TRANSVAGINAL MESH IN PELVIC ORGAN PROLAPSE REPAIR.

Spanish full text

SUMMARY

Introduction: Pelvic organ prolapse (POP) is characterised by the descent or herniation of the uterus, vaginal vault, bladder or bowel into the interior or even out of the vagina. This condition does not cause mortality but can have a great impact on quality of life. It can affect up to 50% of women who have had vaginal births, and can give rise to symptoms in 21% of cases. The aetiology of POP is complex and multifactorial, with the main risk factors being vaginal birth, advanced age and obesity. The therapeutic options are conservative treatment, mechanical or surgical intervention. The latter constitutes the basis of POP repair, particularly for prolapses that are symptomatic or occur at an advanced stage, and has recently incorporated the use of synthetic non-absorbable mesh. This mesh has been associated with different complications, as reported by bodies that have issued alerts regarding its use, such as the Food and Drug Administration (FDA) in 2011, which advises health professionals and patients about the risks of using mesh, including vaginal erosion, pain, infection, urinary complications, bleeding and perforation of organs.

Objectives: To assess the safety, effectiveness and cost of using transvaginal mesh in the surgical repair of POP.

Methods: We conducted a systematic review with a search of the scientific literature from March-April 2013, stipulating no time limit and covering all leading biomedical databases specialised in systematic reviews (Health Technology Assessment, Centre for Reviews and Dissemination, Database of Abstracts of Reviews of Effectiveness, NHS Economic Evaluation Database, Cochrane Library Plus), as well as general databases such as Medline and Embase. The search strategy included the terms, "pelvic organ prolapse" and "transvaginal mesh", among others. Insofar as the type of study was concerned, we only selected systematic reviews, meta-analyses, clinical practice guidelines and randomised controlled trials (RCTs).

Results and discussion: Of the total of 251 publications retrieved, the following were included for review purposes: a recent, quality systematic review undertaken

by the Cochrane Collaboration; three RCTs that updated this same review; and two economic evaluation studies.

The effectiveness of POP treatment was assessed on the basis of the anatomical outcomes of vaginal prolapse repair, measured objectively by quantifying the degree of protrusion. Recently quality-of-life specific questionnaires and other instruments have been developed for the purpose of assessing POP symptomatology. The Cochrane Collaboration review indicated that, in the case of the anterior vaginal compartment, there was insufficient evidence to support the routine use of polypropylene transvaginal mesh whether for objective anatomical repair or for subjective outcomes. In the case of the posterior vaginal compartment, there was no evidence to suggest that outcomes would be improved by adding a (biological or synthetic) graft. The use of polypropylene mesh kits, versus native tissue repair, in various vaginal compartments, led to an improvement in anatomical outcomes but without any differences in terms of symptoms or quality of life. The RCTs that updated this review furnished data along the same lines, with better post-intervention anatomical outcomes in the transvaginal mesh group, though with no differences between the groups treated with and without mesh, when quality of life or the subjective outcomes of prolapse symptomatology were analysed.

In the case of the apical vaginal compartment, mesh erosion and infection rates increased fourfold when mesh was introduced by vaginal placement as opposed to the abdominal approach. Compared to native tissue repair, the use of a polypropylene mesh kit in the anterior, posterior or combined vaginal compartments resulted in a high rate of mesh exposure, which rose as high as 18% and required surgical intervention in half of all patients. Furthermore, the overall reintervention rate was significantly higher after the use of permanent transvaginal mesh than it was after native tissue repair, i.e., 11% versus 3.7% respectively. The RCTs reported mesh exposure of 2.2% to 15.6%. Another adverse effect associated with the use of mesh was the reintervention rate, which was higher in this group, even in a short term.

Variables of hospital activity such as urinary catheterisation time and length of hospital stay were similar in the groups compared.

The economic evaluation studies indicated that the use of transvaginal mesh for treatment of POP is not cost-effective.

Conclusions and recommendations

- The scientific evidence published following the release of the 2011 FDA safety communication affords no data to refute the recommendations made by this body in relation to the higher risk posed by the use of transvaginal mesh as compared to other surgical options in the treatment of POP.

- The quality of the studies that assessed POP surgery in women was rated as good to fair. These studies correspond to RCTs with a good methodological design but have certain limitations, such as a short-term follow-up time.

- The objective and subjective outcomes of vaginal prolapse repair improve, both with surgical treatment using transvaginal mesh and with conventional surgery without mesh, regardless of the prolapse site.

- The anatomical outcomes of prolapse, measured objectively after POP repair, were better with the use of transvaginal mesh. Yet, in terms of symptomatology or quality of life reported by patients post-treatment, no differences were observed between surgery with and surgery without transvaginal mesh.

- "Outcome", defined as the anatomical success of the intervention, does not necessarily coincide with the clinical success of treatment of prolapse.

- Compared to conventional surgery without mesh, the use of transvaginal mesh in POP surgery has severe adverse effects, such as transvaginal mesh erosion, which often requires a new intervention (itself not free of complications) to extract the mesh.

- The prolapse recurrence rate is lower after transvaginal mesh repair but seems to increase the probability of appearance of *de novo* prolapse in the initially unaffected and, by extension, untreated compartments.

- Hospital stay and perioperative variables, such as haemorrhage, haematocrit or decrease in the haemoglobin count, were similar among all patients assessed, regardless of the treatment administered. Duration of the intervention is reduced

10-15 minutes after transvaginal repair without mesh, but it is not clinically relevant.

- The economic evaluation studies indicated that the use of transvaginal mesh in the treatment of pelvic organ prolapse in the anterior compartment is not cost-effective vis-à-vis repair without mesh. This is mainly due to the adverse effects associated with the use of these types of mesh in urogynaecological surgery and the use of marketed kits which increase the cost of the procedure.

- Currently, scientific evidence does not support the generalised use of permanent transvaginal mesh in the surgical treatment of POP.

- Health professionals should assess the potential risks and benefits of the different treatment options on an individualised basis until an algorithm has been defined for the management of patients with pelvic organ prolapse.

- The use of permanent transvaginal mesh is not generally recommended in the treatment of pelvic organ prolapse, and its use as a preventive method in unaffected compartments is not advisable due to the fact that not enough is known about long-term effects and complications.

- Vaginal prolapse repair with transvaginal mesh should only be used in patients in whom the benefit-risk balance is justified when weighed against the other alternatives.

- In line with FDA guidelines, patients should be advised, not only about the risks and benefits of all treatment options, including non-surgical options, surgery without mesh, abdominal surgery with mesh, but also of the probabilities of benefit from these alternatives versus transvaginal surgery with mesh.

- Prior to the intervention, patients should be informed in detail about the adverse effects associated with surgical repair using transvaginal mesh, such as vaginal mesh erosion, pain or dyspareunia, and about the elevated probability of reintervention, with the possibility of sequelae persisting even after the mesh has been extracted.

- A comprehensive record should be kept of all patients treated with transvaginal mesh, on which a note is made of the outcomes of the surgical intervention -with the concept of "successful treatment" being clearly defined- complications, recurrences and total reintervention rate.

- Currently, the use of transvaginal mesh as the first choice should only be implemented in the context of RCTs, since it requires rigorous information which compares the use of synthetic transvaginal mesh to other types of tissue, with a long-term postoperative follow-up (at least 2-5 years) to assess the real results of these techniques in terms of their safety and effectiveness as a treatment for prolapse.

- In view of the dearth of quality information on the results of conservative treatment, including pelvic floor exercise, change of lifestyle and mechanical/prosthetic devices (pessaries), RCTs or studies of good methodological quality should be conducted to evaluate these alternatives of POP repair as compared to the use of mesh or conventional surgery, and to the use of mesh as a first-line option.

- The use of mesh for transvaginal POP repair should be considered as a second-line therapeutic alternative for those cases in which conventional surgery fails.