Understanding NICE guidance

Information for people who use NHS services

Treating vaginal wall prolapse with surgery using mesh

This leaflet is about when and how surgery using mesh can be used in the NHS to treat women with vaginal wall prolapse. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

Interventional procedures guidance makes recommendations on the safety of a procedure and how well it works. An interventional procedure is a test, treatment or surgery that involves a cut or puncture of the skin, or an endoscope to look inside the body, or energy sources such as X-rays, heat or ultrasound. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering how well the procedure works and whether it represents value for money for the NHS.

NICE has produced this guidance because the procedure is quite new. This means that there is not a lot of information yet about how well it works, how safe it is and which women will benefit most from it.

This leaflet is written to help women who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe vaginal wall prolapse or the procedure in detail – a member of your healthcare team should also give you full information and advice about these. The leaflet includes some questions you may want to ask your doctor to help you reach a decision. Some sources of further information and support are on the back page.
What has NICE said?

The evidence says that mesh may work better than traditional surgery which does not use mesh, but there is not much good evidence about how well this procedure works in the long term. In addition, there is a risk of major complications. If a doctor wants to use this procedure for women with vaginal wall prolapse, they should make sure that extra steps are taken to explain the uncertainty about the long-term results and the risk of complications. Some complications can affect quality of life, such as the mesh eroding through the wall of the vagina, which requires further surgery and can cause severe discomfort and sexual difficulties. This should happen before the woman agrees (or doesn’t agree) to the procedure. The woman should be given this leaflet and other written information as part of the discussion. There should also be special arrangements for monitoring what happens to the woman after the procedure.

This is a difficult procedure. It should only be carried out by gynaecologists with special expertise and training.

More research into the different ways of repairing a prolapse and the different types of mesh would be helpful. Research should also look at long-term results, quality of life and any sexual problems experienced.

Other comments from NICE

There are several different mesh types available and different ways of performing the surgery. This made the evidence difficult to interpret. New evidence is being published regularly, so we will take this into account when we review the guidance.
Treating vaginal wall prolapse with mesh

The procedure is not described in detail here – please talk to your specialist for a full description.

Vaginal wall prolapse occurs when the pelvic organs, that is the bladder or rectum and bowel, slip down from their normal position. This may be due to pregnancy, childbirth, hysterectomy or weakness in the pelvic floor muscles, especially after menopause. The prolapsed vaginal wall may bulge into the vagina or, in severe cases, drop below the vaginal opening. This can cause discomfort with a feeling of pressure or heaviness. Sexual function may also be affected. Bladder and bowel problems are common.

A front wall (anterior) prolapse occurs when the bladder and/or urethra bulges down and backwards towards the vagina. A back wall (posterior) prolapse occurs when the rectum and bowel bulge forward. Some women may have prolapse of both the front and back walls of the vagina.

There are a number of surgical procedures used to correct vaginal wall prolapse. Many of these use a material called mesh. Mesh may be made of natural (‘biological’) or synthetic materials, or both combined, and may be absorbable or non-absorbable. They may also differ in other ways, such as structure. Treating a vaginal wall prolapse with mesh is usually done under a general anaesthetic. The aim of the operation is to provide support for the vagina and restore the affected pelvic organs to their natural position, and also to prevent another prolapse. This is achieved by implanting the mesh to strengthen and support the weakened area.

Before the mesh is implanted, some of the stretched tissue may be removed and the natural supporting tissues are tightened (the medical name for this procedure is colporrhaphy). When the supporting tissues have been strengthened, the mesh is stitched over the repair site (this is called an ‘inlay’) or, in the case of combined anterior and posterior prolapse, may surround the whole vagina (‘total mesh’ technique). This provides additional support and reduces the risk of a second prolapse. The mesh is usually implanted using an ‘open’ technique, in which large cuts are made in the pelvic floor. However, some procedures may be done using a special introducer device.

This procedure may not be the only possible treatment for vaginal wall prolapse. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.
What does this mean for me?

If your doctor thinks this is a suitable procedure for you, he or she should tell you that NICE has decided that the benefits and risks are uncertain. This does not mean that the procedure should not be done, but that your doctor should fully explain what is involved in having the procedure and discuss the possible benefits and risks of complications with you. You should only be asked if you want to agree to this procedure after this discussion has taken place. You should be given written information, including this leaflet, and have the opportunity to discuss it with your doctor before making your decision.

You may want to ask the questions below

- What does the procedure involve?
- What are the benefits I might get?
- How good are my chances of getting those benefits? Could having the procedure make me feel worse?
- Are there alternative procedures?
- What are the risks of the procedure?
- Are the risks minor or serious? How likely are they to happen?
- What care will I need after the operation?
- What happens if something goes wrong?
- What may happen if I don’t have the procedure?
Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at 30 studies on this procedure.

How well does the procedure work?

Anterior repair

Thirty studies involving 2472 women provided evidence about how well mesh works for front wall (anterior) prolapse repair and followed progress for an average of 14 months. Three of the studies also looked at the different types of mesh. The results showed that using mesh to repair the prolapse was more successful than no mesh. The studies showed that 29% of repairs without mesh failed, 23% using absorbable synthetic mesh failed, 18% using absorbable biological mesh failed and 9% using non-absorbable synthetic mesh failed.

Most of the studies only included assessments by the surgeon. However, six studies of 832 women included an assessment by the woman. Across all studies, the women felt that the failure rate for no mesh was 11% compared with 2–7% for mesh. In two studies using biological mesh, the reported failure rates were 12% for no mesh and 10% with mesh.

The studies also looked at whether further surgery was required. Women who had been treated with absorbable synthetic mesh had a higher rate of repeat surgery (9%, compared with 1–3% for other types).

The effect of the procedures on bowel symptoms and pain during sexual intercourse was not reported for any of the studies. A study of 28 women showed no difference in quality of life between women who had procedures using biological mesh and no mesh.

Posterior repair

Nine studies involving 417 women looked at back wall (posterior) prolapse repair and followed progress for an average of 12 months. There were no major differences whether mesh was used or not. The studies showed that 14% of repairs without mesh failed and 21% of repairs with mesh failed. The women's assessment showed that 15% of repairs without mesh failed compared with 21% for mesh.

In three studies, bowel problems did not improve in 33% of procedures without mesh, 17% of procedures with biological mesh and 12% of procedures with non-absorbable synthetic mesh.

A study of 45 women showed no difference in quality of life between women who had procedures using biological mesh and no mesh.

You might decide to have this procedure, to have a different procedure, or not to have a procedure at all.
Anterior and/or posterior repair

Fourteen studies involving 1680 women looked at a mixture of anterior, posterior and anterior with posterior repairs, following progress for an average of 13 months. The studies showed that 25% of repairs without mesh failed and 6–8% of repairs with mesh failed. The women’s assessment showed that 41% of repairs without mesh failed compared with 44% for mesh, but in two studies looking at non-absorbable synthetic mesh, none failed.

A study looking at persistent bowel problems showed that bowel problems improved in 20 out of 21 women at an average of 39 months after the procedure. In a different study, painful sexual intercourse had resolved in 9 out of 10 women by 13 months after the procedure.

A study of 60 women showed no difference in quality of life scores between women who had procedures using absorbable synthetic mesh and no mesh.

All types of repair

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that there is a lack of evidence for how well the procedure works in the long term and some uncertainty about how well mesh repair prevents the need for further operations on the vaginal wall. They also said that patient satisfaction and quality of life are important factors in considering how well the procedure works.

Risks and possible problems

Anterior repair

In five studies, damage to pelvic organs occurred in 6 out of 251 women who had non-absorbable synthetic mesh repair.

Seven studies involving 1394 women looked at mesh erosion, where the mesh comes through the walls of the vagina or is exposed. The rates varied according to the type of mesh used and happened in 0.7% of procedures using absorbable synthetic mesh, 6% of procedures using absorbable biological mesh and 10% of procedures using non-absorbable synthetic mesh. Women who had non-absorbable synthetic mesh were more likely to need further surgery as a result of erosion. Four studies showed that the risk of developing new-onset urinary incontinence after the procedure ranged from 0–7% and one study using non-absorbable synthetic mesh showed that 4 out of 11 women developed new problems with sexual function after the procedure.
Posterior repair

Four studies involving 276 women reported damage to organs in 0–4% of mesh repairs and in 3% of no-mesh repairs. Bladder injury occurred in two women and rectal perforation in three women.

Four studies involving 174 women looked at mesh erosion. The rates again varied according to the type of mesh used and happened in 14% of procedures using synthetic mesh, 0% of procedures using absorbable biological mesh, 7% of procedures using non-absorbable synthetic mesh and 14% of procedures using combined synthetic mesh.

No cases of new-onset urinary incontinence were reported in any study. Two studies of 109 women showed that 4 women developed new problems with bowel movements following the procedure (2 experienced constipation, 1 had difficulties in having bowel movements and 1 reported faecal incontinence). Three studies showed that 16 out of 61 women experienced pain during sexual intercourse after the procedure.

Anterior and/or posterior repair

Five studies of 684 women looked at a mixture of anterior, posterior and anterior with posterior repairs, reporting 16 cases of damage to the bladder, urethra or rectum following the procedure.

Mesh erosion happened in 6% of mesh procedures, and 4% of women needed further surgery. In five studies of 355 women, 10% developed new-onset urinary incontinence. In a study of 47 women, 1 developed bowel problems. Ten out of 78 women who had a combined mesh implant and 3 out of 42 women who had a non-absorbable synthetic mesh implant developed new-onset painful sexual intercourse. Other serious complications happened in 1% of patients. One woman developed an abnormal passage between the rectum and vagina.

All types of repair

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that, in addition to mesh erosion and new-onset sexual problems, potential complications of the procedure include infection and vaginal narrowing. One adviser also said that the introducer technique increased the risk of damage to the bowel, bladder and blood vessels in the pelvis.
More information about vaginal prolapse

NHS Direct online (www.nhsdirect.nhs.uk) may be a good starting point for finding out more. Your local Patient Advice and Liaison Service (PALS) may also be able to give you further advice and support.

About NICE

NICE produces guidance (advice) for the NHS about preventing, diagnosing and treating different medical conditions. The guidance is written by independent experts including healthcare professionals and people representing patients and carers. They consider how well an interventional procedure works and how safe it is, and ask the opinions of expert advisers. Intervventional procedures guidance applies to the whole of the NHS in England, Wales, Scotland and Northern Ireland. Staff working in the NHS are expected to follow this guidance.

To find out more about NICE, its work and how it reaches decisions, see www.nice.org.uk/aboutguidance

This leaflet is about ‘Surgical repair of vaginal wall prolapse using mesh’. This leaflet and the full guidance aimed at healthcare professionals are also available at www.nice.org.uk/IPG267

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N1605).

We encourage voluntary sector organisations, NHS organisations and clinicians to use text from this booklet in their own information about this procedure.