Derby and Derbyshire
Clinical Commissioning Group

CLINICAL POLICY ADVISORY GROUP (CPAG)

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

Statement

Derby and Derbyshire CCG, 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 CCG's policy on NICE Interventional Procedures Guidance (IPG), Medical Technologies Guidance (MTG), Diagnostics Guidance (DG and Med Tech Innovation Briefing (MIB).

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

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

Derby and Derbyshire CCG, 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 CCG's policy on NICE Interventional Procedures Guidance (IPG), Medical Technologies Guidance (MTG), Diagnostics Guidance (D G and Med Tech Innovation Briefing (MIB).

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 stress urinary incontinence (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

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. 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 General Surgeon, UHDBFT (Urology and Gynaecology)	July 2020
Consultant General Surgeon, CRHFT(Urology and Gynaecology)	July 2020
Clinical Policy Advisory Group	July, August 2020
Clinical and Lay Commissioning Committee	September 2020

Appendix 2- Document Update

Document Update	Date Updated
Version 1 – policy issued	August 2020