Closing the Chapter on Obtape: A Case Report of Delayed Thigh Abscess and a Literature Review

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Abstract

Background: We report a case of delayed abscess formation 33 months after Obtape transobturator tape insertion, and we review the relevant literature.

Case: A 73-year-old woman presented with groin pain, swelling, and purulent discharge 33 months after Obtape insertion. Examination showed a vaginal erosion and right groin abscess. Oral antibiotics resulted in significant symptomatic improvement. The patient underwent complete tape removal and drainage of infection. She continues to suffer from urinary incontinence.

Conclusion: Abscess formation and undiagnosed mesh erosion can occur up to 33 months after Obtape insertion, longer than previous reports have described. This highlights the need for continued vigilance in patients who have undergone Obtape insertion. Vaginal mesh erosions warrant careful repair in order to avoid delayed infectious complications.

Résumé

Contexte : Nous signalons un cas de formation différée d'un abcès, 33 mois à la suite de l'insertion d'un ruban transobturateur Obtape, et nous analysons la littérature pertinente.

Cas : Une femme de 73 ans présentait des douleurs à l'aine, de l'enflure et un écoulement purulent 33 mois à la suite d'une insertion Obtape. L'examen a révélé une érosion vaginale et un abcès inguinal droit. L'administration d'antibiotiques par voie orale a entraîné une atténuation significative des symptômes. La patiente a subi le retrait intégral du ruban et un drainage de l'infection. Elle continue de présenter une incontinence urinaire.

Conclusion : La formation d'un abcès et une érosion non diagnostiquée du treillis peuvent survenir jusqu'à 33 mois à la suite de l'insertion Obtape, soit un délai plus long que ce que les rapports précédents avaient décrit. Cela souligne l'importance d'une vigilance soutenue en ce qui concerne les patientes qui ont subi une insertion Obtape. Les érosions du treillis vaginal justifient la mise en œuvre d'une réfection rigoureuse afin d'éviter les complications infectieuses différées.

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INTRODUCTION

Suburethral slings are commonly performed for stress urinary incontinence symptoms. With the current demand for minimally invasive surgery, several new devices and accompanying mesh materials have been marketed. The transobturator sling was introduced by Delorme in 2001,[1] as an alternative to the existing TVT, offering the advantage of avoiding the retropubic space and thereby minimizing complications of bladder, bowel, and vascular injuries. The initial tape, called Uratape (Mentor-Porgès, France), was a non-woven, non-elastic, thermally bonded polypropylene mesh with pores < 10 μm in diameter and a central silicone coating intended to reduce the risk of periurethral fibrosis, prevent mesh contraction, and facilitate surgical treatment in the event of reoperation. It was withdrawn from the market mainly because of concerns about poor vaginal healing. Its successor was Obtape (Mentor-Porgès, France), which advertised a larger average pore size of 50 μm and no silicone coating. The other tape characteristics were similar to those of Uratape; the mesh was still non-woven and thus quite rigid and of fixed pore size. Because Health Canada licenses devices for use in Canada on the basis of their similarity to existing products, no long-term studies of Obtape were conducted before its widespread implementation.

We undertook transobturator surgery on a cohort of 52 women before deciding whether to introduce Obtape into our clinical practice, and we followed the women to one year. We found that the rate of erosions was 8/52 (15%).[2] We report here a case of delayed abscess formation and vaginal erosion from our original cohort, and we provide a review of relevant publications.

THE CASE

A 73-year-old woman, gravida 7, para 4, presented in 2002 with symptoms of mixed urinary incontinence, with a predominant stress component. She reported daily use of a pad

Table 1. Retrospective (R) and prospective (P) cohort studies of the Obtape TOT

Author	# pts	Length of f/up mean (range) months	# (%) erosion (time of pres)	Abscess (# pts)	Management	% continent after mesh excision
Abdel-Fattah et al.[4](R)	192	13 (1–45)	14 (7.3) (1 wk to 11 mo)	2 ischiorectal fossa	excision (7 partial, 7 complete)	100 (partial) 25 (complete)
Yamada et al.[5](P)	67	6 (1–9)	9 (13.4) (1–9 mo)	1 left thigh	complete excision	–
Siegel [6]	30	up to 24	6(20) (6 wks to 7 mo)	1 left obturator (6wks)	5 complete excision 1 vag E	unclear (2 pts had 2nd sling after complete excision) 33
Deval et al.[7](P)	129	17 (4–28)	7 (6.2)	2 obturator (9,17 mo)	6 complete	33
Spinosa et al. [8](P)	117	(7–22)	3 (2.5) (13, 15, 18 mo)	–	partial excision	100
Dobson et al. [2]	52	62 wks (52–74wks)	8 (15) (6 wks – 10 mo)	1 groin (10 mo)	excision (1 complete 5 partial)*	20 (1/5)*
Roumeguere et al.[9](P)	60	12	0	–	–	–
Domingo et al.[10](P)	21	12	4 (19) (3,6,8,12 mo)	0	complete excision	75
Grise et al.[11](P)	206	16 (12–33)	4 (1.9) (2,8,13,25 mo)	1 deep adductor (25 mo)	excision (3 partial 1 complete)	"most"

*This information obtained from the original report of five cases of Obtape erosion.[24] Follow-up on continence status not available for the whole cohort of 52 patients.[2]

and mild symptomatic improvement with use of tolterodine. She was not sexually active. She had had four spontaneous vaginal deliveries. She reported no use of hormones after menopause and had no history of previous pelvic surgery. Socially, she described herself as fairly active, despite her symptoms, enjoying deep water running and bowling a few times per week.

Her pelvic examination showed POP-Q stage 2 anterior and posterior prolapse, as well as stage 1 uterine prolapse.[3] Stress incontinence was confirmed on urodynamic testing. No unstable detrusor contractions were seen, and postvoid residual volumes were low. Cystoscopy showed mucosal inflammation, and polypoid cystitis glandularis was diagnosed by biopsy. The patient was given information regarding the new TOT procedure, which was being evaluated in our department at the time. In February 2004, the patient underwent an uneventful Obtape TOT placement, with post-placement cystoscopy confirming an intact bladder and urethra. Antibiotic prophylaxis was administered intraoperatively. In April 2004, the patient returned for a postoperative check-up and complained of worsening of her mixed urinary incontinence symptoms. She began treatment with oxybutynin, and a repeat urodynamic assessment was proposed. However, being disappointed with the results of her surgery, the patient elected to forgo further evaluation and was lost to follow-up. She did not return for the one-year follow-up visit suggested to patients who have an Obtape insertion performed in our department.[2]

In November 2006, the patient was referred to the urogynaecology clinic with symptoms of right-sided medial thigh pain and swelling, followed by purulent drainage from the TOT scar. She denied any vaginal bleeding, discharge, or pain. There were no associated systemic symptoms. She had persistent severe mixed urinary incontinence symptoms. On vaginal examination, the tape was found to be hanging loosely along the anterior wall of the vagina. The patient began treatment with oral antibiotics (cephalexin) and was scheduled for surgical tape removal and abscess debridement. This was performed approximately three weeks later.

Examination under anaesthesia revealed a small area of erythema and nodularity around the TOT scar in the right groin. The previously noted drainage point was sealed, and no further discharge was present. Vaginally, the tape was holding only at the level of the midurethra, where a bridge of tissue encircled the tape like a ring. The rest of the tape was exposed and the vaginal mucosa completely healed around it. Laterally, tunnels of completely healed vaginal mucosa heading towards the obturator spaces on each side were palpable. There was no vaginal discharge or evidence of vaginal infection. A short Allis clamp was used to grasp the exposed

ABBREVIATIONS

TOT	transobturator tape
TVT	tension-free vaginal tape

Table 2. Case reports of abscesses following Obtape TOT

		Vaginal erosion	Abcess		
Author	# pts	(No. months postop)	Type	(No. months postop)	Management
Babalola et al.[12]	1	2	Ischiorectal	10	Complete excision of tape and sinus tract Drain placement Antibiotics
Karsenty et al.[14]	3	10	Thigh/gracilis adductor	10	Complete excision of tape Extensive debridement of necrotic area 2/3 down to knee Wound care w/vacuum therapy
		2	Thigh/adductor	4	Complete tape excision Debridement thigh Healing by secondary intention and vacuum therapy
		?5	Thigh/adductor	6	Complete tape excision Debridement thigh Healing by secondary intention
Goldman[15]	1	One day	Thigh/gracilis adductor	One day	Complete tape excision Debridement thigh Healing by secondary intention
Deffieux et al.[13]	1	7	Thigh	18	Complete tape excision Debridement thigh healing by secondary intetion
Rafii et al.[16]	3	7,6	Obturator	7,6	Complete tape exision
Ismail[17]	1	None	Groin	16	Partial tape excision Abscess drainage

piece of mesh. The mesh, 8 cm in length, was removed with minimal traction on each side. A small incision was made in the skin above the area of nodularity in the right groin, and the subcutaneous tissues were debrided to a depth of approximately 1 cm. No further mesh was identified. The wound appeared clean and was closed with Vicryl sutures in two layers. The vaginal tunnels were left open.

The patient recovered well and has welcomed a repeat urogynaecologic assessment and possibly a repeat anti-incontinence surgical procedure.

LITERATURE REVIEW

We conducted a review of the literature using Medline (1996-present) and the term "Obtape." Studies describing Obtape-related abscesses were selected. We identified nine relevant cohort studies,[2,4–11] two retrospective and seven prospective cohort (Table 1) and six case reports of abscess development[12–17] (Table 2). The reported incidence of vaginal erosion after Obtape insertion ranges from 1.9% to 20%, with more studies reported in the higher range. Most cases are detected in the first year after Obtape insertion and are associated with vaginal discharge, infection, or discomfort for the male partner during intercourse. Most studies had at least one associated abscess to report, also typically in the first year after Obtape insertion. Descriptions of continence status after tape excision are mixed; continence seems to be more common after partial mesh excision than after complete excision, but excision may be attempted only in more severe cases. In addition, four of the six case reports document severe thigh abscesses requiring intravenous antibiotic therapy, surgical debridement, and prolonged wound healing, with extensive residual scarring

We also consulted the US Food and Drug Administration website for any adverse reports in the Manufacturer And User facility Device Experience (MAUDE) database[18] concerning Obtape. Between 2003 and 2006, 198 vaginal erosions with or without associated infections related to the Obtape vaginal mesh were reported.

DISCUSSION

A variety of mesh types have been used for suburethral anti-incontinence sling surgery (Table 3). Histologic study of mesh integration into host tissues[19] shows that, although different polypropylene mesh materials elicit a similar inflammatory response, tissue integration is most complete in macroporous monofilament mesh (pore size > 75 μm) such as the Monarc TOT (AMS, Minnetonka, MN). There is a progressive tissue response to Monarc. In the first three months after surgery, dense columns of host collagenous tissue grow into the mesh between its pores; this extensive integration theoretically reduces the risk of friction between mesh and surrounding host tissues, thereby minimizing

Table 3. Types of suburethral slings

Name	Type	Mesh	Company	Approach
TVT	–	macroporous woven	Gynecare	Retropublic
Uratape	TOT	microporous non-woven	Mentor	Obturator foramen
Obtape	TOT	medium pore size non-woven	Mentor	Obturator foramen
Monarc	TOT	macroporous woven	AMS	Obturator foramen
TVT-O	TOT	macroporous woven	Gynecare	Obturator foramen

risks of erosion. On the other hand, the presence of closely spaced filaments arranged in a multidirectional orientation (such as in Obtape) precludes most host tissue ingrowth. Instead of growing between the mesh pores, collagen and inflammatory cells accumulate at the surface of the mesh and form a capsule around it. In consequence, the mesh moves freely against the surrounding capsule, and friction is more pronounced. This may explain the ease of removal, noted by us and other investigators,[20] of the Obtape months and years after the procedure, with only slight traction needed. The mesh characteristics may explain the low incidence of vaginal erosion reported for TVT-O (Gynecare) and Monarc (AMS). They both use the same type of macroporous woven polypropylene mesh, but the insertion approach is different, TVT-O insertion being "inside-out" and Monarc "outside-in" with the same mesh orientation. Abdel-Fattah et al.[4] report a 1.78% incidence of erosion following TVT-O insertion, compared with 7.29% following Obtape. Moreover, a one-year prospective cohort study comparing TVT-O with Monarc (50 patients per group) reports no mesh exposures in either group.[21] Two retrospective cohort studies[22,23] and one prospective cohort study[5] reported an incidence of Monarc TOT mesh erosion of 0% to 0.5% after more than one year of follow-up. This incidence was similar to that reported for TVT.[22] Insertion of TVT is a well established suburethral sling procedure for stress urinary incontinence, employing a monofilament large pore polypropylene mesh similar to Monarc. The type of implanted material rather than the orientation of the mesh in the vagina (TOT vs. TVT) or the insertion approach (outside-in vs. inside-out) may be the main causative factor behind erosive and infectious complications.

Obtape was removed from the market in March 2006. In most cases described in the literature, abscess formation related to the Obtape TOT was preceded by vaginal tape erosion, similar to our patient's experience. Reports describing abscess without erosion[24] are the exception rather than the norm. Erosion is associated with symptoms of vaginal discharge and male partner discomfort with intercourse. However, our patient did not have discharge and was not sexually active. It is impossible to know when the vaginal erosion occurred in her case; unfortunately, she was not examined at one year after insertion. The exposed foreign body in the vagina may have provided a portal of entry for bacteria leading to the thigh abscess. This suggests that there may be mesh erosions that are not recognized in patients who are not sexually active and who have undergone an Obtape TOT insertion for stress urinary incontinence. These patients should return wherever possible for a follow-up vaginal examination.

Many cases of tape erosion and thigh abscess have been reported following surgery using Obtape, resulting in its withdrawal from the market. Our additional case, occurring later after surgery (33 months) than any previously reported, highlights the need for continued vigilance in patients who have had an Obtape insertion.

When Obtape erodes the vagina, complete excision of the exposed mesh should be performed in order to avoid severe soft tissue infections that may occur some years after surgery. Recurrence of stress incontinence is likely after complete mesh excision. Mesh excision can be attempted in an office setting, since only slight traction may be needed for trimming or even for complete removal. Reporting of complications by clinical users of new materials is very important.[25] New materials and surgical techniques should be carefully evaluated before widespread implementation. Minimally invasive surgery does not imply minimum risk.

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