRA. (III-C)**

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