

National Institute for Health and Care Excellence
IP1816 Laparoscopic removal of uterine fibroids with power morcellation

IPAC date: 10th June 2021

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response
1	Consultee 1 NHS professional NHS Grampian	General	fibroids are oestrogen dependent, sarcomas and STUMPs are not. For premenopausal women if there is objective shrinkage with GnRH analogues wouldn't this give some reassurance as to the benign nature, or conversely, if no shrinkage or growth despite GnRH for 3 months, then this should raise suspicion of possible malignancy.	Please respond to all comments Thank you for your comment. This falls outside the scope of the guidance.
2	Consultee 1 NHS professional NHS Grampian	General	Whilst this document is about power morcellation and risk of dissemination of unexpected malignancy, is there not concern about conservative treatments such as ultrasound focussed or uterine artery embolisation which are potentially leaving a malignancy in situ with no tissue diagnosis?	Thank you for your comment. Assessment of other conventional treatments fall outside the scope of the guidance. Page 51 of the overview lists published NICE guidance related to this procedure.

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response
3	Consultee 1 NHS professional NHS Grampian	General	Should the message be that if having surgery for symptomatic fibroids and family is complete that hysterectomy rather than myomectomy should be the procedure of choice	Please respond to all comments Thank you for your comment. The Interventional Procedures programme at NICE assesses the safety and efficacy of new interventional procedures. The Committee makes recommendations on conditions for the safe use of a procedure including training standards, consent, audit and clinical governance. It does not have a remit to determine the placement of a procedure in the pathway of care for a disease or condition.
4	Consultee 2 Specialist Society British Society for Gynaecological Endoscopy (BSGE)	Section 1.1	We agree that the concern has arisen from inappropriate case selection re. risk of sarcoma. If you really think someone has a leiomyosarcoma or other uterine malignancy you should not be doing myomectomy, subtotal or any other conservative procedure. They will be upstaged regardless of using morcellation or not.	Thank you for your comment. The indication for this guidance is uterine fibroids but not malignancy. Section 3.6 describes ' <i>...If malignancy is considered, this should be discussed with a gynaecological multidisciplinary team</i> '.

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response
5	Consultee 2 Specialist Society (BSGE)	Section 1.1	<p>‘For women who are postmenopausal or over 50, evidence on the safety of laparoscopic removal of uterine fibroids with power morcellation shows serious complications.’</p> <p>Is this true? Is there evidence of increased complications in this age group?</p> <p>This statement is not correct. There is a slightly increased risk of malignancy in this age group, hence the risk of spreading malignancy might be higher. This paragraph needs rewording</p>	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>Section 1.1 has been changed to: <i>‘Evidence on the safety of laparoscopic removal of uterine fibroids with power morcellation shows potentially serious complications. In particular there is a risk of spreading undiagnosed malignant tissue, which has higher prevalence in people who are postmenopausal or over 50. Evidence on the procedure’s efficacy is limited in quantity. Therefore:</i></p> <ul style="list-style-type: none"> • <i>For people who are postmenopausal or over 50, this procedure should not be used. Find out why NICE recommends not to use some procedures on the NICE interventional procedures guidance page</i> • <i>For people who are premenopausal or 50 or under, this procedure should only be used with special arrangements for clinical governance, consent and audit or research. Find out what special arrangements mean on the NICE interventional procedures guidance page.’</i>

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response
6	Consultee 2 Specialist Society (BSGE)	Section 1.2	<p>‘For women who are premenopausal or 50 or under, evidence on the safety of laparoscopic removal of uterine fibroids with power morcellation shows the potential for serious complications. In particular, the risk of spreading undiagnosed malignant or benign tissue. However, the prevalence of undiagnosed malignant tissue is lower than in women who are postmenopausal or over 50. Evidence on the procedure’s efficacy is limited in quantity.’</p> <p>Power morcellators are potentially dangerous instruments in untrained hands but so is a trocar/port assembly and a scalpel.</p> <p>Seeding of morcellated fibroid tissue is a recognised phenomena but rare (0.12-0.9% morcellation, 0.2-1.2% power morcellation). This can occur after hysterectomy (vaginal or open) and myomectomy without any morcellation</p> <p>Leren V et al . Parasitic leiomyomas after laparoscopic surgery with morcellation. Acta Obstet Gynecol Scand 2012;91:1233-6.</p> <p>Seidman MA et al. Peritoneal dissemination complicating morcellation of uterine mesenchymal neoplasms. PLoS One 2012;7:50058)</p> <p>The last sentence in this section is not correct. There is ample evidence that myomectomy and hysterectomy are efficient. Both open and laparoscopic myomectomy carry a risk of spreading malignancy, but there is a possibility that morcellation may increase the risk of spread and compromise survival.</p>	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>The committee has considered this comment but has decided not to change the recommendation for women who are premenopausal or 50 or under – special arrangements.</p> <p>The IP programme does not assess the efficacy and safety of comparator interventions. Section 1.6 states that <i>‘This procedure should only be done by a surgeon with specific training in both laparoscopic surgery and using containment systems.’</i></p> <p>The committee makes decisions based on the assessment of the efficacy and safety of the procedure and section 3.7 states that <i>‘The committee was informed that myomectomy without morcellation is also associated with a risk of disseminating previously undiagnosed malignancy’.</i></p> <p>Ref 1 (Leren et al 2012) was included in the appendix of the overview. Ref 2 (Seidman et al 2012) has been added to the appendix.</p>

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response
7	Consultee 2 Specialist Society (BSGE)	Section 1.4	We strongly agree that information for patients/ those offering the procedure should be included in the information provision etc. and as proposed in this consultation.	Please respond to all comments Thank you for your comment.
8	Consultee 2 Specialist Society (BSGE)	Section 1.6	<p>‘This procedure should only be done by a surgeon with specific training in both laparoscopic surgery and using containment systems.’</p> <p>There are other references to containment systems in the document (including recommendation 1.3 calling for research into their use) but it does not seem to state explicitly that containment systems should be used. Even the recommendation 1.6 is not a clear recommendation for practice. If surgeons have to be trained in the use of bags then should they routinely use them? The implication is that they should but it’s not clear .</p>	<p>Thank you for your comment.</p> <p>Section 1.3 has been renumbered 1.2 and changed to: <i>“Further research should report the details of patient selection, surgical technique (including any containment system when used) and long-term outcomes.”</i></p> <p>Section 1.6 has been renumbered 1.5 and changed to: <i>“This procedure should only be done by a surgeon with specific training in laparoscopic surgery. When an in-bag technique is needed, the surgeon should also have specific training in using containment systems.”</i></p>

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response
9	Consultee 2 Specialist Society (BSGE)	Page 5 Line 3.4	We were surprised that “although patient commentary sought none received” We wonder how this was approached/ ascertained?	Please respond to all comments Thank you for your comment. For each procedure considered by the Interventional Procedures Advisory Committee, the NICE Public Involvement Programme contacts national patient organisations that represent patients affected by the condition(s) relevant to the procedure, including those that have a specialist interest in issues relating to equalities. The patient organisations are asked if they would like to contribute to the consultation process and those that express an interest in being involved are contacted by the IP Programme team.
10	Consultee 2 Specialist Society (BSGE)	Section 3.6	The guidance could maybe re-emphasise what was stated in RCOG/BSGE guidance 2019: - The guiding principle should be that if sarcoma is suspected morcellation or breaching of a fibroid capsule should not be undertaken ; - No “biomarkers” (Imaging/blood or urine tests) that can reliably diagnose a uterine sarcoma	Thank you for your comment. The committee has considered this comment but decided not to change committee comment 3.6.

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response
11	Consultee 2 Specialist Society (BSGE)	Section 3.8	<p>‘The committee was informed that containment systems (the in-bag technique) were increasingly used in this procedure to reduce the risk of disseminating non-malignant or malignant cells.’</p> <p>This is not proven and containment systems themselves can result in significant complications in their own right.</p>	<p>Please respond to all comments</p> <p>Thank you for your comment.</p> <p>Committee comment 3.8 has been changed to: <i>“The committee was informed that containment systems (the in-bag technique) were increasingly used in this procedure with the aim of reducing the risk of disseminating benign or malignant cells.”</i></p> <p>Committee comment 3.9 reflects that the committee were made aware of evidence of the potential complications that can arise from the use of containment systems.</p>

"Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees."