PE1517/NNNN
Royal College of Obstetricians and Gynaecologists submission of 20 November 2020

The Royal College of Obstetricians and Gynaecologists (RCOG) has gathered feedback from key stakeholders on petition PE1517, including the British Society of Urogynaecology (BSUG) and the RCOG's Scottish Committee. Please see below our views on the calls of the petition.

Following the initial suspension of all vaginal mesh for both prolapse and incontinence, there is now evidence to show that there is no benefit to the use of vaginal mesh for prolapse and the RCOG support the NICE 'Transvaginal mesh repair of anterior or posterior vaginal wall prolapse, Interventional procedures guidance' (IPG599) which notes that the evidence on the safety of transvaginal mesh repair of anterior or posterior vaginal wall prolapse shows this procedure should only be used in the context of research.

The views expressed here are therefore in relation to transvaginal mesh for stress urinary incontinence (Retropubic TVT) which has been shown by NICE to be equivalent to the native tissue procedures.[1]

Views on the suggested suspended use of polypropylene Transvaginal Mesh (TVM) procedures.

The RCOG is in agreement with the following statement in the Scottish Government's interim report of its 'Transvaginal mesh implants independent review':

"Many women have experienced a positive outcome following a transvaginal mesh implant procedure. No procedure is without risk and therefore many people, including the broad clinical community consider that polypropylene mesh should continue to be used in these procedures as it presents an acceptable level of risk, supported by a number of studies, including research by the UK regulator for medical devices, the Medicines and Healthcare product Regulatory Agency (MHRA)."[2]

The RCOG is committed to patient safety and is constantly assessing how it can improve care to make it safer and reduce the risks associated. We agree that work to improve clinical governance of these procedures is required, including improving the informed consent process, work of which is underway by the College and BSUG, as outlined below.

The RCOG supported the implementation of high vigilance restrictions on use of vaginal mesh in 2018, which is still in place. However, the suspension of vaginal mesh completely could adversely impact upon some women who suffer from incontinence and require surgery and treatment, in the form of polypropylene Transvaginal Mesh (TVT-retropubic), in order to treat this debilitating condition.

[1] NICE, Urinary incontinence and pelvic organ prolapse in women: management NICE guideline [NG123] (2019)
[2] Scottish Government, Transvaginal mesh implants independent review: interim report (2015)

Views on the suggested initiation of a Public Inquiry and/or comprehensive independent research to evaluate the safety of mesh devices using all evidence available, including that from across the world.

We agree with comprehensive independent research forming the basis of future recommendations and practice. This is being undertaken by the London School of Hygiene & Tropical Medicine (LSHTM) independently to investigate what the impact of transvaginal mesh procedures are on autoimmune disease compared to non-mesh procedures as well as studying the differences in long term outcomes of mesh versus non mesh continence procedures. Reviewing mesh procedures in isolation however is not beneficial as informed choices are based on the comparison to other procedures undertaken for the same clinical condition. This is why we feel that any research should be into the use of mesh as well as its comparators.

Furthermore, the RCOG considers that the implemented recommendations of the Scottish Government's 'Transvaginal mesh implants independent review' should be reviewed and evaluated and that any recommendations which are yet to be implemented are done so without delay.[3]

The Scottish Government should also consider the findings of The Independent Medicines and Medical Devices Safety (IMMDS) Review. Although the remit of the Review was to consider how the healthcare system in England responds to reports from patients about harmful side effects from medicines and medical devices, valuable learnings can be taken from that report in Scotland and the other devolved nations, where similar systems are in place. The RCOG recommends a coordinated approach and plan to address the findings of the IMMDS Review across England, Scotland, Wales and Northern Ireland would be beneficial so that women can receive the same quality of care, treatment and support irrespective of their location.

Views on the suggested establishment of a Scottish Transvaginal Mesh implant register with view to linking this up with national and international registers.

The British Society for Urogynaecology (BSUG) runs the BSUG database which was established in 2004. BSUG and the RCOG continue to call for mandatory prospective data collection through the BSUG database. This would provide more accurate information regarding outcomes, including both success and complication rates, and provide comprehensive data to inform women and healthcare professionals about the benefits and risks of all urogynaecological procedures, including those that use mesh. The RCOG and BSUG also strongly encourage reporting of all complications related to all medical procedures to the Medicines and Healthcare products Regulatory Agency (MHRA).

NHS Digital has the responsibility of setting up the National Registry, a project which is underway. NHS Digital has started piloting data entry and we expect the Registry to be functional by March 2021. This is to be made available to the devolved nations as well. It would be more appropriate to collect data in a UK registry as patients move freely between the devolved nations hence to have separate Registries would not be logical.

[3] Scottish Government, Transvaginal mesh implants independent review: final report (2017)

We therefore strongly recommend that this National Registry is also implemented in Scotland so that there is a consistent approach to data recording across the UK.

Views on the suggested introduction of fully Informed Consent with uniformity throughout Scotland's Health Boards.

The RCOG believes that consent is a fundamental part of clinical practice.

Since 2004, the College has produced an 'Obtaining Valid Consent' guideline, which has been updated three times, most recently in 2015, and is currently being updated in line with the new GMC guidance on 'Decision making and consent' (September 2020). The purpose of the advice is to provide a good practice framework for obtaining valid consent in obstetrics and gynaecology. The College also has a Consent Advice series, which promotes good practice in this area focusing on specific procedures.

All of this information is brought together on our consent hub, setting out how to apply these resources and also referencing the Montgomery ruling. These resources have been highlighted to our members on a number of occasions via our regular member communications.

The RCOG also has a dedicated page on its website bringing together resources for healthcare professionals and women/the public on mesh, to support evidence-based care and shared, informed decision making.

Additionally, the College provides patient facing information to ensure that women receive consistent, high-quality information about risk, including Clinical Governance Advice on 'Presenting Information on Risk' and patient information on 'Understanding how risk is discussed in healthcare'. The College has a patient information leaflet on pelvic organ prolapse, which is currently being updated, as well as patient resources on incontinence and bladder problems. BSUG have a range of patient information leaflets on prolapse and incontinence and we are also working with BSUG to co-produce a Shared Decision Aid for stress urinary incontinence. The aid will help women to consider their surgical options after non-surgical options have been exhausted, guiding their thinking around the outcomes that are important to them to help make decisions.

BSUG are planning to incorporate training for obtaining informed consent to clinicians in forthcoming meetings and workshops and the RCOG is collaborating with BSUG and other Specialist Societies to develop Patient information leaflets and Patient Decision Aids for mesh removal.

The experiences of women and the issues raised in reports, parliamentary questions and debates, and the media stress the importance of ensuring consent and an understanding of risk are central to issues of patient safety. The RCOG and BSUG therefore remain committed to improving informed consent processes to all our membership, within and without of Scotland.

We consider that the recently published NICE Patient Decision Aids go a long way to ensuring patients give informed consent and encourage all clinicians performing prolapse and incontinence surgery to use these.

Write to the MHRA and ask that they reclassify TVM devices to heightened alert status to reflect ongoing concerns worldwide.

This is not within the remit of the RCOG.

Views on the evidence presented at the Public Petitions Committee's meeting on 22 October 2020.

The College is unable to comment on the information presented by Dr Veronikis as published data is not available on the outcomes of the mesh removal surgeries that he has performed.

The RCOG will work with NHS England, the Royal College of Surgeons, BSUG, the British Association of Urological Surgeons and the Pelvic Floor Society to produce an England-wide mesh removal service. Our aim is that this will be a world-leading, patient centred NHS service, which will provide safe, high-quality care with full consent and where women will have easy access to robust patient information. These centres will share learning and outcomes data so that we can continue to improve the service provided to women. We highly recommend that NHS Scotland and the Scottish Government collaborate with NHS England on this project and with its Complex Mesh Removal Surgical Service delivered by NHS Greater Glasgow & Clyde so that learning can be shared across the UK and care improved for all women requiring this service.