

Wandsworth NHS Policy on minimally invasive surgery for uterine fibroids

This policy applies to uterine artery embolisation for fibroids, Laparoscopic Laser Myomectomy and MRI-guided percutaneous laser ablation of fibroids.

Introduction

Uterine fibroids or leiomyomata are benign tumours that occur in the uterus. They are the most common type of female tumour and their aetiology is not fully understood. They are found anchored to the uterine wall and can vary in size from the size of the grape to large masses that can be palpated through the uterine wall.¹ They are four types of fibroids – submucous, subserous, intramural and pedunculated

NICE has produced several interventional procedures guidance related to surgery for fibroids:
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Uterine artery embolisation for fibroids – IPG 94 (2004)

Laparoscopic Laser Myomectomy – IPG 23 (2003)

MRI-guided percutaneous laser ablation of fibroids – IPG 30 (2003)

The PCT is receiving an increasing number of requests to fund these procedures this paper states RTPCT commissioning policy.

Risk factors

Fibroids rarely occur before menarche or after menopause suggesting that they result from hormonal stimuli. Early menarche is associated with higher risk of fibroids but parity, shorter birth intervals and age of first birth ≥ 35 is appears to reduce risk. The association between fibroids and oral contraceptive use is inconsistent. Higher BMI, low levels of physical activity and hypertension are both associated with increased risk. African American women have been found to have a two-fold risk of fibroids compared to white women in the US. Smoking appears to lower the risk of fibroids possibly due to the interference of nicotine with the production of oestrogens and association of heavy smoking and lower BMI.¹

Symptoms

Fibroids can result in any three of the following symptoms:

- Bleed irregularities such as heavy menstrual cycles, irregular bleeding and anaemia
- Mass effects related to the size and location of the fibroid such as pelvic pressure or pain, urinary frequency, constipation or painful bowel movements and dyspareunia.
- Complications related to pregnancy such as infertility, miscarriage and preterm birth

Prevalence

A cohort study of over 1300 black and white women aged between 35-49 years undertaken in the US, found that the overall prevalence of fibroids was 35% (45% black and 21% in white women (Baird et al 2003). Clinically relevant tumours among women aged between 35-39 was 10-15% in white women and 35 % in white women in their forties.⁵ Extrapolating these figures to RTPCT there are approximately 4,700 women aged between 35-49 with fibroids.

Approximately 980 women aged 35-39 and 5,100 women in their forties who have symptomatic fibroids

Interventions

Fibroids can be managed by:

- Open or laparoscopic surgical removal of the entire uterus (hysterectomy) this includes open or laparoscopic
- Open or laparoscopic surgical removal of the fibroid (myomectomy)
- Medical management including oral contraceptives, hormone therapy, intrauterine devices, non-steroidal anti-inflammatory drugs etc
- Uterine artery embolisation
- Endometrial ablation
- In situ destructive techniques by focused ultrasound guided MRI

This policy refers to laparoscopic laser myomectomy, uterine artery embolisation and MRI-guided percutaneous laser ablation of fibroids

Uterine artery embolisation

UAE involves occlusion of the uterine arteries with tiny particles which causes the fibroid to shrink and but is believed not to have a permanent adverse effects on the rest of the uterus.

NICE commissioned a review of the evidence of UAE and found that the procedure was efficacious in reducing mean fibroid volume from between 40-70% but the reduction in volume did not correlate with changes in symptoms. Improvement in symptoms was reported in between 62-95% of women. The procedure was associated with several complications including the need for hysterectomy in 0.5-11.8%, infection, fever and death. Ovarian dysfunction also occurred in 2.5 – 14% of women. Its effect on fertility was unclear. Most studies were small and of poor quality and there was little information on the long-term effects of this procedure.⁶

The NICE clinical guideline on heavy menstrual bleeding (HMB) states that when surgery for fibroid-related HMB is felt necessary, UAE, myomectomy and hysterectomy must all be considered, discussed and documented. UAE should be considered in women with HMB associated with fibroids who want to retain their uterus and /or avoid surgery.⁷

NICE Recommendation:

Current evidence on UAE suggests that it is safe enough for routine use and there are symptomatic benefits in the majority of patients in the short term. However more evidence is required on the degree and duration of the benefits and of its effects on fertility

Laparoscopic Laser Myomectomy

This procedure involves the destruction of fibroids using a laparoscope passed through a small incision in the abdomen and through the wall of the uterus. The fibroids are destroyed with a laser. In review of the evidence undertaken by the NICE, several case series and one systematic review were identified. The quality of the studies was poor and it was therefore difficult to identify the patients who would benefit from this procedure or generalise the findings of the research. There were indications that the procedure may be suitable for small fibroids, most of which are asymptomatic, and therefore the Specialist Advisors to NICE questioned the clinical value of the procedure

NICE Recommendation:

Current evidence on the safety and efficacy of laparoscopic laser myomectomy does not appear adequate to support the use of this procedure without special arrangements for consent, audit or research.

MRI-guided percutaneous laser ablation of fibroids

Under MRI guidance, needles are inserted into the skin into the centre of a fibroid. Laser fibres are inserted into the needles and laser energy used to destroy the fibroid. (NICE IPG)

Four small UK case series found a three-month (short-term) decline in fibroid volume of about 30%. Adverse effects were minor and transient and included urinary tract infections, skin burns and vaginal bleeding. Because the studies were small and not randomised the findings cannot be generalised or patients likely to benefit identified. The level of evidence for this procedure is weak and the clinical outcomes modest. There is little evidence on the long-term outcomes of this procedure

NICE recommendation:

Evidence on the safety and efficacy of MRI-guided percutaneous laser ablation of uterine fibroids is insufficient to support its use without special arrangements for consent, audit and research.

RTPCT policy on surgery for uterine fibroids

- WPCT will only fund the following procedures for fibroids in exceptional circumstances:
 - MRI-guided percutaneous laser ablation
 - Laparoscopic laser myomectomy
- WPCT will fund UAE of fibroids in the following circumstances:
 - The fibroids is greater than 3 cm in diameter AND
 - The fibroid is causing other symptoms that have a severe impact on the woman's quality of life such as heavy or painful menstrual bleeding, problems with fertility or pressure symptoms AND
 - The woman wants to avoid surgery and/or retain her uterus

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Policy approved by NHS Wandsworth Clinical Effectiveness Group 1st April 2009.

References:

¹ Agency of Healthcare research and clinical quality: Management of uterine fibroids: an update of the evidence. AHRQ Publication No 07-e011 July 2007

² NICE Uterine artery embolisation for fibroids – IPG 94 (2004)

³ NICE Laparoscopic Laser Myomectomy – IPG 23 (2003)

⁴ NICE MRI-guided percutaneous laser ablation of fibroids – IPG 30 (2003)

⁵ Baird DD, Dunson DB et al. High cumulative incidence of uterine leiomyoma in black and white women: ultrasound evidence. Am J Obstet Gynecol. 2003 Jan, 188 (1): 100-7

⁶ Coleman, Ayiku et al. Systematic review of the efficacy and safety of uterine artery embolisation in the treatment of fibroids. SchHARR University of Sheffield. July 2004.

⁷ NICE Heavy Menstrual Bleeding Clinical Guideline 44 July 2007

RTPCT Policy on minimally invasive surgery for uterine fibroids. RTPCT 2008