



Stress urinary incontinence after transvaginal mesh surgery for anterior and apical prolapse: preoperative risk factors

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Abstract

Introduction and hypothesis Debate persists over whether surgery to correct pelvic organ prolapse (POP) should be combined with midurethral sling (MUS) insertion. The aim of this study was to evaluate the incidence of stress urinary incontinence (SUI) up to 12 months after transvaginal mesh surgery, with or without MUS, and to identify risk factors for postoperative SUI.

Methods This retrospective single-center study included patients who underwent transvaginal mesh surgery with Uphold™ between October 2010 and December 2017. The primary outcome was the prevalence of SUI at 12 months postoperatively. Univariate and multivariate logistic regression was used to identify risks factors for postoperative SUI.

Results Of the 308 women included, 123 (40%) were continent (no SUI), 108 (35%) had SUI, and 76 (25%) had occult SUI. Forty-nine patients (15.9%) had a concomitant MUS procedure. At 12 months after surgery, 35.9% of patients without concomitant MUS had SUI vs 14.3% with ($p = 0.003$). Thirty-five patients (29%) developed de novo SUI. Postoperative complications were more common in patients with concomitant MUS (30.6% vs 17%; $p = 0.003$). The best predictor of postoperative SUI was the presence of preoperative SUI (OR 2.52 (1.25–5.09)). Concomitant MUS ($p < 0.001$), and prior POP surgery ($p = 0.034$) were protective factors for postoperative SUI.

Conclusion Preoperative SUI is the most important risk factor for postoperative SUI. However, given the higher risk of postoperative complications with concomitant MUS and the acceptable rate of de novo SUI rate without it, two-stage surgery seems preferable for patients with preoperative SUI.

Keywords Pelvic organ prolapse · Stress urinary incontinence · Vaginal surgery · Polypropylene mesh · Anterior sacrospinous ligament fixation

Introduction

Lower urinary tract symptoms are frequently associated with pelvic organ prolapse (POP). In one study for example, approximately 55% of women with stage II POP and 33% with stage IV POP had concurrent stress urinary incontinence (SUI) [1]. The lower rate found with more advanced POP is

probably due to kinking of the urethra in stage III and IV POP. In some cases, SUI is only present on prolapse reduction (occult SUI) or develops after surgical treatment of POP in a previously asymptomatic woman (de novo SUI) [1].

During their lifetime, 11% of women will undergo at least one operation for POP, urinary incontinence, or both [2]. Although the use of transvaginal mesh (TVM) improved the anatomical results of prolapse surgery and reduced reintervention rates for POP recurrence, some studies suggest that it might increase the likelihood of subsequent surgery for SUI [3]. A 2018 Cochrane review found, based on seven studies in 907 patients, that anterior armed mesh repair may slightly increase the risk of postoperative de novo SUI (risk ratio [RR] 1.58; 95% confidence interval [95% CI] 1.05–2.37) [4]. In another study, women with TVM were more likely to develop de novo SUI than those who had anterior native tissue repair (13% vs 8%) [5].

However, the Uphold is a third-generation TVM system potentially requiring less paravesical dissection, which may

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reduce postoperative SUI rates [6]. Some studies have described low urinary tract symptoms after an Uphold procedure. Altman et al. reported that 6% of patients had de novo SUI after an Uphold procedure [7]. Allègre et al. reported that 50% of women with pre-existing SUI who did not undergo MUS insertion, no longer had SUI at 12 months [8].

Routine prophylactic anti-incontinence surgery can lead to over-correction and the development of voiding dysfunction, with higher rates of postoperative catheterization [9, 10]. De novo overactive bladder (OAB) occurs in 12% of women after POP surgery, with or without concomitant MUS [10]. Mild complications were more common with concomitant MUS than with POP surgery alone (47% vs 17%) in the CUPIDO II trial [5].

Whether or not to treat incontinence with concomitant MUS in POP surgery, to perform preoperative tests for occult SUI, and or to combine MUS with POP repair is still subject to lively debate [6].

The aim of this study was to evaluate the incidence of SUI up to 12 months after bilateral anterior sacrospinous fixation using the Uphold system, and to identify the risk factors for postoperative SUI.

Materials and methods

This study was a retrospective audit of all consecutive patients who underwent bilateral anterior sacrospinous fixation with TVM (Uphold; Boston Scientific, Natick, MA, USA) for \geq stage II anterior/apical POP between October 2010 and December 2017 in a single French tertiary referral center. Ethical approval was obtained from the local ethics committee and the Institutional Review Board (approval 14/12.01), and all the women gave informed consent.

Patients who had previously had anti-incontinence procedures (MUS, retropubic colposuspension, or Burch procedure) were excluded. The preoperative workup comprised a standardized physical examination, including POP quantification (POP-Q) [11, 12], an interview including assessment of subjective SUI, and a multichannel urodynamic study. The International Urogynecological Association and International Continence Society (IUGA/ICS) define occult SUI as observed involuntary stress leakage from the urethra on prolapse reduction in women without symptoms of SUI [11]. Occult SUI was detected during physical examination on prolapse reduction with a cough stress test or by urodynamic testing with a half-full bladder (250–300 ml).

Hospital records were obtained to collect demographic information, medical history, and symptoms of lower urinary tract and pelvic floor dysfunction. All patients had \geq stage II prolapse (point Ba and/or C ≥ -1) preoperatively.

All surgical procedures were performed by experienced urogynecological surgeons or under their direct supervision.

The procedure has been described in detail elsewhere [13]. Briefly, the procedure was performed under regional or general anesthesia, depending on the patient's preference and medical considerations. After local infiltration of diluted lidocaine with epinephrine 1%, a longitudinal incision was made in the anterior vaginal wall, and the paravesical space was opened by a combination of blunt and sharp dissection. Both mesh arms were inserted using the Capio™ or Capio™ Slim suture capture device (Boston Scientific) 2 cm medial to the ischial spine on the sacrospinous ligament. This allows the mesh arms to pass through the sacrospinous ligament without direct fixation. The mesh was then positioned in a tension-free fashion as per the manufacturer's instructions. The mesh was attached at the level of the cervix or the interior surface of the vaginal vault/the uterosacral ligaments in the event of prior hysterectomy or concomitant hysterectomy respectively, with two polypropylene sutures (Prolene™ 2/0, Ethicon, Issy-les-Moulineaux, France), and to the vesicovaginal fascia at the level of the bladder neck with a poliglecaprone suture (Monocryl Plus™ 3/0; Ethicon). Concomitant procedures (e.g., MUS, posterior prolapse repair, or hysterectomy) were performed at the surgeon's discretion as medically indicated. The patients received an intravaginal pack with a paraffin and povidone–iodine-soaked gauze and a urinary catheter for 24 h.

On postoperative day 1, after removal of the catheter, patients were encouraged to urinate freely, and bladder scans were performed to measure the postvoid residual. Sterile intermittent catheterization was performed when the postvoid residual urine volume exceeded 150 ml. Patients with persistent retention were taught intermittent self-catheterization.

Outpatient follow-up visits were scheduled at 6 weeks to 3 months and 6 months to 1 year. The 12-month postoperative assessment comprised a standardized physical examination and interview. The primary outcome of this study was patient-reported postoperative SUI at 12 months, irrespective of the degree of bother it caused. The secondary outcomes were the presence of other lower urinary tract symptoms, such as urinary retention, urinary urgency, and/or urge incontinence, and whether subsequent surgery for SUI was performed (MUS or urethral bulking agent).

Data are reported as the median and standard deviation (SD), or number and frequency, as appropriate. Continuous variables were compared using Student's *t* test, or the Mann–Whitney test when normal distribution was not verified. The Chi-squared test was used to compare categorical data, and the McNemar test for intragroup comparisons. We used univariate analysis to identify risk factors for postoperative SUI, evaluating: age, body mass index (BMI), menopausal status, parity, prior POP surgery, prior hysterectomy, POP stage, preoperative SUI status (SUI, occult SUI, or no SUI), urodynamic data, concomitant MUS, concomitant hysterectomy, and anatomical recurrence (Ba and/or C ≥ -1 cm). Multivariate logistic regression was performed using the variables associated

with postoperative SUI in univariate analysis ($p < 0.20$), known risk factors based on previous studies. The results of this analysis are expressed as odds ratios (ORs) with their 95% CI. A p value of <0.05 was considered statistically significant. Statistical analysis was performed using R 2.9.2 (R Development Core Team [2009] R Foundation for Statistical Computing, Vienna, Austria).

Results

Baseline characteristics

A total of 406 patients underwent the operation of interest between October 2010 and December 2017. After excluding 46 patients for prior SUI surgery and 52 patients owing to lack of data, 308 patients were included in the study.

The baseline characteristics of the patients are summarized in Table 1. The median age was 69 ± 7.4 years. The median POP-Q values before surgery show that most patients had stage II anterior or apical prolapse. Our cohort included 32 patients who had previously undergone hysterectomy and 31 patients who had already had POP surgery. We performed 42 concomitant hysterectomies (13.6%), 49 concomitant MUS procedures (15.9%), and 210 concomitant posterior repairs (68%).

Urinary outcomes

Figure 1 shows the SUI outcomes 12 months after surgery, depending on the presence of preoperative self-reported SUI (35%; $n = 108$), occult SUI through testing (25%; $n = 76$), or no SUI (40%; $n = 123$), and whether concomitant MUS was performed.

Among the patients with preoperative SUI, 51% ($n = 38$) of those who underwent POP surgery without MUS placement no longer had SUI 12 months post-surgery, whereas 18% ($n = 6$) of those who had concomitant MUS still had SUI at 12 months. In the occult SUI group, 93% ($n = 13$) of patients who had concomitant MUS were free of SUI at 12 months, but 37.5% ($n = 24$) of those who did not receive a MUS had postoperative SUI. Finally, 29% ($n = 35$) of patients who were continent before surgery and did not receive an MUS developed de novo SUI, whereas 69% ($n = 84$) were still continent 12 months after prolapse surgery.

Table 2 shows the effect of concomitant MUS on urinary outcomes at 12 months (median follow-up 12 ± 9 months). Postoperative SUI was significantly more common in patients without concomitant MUS than with (35.9% vs 14.3%; $p = 0.003$). The reported complications were urinary infection, hematoma, voiding dysfunction, and urinary retention requiring postoperative catheterization. The postoperative complication rate was higher in patients with concomitant MUS

Table 1 Baseline characteristics of the study population ($n = 308$)

	Median \pm SD, or % (n)
Age	69 ± 7.4
BMI	25 ± 4
Parity	2 ± 1.45
Smoker	6 (20)
Postmenopausal	93 (286)
Hormone replacement therapy	7.8 (24)
POP-Q points (centimeters)	
Ba point	1 ± 1.9
C point	0 ± 3
Bp point	-1.75 ± 1.5
Prior surgeries	
Hysterectomy	10 (32)
Prolapse surgery	10 (31)
Preoperative symptoms	
Overactive bladder	61 (188)
Difficulty to void	49.7 (153)
Constipation	36.7 (113)
Obstructed defecation	32.1 (99)
Anal incontinence	17.5 (54)
Sexually active	34 (106)
Dyspareunia	1.9 (6)
Concomitant procedures	
Hysterectomy	13.6 (42)
Midurethral sling	15.9 (49)
Posterior repair	68 (210)
Surgical parameters	
Operative time (min)	98 ± 34

BMI body mass index, POP-Q pelvic organ prolapse questionnaire, SD standard deviation

(30.6% [15/49] vs 17% [44/259]; $p = 0.03$). However, the two groups had similar reoperation rates for mesh exposure (4.1% [2/49] with concomitant MUS vs 0.8% [2/259] without MUS; $p = 0.24$). Patients with concomitant MUS were more likely to have difficulties voiding after surgery (16.3% [8/49] vs 7.3% [19/259] in the group without MUS; $p = 0.05$). Among the secondary outcomes: lower urinary tract symptoms before and after surgery in women with and without concomitant MUS are presented in Table 3. Overactive bladder and difficulty voiding seem to be improved by TVM surgery independently of the incontinence surgery.

Identification of risk factors for postoperative SUI

The results of univariate and a multivariate logistic regression analysis for potential risk factors for the presence of postoperative SUI are provided in Table 4.

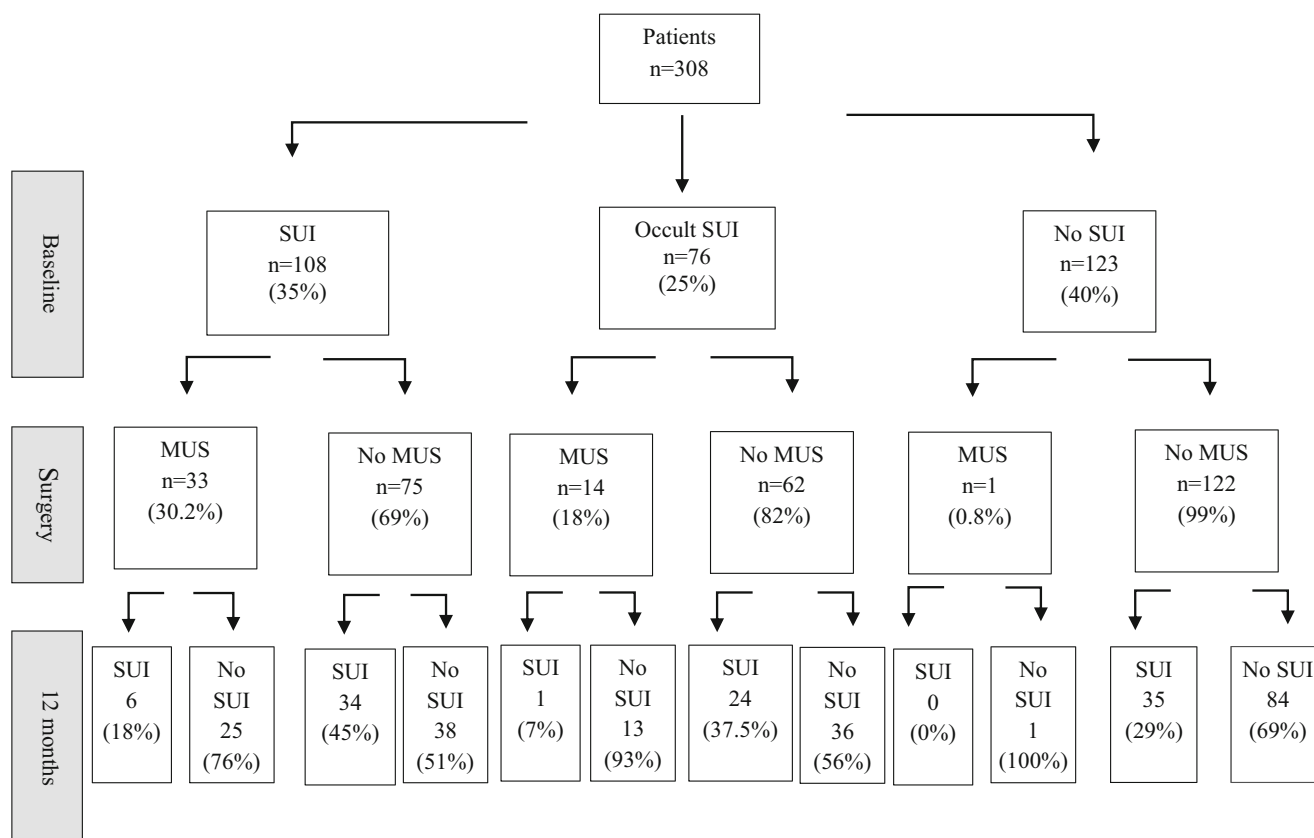


Fig. 1 Flow chart showing the preoperative stress urinary incontinence (SUI) status of the 308 patients included, the type of surgery they received (with or without a midurethral sling [MUS]), and their postoperative SUI status

Concomitant MUS ($p < 0.001$), and prior prolapse surgery ($p = 0.05$) were protective factors for postoperative SUI. BMI was not an independent risk factor in this study, but was close to the significant threshold ($p = 0.052$).

The best predictor of postoperative SUI was the presence of preoperative SUI, which was an independent risk factor (OR 2.68 [1.35–5.31]). Conversely, occult SUI was not an independent risk factor for postoperative SUI (1.07 [0.52–2.21]).

Table 2 Urinary and other outcomes at 12 months

	Concomitant MUS ($N = 49$), % (n)	No MUS ($N = 259$), % (n)	p value
Postoperative SUI	14.3 (7)	35.9 (93)	0.003
Postoperative complication	30.6 (15)	17 (44)	0.03
Reoperation for exposure	4.1 (2)	0.8 (2)	0.24
Difficulty to void	16.3 (8)	7.3 (19)	0.05
Overactive bladder	32.7 (16)	18.5 (48)	0.02

SUI stress urinary incontinence, MS midurethral sling

Discussion

This retrospective study in a large cohort of 308 patients shows that anterior sacrospinous fixation with the Uphold system, like other surgery for anterior and apical prolapse, can induce postoperative SUI at 12 months. The incidence of de novo SUI was 29%, which is consistent with rates of about 9.9 to 43% found in other studies [9, 14–16]. Correction of prolapse might induce de novo SUI by reducing urethral kinking and remove the mechanical stress continence mechanism. The risk is higher with mesh surgery. In Maher's Cochrane review, permanent mesh was associated with higher rates of de novo SUI than native tissue prolapse repair (RR 1.39, 95% CI 1.06–1.82) [3].

However, Lo et al. suggest that, by reducing paravesical dissection, the Uphold mesh may reduce the risk of de novo SUI [6]. In our study, symptoms improved in 51% of women with preoperative SUI who did not undergo a concomitant MUS procedure. Similarly, symptoms improved in 56% of women with occult SUI without concomitant MUS. These rates seem higher than in previous studies. Lensen et al.'s and Borstad et al.'s trials, for example, found that prolapse surgery alone had corrected pre-existing SUI in 39% and

Table 3 Secondary outcomes: lower urinary tract symptoms at preoperative and postoperative follow-up, with and without concomitant MUS, % (n)

	No MUS (n = 259)			Concomitant MUS (n = 49)		
	Preoperative	Postoperative	p*	Preoperative	Postoperative	p*
Overactive bladder	59 (153)	18 (48)	<0.01	71 (35)	32 (16)	<0.01
Stress incontinence	29 (75)	35 (93)	0.04	67 (33)	14 (7)	<0.01
Difficulty to void	46 (121)	7 (19)	<0.01	65 (32)	16 (8)	<0.01

MUS midurethral sling

*McNemar test

27% of patients 1 year after surgery [13, 14]. This difference may be due to the use in our study of ultra-light mesh. In Lensen's trial for example, surgeons used several methods for prolapse surgery, including uterosacral ligament suspension, sacrospinous fixation, Manchester, or apical (Prolift™) mesh. [14]. In the present study, 69% of patients who had pre-existing SUI did not undergo concomitant MUS; some of these patients had mixed incontinence and were urgency-predominant. Moreover, in our center we currently promote surgery in two stages. Thus, women with pre-existing SUI undergo a concomitant MUS only if the symptoms are significant, with no risk of postoperative voiding dysfunction.

We found a 10.7% risk of requiring a second intervention for postoperative SUI, regardless of preoperative status. During the follow-up period, only 33 (33%) patients among

the 100 patients (33%) with postoperative SUI underwent a second intervention. Other studies have reported between 5 and 20% of patients undergoing a second intervention for additional MUS at 6, 12, or 24 months after POP surgery [5, 9, 16–18]. In the CUPIDO II trial, women with occult SUI had a 13% risk for needing additional MUS after prolapse surgery [5]. In the randomized controlled OPUS trial, 7.3% and 11% of patients with concomitant MUS and without concomitant MUS respectively required treatment for SUI after 1 year of follow-up [9]. Although some patients had persistent postoperative SUI, these symptoms do not appear to be bothersome, given the low secondary intervention rate. In the trial by Oride et al., only 2 among 31 patients underwent a second intervention for postoperative SUI [19].

Table 4 Logistic regression of risk factors for postoperative stress incontinence

Variable	Univariate analysis		Multivariate analysis	
	OR (95% CI)	p value	OR (95% CI)	p value
Age	1.03 (0.99–1.07)	0.159	1.01 (0.98–1.06)	0.473
BMI	0.93 (0.87–1)	0.063	0.93 (0.87–1.01)	0.074
Menopausal status	0.48 (0.07–3.44)	0.462		
Parity	0.78 (0.62–0.98)	0.035	0.84 (0.67–1.06)	0.12
Prior prolapse surgery	0.12 (0.55–1.40)	0.045	0.35 (0.11–1.11)	0.05*
Prior hysterectomy	0.92 (0.31–2.78)	0.888		
Preop POP-Q stage	0.88 (0.55–1.4)	0.58		
Concomitant MUS	0.38 (0.15–0.98)	0.044	0.17 (0.06–0.46)	< 0.001*
Concomitant hysterectomy	1.22 (0.54–2.74)	0.628		
Anatomical recurrence	0.35 (0.08–1.64)	0.183	0.31 (0.06–1.47)	0.099
Urodynamic data				
Qmax	0.9992 (0.99–1.00)	0.616		
Maximum urethral closure pressure)	0.9961 (0.98–1.01)	0.878		
Preoperative SUI status				
No SUI	Reference	Reference	Reference	Reference
SUI	1.33 (0.6–2.62)	0.418	2.68 (1.35–5.31)	0.005*
Occult SUI	1.35 (0.62–2.91)	0.45	1.07 (0.52–2.21)	0.859

BMI body mass index, POP-Q pelvic organ prolapse questionnaire, MUS midurethral sling, Qmax maximum quantity, SUI stress urinary incontinence, CI confidence interval

*Statistically significant ($p < 0.05$)

Concomitant MUS appears to reduce the incidence of postoperative SUI. Wei et al. found a 12-month SUI rate of 27.3% with MUS vs 43% without [9]. In our study, concomitant MUS was associated with more postoperative complications and difficulties voiding. Indeed, like a number of previous studies, we report a higher risk of difficulties voiding with concomitant MUS (16.3% vs 7.3% without MUS) [6]. It is nevertheless important to weigh up the pros and cons of concomitant MUS. This debate is even more acute nowadays because MUS as transvaginal mesh is being questioned. Indeed, a secondary intervention with colposuspension is not the same issue as with MUS, especially in terms of morbidity and risk for de novo recurrent prolapse [20, 21]. Even if the colposuspension became less invasive with the use of laparoscopy, the MUS procedure is less invasive, more standardized and has a shorter learning curve [20]. It would probably be useful to identify preoperative characteristics that predict a woman's risk for postoperative SUI.

We identified concomitant MUS, and prior POP surgery as protective factors for postoperative SUI. The presence of pre-existing SUI is the best independent risk factor for postoperative SUI, with an OR of 2.68 (1.35–5.31). Unlike Lensen et al., we did not find BMI to be an independent risk factor, although it was close to the significance threshold ($p = 0.074$) [14]. Even though we did not find concomitant hysterectomy to be an independent risk factor for postoperative SUI, the role of hysterectomy in the incidence of postoperative SUI remains controversial, with some studies [22–24] concluding that hysterectomy is an independent risk factor, whereas others did not [25].

The strengths of this study are the large number of patients, and the single standardized surgical technique, performed by experienced surgeons. In addition, we identified risk factors for postoperative SUI following prolapse surgery with TVM using multivariate analysis, and all patients underwent a urodynamic study to determine their preoperative incontinence status. Its possible limitations are the retrospective analysis of our data, and the fact that we studied a selected population in a single tertiary referral center. Moreover, as patients were included over a 7-year period, the results could be biased by changes in the management of SUI, possible modifications to the surgical procedure, and the effect of the learning curve.

Another potential limitation of our study is that our focus on mesh surgery alone may limit the generalizability of our findings to the general population.

Conclusion

The Uphold™ system is a TVM for anterior and apical prolapse that can cure SUI without a concomitant anti-incontinence procedure, with a low rate of subsequent interventions for postoperative SUI. Preoperative SUI was the only

independent risk factor identified for postoperative SUI, whereas preoperative occult SUI was not. Concomitant MUS placement seems to be associated with higher rate of postoperative complication. It seems preferable to opt for surgery in two stage for patients with preoperative SUI associated with POP.

Contributions M. Bideau, G. Callewaert, and L. Allègre contributed equally to this work and should be considered as joint first authors. They were involved in data analysis and manuscript writing. B. Fatton was involved in project/protocol development and data collection. De Tayrac was the principal investigator during the clinical trial and was involved in project/protocol development, data collection, and manuscript writing. All authors reviewed and/or edited the manuscript prior to submission.

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Compliance with ethical standards

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