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RESEARCH ARTICLE

# Complications of TVT Treatment of Stress Urinary Incontinence in Women

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#### Abstract

The accent of the publication is the complications after the application of various TVT slings to correct stress urinary incontinence in women. The aim is to determine the type of complications and their frequency according to the method of TVT surgery. For the period 2005-2019, 436 women underwent TVT surgery, and 80 (18.3%) developed complications. In 334 women by the method of TVT-O-postoperative complications had 47 women (14.1%), in 78 operated by TVT-R, with postoperative complications were 23 patients (29.5%), and in 24 patients with TVT-Ophira-5 (20.8%) had postoperative complications. A retrospective method was used to determine the percentage of different complications depending on the type of TVT sling applied. The study concluded that intraoperative complications in 5 women (1.15%) obtained with the TVT-R method alone, and postoperative complications were observed in 75 of women (17.2%), using all three methods.

**Keywords:** Stress urinary incontinence (SUI); TVT sling operations; Intraoperative complications; postoperative complications; Recurrence.

#### Introduction

Currently, stress urinary incontinence is one of the most complex problems in modern urogynecology. According to various sources, stress urinary incontinence affects 20 to 50% of women [1]. The gradual aging of the population, the high prevalence of obesity and diabetes at the moment, are risk factors for urinary incontinence, the popularity of surgical operations, which today are performed by a wide range of specialists, will inevitably lead to an increase in the number of women for surgery.

Even if the effectiveness of sling operations is maintained at 80-85%, the number of patients who will not be helped by the operation, i.e. the remaining 15-20%, will be significant.

Stress urinary incontinence in women is a current problem of urology, which does not endanger patients' lives, but significantly degrades their quality, which often leads to social maladaptation [2, 3]. According to epidemiological studies, the incidence of

urinary incontinence in women is very significant: up to 25% of young women, 44 to

57% of post-menopausal women, and up to 75% of elderly women have problems with urinary continence [4]. Mesh insertion is the most common surgical procedure used to treat stress urinary incontinence (SUI) in women [5], with 3.7 million meshes sold worldwide between 2005 and 2013 products (Medicines and Healthcare Regulatory Agency [6]. However the safety of these procedures is the subject international debate and control [7] with court actions against mesh manufacturers underway in various countries, including Australia, Belgium, Canada, England, Israel, Italy, the Netherlands, Scotland, USA, and Venezuela [8].

In the USA, the FDA has proposed to raise the risk classification of urogynaecological meshes, requiring prior notification and special controls (American Urogynecologic Society (AUGS) & Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction [9]. Substantial safety and efficacy data support the role of synthetic mesh midurethral slings as a primary surgical treatment option for female SUI.

However, mesh-related complications can occur [10]. Complications associated with mesh procedures for SUI include haemorrhage, perforation. organ mesh erosion, infection, IVO and pain [11], which require further surgery. mav considering the complications that occurred after performing sling operations, it can be found that almost all of them are based on violations in the technique of performing the operation, which can occur both on the operating table and after a significant period of time.

Therefore, the correct positioning of the patient on the operating table and following the anatomical landmarks allow avoiding most of the complications. The only thing that cannot be included in the specific recommendations is the control over the degree of tension of the tape. The most common method of assessing the tension of the tape is the cough test, which is performed during the operation. Currently, sling operations are performed mainly under spinal or local anesthesia, which allows the test to be performed.

#### **Materials and Methods**

The present study is based on the results of surgical treatment of 436 patients with stress urinary incontinence that underwent three methods of implanting synthetic polypropylene midurethral slings. The operations were performed at the University Hospital in Ruse and the University Hospital "Deva Maria"-Burgas for the period 2005 - 2019. The study is retrospective. TVT-O-334 operations were performed, TVT-R - 78 operations and TVT-Ophira-24.

#### **Preoperative Evaluation**

The evaluation of patients was performed during preoperative visits. All the patients that reported symptoms of urinary incontinence were specifically investigated with the Q tip test and a urodynamic assessment to determine the type of incontinence and its relative severity. The patients were preoperatively studied with ambulatory urodynamics, measurement of

residual volume, and subtracted cystometry, study of the Leak Point Pressure, uroflowmetry, pressure-flow studies.

# **TVT-O Technique**

A 2-cm midline incision was made under the midurethra. Metzenbaum scissors were used to dissect under the vagina epithelium in the periurethral tissues, until the scissors tip met the medial portion of the ischiopubic ramus. The elical device was placed through the suburethral tunnel until the medial surface of the ischiopubic ramus was reached. The device was popped through the obturator membrane and then rotated sharply around the ischiopubic ramus to exit through the skin. The TVT Obturator System (Gynecare Ethicon) was used.

The polypropylene sling was then pulled out through the skin incision and held. The procedure is repeated on the opposite side. A cystoscopy was performed to ensure no bladder injury. The sling is tensioned and, at this point, the patient was asked to cough or perform a Valsalva maneuver (cough test). Finally the plastic sleeves were removed and the skin and vaginal incision closed.

#### TVT-R

The operation is carried out under local anaesthesia using 0.25% prilocaine with adrenaline. Two minimal (1 cm) incisions, 5 cm apart, are made in the abdominal skin just above the superior rim of the pubic bone. A sagittal incision 1.5 cm long is made in the sub urethral vaginal wall starting 1 cm from the external urethral meatus.

After minimal bilateral paraurethral dissections of the vaginal wall a special prolene tape covered by a plastic sheath is introduced. The procedure is then repeated on the other side. The tape therefore is placed in a U-formed shape around the mid-urethra, where the high-pressure part of the organ is located, and, from functional aspects, the main insertion of the pubourethral ligaments and pubococcygeus muscles are arranged.

The instrument consists of two needles to which a prolene tape covered by a plastic sheath is connected. Each needle can be mounted to a handle for insertion of the tape. When the needle tip has reached the abdominal incision the needle is disconnected from the handle. A cathether guide introduced into the Foley catheter facilitates

identification of the urethra and bladder neck.

Simultaneously this catheter guide enables the bladder neck to be moved sideways, in turn avoiding injury to the bladder neck at insertion of the needle. After cystoscopy to make sure that the bladder is undamaged, the tape is adjusted without tension under the urethra. During this adjustment the woman is asked to cough to confirm that she has become continent by the procedure. The plastic sheath covering the prolene tape is removed and, due to the strong friction between the special prolene tape and the tissue canals created by procedure, no fixation of the tape is necessary and should not be carried out. The vaginal and abdominal incisions are then closed, after cutting the abdominal ends of the tape in the subcutaneous tissue without any fixation.

In case of a loose suburethral vaginal wall, excessive tissue is excised before closure of the vaginal incision. One advantage of this procedure is that the surgeon can make sure that continence (i.e. no urinary leakage on coughmg) has been obtained during the operation, without elevation of the urethra, thereby avoiding post-operative urinary retention.

By the same token, the operation is individualised, since the adjustment of the tape is carried out according to each woman's requirements. This is why the procedure should be performed under local anaesthesia. After the operation the bladder is emptied and no catheter is inserted [12].

#### TVT-Ophira

In the Ophira mini sling group, a vertical incision of 1 cm was made on the anterior vaginal wall mucosa at the level of the mid urethra. A gentle minimal dissection was made towards the inferior ramus of pubic bone. The delivery trocar was attached to the arms of mini sling mesh, guided by the surgeon's index finger towards the urethrapelvic ligament. When half the length of the mesh was within the incision, the deploying button at the handle of the trocar was retracted to make a strong fixation of the mini sling mesh in the place.

The same steps were repeated on the other side. Foley catheter was left in place and removed 6 to 48 hours postoperative. All patients underwent cystourethroscopy during the procedure to rule out urethral or bladder penetration.

Furthermore, the 1-h PAD test and the incontinence quality of life (I-QOL) questionnaire were administered [13]. The patients were visited and followed-up regularly at one week and 1, 3, 6 and 12 months postoperative. At each visit they were examined and re-evaluated by objective measures (cough stress test with a full bladder) and subjective means (IIQ scores).

The women were asked to describe their satisfaction from the surgery, on a visual analogue scale of 0-10, whether or not they would have the procedure repeated if their incontinence returned, and whether they would recommend the procedure to a friend.

A visual analogue scale of 8-10 and positive answers to another two questions were defined as satisfaction. The complications were recorded. Urine culture and ultrasound was repeated at each visit. Residual urine of more than 100 ml was considered significant. Approval for this study was granted by the local human institutional investigation committees. All patients were informed about the study and procedures and gave their informed consent.

#### Results

#### **Bleeding**

I had an intraoperative bleeding complication in 1 (0.2%) patient operated on by TVT-R.

# Injuries to the Organs in the Small Pelvis

Trauma to the pelvic organs is observed in cases where the surgeon puts the sling in the wrong position by accident. Perforation of the bladder, urethra and vaginal arch is possible. Out of 436 operated patients for the treatment of stress urinary incontinence, 4 patients received the intraoperative complication - bladder trauma.

The frequency of intraoperative complications in 436 TVTs is indicated in Table 1.

Table 1: Intraoperative complications in operated patients

Complications	TVT-O n=334	TVT-R n=78	TVT-Ophira n=24
Blood loss >100ml, n (%)	0	1 (1.3%)	0
Vaginal perforation, n (%)	0	0	0
Bladder injury, n (%)	0	4 (5.1%)	0

There is a certain group of patients in whom performing sling operations is associated with significant difficulties. Aggravating factors include: obesity, recurrence of urinary incontinence after previous anti-stress operations; the presence in the anamnesis of urethroplasty; pelvic fractures with impaired pelvic ring integrity; after applied radiation therapy of the pelvic organs. Of course, the probability of complications in these patients is higher. Many complications are based on

various disorders in the operative technique, but often these complications appear some time after the operation. The frequencies of postoperative complications in these 436 TVT operations are presented in Table 2.

Lower urinary tract infections-the behavior in this complication is to analyze sterile urine with an antibiogram and prescribe an antibiotic according to the antibiogram. In 436 operated women, I do not have a patient with this complication.

Table 2: Postoperative complications in operated patients

Complications	TVT-O n=334	TVT-R n=78	TVT-Ophira n=24
Lower urinary tract infection, n (%)	0	0	0
Intravesical obstruction, n (%)	33 (9.9%)	12 (15.38%)	0
Pain syndrome, n (%)	6 (1.8%)	6 (7.7%)	4 (16.7%)
Erosion of the vaginal walls, n (%)	0	1 (1.3%)	0
Urethral erosion, n (%)	0	1 (1.3%)	0
Urgency of urine de novo, n (%)	4 (1.2%)	3 (3.8%)	1 (1.5%)
Perineal abscess, n (%)	2 (0.6%)	0	0
Hematoma of the perineum, n (%)	2 (0.6%)	0	0

#### Pain Syndrome

In my study, 16 (3.7%) patients had pain syndrome: 6 patients received this postoperative complication after TVT-O administration, 6 in TVT-R and 4 women had pain syndrome after TVT-Ophira (Table 2).

#### **Intravesical Obstruction (IVO)**

The main reason for this complication is the excessive compression of the urethra by the band. Additional causes are swelling of the adjacent tissues and obesity. The amount and timing of IVO treatment resulting from a sub urethral sling depends entirely on the symptoms that concern the patient. 45 (10.3%) patients received these postoperative complication. 33 women after TVT-O and 12 after TVT-R.

After using TVT-Ophira minis ling, there are no patients with this complication. In the presence of acute urinary retention, periodic catheterization of patients is required to overcome intravesical obstruction. In my study, it was performed in 16 of the patients who received IVO in the early postoperative period. I performed a procedure to relieve the tension in the sling on 24 women.

17 of them were operated by TVT-O and 7 women operated by TVT-R. After the procedure, the intravesical obstruction in everyone was overcome. Sling removal was necessary in 5 of my patients. Of these, 4 women were operated by the TVT-O method and 1 by the TVT-R method.

#### **Erosion**

In case of erosion of the vaginal walls - the visible part of the strip is removed; the vaginal mucosa is mobilized and sutured over the areas of erosion. 1 patient received this complication after receiving TVT-R.

In case of urethral erosion - the vaginal mucosa is mobilized, the site of erosion is refreshed and the damaged part of the urethra is sutured. A urethral catheter is inserted for at least 30 days. 1 patient received this complication after receiving TVT-R.

#### Urgency of Urine de Novo

In my retrospective study, a total of 8 patients (1.8%) developed urinary urgency de novo after sciatica surgery. 4 women after TVT-O, 4 after TVT-R and 1 patient had de novo urgency after TVT-Ophira.

The behavior of abscesses and hematomas of the perineum is according to the rules of classical surgery. Of all 436 sling patients, 4 received these complications.

#### Relapses

One of the most difficult issues with tapes is controlling the degree of tension. The very term "tension-free" means "without tension". In this case, this means that the ends of the tape are not fixed, but are located in the thickness of the muscles. Accordingly, the only force that holds the ends of the sling is

the pressure created by the surrounding tissues.

Of course, the tape exerts a certain pressure on the posterior wall of the urethra. But the only objective method for assessing the degree of pressure (and therefore the degree of tension in the band) is a cough test performed directly during the operation. Other control methods do not give concrete results. The percentage of patients who developed recurrence after implantation of suburethral polypropylene tape is shown in Table 3.

Table 3: Recurrent form of stress urinary incontinence in operated patients

Operated patients	TVT-O	TVT-R	TVT-Ophira
n= 436	n=334	n=78	n=24
Repeated anti-stress surgery followed by TVT-R, n	8 (2.4%)	3 (3.8%)	0

# **Risk Factors for Relapse**

The guidelines for the treatment of urinary incontinence published at the National Institute of Health UK (NICE) in the United Kingdom list the risk factors for recurrence of urinary incontinence after surgery. they include particular, old age, maximum urethral closure pressure, high rate of maximum urine flow, presence of nocturia and urgency, daily loss of more than 10 g of urine, obesity, urethral mobility angle below 30%, use of general anesthesia, concomitant surgical treatment, prolapse, insufficient experience of the surgeon, as well as repeated sling operations.

The presence of concomitant genital prolapse in women is also not a rare clinical situation. Approximately 40% of patients with pelvic prolapse have stress urinary incontinence [14].

#### Significance

When placing different types of sling, a number of complications can often develop. Patients should have a detailed history, preand postoperative examinations: physical, microbiological, ultrasound, urethrocystoscopy, urofluorometry and cystotonometry.

In my study of complications after TVT sling surgery to treat stress urinary incontinence in 436 women, the rate of all complications was 18.3% (80 women). Intraoperative complications were experienced by 5 women (1.15%) operated by the TVT-R method. Blood loss more than 100 ml - 1 woman,

bladder injury - 4 women. Postoperative complications were observed in 75 of women (17.2%). Of the 334 women who underwent TVT-O surgery, 47 of them had various postoperative complications (14.1%). 33 patients developed intravesical obstruction, 6 patients had pain syndrome, 4 patients had

de novo postoperative urgency, and 4 patients had abscess and peritoneal hematoma.

Out of all 78 women operated on for the treatment of stress urinary incontinence by the TVT-R method - 23 women (29.5%) received postoperative complications. 12 of them developed intravesical obstruction, 6 patients - pain syndrome, 1 patient - urethral erosion and 1 - vaginal wall erosion, postoperative urgency de novo had 3 of the patients with TVT-R. Of the 24 women operated on with TVT-Ophira for the treatment of stress urinary incontinence-postoperative complications were received by 5 women (20.8%).

4 of them had *pain syndrome* and 1 woman developed *de novo urgency*. Recurrence of stress urinary incontinence occurred in 11 (2.5%) of all 436 patients, 8 of whom were operated by TVT-O method, and 3 by TVT-R, in patients operated by TVT-Ophira - no patient with relapse.

# **Discussion**

Despite the relatively simple way of performing sling operations, as well as the existence of a number of studies proving the safety of the placement of synthetic tapes, there is a high probability of complications, often quite complicated. The use of suburethral synthetic slings can lead to complications - intraoperative and postoperative.

The source of bleeding can be an incision in the anterior wall of the vagina, periurethral veins, veins in the retropubic space, and much less often obturator vessels and veins in the walls of the pelvis. In practice, bleeding is considered significant, the volume of which exceeds 100 ml.

The most common bleeding is in the formation of paraurethral tunnels. Such bleeding is usually intravenous, so the operation should be completed as soon as possible. Attempts to find the bleeding vessel are almost doomed to failure, which will only increase the volume of blood loss. Subsequently, in order to achieve hemostasis, it is possible to use hemostatic preparations and a tight vaginal tamponade.

For hematomas with a volume greater than 100-150 ml, ultrasound-guided drainage may be used. The main reason for the perforation of the bladder is the violation of the surgical technique. In case of perforation, the needle should be removed together with the tape and an attempt should be made to push it in the right direction. Subsequently, such a patient will need prolonged drainage of the bladder with a urethral catheter.

Urethral injury - is a rare complication in sling operations, regardless of access choice, TVT-O or TVT-R. The cause of trauma to the urethra is too deep an incision in the anterior vaginal wall, as well as the wrong direction of dissection in the formation of paraurethral canals. Observed damage to the urethra should be removed immediately. In case of injury to the urethra, it is necessary to restore its integrity and place a urethral catheter for at least 30 days.

Perforation of the Vaginal Arch is one of the common intraoperative complications during TVT-O implantation. The reason for this complication may be lack of experience in performing this operation, as well as individual features of the structure of the vagina. In case of perforation, the vaginal defect should be sutured with several single sutures, after which the operation can continue.

One of the most common complications of TVT-O sling placement is inguinal pain. The cause can be trauma to the thigh muscle, the formation of a hematoma in the depth of the muscle, as well as damage to a branch of the obturator nerve. An infectious-inflammatory process at the site of the tape should not be ruled out as a cause of pain in the groin and thigh. Groin pain of this origin can last for several weeks. Symptomatic and antibiotic treatment is recommended for these patients, which in most cases leads to a positive result.

# Pain Syndrome

The cause of pain during intercourse may be erosion of the tape or the placement of the tape in the surface layer of the vaginal mucosa.

Another possible cause of pain syndrome may be trauma to various nerves that affect the needle, in particular the dorsal nerve of the clitoris. However, it should be noted that in many cases the genesis of pain remains unclear.

If the woman's complaints persist for a long time, it is advisable to perform a magnetic resonance imaging (MRI) of the pelvis to determine the location of the tape. It is necessary to exclude all possible causes of pelvic pain (myositis, abscess). If none of the causes is confirmed, trauma to a branch of the obturator nerve should be suspected. Unfortunately, there are no recommendations for the treatment of such patients. We can recommend continuation of symptomatic treatment with analgesics and physiotherapy.

#### **Intravesical Obstruction (IVO)**

In my opinion, in the presence only of IVO, without pain or overactive bladder, we can limit ourselves to cutting the sling. If the patient complains of pain or in the postoperative period there is a clinic of overactive bladder and intravesical obstruction, then the sling should be removed as much as possible.

# Erosion

A common cause of erosion is the incorrect passage of the band to the vaginal mucosa and urethra. The main tactic of treatment is to try to sew up the defect. This requires tissue mobilization over the eroded area. If this is not possible, part of the strip located in the area of erosion is cut, followed by suturing of the resulting defect.

#### Urgency of Urine de Novo

Many reasons for the development of urgent (emergency) incontinence after performing a sling operation have been described. The most common are as a result of urinary tract infection, iatrogenic intravesical obstruction, bladder perforation or idiopathic urgency.

Given the relationship between the occurrences of urge incontinence after antistress surgery, the presence of intravesical obstruction should be considered as a major factor until proven otherwise [15].

In the case of exclusion of urinary tract infection, iatrogenic intravesical obstruction and disruption of urinary tract integrity, the tactics of treatment of patients with urgent urination after sling surgery do not differ from that in the presence of idiopathic urgency [16]. Behavioral therapy combined with oral anticholinergics is the least invasive and is usually first-line treatment in patients with urgency after TVT surgery.

In case of ineffectiveness of conservative treatment and drug therapy in women, intradermal administration of 100 units of botulinum toxin may be suggested. Excessive tension in the sling can lead to the development of intravesical obstruction, which in turn leads to the appearance of symptoms of urgency. In any case, severe intravesical obstruction, accompanied by urgent urinary incontinence and hyperactive bladder, usually requires in-depth analysis.

The use of anticholinergic drugs is ineffective and sometimes worsens the patient's symptoms, making urination even more difficult. The same applies to the use of botulinum toxin, which is very likely to lead to urinary retention. Elimination of intravesical obstruction is the only correct solution in this situation. Urinary tract infection is the most common complication after a suburethral synthetic sling, leading to urgency in women.

Thus, any patient with urgent incontinence after TVT surgery should first be examined for urinary tract infection, along with the determination of residual urine. If there is a significant amount of residual urine, it is not always easy to deal with the infection. As a rule, long-term antibiotic treatment is used.

In the absence of effect, dissection of the band and elimination of residual urine should be considered.

A urinary tract infection is sometimes a sign of a sling protrusion in the urinary tract. There are several methods for treating patients with recurrent urinary incontinence - injection of volume-forming preparations, Birch surgery, artificial bladder sphincter and most often repeated sling surgery.

This category of patients is probably one of the most difficult among all urogynecological patients. It is appropriate to talk about certain recommendations, guided by how to choose one or another method of treatment, while applying an individual approach to each patient. I think there are two main reasons for recurrence - the wrong location of the tape and the insufficient degree of tension.

In her study, Flock determined the location of the sling using ultrasound in patients after TVT surgery. The location of the band with respect to the total length of the urethra is assessed, as well as the distance to the hypoechoic center - the lumen of the urethra.

In patients treated for urinary incontinence, the ratio of the location of the band to the total length of the urethra is 1/3 while the distance to the hypoechoic center of the urethra is  $4.6 \pm 1.5$  mm. In 32% of patients with recurrent urinary incontinence, the band was located in the proximal or distal third of the urethra [17]. Similar results using MRI were obtained by Rinne, who assessed the location of the urethra in patients after TVT-R and TVT-O surgery [18].

# The Choice of Treatment for Recurrence of Urinary Incontinence

The choice of a specific method of treatment is made individually. However, general recommendations can be made to help with this choice. The pubourethral ligaments play a key role in the process of urinary retention. The pubourethral ligament is a double ligament that begins at the back of the symphysis and, like a fan, ends medially in the middle urethra and laterally in the pubococcygeal muscle and vaginal wall. With the contraction of the upper muscles, a kneeshaped bend of the urethra appears in the area of attachment of the pubourethral

ligament. All modern synthetic tapes are prostheses designed to replace these connections.

However, as is clear from the description, the anatomy of the pubourethral ligament is more compatible with TVT-R than with the transobturator ligament. In this way, the TVT-R seems to cover the urethra, while the transobturator band provides support only on its underside. In other words, the 'hammock' effect in TVT-R is higher than in transobturator sling [19].

But what to do in a situation where TVT-R has been used for the first time? In this case, it is important to determine how the tape is located. Unfortunately, this can often only be done during surgery. If the previous sling is placed correctly, the same access can be used, but the degree of the tension of the sling must be adjusted higher than the previous degree of tension.

If the first sling is not inserted correctly, another access must be used. This is because the reinstalled sling can migrate and regain the wrong position of the first one. The second important aspect of surgical treatment of patients with recurrence of urinary incontinence after surgery is the need to dissect the previously placed sling.

I believe that if the tape is located with insufficient compression, especially in the area of the middle urethra, then it is necessary to remove it. However, if the previous suburethral band is not detected during the secondary operation and does not cause obstruction, then its removal is impractical, as this can lead to injury to the urethra.

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#### Significance

The high percentage of SUI requires the application of an equally high percentage of slings. Along with the success of this TVT sling surgery, intra- and postoperative complications have developed in some cases. From the indicated intra- and postoperative complications, it can be concluded that the least and mildest complications occur with the Ophira mini sling.

These slings have the advantage that they can be administered under local anesthesia, which makes the cough test as accurate as possible. The advantages of the Ophira minisling over the traditional ones are mainly related to the avoidance of the retropubic and transobturator space. The chronic and sometimes incurable complications of TVT-O and TVT-R suggest other methods of treating stress urinary incontinence.

# Conclusion

Urinary incontinence in women is a complex condition. sometimes with several pathogenetic mechanisms. The doctors involved in the treatment of this problem must have the appropriate professional competence. When treating women with urinary incontinence, we must make sure that there is a correspondence between the symptoms and the objective data proving the incontinence.  $\operatorname{It}$ isnecessary for urogynecologist to be sure which pathology he will deal with and to know the methods ofelimination the intrapostoperative complications indicated in the publication

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