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NEW HEALTH EVIDENCE GIVES WOMEN INFORMED CHOICE IN THE PROLAPSE SURGERY DEBATE

New evidence published today highlights benefits and harms of using artificial mesh when compared with tissue repair in the surgical treatment of vaginal prolapse. Slightly better repair with mesh needs to be weighed carefully against increased risk of harms.

A new Cochrane systematic review published today summarizes evidence that addresses a long-standing controversy in the surgical repair of vaginal prolapse. It will help women and surgeons to make better informed choices about surgical treatment and reinforces the need for careful consideration of the advantages and disadvantages of grafting artificial material compared with using tissue to repair the anatomy of the vagina.

A new Cochrane systematic review published today summarizes evidence that addresses a long-standing controversy in the surgical repair of vaginal prolapse. It will help women and surgeons to make better informed choices about surgical treatment and reinforces the need for careful consideration of the advantages and disadvantages of grafting artificial material compared with using tissue to repair the anatomy of the vagina.

A vaginal prolapse occurs when the walls of the vagina become weak and collapse inwards. This can be a distressing disorder as there is a feeling of a lump or bulge low in the vagina which is exacerbated by physical activities. This affects up to a third of women who have had children, as well as those who are overweight or have a chronic cough.

Many women undergo surgical treatment to help with bladder, bowel and sexual function. Until the 1990s surgeons used a number of different techniques to repair prolapse such as vaginal hysterectomy or by cutting or repairing different muscles of the walls of the vagina. Following the successful use of tapes for continence surgery and mesh for hernia repair, gynaecology surgeons began to adopt grafting artificial material called a mesh to carry out this operation in the 1990s and 2000s. Over the last few years many questions have been raised about the safety of implanting an artificial mesh. There have been a number of reports of women suffering pain and mesh exposure after transvaginal mesh surgery.

An international team of researchers looked at evidence from randomized trials to look at how the two surgical approaches compared. They included information from 37 trials involving 4023 women. The mesh used in many of the studies were withdrawn from use in 2011, and the newer, lightweight transvaginal permanent meshes still available, have not been evaluated within a randomized study.

The review found that whilst transvaginal permanent mesh probably reduces the risk that women will be aware of prolapse compared with tissue repair, the overall size of the benefit was small.1 Based on their analysis, 19% of women who underwent native tissue repair compared with 12% women who had permanent mesh repair were aware of prolapse subsequently. This data came from studies that followed women up over periods of between 1

and 3 years. However, there are some major problems reported with permanent transvaginal mesh. The average reoperation rate for prolapse, urinary incontinence, or mesh exposure after mesh repair was 11% compared with around 5% in women who had tissue repair.

Permanent mesh is also associated with higher rates of bladder injury than tissue repair, and higher rates of stress incontinence. Across all the studies, 8% of women who had mesh implanted subsequently had it re-operated. In Scotland, the Health minister called for hospitals to consider the suspension of mesh operations until more evidence is available. An independent Scottish interim review reported in 2015 and expressed concern for both the effectiveness and adverse events related to transvaginal mesh for prolapse surgery. A report by the Accident Compensation Commission in New Zealand in 2015 recommended the establishment of a multi-agency registry as a means of tracking the associated complications.

Lead Author, Associate Professor, Chris Maher, from the University of Queensland, Brisbane said, 'This is a very significant review informing women about the surgical options available for the treatment of this debilitating condition. It summarizes the evidence of effectiveness of these approaches and their complications. It provides women with more information to make an informed choice about what treatment is best for them."

Author, Corinna Christmann-Schmid added, "This evidence underlines the need to balance potential harms against the potential benefits of surgery. One in twelve women who have mesh then require repeat surgery for mesh exposure, and we can expect 7% more women to experience subjective success, when compared with tissue repair without mesh." Women and their surgeons need to discuss these benefits and harms at the time of considering surgery. This is particularly important since the availability of the mesh used now is likely to be different from what was available when the studies were carried out.

Professor of Obstetrics and Gynaecology from the University of Auckland, Cindy Farquhar, commented "Gynaecologists should be wary of adopting new innovations that have not been fully evaluated by clinical trials. This is particularly important as many surgical devices do not require FDA or similar regulatory approvals."

Full citation: Maher C, Feiner B, Baessler K, Christmann-Schmid C, Haya N. Marjoribanks J: Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse. Cochrane Database of Systematic Reviews 2016, Issue 2. Art. No.: CD012079. DOI: 10.1002/14651858.CD012079