

Long-term risk of complications after mid-urethral sling IVS implantation

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Abstract

Introduction. Results of short-term evaluation of multifilament microporous midurethral tape IVS differ a great deal. During the first year of implantation, erosions have been observed in 0%–26% of operated women. Long-term observations are rare. They suggest high risk of extrusion and infection even after years of implantation.

Objective. The purpose of the study was to evaluate long-term risk of complications after IVS implantation.

Material and methods. Between 2001–2005, 72 women were operated on with the use of IVS mid-urethral tape.

Results. Two women had vaginal erosions during the first 3 months after the operation. Twelve women had vaginal erosions, purulent vaginal discharge, with IVS tape sticking out of the abdominal wall or vagina, and abdominal abscess. These complications were diagnosed between 9 months and 6 years after IVS implantation. The patients were operated on vaginally and open abdominally, 1–5 times because of complications after IVS implantation.

Conclusions. In the case of post-IVS complication, as much tape as possible should be excised. Long-term follow up on patients with IVS implantation should be recommended to the centres where IVS tape was used, even to patients after removal of the tape. Risk of erosion, extrusion and infection after midurethral multifilament microporous IVS tape implantation is too high – which is the reason it should no longer be used.

Key words

stress urinary incontinence, IVS, multifilament tape, long-term outcome, erosion, abscess

INTRODUCTION

Stress urinary incontinence is among the most frequent chronic female disorders [1]. There are different methods of non-operative and operative treatment. First, a mid-urethral sling TVT (Johnson & Johnson) was introduced by Ulmsten and Petros more than 15 years ago, and quickly became a very popular operation for the treatment of stress urinary incontinence (SUI) in women, because of its high cure rate and low risk of complications [2, 3]. Based on this success, many companies started to produce mid-urethral slings using different materials, approaches and implantation techniques, but were introduced without long-term prospective studies. One of them was IVS (Tyco) [3, 4, 5]. The TVT tape is a macroporous monofilament tape, whereas the IVS tape is a multifilament tape with small pores. Some short-term studies have shown a high incidence of erosion and extrusion with the IVS tape; others reported 0% of erosion risk in first year after implantation [6, 7, 8, 9, 10, 11]. Long-term observations are rare. They suggest high risk of extrusion and infection even after years of implantation [12, 13].

OBJECTIVE

The purpose of this study was to evaluate long-term risk of complications after IVS implantation.

MATERIAL AND METHODS

Between 2001–2005, 72 women were operated on using IVS mid-urethral tape by 2 gynaecologists from urogynecologic unit after training. At that time, this was the tape in use at the Clinic of Operative and Oncologic Gynaecology to treat stress urinary incontinence (SUI) in women without signs of paravaginal defect and without symptoms of urge incontinence.

According to practice in the clinic, before the urogynecologic operations, all patients underwent a routine assessment, including urogynecologic examination, pad test and urodynamic evaluation. According to the clinical guidelines, the patients included in the study were offered midurethral tape IVS to treat stress urinary incontinence (SUI).

The IVS tape was implanted midurethrally according to the 'cook book' by Ulmsten and Petros [1]. Cystoscopic bladder and urethra control was performed twice, after every insertion of the IVS needle. A cough test was performed with 250–300 ml saline in the bladder in each case. Incisions were closed with absorbable stiches. The Foley catheter was removed the day after the operation. Routine 1-day antibiotic prophylaxis was used according to clinical protocol. Abdominal stiches were removed on the third day. Follow-up was routinely offered after 1–3 months and 1 – 5 years.

RESULTS

The mean age of the patients was 60 (range 34–82), mean parity was 2 (range 0–5) and mean BMI 29 (range 21–37). 12 patients had had urogynecologic operations performed in the past: pelvic organ prolapse (POP) repair – 10, Burch colposuspension – 4; and 1 patient had had radiotherapy

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to treat cervical cancer in the past. Additionally, with IVS implantation, 8 patients had additional operations: anterior repair – 2, posterior repair – 8, transvaginal sacrospinous fixation Amreich-Richter – 1.

No complications were observed during any of the operations. During the perioperative period, there was no case of haematoma needing evacuation and no case of post-void urinary residual lasting longer than 24 hours.

Patients had the possibility to visit the out-patient clinic in unexpected situations concerning their urogynecological condition. They were offered routine visits 1–3 months (Visit 1) and 1 year after procedure. Sixty-one women attended Visit 1 and 57 patients attended Visit 2. Twenty-one patients came for a control visit in 2007; no complications were found in any of them.

Two patients visited 4–6 weeks after the operation with voiding difficulties. Ultrasound evaluation showed post-void residual over 100 ml. After 2 weeks of pharmacological treatment, however, the residual did not resolve. In both patients, the tape was partially excised. There was no post-void residual after re-operation, and 4–6 weeks after re-operation, during the control visit, there were no signs of post-void residual.

Two patients visited 4–8 weeks after the operation with signs of *de novo* urge without incontinence and without post-void residual. After pharmacologic treatment the symptoms decreased.

In 2001–2011, 14 patients were re-operated on because of erosions, vaginal discharge, IVS tape protruding from the abdominal wall or vagina, with abdominal abscess, which were post-IVS implantation complications.

In 2 patients, vaginal erosions were noticed on Visit 1. After removing the edges of erosions without removing the tape, the vaginal wall was closed with absorbable sutures. After 4 weeks, one patient was cured. In one woman, erosion was found again. After removing a part of the tape IVS and edges of erosion, the vaginal wall was closed with absorbable sutures. After 4 weeks, no more signs of erosion were found.

Between 9 months and 2 years, 6 patients attended the out-patient clinic because of purulent vaginal discharge; in four of them vaginal erosion was seen. In 2 of them, no erosion was noted; however, after further examination in an operating room (OR), in one patient a very small erosion was found. In the other woman, no signs of erosion were seen, therefore so D&C was performed. Histopathology showed no abnormality, but because vaginal discharge was still noticed the patient was again examined in OR, and a small erosion was found.

In all 6 cases, a part of the IVS tape and edges of erosion were removed, and the vaginal wall closed with absorbable sutures. Five patients were cured after 4 weeks. Two of them reported 1–2 years later with vaginal discharge. In both cases, IVS tape protruded from the vagina and was removed with little force. The vagina was not sutured. On the control visit 4 weeks later, the patient had not noticed any vaginal discharge, and there were no signs of erosions.

The fifth patient, who was cured on the control visit, entered the department more than 6 years after IVS implantation with abdominal abscess. Through an abdominal incision, a big part of the IVS was removed. Eight weeks later during the control visit, abdominal wall was healed.

In the sixth patient on control visit 4 weeks after excision of erosion and partial excision of tape, there were signs

of erosion. The patient had two more vaginal excisions performed. On the control visit, erosion was again noted. Eight weeks after the last procedure, IVS tape was found sticking to the vagina and removed with almost no force. The vagina was not sutured. On the control visit 4 weeks later, vaginal discharge was seen and no signs of erosions. Six weeks later, the patient reported with signs of an abdominal abscess, which was abdominally operated.

Two patients reported 2–3 years after IVS implantation with IVS tape protruding from the abdominal wall. Both had the tape removed abdominally and there were no problems with post-operative healing.

Four patients were admitted the department with abdominal abscess 2–6 years after IVS implantation. In all cases, an abdominal operation was performed and a big part of the IVS tape was removed. In one patient a few weeks earlier, an abscess in mid-abdomen was operated on in the surgery department. In one patient, 5 months after healing of the abdominal wall, there were again signs of abdominal abscess. The second abdominal operation was successful.

Mid-term and long-term complications after IVS implantation are summarized in Table 1.

Table 1. Summary of mid-term and long-term complications after IVS implantation (n=12)

First complication/symptom	First procedure	Next procedure	Remaining procedures
	1- tape removed vaginally – cured	(-)	(-)
	2- tape removed vaginally – cured	(-)	(-)
	3- tape removed vaginally – cured	1 year later – vaginal discharge, tape protruding into vagina, tape evacuated	(-)
Purulent vaginal discharge – vaginal erosion (n=6) 9 months – 2 years after IVS	4- tape removed vaginally – cured	2 years later – vaginal discharge, tape sticking protruding into vagina, tape evacuated	(-)
	5- tape removed vaginally – cured	6 years later – abscess – operated abdominally	(-)
	6- tape removed vaginally – cured	2x removal of tape vaginally because of vaginal erosion	evacuation of tape protruding into vagina, 10 weeks later – abscess, operated abdominally
Tape protruding from abdominal wall (n=2) 2–3 years after IVS	1 – abdominally removed	(-)	(-)
	2 – abdominally removed	(-)	(-)
	1 – Abdominal operation	(-)	(-)
	2 – Abdominal operation	(-)	(-)
Abdominal abscess (n=4) 2–6 years after IVS	3 – Abdominal operation	Abdominal operation	(-)
	4 – Abdominal operation – surgery department	Abdominal operation	(-)

DISCUSSION

The presented study confirms that there is a high risk of erosion, vaginal discharge, extrusion and retropubic abscess even years after IVS implantation. In the studied population of women, no very high percentage of erosions were found during the first 3 months after procedure. Most of the complications were detected between 9 months and 6 years after IVS implantation. Total removal of IVS tape did not guarantee that an abscess would not occur. One retropubic abscess was diagnosed a few weeks after total removal of the tape. One patient underwent an operation in the surgery department because of abscess formation in the mid-abdomen. A few weeks later, the patient returned to the department with a new abscess formation in the lower abdomen. Patient herself suspected that the problem might be due to the IVS implantation.

The presented study suggests that some erosions after IVS may not be easy to detect. Two patients with vaginal discharge had to be examined under general anaesthesia to detect finally very small vaginal erosions (1 of them twice). It is possible that some erosions may occur months and years after IVS implantation.

Short-term evaluation of multifilament microporous tape IVS was been presented in a few studies, but the results differ greatly, from 0% – 26% [6, 7, 8, 9, 10, 11, 14]. There is little data presenting long-term effects and complications after IVS mid-urethral tape, but it does present a more unequivocal picture of IVS effect on women's periurethral and retropubic regions, and confirms a high risk of complications that exist even years after tape implantation [12, 13].

Rechberger et al. [14] during the median follow-up of 13 1/2 months did not find any case of erosion. Prien-Larsen et al. [13] found in 26% of patients vaginal erosions in the first year after surgery. Lim et al. [15] found 1.7% vaginal erosions during observation of 12 weeks. Meschia et al. found 9% erosions (8). In a retrospective study, Bafghi et al. [10, 11] found vaginal erosions in 9.2% of the women during 12 months of observation. Sivaslioglu et al. [16] followed 98 patients and after 3 1/2 years found 13.6% vaginal erosions. These authors suggested that this high percentage of erosions was caused by diabetes in the operated patients. They also suggested that a high percentage of erosions in other studies was probably caused by wrong operative technique. Vaginal erosions were found by Prien-Larsen et al. [13] in 11.8% of women in the IVS group compared to none in the TVT group, and the time to diagnosis was evenly distributed over the 56 months (range: 36–79) of observation. These authors had only one patient with DM. Patients during IVS and TVT procedure were operated with the same technique. They concluded that high risk of erosions after IVS procedure is caused by biological properties *in vivo* of multifilament microporous IVS tape. In their opinion, neither diabetes nor operative technique is responsible for high percentage of erosions after IVS implantation. In 25 patients, Glavind et al. [12] found vaginal erosions in 28% of the patients during 5 years of observation. This study showed that the risk of erosion and abscess formation persisted up to 5 years after the operation.

IVS is knitted from multifilament, polypropylene yarn and is a type III mesh with microporous components, which allows the harbouring of bacteria but not macrophages. This might be the reason for the high rate of erosion and abscess

formation. The extent of bacterial adherence depends on the mesh surface area. Multifilament meshes have a 205% increase in surface area compared to monofilament meshes. This may explain infection occurring months to years after implantation [12, 13, 17].

The patients in the presented study were operated on vaginally and open abdominally. They were operated on from 1–5 times because of complications after IVS implantation. There are only a few studies concerning the details of IVS excision. The authors did not perform the procedure vaginally, abdominally and laparoscopically, and they often had to perform a couple of operations to remove IVS tape from one patient (from 1- 4). In these cases, they often changed the route of the operation. They observed abscess formation even after removing a big part of the tape. Some patients, after partial removal of IVS, were operated on in another department for retropubic abscess [10, 11, 12, 13]. The authors of the presented study did not find in the literature information about abscess formation after total removal of the tape, which what happened to one of the patients in this study. In the case of post-IVS complication, an attempt should be made to excise as much tape as possible. The same suggestion is to be found in Goldstein's publication [18].

Glavind et al. [12] concluded that special attention should be paid to patients who, even after many years, complain of vaginal discharge or a suprapubic abscess. Furthermore, attention should be paid to the fact that a patient with an abdominal abscess is often admitted to other departments. The presented study confirmed these conclusions. It is suggested that centres where IVS was used should try to contact with all the patients involved and inform them about possible risk of erosion and abscess formation years after IVS implantation, even after partial or total tape removal. Patients should have possibility to be under control and advised to contact the clinic when vaginal discharge or signs suggesting abscess are present.

In this study, no results are presented of the cure rate of stress urinary incontinence because the number of patients was too low. Comparative studies of TVT and IVS showed that the outcomes of TVT were effective and stable in the long-term, while in the IVS groups there were observed significant declines in cure rate in long-term observations [13].

It is the opinion of the authors of the current study, by reason of All the information obtained, that IVS mid-urethral tape should no longer be used because of the high risk of complications which can occur even years after the procedure.

Longitudinal controlled studies are the only way by which the surgical and scientific communities can ascertain the durability and success of suburethral slings, and the material from which they are comprised. It seems clear that knitted macroporous polypropylene is the material of choice for suburethral implantation at the moment [3, 12].

CONCLUSIONS

In the case of post-IVS complication, as much tape as possible should be excised. Long-term follow-up on patients with IVS implanted should be recommended to the centres where the IVS tape was used, even to patients after removal of the tape. The risk of erosion, extrusion and infection after midurethral

multifilament microporous IVS tape implantation is too high – which is the reason why it should no longer be used.

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