NICE National Institute for Health and Care Excellence

NICE Pathways

Assessing and managing complications associated with mesh surgery

NICE Pathways bring together everything NICE says on a topic in an interactive flowchart. NICE Pathways are interactive and designed to be used online.

They are updated regularly as new NICE guidance is published. To view the latest version of this NICE Pathway see:

http://pathways.nice.org.uk/pathways/urinary-incontinence-and-pelvic-organ-prolapse-in-women
NICE Pathway last updated: 03 September 2020

This document contains a single flowchart and uses numbering to link the boxes to the associated recommendations.

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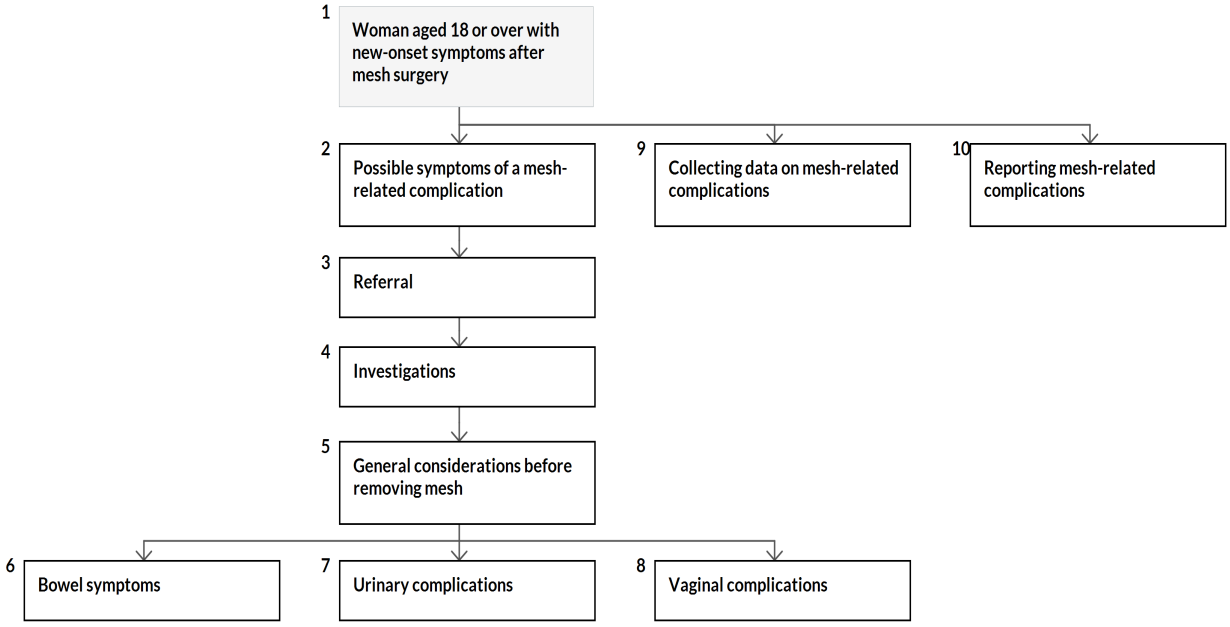

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1 Woman aged 18 or over with new-onset symptoms after mesh surgery

No additional information

2 Possible symptoms of a mesh-related complication

For women who report new-onset symptoms after having mesh surgery for UI or POP, evaluate whether the symptoms might be caused by a mesh-related complication. These symptoms could include:

- pain or sensory change in the back, abdomen, vagina, pelvis, leg, groin or perineum that is:
  - either unprovoked, or provoked by movement or sexual activity **and**
  - either generalised, or in the distribution of a specific nerve, such as the obturator nerve
- vaginal problems including discharge, bleeding, painful sexual intercourse, or penile trauma or pain in sexual partners
- urinary problems including recurrent infection, incontinence, retention, or difficulty or pain during voiding
- bowel problems including difficulty or pain on defaecation, faecal incontinence, rectal bleeding or passage of mucus
- symptoms of infection, either alone or in combination with any of the symptoms outlined above.

See the NICE guideline to find out why we made this recommendation and how it might affect practice.

3 Referral

Refer women with a suspected mesh-related complication to a urogynaecologist, urologist or colorectal surgeon for specialist assessment.

For women who are referred for specialist evaluation of a suspected mesh complication:

- take a history of all past surgical procedures for prolapse or incontinence using mesh, including the dates, type of mesh and site of mesh placement and the relationship of the symptoms to the surgical procedure(s)
- consider using a validated pelvic floor symptom questionnaire and a pain questionnaire to aid assessment and decision making

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- perform a vaginal examination to:
  - assess whether mesh is palpable, exposed or extruded
  - localise pain and its anatomical relationship to mesh
- consider performing a rectal examination, if indicated, to assess for the presence of mesh perforation or fistula
- consider performing a neurological assessment to assess the distribution of pain, if present, sensory alteration or muscle weakness.

For women with a confirmed mesh-related complication or unexplained symptoms after a mesh procedure:

- refer to a consultant at a regional centre specialising in the diagnosis and management of mesh-related complications **or**
- if the woman has a vaginal exposure of mesh that is smaller than 1 cm^2 and no other symptoms, follow the recommendations on vaginal complications [See page 6].

Rationale and impact

See the NICE guideline to find out why we made these recommendations and how they might affect practice.

4 Investigations

The responsible consultant should develop an individualised investigation plan for each woman with suspected or confirmed mesh-related complications, involving other members of the regional MDT if needed, and use the table on investigations for assessing suspected mesh-related complications [See page 10] to inform decisions on possible investigations.

See the NICE guideline to find out why we made this recommendation and how it might affect practice.

5 General considerations before removing mesh

If a woman who has had a mesh procedure to treat UI or POP is thinking of having the mesh removed, discuss the decision with her and with a regional MDT.

When discussing surgery to remove mesh, explain to the woman that:

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- there is limited evidence on the benefits of partial or complete removal compared with no mesh removal
- surgery to remove mesh can have significant complications including organ injury, worsening pain, and urinary, bowel and sexual dysfunction
- it is not certain that removing the mesh will relieve symptoms
- it might not be possible to remove all of the mesh
- removing only part of the mesh might be just as effective at improving symptoms as removing all of it
- UI or prolapse can recur after the mesh has been removed.

See the NICE guideline to find out why we made these recommendations and how they might affect practice.

6 Bowel symptoms

For women who present with functional bowel disorders after mesh surgery for POP, follow the NICE Pathway on faecal incontinence for women with faecal incontinence or locally agreed protocols for women with obstructed defecation.

For women with bowel complications that are directly related to mesh placement, such as erosion, stricture or fistula, discuss treatment with a regional MDT that has expertise in complex pelvic floor dysfunction and mesh-related problems. Use this discussion to formulate an individualised treatment plan with the woman.

Explain to women with bowel complications directly related to mesh placement that:

- complete removal might not be possible
- bowel symptoms might persist or recur after mesh removal
- they might need a temporary or permanent stoma after mesh removal.

Rationale and impact

See the NICE guideline to find out why we made these recommendations and how they might affect practice.

7 Urinary complications

Refer women who have mesh perforating the lower urinary tract to a centre for mesh

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complications for further assessment or management.

For women with urinary symptoms after mesh surgery for SUI or POP who are considering mesh removal surgery, explain that:

- urinary symptoms might not improve and new symptoms might occur after complete or partial removal of the mesh
- SUI might recur after mesh removal, and the risk of this happening is higher with complete than with partial mesh removal
- complete removal of the mesh might not be possible
- further treatment might be needed for mesh complications, or recurrent or persistent urinary symptoms
- there is a risk of adverse events such as urinary tract fistula.

Discuss division of mesh sling with women who have voiding difficulty after mesh sling surgery.

Refer women considering excision of mesh sling for persistent voiding dysfunction to a centre specialising in the diagnosis and management of mesh-related complications for assessment and management.

For women considering surgery to alleviate voiding symptoms caused by mesh surgery, explain that:

- the risk of recurrent SUI is higher after mesh excision than mesh division
- further surgery might be needed.

Rationale and impact

See the NICE guideline to find out why we made these recommendations and how they might affect practice.

8 Vaginal complications

Discuss non-surgical treatment with topical oestrogen cream with women who have a single area of vaginal mesh exposure that is smaller than 1 cm^2.

Offer a follow up appointment within 3 months to women with vaginal mesh exposure who choose treatment with topical oestrogen cream.

Consider partial or complete surgical removal of the vaginal portion of mesh for women:

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- who do not wish to have treatment with topical oestrogen **or**
- if the area of vaginal mesh sling exposure or extrusion is 1 cm^2 or larger **or**
- if there is vaginal mesh extrusion **or**
- if there has been no response to non-surgical treatment after a period of 3 months.

Offer imaging and further treatment to women who have signs of infection in addition to vaginal mesh exposure or extrusion.

Discuss with women who have vaginal complications after mesh sling surgery for SUI that:

- complete removal of the vaginal portion of mesh sling is associated with a greater risk of recurrence of SUI than partial removal
- partial removal is associated with a higher rate of further mesh sling extrusion
- complete removal might not be possible.

Explain to women who have vaginal complications after vaginally placed mesh for POP that:

- complete removal might not be possible
- complete removal has a higher risk of urinary tract or bowel injury than partial removal
- there may be a risk of recurrent prolapse.

Explain to women who have vaginal complications after abdominally placed mesh for POP that:

- removal is associated with a risk of urinary tract and bowel injury
- there is a risk of recurrent prolapse
- they might need abdominal surgery to remove the mesh
- complete removal might not be possible.

For women who have pain or painful sexual intercourse suspected to be related to previous mesh surgery:

- if specialist assessment indicates a mesh-related complication, seek advice from a regional MDT
- if assessment and investigation do not show a mesh abnormality such as vaginal extrusion or exposure, or an infection, consider non-surgical treatments such as pain management, vaginal oestrogen, dilators, counselling (including psychosexual counselling) and physiotherapy
- if pain does not respond to initial management, seek advice from a regional MDT.

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Rationale and impact

See the NICE guideline to find out why we made these recommendations and how they might affect practice.

9 Collecting data on mesh-related complications

Ask women having surgery for SUI or POP, or who have experienced complications related to these types of surgery, for their consent to enter the data listed below into a national registry. Give each woman a copy of her data.

Providers must ensure that the following data are collected in a national registry of surgery for UI and POP:

- the woman's NHS number
- hospital and consultant identifiers
- date and details of the procedure
- for procedures involving mesh, the mesh material, manufacturer, product unique identification code and type of sutures used
- for procedures involving colposuspension, the type of sutures used
- for procedures involving bulking agent, the bulking material, manufacturer and product unique identification code
- date and details of any investigation for complications
- date and details of any surgical or non-surgical intervention for complications.

The national registry of surgery for UI or POP in women must ensure that follow-up data are collected on key short- and long-term (at least 5 years) outcomes, including:

- validated relevant outcome measures
- adverse events including pain
- suspected and confirmed mesh-related complications.

The national registry of surgery for urinary incontinence and pelvic organ prolapse in women should report annually and be quality assured.

Rationale and impact

See the NICE guideline to find out why we made these recommendations and how they might affect practice.

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10 Reporting mesh-related complications

The responsible consultant must ensure that details of any confirmed mesh-related complications are:

- recorded in a national registry (see collecting data on mesh-related complications [See page 8]) **and**
- reported to the Medicines and Healthcare Products Regulatory Agency.

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Investigations for assessing suspected mesh-related complications

Individualised investigation plans may include, but are not limited to, 1 or more of these investigations:

Investigation	Type of mesh	Indications	Benefits and risks
Examination under anaesthesia	All types of mesh	Pain or suspected: • vaginal or rectal exposure or extrusion • sinus tract, urinary or bowel fistula	Benefits: Allows diagnosis when not revealed by awake examination or when an awake examination is not tolerated Risks: Anaesthetic risk
Cystourethroscopy	All types of mesh	Suspected: • urethral perforation • bladder perforation • fistula • calculus on suture or mesh material	Benefits: • allows diagnosis by direct visualisation • aids management planning Risks: Anaesthetic risk and risk of urinary tract infection
Sigmoidoscopy	Abdominally,	Suspected bowel	Benefits:

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	laparoscopically or vaginally placed mesh for pelvic organ prolapse	perforation by mesh	• allows diagnosis by direct visualisation • aids management planning Risks: • anaesthetic risk if carried out under anaesthetic • risk of bowel perforation
Laparoscopy	Abdominally or laparoscopically placed mesh for pelvic organ prolapse	• Pain • Suspected bowel entrapment around mesh • Suspected adhesions secondary to mesh placement	Benefits: • allows diagnosis by direct visualisation • aids management planning Risks: • anaesthetic risk • risks of laparoscopy, including bowel injury
MRI, protocolled and reported by a clinician with experience in interpreting mesh complications	All types of mesh	• Suspected mesh infection • Anatomical mapping of suspected fistula • Anatomical	Benefits: • shows implanted material and complications nearby • shows location

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		• mapping and mesh localisation to guide further surgery • Back pain following abdominal mesh placement with mesh attachment to sacral promontory • Identification of discitis or osteomyelitis	• of mesh in relation to the vaginal wall and sacrum Risks: Generally regarded as safe, with a low risk of short- and long-term harms. Risk of contrast media injection.
Ultrasound scan (transperineal, transvaginal or translabial, or 3D), performed and reported by a clinician with experience in interpreting mesh complications	Vaginally placed mesh to treat incontinence	• Pain • Voiding dysfunction • Suspected infection • Suspected urethral mesh perforation • Anatomical mapping to guide excision surgery	Benefits: • shows implanted material and local complications • identify mid-urethral slings • shows location of mesh in relation to the vaginal wall and urethra Risks: Discomfort
CT	All types of mesh, although CT is not commonly used	Suspected: • urinary tract injury	Benefits: May be useful in assessing for urinary

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	to show implanted material	• bowel injury • bowel obstruction	fistulae or bowel injury Risks: Potential radiation-related harms and risk of contrast media injection
Fluoroscopic studies (cystography or contrast enema) Perform with water-soluble contrast media. Fluoroscopic studies and CT may be used according to local preference and expertise.	All types of mesh	Suspected urinary or bowel fistula	Benefits: Aids management planning Risks: Potential radiation-related harms
Urinary flow studies and post-void residual volume assessment or cystometry	All types of mesh	• Voiding dysfunction • Urinary incontinence	Benefits: Aids management planning Risks: Urinary tract infection and radiation risks if fluoroscopy is used
Neurophysiology, including nerve conduction studies.	All types of mesh	Suspected nerve injury	Benefits: Allows diagnosis of impaired nerve function

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			Risks: Nerve conduction studies are difficult to perform and can induce more pain

Glossary

MDT

multidisciplinary team

POP

pelvic organ prolapse

SUI

stress urinary incontinence

UI

urinary incontinence

Sources

Urinary incontinence and pelvic organ prolapse in women: management (2019) NICE guideline NG123

Your responsibility

Guidelines

The recommendations in this guideline represent the view of NICE, arrived at after careful

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consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Technology appraisals

The recommendations in this interactive flowchart represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, health professionals are expected to take these recommendations fully into account, alongside the individual needs, preferences and values of their patients. The application of the recommendations in this interactive flowchart is at the discretion of health professionals and their individual patients and do not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

Commissioners and/or providers have a responsibility to provide the funding required to enable the recommendations to be applied when individual health professionals and their patients wish to use it, in accordance with the NHS Constitution. They should do so in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of

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implementing NICE recommendations wherever possible.

Medical technologies guidance, diagnostics guidance and interventional procedures guidance

The recommendations in this interactive flowchart represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take these recommendations fully into account. However, the interactive flowchart does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Commissioners and/or providers have a responsibility to implement the recommendations, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this interactive flowchart should be interpreted in a way that would be inconsistent with compliance with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

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