Treatment injury case study

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November 2008

EVENT: Gynaecological mesh placement

INJURY: Infection

Case study

Jane, a 48-year-old mother of three, underwent a bladder neck suspension for treatment of stress incontinence.

One year later, Jane visited her GP complaining of continual spotting and a smelly vaginal discharge. A vaginal examination revealed what looked like an edge of foreign material, so Jane's GP referred her to the public hospital gynaecology clinic.

Key points

- Clinical experience indicates vaginal mesh sheets carry a risk of microbial contamination, and resulting infections can be severe
- Severe infections involving first-generation xenografts are not recorded internationally
- Minimal infection may be treated in the office – treatment will typically involve trimming/ extracting visible mesh, antibiotics and local oestrogen
- As well as infection, polymesh is associated with subcutaneous thickening and stiffening
- FDA-reported complications associated with vaginal mesh sheets include:
  - erosion through vaginal epithelium
  - infection
  - pain
  - urinary problems
  - recurrence and/or incontinence
  - bowel, bladder and blood vessel perforation during insertion
  - requirement for additional surgical procedures.

At the clinic, the gynaecologist trimmed a small piece of mesh that was extruding through the vaginal wall. Jane was given a course of antibiotics and advised to contact the clinic if she continued to have problems.

Jane's symptoms did continue, including vaginal bleeding, a smelly vaginal discharge, pain on intercourse and urinary incontinence.

Six months after her first clinic visit, Jane presented at the Emergency Department with severe iliac fossa pain, rigors and a continued smelly discharge. She had also lost a significant amount of weight.

The examining doctor noted extensive cellulitis, extending from the mons pubis and across the lower part of Jane's abdomen. Intravenous antibiotics were commenced, however, Jane's condition deteriorated and it was decided to conduct exploration under general anaesthetic.

During surgery, the operating gynaecologist found a large necrotic abscess that required drainage and excision. All remaining mesh was removed.

Although Jane improved overnight, she returned to theatre the next day for removal of the vaginal pack and re-examination. The surgeon found that the necrosis had advanced and, with the support of another surgeon, proceeded to undertake an extensive debridement of the wound and surrounding tissue.

After this Jane spent two weeks in the Intensive Care Unit, where she required ventilated support, intensive antibiotic therapy and multiple blood transfusions. She also underwent a series of further debridement surgeries.

Jane was eventually discharged requiring district nurse care and input from a plastic surgeon.

Expert commentary

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Risks associated with polypropylene mesh

This case illustrates the infection hazard associated with the implantation of sterile mesh products through open vaginal surgery.

There are many types of synthetic mesh – the most commonly used is the thermoplastic polymer polypropylene.

Compared with the use of polypropylene mesh patches to correct abdominal wall herniae, the placement of mesh sheets in the vagina has been less satisfactory. Experience has shown that:

- microbial contamination of mesh placed through an open vaginal wound is inevitable
- infections occur even with the use of prophylactic antibiotics
- both sub-urethral tapes and larger sheets of mesh are susceptible to infection (the latter may also cause subcutaneous thickening and stiffening, which is disadvantageous in the vagina).

The references at right highlight the severe pelvic infection that can occur in the apical, anterior or posterior pelvic compartments following the implantation of polypropylene mesh. The first four references describe cases of necrotising fasciitis that have followed the implantation of tape or mesh.

Managing graft erosion and inclusion

In the presence of minimal infection, the management of graft erosion generally requires:

- office extraction
- trimming of visible mesh
- use of antibiotics, and local oestrogen if indicated.

Following graft inclusion, be very alert to the possibility of extensive tissue damage or infection, implying the presence of necrotising fasciitis. A unified interdisciplinary clinical approach is recommended in severe necrotising fasciitis with rapid progression and systemic toxaemia[1].

Physicians dealing with the primary and specialist care of women undergoing POP surgery with graft inclusion should read the online health notification *Serious complications associated with transvaginal placement of surgical mesh in repair of pelvic organ prolapse and stress urinary incontinence*, posted by the US Food and Drug Administration at http://www.fda.cdrh/safety/102008-surgicalmesh.html.

Second-generation xenografts

In recent years, various new mesh materials have become available, including submucous porcine small intestine, bovine pericardium and others, which promote the ingrowth of host blood vessels and cells to effect tissue regeneration.

World literature shows no record of serious infection complications associated with these materials. Further experience will confirm whether these second-generation xenografts have significantly fewer infection problems than polypropylene.

References

1. Abdel-Fattah M, Ramsay I; West of Scotland Study Group. *Retrospective multicentre study of the new minimally invasive mesh repair devices for pelvic organ prolapse*. BJOG. 2008 Jan;115(1):22-30.
2. Goldberg J, Weinstein M, Fagan M, Nagy M, Nyirjesy P. *Gluteal necrotising fasciitis: an unusual complication of abdominal sacrocolpopexy*. Am J Obstet Gynecol. 2001 Nov;185(5):1273-4.
3. Johnson DW, Elhajj, O'Brien-Best EL, Miller HJ, Fine PM. *Necrotising fasciitis after tension free vaginal tape (TVT) placement*. Int Urogynecol J Pelvic Floor Dysfunct. 2003 Oct;14(4):291-3.
4. Flam F, Boijsen M, Lind F. *Necrotising fasciitis following transobturator tape treated by extensive surgery and hyperbaric oxygen*. Int Urogynecol J Pelvic Floor Dyfunct. 2008 May 29 (Epub ahead of print).
5. US Food and Drug Administration. *Serious complications associated with transvaginal placement of surgical mesh in repair of pelvic organ prolapse and stress urinary incontinence*. http://www.fda.gov/cdrh/safety/102008-surgicalmesh.html October 21 2008.

Claims information

Between July 2005 and October 2008, ACC received 127 treatment injury claims relating to pelvic floor repair (laparoscopic and non-laparoscopic), TVT tape/colposuspension and vaginal repair.

Of these claims, 104 were accepted. Thirty-four claims involved mesh-related complications, with common injuries including vaginal damage/tear, wound infection, nerve damage, haemorrhage/bleeding and abscess.

Less common injuries included perforated bladder, infected haematoma and laceration.

Reasons for declining claims included no injury, that the injury was an ordinary consequence of treatment or that there was no causal link between treatment and the injury claimed.

How ACC can help your patients following treatment injury

Many patients may not require assistance following their treatment injury. However, for those who need help and have an accepted ACC claim for treatment injury, a range of help is available.

This help will depend on the specific nature of the injury and the applicant's personal circumstances, but may include things like:

- a contribution towards treatment costs
- weekly compensation for lost income (if there's an inability to work because of the injury)
- help at home, with things like housekeeping and childcare
- a contribution to the cost of travel to and from treatment
- changes to the home, such as the installation of rails and wheelchair ramps
- personal aids, such as crutches and wheelchairs.

No help can be given until a claim is accepted, but it's a good idea to keep receipts for any injury-related costs, as ACC may be able to reimburse these.

It's important to make a claim for a treatment injury as soon as possible after the injury. This will ensure ACC is able to investigate, make a decision and, if covered, help your patient with their recovery.

About this case study

This case study is based on information amalgamated from a number of different accepted claims. The name given to the patient is therefore not a real one.

The case study has been produced by ACC's Treatment Injury Centre, to provide health professionals with:

- an overview of the factors leading to treatment injury
- expert commentary on how similar injuries can be avoided in the future.

Send your feedback: AdminTeamTI&PS@acc.co.nz

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