CLINICAL POLICY ADVISORY GROUP (CPAG)

Vaginal (Synthetic) Mesh to Treat Stress Urinary Incontinence (SUI) or Urogynaecological Prolapse Policy

Statement

NHS Derby and Derbyshire ICB, in line with its principles for procedures of limited clinical value has deemed the use of vaginal (synthetic) mesh to treat stress urinary incontinence (SUI) or urogynaecological prolapse should not routinely be commissioned.

This policy should be read in conjunction with the ICB's policy on NICE Interventions, Diagnostics, Medical and Health Technologies and Innovation Programmes.

These commissioning intentions will be reviewed periodically. This is to ensure affordability against other services commissioned by the ICB.

1. Background

Pelvic Mesh can be used for Pelvic Organ Prolapse and Stress Urinary Incontinence.

Pelvic Organ Prolapse (POP) describes a variety of conditions that occur when one or more pelvic organs drop out of their normal position, often pushing into the vagina, causing a bulge. The bladder can push into the front, or anterior, wall of the vagina causing a prolapse (a cystocele). The rectum can push into the back, or posterior, wall of the vagina causing a prolapse (a rectocele). The uterus, or if the woman has had a hysterectomy the vaginal vault, can prolapse downwards into the vagina. In more severe cases prolapses can protrude out of the vaginal opening.

Stress Urinary Incontinence (SUI) is the involuntary leaking of urine when the bladder is under pressure. SUI can be caused when the pelvic tissues, ligaments and muscles, which support the bladder and urethra, are weakened or damaged so that the sphincter that closes the urethra fails when under pressure, and urine leaks out.

During surgery mesh can either be inserted through an incision in the vagina (transvaginal insertion) or through an incision in the abdomen (abdominal insertion).

2. Recommendation

NHS Derby and Derbyshire ICB, in line with its principles for procedures of limited clinical value, has deemed the use of vaginal (synthetic) mesh to treat stress urinary incontinence (SUI) or urogynaecological prolapse should not routinely be commissioned.

This policy should be read in conjunction with the ICB's policy on NICE Interventions, Diagnostics, Medical and Health Technologies and Innovation Programmes.

3. Rationale for Recommendation

Over the past decade concerns about transvaginal[1] POP mesh have led to increased restrictions both in the UK and abroad. In 2011 the Food and Drug Administration (FDA)[2] concluded that 'serious adverse events are NOT rare' in transvaginal POP mesh repairs. In response the Medicines and Healthcare products Regulatory Agency (MHRA) commissioned the 2012 York report[3] and published their own 2014 Summary paper.[4] These reports concluded mesh for SUI was safe, but caution was needed when using transvaginal POP mesh. The 2015 European Union (EU) Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) Opinion[5] found similarly – transvaginal POP repair should only be considered in complex cases where non-mesh repair had failed.

In 2017 the Scottish Transvaginal Mesh Implants Independent Review[6] recommended stopping transvaginal POP mesh surgery. National Institute for Health and Care Excellence (NICE) guidance was promptly changed, and since then transvaginal POP mesh surgery has been restricted to research trials only.[7] In 2018, NHS Improvement and NHS England[8] issued a national 'pause' in the use by the NHS of surgical mesh/tape to treat SUI and for urogynaecological prolapse where the mesh is inserted through the vaginal wall.

4. Useful Resources

- NICE, 2019, Surgery for stress urinary incontinence – Patient decision aid, available at: https://www.nice.org.uk/guidance/ng123/resources/surgery-for-stress-urinary-incontinence-patient-decision-aid-pdf-6725286110

- H. L. Ong et al., Development, validation and initial evaluation of patient-decision aid (SUI-PDA©) for women considering stress urinary incontinence surgery. International Urogynecology Journal, (2019). http://dx.doi.org/10.1007/s00192-019-04047-z

- The Minister for Patient Safety, Suicide Prevention and Mental Health updates Parliament on the government's response to the recommendations of the IMMDS Review, Update on the government's response to the Independent Medicines and Medical Devices Safety Review - GOV.UK (www.gov.uk) published 11/01/21

5. References

1. An incision site in the abdomen is cleaned pre-operatively with an antiseptic agent, the vagina is not disinfected, and is sometimes referred to as a 'clean contaminated' site.
2. Public Health Notification: Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse (13 July 2011), available at http://www.fda.gov/downloads/MedicalDevices/Safety/AlertsandNotices/UCM262760.pdf
3. J. Mahon, M. Cikalo, D. Varley, J. Glanville, Medicines and Healthcare Products Regulatory Agency – Summaries of the Safety/Adverse Effects of VaginalTapes/Slings/Meshes for Stress Urinary Incontinence and Prolapse – Final Report, York Health Economics Consortium (2012
4. MHRA A summary of the evidence on the benefits and risks of vaginal mesh implants 28 October 2014 Available at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/402162/Summary_of_the_evidence_on_the_benefits_and_risks_of_vaginal_mesh_implants.pdf
5. Scientific Committee on Emerging and Newly Identified Health Risks, 2015, Opinion on the safety of surgical meshes used in urogynecological surgery, available at: http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_049.pdf
6. The Scottish Independent Review of the use, safety and efficacy of transvaginal mesh implants in the treatment of Stress Urinary Incontinence and Pelvic Organ Prolapse in women Final Report Final Report March 2017 http://www.gov.scot/Resource/0051/00515856.pdf
7. 2017 NICE (UK) Guidance IPG59913.
8. NHS Improvement and NHS England letter, VAGINAL MESH: HIGH VIGILANCE RESTRICTION PERIOD: Immediate action required, all cases should be postponed if it is clinically safe to do so, 09/07/2018, https://i.emlfiles4.com/cmpdoc/9/7/2/8/1/1/files/47633_mesh-letter-to-acute-ceos-and-mds.pdf

6. Appendices

Appendix 1 - Consultation

All relevant providers/stakeholders will be consulted via a named link consultant/specialist. Views expressed should be representative of the provider/stakeholder organisation. CPAG will consider all views to inform a consensus decision, noting that sometimes individual views and opinions will differ.

Consultee	**Date**
Consultant Obstetrician & Gynaecologist Clinical Audit Lead for O&G, CRHFT	April 2023
Consultant Obstetrician & Gynaecologist, CRHFT	April 2023
Consultant Obstetrician & Gynaecologist, Clinical Director O&G, CRHFT	April 2023
Consultant Obstetrician & Gynaecologist, UHDBFT	April 2023
Consultant Urological Surgeon, UHDBFT	April 2023
Clinical Policy Advisory Group (CPAG)	April 2023

Appendix 2 - Document Update

Document Update	**Date Updated**
Version 2.0 Policy review. Minor updates have been made, which include: • Re-wording to reflect the new NHSDDICB organisation. Section 4. Useful Resources updated with 'Update on the government's response to the Independent Medicines and Medical Devices Safety Review'	April 2023