NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional Procedures Programme

Specialist Adviser questionnaire

Before completing this questionnaire, please read Conflicts of Interest for Specialist Advisers.

Please respond in the boxes provided.

Please complete and return to: azad.hussain@nice.org.uk and IPSA@nice.org.uk

Procedure Name: Transcervical radiofrequency ablation for symptomatic uterine fibroids'

Name of Specialist Advisor: Bruce Ramsay

Job title: Consultant Gynaecolgist, Peterborough

Professional Regulatory Body: GMC X

Other (specify) ☐

Registration number: 3254242

Specialist Society: I am a member of RCOG, BSGE and BGCS but am not representing them here as these are my personal opinions and observations

Nominated by (if applicable): N/A

1 About you and your speciality's involvement with the procedure

1.1 Do you have adequate knowledge of this procedure to provide advice?

X Yes.

☐ No – please answer no more questions and return the form

Comments:

1.2 Is this procedure relevant to your specialty?

X Yes.

☐ No - please answer no more questions. Please give any information you can about who is likely to be doing the procedure and return the form.

Comments:

Fibroids and heavy menstrual bleeding are common gynaecological problems

1.3 Is this procedure performed by clinicians in specialities other than your own?

☐ Yes – please comment

X No

Comments:

1.4 If you are in a specialty that does this procedure, please indicate your experience with it:

☐ I have never done this procedure.

X I have done this procedure at least once.

☐ I do this procedure regularly.

Comments:

I have seen the technique in action and carried out 10 independent procedures myself and followed up the patients for several months

1.5 If your specialty is involved in patient selection or referral to another specialty for this procedure, please indicate your experience with it.

☐ I have never taken part in the selection or referral of a patient for this procedure.

X I have taken part in patient selection or referred a patient for this procedure at least once.

☐ I take part in patient selection or refer patients for this procedure regularly.

Comments:

I witnessed patient selection in a European centre with a lot of experience and then selceted and consented my own patients without any problems as above

1.6 Please indicate your research experience relating to this procedure (please choose one or more if relevant):

I have done bibliographic research on this procedure.

☐ I have done research on this procedure in laboratory settings (e.g. device-related research).

☐ I have done clinical research on this procedure involving patients or healthy volunteers.

X I have had no involvement in research on this procedure.

☐ Other (please comment)

Comments:

I obviously reas published research on the technique and talked to those currently performing it regularly in Europe before offering to my patients but have not been actively involved in the R+D of the procduct

1.7 Please estimate the proportion of doctors in your specialty who are doing this procedure (choose one):

☐ More than 50% of specialists engaged in this area of work.

☐ 10% to 50% of specialists engaged in this area of work.

X Fewer than 10% of specialists engaged in this area of work.

☐ Cannot give an estimate.

Comments:

This is a new technique and so far only a handful of UK gynaecologists have tried it out. However the potential market is large since more than 50% of specialists will see patients who may benefit from it.

2 About the procedure

2.1 Does the title used above describe the procedure adequately?

X Yes

☐ No - If no, please suggest alternative titles.

Comments:

2.2 Which of the following best describes the procedure (choose one):

☐ Established practice and no longer new.

X A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.

X Definitely novel and of uncertain safety and efficacy.

☐ The first in a new class of procedure.

Comments:

This depends on your interpretation.

Transcervical resection of fibroids has been an established technique for years. This originally used a resection loop and then mechanical morcellators such as myosure. It uses an optical hysteroscope to visualise the fibroid then it is cut away. It only works for fibroids adjacent to the uterine cavity not in the wall. The risks are bleeding and uterine perforation and adhesion formation.

The Sonata device visualises the fibroids with ultrasound probe transcervically and then electrodes are inserted into the fibroid to heat it up (with radiofrequency energy) and destroy it rather than cutting it out. It allows fibroids deeper in the wall of the uterus to be treated. In my view the risk of complications like bleeding and uterine perforation are likely to be less with the Sonata technique due to its method of action.

2.3 What is/are the best comparator(s) (standard practice) for this procedure?

Surgical myomectomy procedure (either open or laparoscopic) is the direct comparison. This is a more major surgical procedure with extended recovery period for patient.
Fibroid embolization would not be recommended for those wishing to preserve fertility when Sonata can be used in this group
Transcervical resection of fibroid can only be used for small fibroids directly adjacent to the cavity

2.4 Are there any major trials or registries of this procedure currently in progress? If so, please list.

Not to my knowledge – the company making the device will keep records of all procedures

2.5 Please list any abstracts or conference proceedings that you are aware of that have been *recently* presented / published on this procedure (this can include your own work). Please note that NICE will do a comprehensive literature search on this procedure and we are only asking you for any very recent or abstracts or conference proceedings which might not be

found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

Alll published work to my knowledge has been submitted to NICE already

3 Safety and efficacy of the procedure

3.1 What are the potential harms of the procedure?

Please list any adverse events and major risks (even if uncommon) and, if possible, estimate their incidence:

Adverse events reported in the literature (if possible please cite literature)

Post op pain, vaginal bleeding/discharge, infection. All these events seem rare from the published literature.

It does not guarantee to improve heavy menstrual bleeding in all cases but seems to help in over 90% who need no further treatment a year after procedure

Anecdotal adverse events (known from experience)

Minimal pain in my 10 cases, all discharged as day cases. Repeat USS shows decreasein fibroid volume of 50%+ when rescanned 2-3 months after procedure with 9 out of 10 women requiring no further treatment for symptoms

Theoretical adverse events

Bleeding and infection and expulsion of necrotic fibroid tissue but I have not witnessed any of these myslef

3.2 Please list the key efficacy outcomes for this procedure?

Objective reduction in fibroid size. Subjective improvement in heavy menstrual bleeding or pressure symptoms from fibroid.
Long term fertility success rates would need looking at in the future

3.3 Please list any uncertainties or concerns about the *efficacy* of this procedure?

Will need long term 5 year FU with larger numbers (as happenbed when endometrial ablation techniques were first introduced) to reassure that the initial demonstrated benefits are sustained over time.

3.4 What clinician training is required to do this procedure safely?

The company provided me with some of the most thorough, safety focussed training I have ever received when using a new medical device. They have supported me with a highly experienced nurse operator for the equipment on each occasion I have used it. The doctors undertaking this technique will ideally already have skills with transvaginal ultrasound and hysteroscopy on which to build. They can can then witness the technique in action and use a simulator model to practice before undertaking procedure on patients under GA with direct supervision form the applications specialist of the manufacturer.
I was confident after first 3 cases of all aspects of the procedure

3.5 What clinical facilities are needed to do this procedure safely?

Intially GA day case operating theatre environment (as an laternative to myomectomy as mentioned above). I am currently trying out a few patients with local anaesthetic and sedation in theatre as the next step.

3.6 Is there controversy, or important uncertainty, about any aspect of the way in which this procedure is currently being done or disseminated?

Not to my knowledge

4 Audit Criteria

Please suggest potential audit criteria for this procedure.

4.1 Beneficial outcome measures. This should include short and long term clinical outcomes, quality-of-life measures and patient related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured:

Objective clinical follow up. Standard validated HMB/ quality of life questionnaire pre procedure then at 3, 6 months (and up to 5 years eventually). Measurement of fibroid by USS before and then at 3/6 months post procedure. Re-intervention rates (eg hysterectomy) It would be important to know the fertility aspirations/contraceptive needs of the patients.

4.2 Adverse outcome measures. This should include early and late complications. Please state the post procedure timescales over which these should be measured.

Immediate complications up to 3 months post procedure to include readmission, haemorrhage, infection, perforation. Need for reoperation in the medium term and information collected on any pregnancies achieved after the procedure.

5 Uptake of the procedure in the NHS

5.1 If it is safe and efficacious, in your opinion, how quickly do you think use of this procedure will be adopted by the NHS (choose one)?

X Rapidly (within a year or two).

☐ Slowly (over decades)

☐ I do not think the NHS will adopt this procedure

Comments:

I think patient demand will be strong for this procedure. NHS uptake will be challenged by the cost of the device since the benefits (shorter hospital stay, shorter time in theatre, quicker return to usual activity) can be difficult to quantify in business plans

5.2 If it is safe and efficacious, in your opinion, will this procedure be carried out in (choose one):

x Most or all district general hospitals.

x A minority of hospitals, but at least 10 in the UK.

☐ Fewer than 10 specialist centres in the UK.

☐ Cannot predict at present.

Comments:

Intially in a few centres due to the need for training but then can be rolled out with one or two consultants offering the treatment in each hospital when they are trained

5.3 If it is safe and efficacious, in your opinion, the potential impact of this procedure on the NHS, in terms of numbers of patients eligible for treatment and use of resources:

☐ Major.

☐ Moderate.

X Minor.

Comments:

This will allow some of the women currently treated with myomectomy procedures to have this instead which will be very benifical to them individually and free up theatre operating time and inpatient beds for the NHS but overall numbers will remain limited I believe

6 Other information

6.1 Is there any other information about this procedure that might assist NICE in assessing the possible need to investigate its use?

Comments:

No

7 Data protection and conflicts of interest

7.1 Data Protection

The information you submit on this form will be retained and used by the NICE and its advisers for the purpose of developing its guidance and may be passed to other approved third parties. Your name and specialist society will be published in NICE publications and on the NICE website. The specialist advice questionnaire will be published in accordance with our guidance development processes and a copy will be sent to the nominating Specialist Society. Please avoid identifying any individual in your comments.

☐ I have read and understood this statement and accept that personal information sent to us will be retained and used for the purposes and in the manner specified above. For more information about how we process your personal data please see our privacy notice

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7.2 Declarations of interest by Specialist Advisers advising the NICE Interventional Procedures Advisory Committee

Nothing in your submission shall restrict any disclosure of information by NICE that is required by law (including in particular, but without limitation, the Freedom of Information Act 2000).

Please submit a conflicts of interest declaration form listing any potential conflicts of interest including any involvement you may have in disputes or complaints relating to this procedure.

Please use the "Conflicts of Interest for Specialist Advisers" policy as a guide when declaring any conflicts of interest. Specialist Advisers should seek advice if needed from the Associate Director – Interventional Procedures. Conflicts of Interest for Specialist Advisers

Declarations of interest form			
Type of interest	**Description of interest**	**Relevant dates**	
		Interest arose	**Interest ceased**
None			

* Guidance notes for completion of the Declarations of interest form

Name and role	Bruce Ramsay
Description of interest	Provide a description of the interest that is being declared. This should contain enough information to be meaningful to enable a reasonable person with no prior knowledge to be able to read this and understand the nature of the interest. Types of interest: **Direct interests** **Financial interests** - Where an individual gets direct financial benefits from the consequences of a decision they are involved in making. *For examples of financial interests please refer to the policy on declaring and managing interests.* **Non-financial professional and personal interests -** Where an individual obtains a non-financial professional or personal benefit, such as increasing or maintaining their professional reputation, from the consequences of a decision they are involved in making. *For examples of non-financial interests please refer to the policy on declaring and managing interests.* **Indirect interests -** Where there is, or could be perceived to be, an opportunity for a third party associated with the individual in question to benefit. A benefit may arise from both a gain or avoidance of a loss.
Relevant dates	Detail here when the interest arose and, if applicable, when it ceased.
Comments	This field should be populated by the guidance developer and outline the action taken in response to the declared interest. It should include the rationale for this action, and the name and role of the person who reviewed the declaration.

Thank you very much for your help.

Dr Tom Clutton-Brock, Interventional Procedures Advisory Committee Chair

Mirella Marlow Programme Director