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Short Report

Can we still have a clear conscience, routinely offering vaginal mesh operations in plastic and reconstructive surgery of the pelvic organ prolapse?

Können wir noch mit gutem Gewissen routinemäßig vaginale Mesh-Operationen in der plastischen und rekonstruktiven Chirurgie des Beckenorganvorfalls anbieten?

Abstract

Introduction: Since many years, plastic and reconstructive surgery in pelvic organ prolapse (POP) has been performed by vaginal mesh surgery. Although warnings from the scientific societies and the FDA have been published, vaginal mesh surgery still remains a routine treatment of genital prolapse in the female.

Background: Many third-degree referral centres in operative gynaecology found a high number of severe complications after mesh repair. Compared to the minor complications known from the classical non-mesh plastic and reconstructive surgery, there is a clear difference concerning the severity of complications. Additionally, mesh vaginal surgery was implemented in gynaecological prolapse operations because of the relatively high recurrence rate in classical vaginal surgery without implants; no major studies however have revealed a lower long-term recurrence rate with mesh vaginal techniques.

Discussion: As the recurrence rate could not be lowered evaluating the meta-analysis of the published scientific studies, the higher rate of severe complications should emphasise the fact that the risk of vaginal mesh surgery is too high for these techniques to be implemented in the surgical work of a routine gynaecological operative department.

Conclusion: Vaginal mesh surgery can no longer be a primary plastic and reconstructive therapy of pelvic organ prolapse in a routine gynaecological operative setting and department, due to the high rate of severe complications.

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Introduction

Pelvic organ prolapse (POP) with and without stress urinary incontinence (SUI) is one of the most common diseases in elderly women. Every case is an individual challenge to the gynaecological surgeon to treat his patient in a successful way and to avoid severe complications. As the abdominal and vaginal route of POP correction has a good overall satisfaction rate, but a relatively high recurrence of up to 30%, new methods were sought after. More than a decade ago, the use of synthetic vaginal mesh became an alternative to the known techniques. Normally a new drug, medical devise or a new surgical technique are only implemented in the routine gynaecological surgery work after extensive studies and a positive vote of the scientific societies. In case of the vaginal mesh, very quickly after the introduction by the industry, many gynaecological surgeons were convinced of the positive effects and started using these devises. Thorough clinical studies with at least a medium follow-up concerning complications and surgical experience using these meshes were missing, but the new techniques were readily accepted.

Soon after the implementation of the vaginal mesh in POP operations by a higher number of gynaecological surgeons, the first severe complications were reported. During the gynaecological surgery congress of the Forum Operative Gynaecology in Berlin 2007, already more than 400 known complications with a potential need of difficult revision surgery were presented. The food and drug administration in the USA (FDA) first warned in 2008, with specifications of the danger in 2011, 2012 and 2013. Nevertheless vaginal mesh operations are still routinely performed in the primary and secondary treatment of POP, in knowledge of the high rate of severe complications and the possible need for high level revision operations.

Background

Mesh operations started in hernia repairs in the 1950s. In the 1970s, the first mesh operations in women were used to repair POP with and without SUI [1]. POP is a very common female problem, occurring when the vagina is descending, requiring plastic and reconstructive surgery. Weak pelvic muscles, result of childbirth or general weakness of the connective tissue, gives a prolapse risk of 30–50% to all women during their entire life [2]. Today SUI is a well-known problem, even in younger women, meaning that the bladder leaks during increased abdominal pressure or activity. As there is a restriction in sexual activity and normal life, reconstructive surgery by vaginal or abdominal route has always been one of the routine operations in gynaecology. As one third of these operations without vaginal mesh had a recurrence, new operative methods and devises were looked after. The mesh, already routinely used for hernia repair, was implemented in vaginal surgery. A broader usage led manufactures to create new devices, invest in mesh products and propagate the *vaginal mesh as the routine operative method in the primary and secondary correction of POP*. During the congress of the German gynaecological surgeons – the Forum Operative Gynaecology in 2007, Berlin – Eckhard Petri of Greifswald and congress president Rudy Leon De Wilde of Oldenburg reported on more than 400 severe complications after vaginal mesh POP surgery, many of them requiring high level revision surgeries. In 2008 the FDA reported on rare but severe complications after vaginal mesh in the surgical treatment of POP [3]. In 2011 they updated their statements and warned patients and surgeons that severe complications increased [1], [4]. In 2012 and 2013 they underlined their statement and warned explicitly about the increasing problem [1]. Vaginal mesh showed to erode or perforate the vaginal wall causing bleeding, pain and infection; also other organs were penetrated such as the bladder, the bowel or blood vessels. Complications seldomly or never reported before, like penile lacerations after intercourse, osteomyelitis, nerve damage and large fistula occurred [5].

Discussion

In knowledge of all those complications and the many warnings regarding the use of vaginal mesh implants in plastic and reconstructive POP surgery, it cannot be in the interest of patients and surgeons to use these techniques in the primary correction. As a third-degree referral centre in gynaecology, nearly every week patients are presented at our department with a problem caused by a mesh implantation. Also in the literature up to 30% of patients with a vaginal mesh placement have some kind of complaint [6], but, as there are no sufficient data, the problem could even be higher [5]. A systematic review of the recent literature concerning mesh complications shows that the problem is existing and increasing [7]. Countless studies have been presented concerning the use of vaginal mesh, but up until today there is still a lack of data showing that the long time follow-up recurrence rate is really much lower than in the conventional vaginal and abdominal way. The cost of the vaginal mesh itself, the high cost of revision surgeries and the lack of a documented lower recurrence rate during longer follow up makes the indication questionable [2].

Summary

Vaginal mesh surgery can no longer be a primary plastic and reconstructive therapy in POP due to the high rate of severe complications.

Notes

Competing interests

The authors declare that they have no competing interests.

Authors' statement

This short report reflects the discussion on "patient safety" during the 51st annual meeting of the German Society of Plastic and Reconstructive Surgery (DGPW) in Berlin, 10.–12. October 2013.

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