

## CLINICAL REPORT

# Genital Psoriasis Awareness Program: Physical and Psychological Care for Patients with Genital Psoriasis

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**Genital psoriasis is a neglected manifestation of psoriasis, although it affects numerous patients and has major effects on (sexual) quality of life ((S)QoL). We aimed to assess the value of specialised care for patients with genital psoriasis. Patients were treated for at least one year at a specialised research outpatient clinic with extensive attention for genital lesions and (S)QoL. The genital lesions were treated according to a stepwise algorithm. First follow-up was planned after 6 weeks; subsequent follow-up visits were scheduled every 3 months. At every visit, psoriasis severity and (S)QoL were measured with validated tools. Differences in scores between visits were analysed by a mixed model for repeated measures. Forty-two patients were included (M:F = 25:17). All objective and subjective genital psoriasis severity and QoL parameters improved significantly within the first follow-up period of approximately 6 weeks. In female patients, (S)QoL also significantly improved. In conclusion, genital psoriasis can relatively easy be treated within limited time exposure, resulting in significant improvement of QoL. Prompt and simple adjustments in the provided care are enough to accomplish this. Key words: psoriasis; quality of life; sexual dysfunction; genital diseases; awareness; questionnaires.**

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Psoriasis in the genital area is a rather neglected manifestation of psoriasis. However, the number of patients affected with genital psoriasis is considerable. Several studies show that involvement of the genital skin occurs in 29–46% of psoriasis patients at some point during the course of the disease (1–6).

Most patients with genital psoriasis experience localised mild to moderate sensory skin symptoms such as itch, pain and/or burning (7–10). Diagnosis of genital psoriasis can usually be made on the basis of its typical clinical appearance that includes symmetrical, well-

demarcated, brightly erythematous thin plaques that usually lack the typical dry scaling (11). Sometimes, evident scaling is seen on the more keratinising regions of the genital skin and lesions may be accompanied by painful rhagades or fissures (12–15).

Patients with genital psoriasis have significantly worse quality of life (QoL) scores compared with patients without genital lesions (16–18). In addition, numerous patients with psoriasis have sexual dysfunction (16, 19, 20). Out of all patients with psoriasis, 25–40% report a decline of sexual activity since the onset of psoriasis, mainly due to diminished sexual desire, embarrassment of physical appearance and inconvenience caused by scaliness of the skin or topical therapy (16, 21). Particularly in women, there is evidently more sexual distress and probably also sexual dysfunction when genital skin is affected (16, 22).

Treatment of genital lesions is challenging, as the genital skin is thin and sensitive. Based on a systematic literature review about this topic, there is room for mild to moderate potent corticosteroids, possibly combined with vitamin D analogues or tar-based treatment (11). A third-line treatment option is the use of an immunomodulator, although evidence is still scarce. Systemic treatment is generally not used solely for genital psoriasis (11); however, when prescribed it can also improve genital lesions (23, 24).

Genital lesions and the accompanying deterioration of (sexual) QoL (S)QoL are seldom subject of discussion at the outpatient clinic (1, 25). An earlier study showed that < 10% of the patients believe that sufficient attention is given to sexual problems by their doctors, while many patients believe that it would have been beneficial to have received more care in this area (16, 26). A possible explanation for this incongruence is that patients might be uncomfortable about or unaware of the possibility of discussing sexual problems with their clinicians (27).

It is clear that there is room for improvement in physical and psychological care for patients with genital psoriasis. Therefore, a research outpatient clinic with extensive attention for (S)QoL and topical therapy for patients with genital psoriasis was introduced. Based on the data collected from this clinic, this study will provide an overview of the changes in disease severity

and (S)QoL parameters during follow-up. Additionally, results of the evaluation of the clinic by the patients after follow-up are presented.

## METHODS

### Study population

Patients with psoriasis and genital symptoms who participated in a previous questionnaire-based study on (S)QoL in patients with genital psoriasis (16) or who visited the regular dermatology outpatient clinic of the Radboud university medical center were invited during March 2010 and October 2011 to visit our research outpatient clinic.

Patients were included for follow-up when they had clinically (confirmed by a dermatologist) or histopathologically confirmed genital psoriasis, were aged over 18 years and consented to participation. According to the local Medical Research Ethics Committee, medical ethical review was not required for this study.

### Study design

We conducted a cohort study between March 2010 and September 2012. Patients were assessed for eligibility at baseline and, when included, followed for at least one year. The first follow-up visit (V1) was planned 6 weeks after baseline visit. Further follow-up visits were basically scheduled every 3 months during one year. However, the schedule was intensified when medically needed (i.e. when treatment was adjusted). Also, when patients did not comply with the exact scheme, data were taken into account. All patients were followed and all data were collected by one of the clinical investigators (KM).

At every visit, measurements determining psoriasis severity and (S)QoL were completed. In case of possible sexual dysfunction or impaired QoL, patients were offered referral to a sexologist or (dermato) psychologist.

After completing follow-up, patients were requested to evaluate the care offered at the outpatient clinic by filling in an anonymous evaluation form. This form contained questions about change of physical complaints during follow-up, attention for (S)QoL at the outpatient clinic and the overall benefit from visiting the outpatient clinic.

### Treatment algorithm

At baseline, topical therapy was selected according to a step-wise treatment algorithm, which we published in 2011 (11). An overview of the prescribed treatments is shown in Table I. Additionally, the daily use of an emollient was advised to all patients. When the patient was already effectively treating the genital psoriasis with treatment comparable to our algorithm, this was continued. When, according to the clinical investigator, at follow-up there was insufficient clinical improvement in spite of compliance we prescribed the next step in the algorithm.

We considered the use of systemic medication for non-genital psoriatic lesions relevant when started during the study period and duration was sufficient to have possible systemic effects on genital lesions.

### Outcome measures

Psoriasis severity and (S)QoL assessments were conducted at baseline and every follow-up visit (see Table S1<sup>1</sup> and Appendix S1<sup>1</sup>).

### Statistical analysis

All data were stored in an electronic database and statistical analysis was performed using IBM SPSS Statistics 20. Data for all included patients were analysed. Two-sided *p*-values < 0.05 were considered significant. Continuous variables were presented as median (range) or mean ± SD, depending on their distribution pattern. Categorical variables were summarised by counts and percentages. Missing values were processed as described for the different scoring systems. For other variables, missing data remained missing.

Differences between men and women at baseline were tested with Students' *t*-test or Mann-Whitney *U* test. The association between variables was evaluated with Spearman's or Pearson's (two-tailed) correlation coefficient, depending on the distribution of the data.

The course of psoriasis severity and (S)QoL during the study period was modelled with a restricted maximum likelihood-based linear mixed model for repeated measures, using an autoregressive correlation structure with lag 1 and custom hypothesis

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Table I. Treatment algorithm and overview of prescribed therapy for genital psoriasis

Step	Modality	Intensity	Frequency/ day	Patients <i>n</i>	Remarks
1	Mild potent corticosteroid cream	2 weeks daily, then intermittent: 4 days/week	Once	16	
2	Mild potent corticosteroid cream + Vitamin D analogue ointment	Intermittent: 4 days/week Daily	Once Twice	18	<i>n</i> =5 Started mild corticosteroid cream concurrently with vitamin D analogue ointment
3	Moderate potent corticosteroid cream	2 weeks daily, then 2 weeks intermittent: 4 days/week	Once	5	<i>n</i> =2 Started short-term higher potent corticosteroid cream before step 1 and 2 because of severe lesions
	Followed by: Mild potent corticosteroid cream + Vitamin D analogue ointment	Intermittent: 4 days/week Daily	Once Twice		<i>n</i> =1 Used mild corticosteroid cream before inclusion, Vitamin D ointment and higher potent steroid cream were added during the study.
4	Calcineurin inhibitor cream (whether or not combined with mild potent corticosteroid cream)	2 weeks daily, Then tempered to intermittent	Twice Once	0	
5	Coal tar cream	Intermittent: 4 days/week	Once		
	+ Mild potent corticosteroid cream	Daily	Twice	0	
Other		Intermittent: 4 days/week	Once	3	<i>n</i> =2 Daily tacrolimus ointment at baseline, addition of mild potent corticosteroid cream <i>n</i> =1 Alternating mild and higher potent corticosteroid cream

testing. This model corrects for missing data and variation in follow-up interval. Skewed variables were log transformed before analysis. In order to evaluate whether psoriasis severity and (S)QoL improved after the baseline visit, mean scores of variables during the total follow-up period were compared to scores at baseline. In order to evaluate whether there was additional improvement after V1, mean scores of variables at follow-up visits 2–6 were compared with V1. In a similar way, we evaluated whether there were additional benefits in the treatment period between follow-up visit 2 and follow-up visits 3–6.

## RESULTS

### *Baseline characteristics*

Fifty-one patients who visited the outpatient clinic were screened for inclusion. Nine patients appeared to have other diagnoses than genital psoriasis (eczema  $n=3$ , lichen sclerosus  $n=1$ , lichen simplex  $n=1$ , unspecified  $n=1$ ) or had no visible skin lesions and had no previous diagnosis of genital psoriasis ( $n=3$ ) and were therefore excluded. As a result, data of 42 patients were eligible for inclusion. Characteristics of these patients are depicted in Table SII<sup>1</sup>.

The median interval between baseline and V1 was 6 weeks (range 4–24 weeks) and the median interval between the follow-up visits was 13 weeks (range 4–43 weeks). Patients had a median number of 5 follow-up visits. Two patients were lost to follow-up before V1.

The cohort consisted of 25 (60%) men and 17 (40%) women. Mean age at inclusion was 50 years, ranged between 20 and 80 years and was similar for both genders. Patients had a mean  $\pm$  SD age of  $40.7 \pm 15.1$  years at diagnosis of genital psoriasis and the median duration of genital psoriasis was 7.7 years, range 0.7–52.2 years. In addition to genital psoriasis, 22 patients (55%) had also perianal psoriatic lesions; men and women were equally affected.

Thirty patients (71%) were using therapy for genital psoriasis at baseline; 6 were treated with mild potent corticosteroid cream, in accordance with our protocol. The remaining 24 patients used either too potent ( $n=10$ ) or too mild ( $n=2$ ) corticosteroids, solely vitamin D analogues ( $n=3$ ) or emollients ( $n=3$ ). Six patients received other therapies such as coal tar ointment with precipitated sulphur, mild potent corticosteroid cream combined with either silver sulphadiazine or fucidic acid cream and calcineurin inhibitor cream whether or not combined with fucidic acid cream.

During the study, all 42 patients received topical therapy for their genital psoriasis, see Table I. The vast majority of patients ( $n=34$ , 81%) showed adequate improvement with the use of a mild potent corticosteroid cream with or without the addition of Vitamin D analogue ointment. Two of those patients were also prescribed 5% or 10% salicylic acid because of substantial desquamation of keratinised skin. Higher potent corticosteroid cream was prescribed in 5 patients. Two

of them started with this high potent therapy followed by milder corticosteroid and Vitamin D analogue, because of the severity of genital lesions at baseline visit. Three patients used other topical therapies.

Eight patients used relevant systemic therapy for their non-genital psoriasis during the study: UVB ( $n=5$ ), methotrexate ( $n=2$ ) and fumaric acid ( $n=1$ ). In addition to treatment at the research outpatient clinic, one patient was referred to a sexologist and 6 patients consulted a dermatopsychologist.

### *Psoriasis severity and (sexual) quality of life*

Psoriasis severity and (sexual) QoL data at baseline are summarised in Table II. Severity of psoriasis in general was moderate (PASI 5.7, SD 4.1). There were no significant differences between men and women concerning baseline scores of psoriasis severity and (dermatological) QoL.

The investigator classified the severity of genital psoriasis as mild to moderate in the vast majority of patients ( $n=29$ , 69%) (Investigators Global Assessment (IGA): mean 2.5). Most patients ( $n=24$ , 57%) experienced the genital psoriasis as being (very) mild (Patient Global Assessment (PGA): mean 2.2). Two patients had no visible lesions at baseline. IGA and PGA showed to be moderately correlated  $r=0.50$ ,  $p=0.001$ ).

Median EQ-5D index and mean EQ-VAS were 0.84 (similar to age-matched norm score of general population) (28) and 72.7 (slightly lower than age-matched general population) (28), respectively. Mean DLQI score was 9.1, indicating a moderate adverse effect on the patient's life (29). EQ-5D index and DLQI showed a very weak negative association at baseline ( $r=-0.3$ ,  $p=0.060$ ). Patients had mean scores for SQoL of 22.8 (Female sexual distress scale [FSDS]) and 70.7 (SQoL questionnaire for use in men [SQoL-M]). There was hardly any association between the duration of genital psoriasis and SQoL (FSDS:  $r=0.06$ ,  $p=0.844$ . SQoL-M:  $r=0.39$ ,  $p=0.056$ ). Eight of the 13 women with baseline FSDS data (62%) were identified as having sexually-related personal distress. No cut-off values are available for the SQoL-M.

### *Follow-up data*

As shown in Table II, a significant improvement in all variables, except for EQ-VAS and SQoL-M was obtained between the baseline visit and V1. For all variables, except for BSA, VAS Itch, DLQI and FSDS no further significant changes were found after V1. Scores of BSA, VAS Itch (Fig. 1), DLQI and FSDS showed also significant changes after V1 with no further significant changes after V2. Women showed significant improvement on more parameters (BSA, PASI, IA, SUM, IGA, PGA, VAS Itch, VAS Pain, VAS Burning, DLQI and FSDS) compared to men (BSA, IA, SUM, IGA, VAS Itch, DLQI) (detailed data not shown).

Table II. Psoriasis severity and (sexual) QoL: baseline data and effect during follow-up

Variable	Baseline value <sup>a</sup>	V1 vs. Baseline		V2-6 vs. V1		V3-6 vs. V2	
		Mean (95% CI)	<i>p</i> -value	Mean (95% CI)	<i>p</i> -value	Mean (95% CI)	<i>p</i> -value
BSA <sup>b</sup>	3.9 (0.2–56.5)	<b>–58% (–75%, –29%)</b>	<b>0.001</b>	<b>–44% (–67%, –6%)</b>	<b>0.030</b>	–24% (–56%, 31%)	0.318
PASI	5.7 ± 4.1	<b>–1.5 (–2.6, –0.5)</b>	<b>0.004</b>	–0.4 (–1.4, 0.7)	0.502		
IA	38.0 ± 40.2	<b>–17.6 (–29.9, –5.4)</b>	<b>0.005</b>	2.3 (–10.3, 15.0)	0.717		
SUM	4.3 ± 2.0	<b>–1.6 (–2.3, –0.8)</b>	<b>&lt;0.001</b>	0.0 (–0.8, 0.7)	0.941		
IGA	2.5 ± 1.0	<b>–1.2 (–1.5, –0.8)</b>	<b>&lt;0.001</b>	–0.2 (–0.6, 0.1)	0.213		
PGA	2.2 ± 1.2	<b>–0.9 (–1.3, –0.5)</b>	<b>&lt;0.001</b>	0.0 (–0.4, 0.4)	0.934		
VAS Itch	56.1 ± 28.2	<b>–30.9 (–40.0, –21.7)</b>	<b>&lt;0.001</b>	<b>–11.1 (–20.2, –1.9)</b>	<b>0.018</b>	0.4 (–9.2, 10.0)	0.937
VAS Pain	35.8 ± 31.8	<b>–21.5 (–30.1, –12.8)</b>	<b>&lt;0.001</b>	–7.5 (–16.3, 1.3)	0.094		
VAS Burning	40.0 ± 30.7	<b>–19.2 (–28.9, –9.5)</b>	<b>&lt;0.001</b>	–6.0 (–16.0, 4.0)	0.238		
EQ-5D index <sup>b</sup>	0.84 (0.01–1.00)	<b>20% (2%, 40%)</b>	<b>0.024</b>	2% (–14%, 20%)	0.853		
EQ-VAS	72.7 ± 18.3	5.2 (–0.30, 10.7)	0.064	1.6 (–4.1, 7.3)	0.585		
DLQI	9.1 ± 8.1	<b>–5.0 (–6.9, –3.0)</b>	<b>&lt;0.001</b>	<b>–2.2 (–4.2, –0.2)</b>	<b>0.030</b>	–1.5 (–3.6, 0.5)	0.137
FSDS	22.8 ± 16.2	<b>–14.7 (–20.3, –9.0)</b>	<b>&lt;0.001</b>	<b>–8.1 (–13.5, –2.7)</b>	<b>0.004</b>	–5.4 (–10.8, 0.1)	0.054
SQoL-M	70.7 ± 31.6	5.5 (–4.3, 15.3)	0.270	4.1 (–5.9, 14.1)	0.420		

<sup>a</sup>Data are given as mean ± standard deviation or median (range). <sup>b</sup>Log transformed data; effects in percentages.

Two-tailed *p*-value <0.05, statistically significant improvement of variable is shown in bold.

V1: First follow-up visit; V2–6: Second–sixth follow-up visit; CI: confidence interval; BSA: body surface area; PASI: Psoriasis Area and Severity Index; IA: investigators assessment of affected genital skin in cm<sup>2</sup>; SUM: sum of severity score for erythema, desquamation and induration; IGA: Investigators Global Assessment; PGA: Patient Global Assessment; VAS: visual analogue scale; EQ-5D index: 5-Dimension European QoL – index-score; EQ-VAS: 5-Dimension European QoL – visual analogue scale; DLQI: Dermatological Life Quality Index; FSFS: Female Sexual Distress Scale; SQoL-M: Sexual QoL questionnaire for use in men.

Of all included patients, 27 (mean age 54.4 years; 18 men, 9 women) filled out the evaluation form regarding their visits to the research outpatient clinic. Sixteen patients (59%) experienced an improvement of their complaints, 8 (30%) remained stable and 3 (11%) reported deterioration of genital psoriasis. All 27 patients rated the attention for QoL as sufficient. Twenty-four patients gave their opinion about the attention for SQoL: 22/24 (92%) defined this as sufficient. Of the 24 patients who answered the question, 22 (92%) indicated that they benefitted from visiting the research outpatient clinic.

## DISCUSSION

This unique cohort study following patients with genital psoriasis who visited a research outpatient clinic focusing on care for genital psoriasis and possible ad-

ditional psycho-sexual effects provided new insights in the value of such specialised care. Objective and subjective genital psoriasis severity and QoL significantly improved within the first follow-up period of approximately 6 weeks. In female patients, SQoL also significantly improved. Furthermore, the majority of patients highly appreciated this specialised care.

The studied cohort, consisting of patients with a diagnosis of genital psoriasis, had moderate to severe psoriasis in general and mild to moderate genital lesions. Dermatological QoL was moderately affected, as shown by the mean DLQI score of 9.1 (29). Besides, SQoL was highly upset in female patients (over 60% of the patients were classified as having distress; mean FSFS was 22.8). In men, the SQoL-M data (mean 70.7) indicated slightly diminished SQoL when compared to the normal value of 87.1 (30). These findings are in accordance with prior studies, showing that involvement of genital skin in patients with psoriasis is one of the situations that lead to a significantly impaired (S) QoL despite relatively mild psoriasis severity scores (16, 31). Particularly in women with genital psoriasis, sexual distress is higher and sexual function is more significantly impaired compared to those without genital lesions (16, 22). These findings are confirmed in several other studies that show an impact of (genital) psoriasis on sexual function in 30–70% of patients with psoriasis (21, 32–35).

It is interesting that both the objective and subjective severity of genital psoriasis as well as DLQI-scores show significant and clinically relevant improvement between baseline and V1 after approximately 6 weeks when topical therapy for genital lesions is prescribed and attention is given to problems causing (sexual) dysfunc-

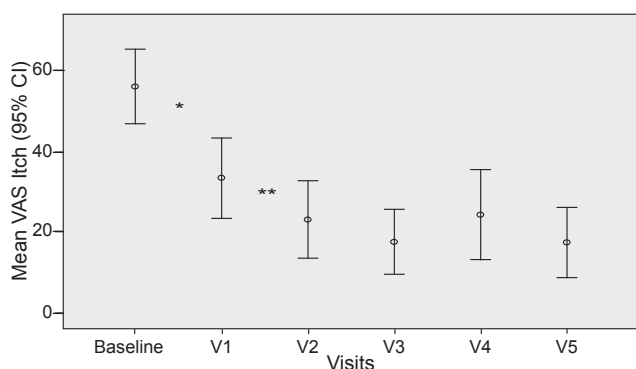


Fig. 1. Visual analogue scale (VAS) itch during follow-up. Illustration of mean VAS itch (95% CI) scores during follow-up. Significant improvement between baseline and first follow-up visit (V1)\* and between V1 and second–sixth follow-up visit (V2–6)\*\*; V6 is not shown because of extensive confidence interval (CI).

tion. Women showed improvement on more parameters than men. However, significant improvement on several disease severity and QoL parameters was seen in both genders. It should be remarked that study groups in this gender specific analysis were small and that analysis therefore may not have shown significant improvement for some variables in men. For most parameters a plateau was reached already after V1 (6 weeks interval). BSA, VAS itch, DLQI and FSDS improved even further, up to the second follow-up visit at 19 weeks, after which a plateau was reached. In women, SQoL improved, while in men it did not improve notably. An explanation for this may be that the SQoL in men was not severely enough affected, so there was less room for improvement.

The fact that clinical improvement has a substantial beneficial effect on sexual life and that time dedicated to explanation of disease as well as treatment support is associated with improved QoL in a very short time has been described before (33, 36). These findings suggest a need for attention for possible genital psoriasis during the first consultation in daily clinical practice. It is also worthwhile to invest time and promptly address sensitive issues like impact on QoL and sexual health as this can have major and rapid beneficial effects for psoriasis patients.

There might be a role for a dedicated nurse practitioner in the care for patients with (genital) psoriasis focusing on education, treatment support and psychosocial needs (36, 37). It is proven that visiting a dedicated, multidisciplinary clinic is associated with an improvement in QoL (38). Therefore, a multidisciplinary, well-trained health care team of a dermatologist collaborating with a gynaecologist, urologist, (dermato-) psychologist or sexologist would be of excellent value for the comprehensive management of genital psoriasis and its implications.

Eight patients used relevant systemic medication for their non-genital psoriasis, which may have biased the study outcomes we presented. However, analysis without those patients, showed roughly similar effects during follow-up. It can be stated that whether or not treated with systemic psoriatic medication, genital psoriasis severity, disease-specific QoL and female sexual health significantly improve within the first follow-up period with focusing on care for genital psoriasis and its possible additional psycho-sexual effects.

The average baseline EQ-5D index value was similar to that of the age-matched general population (28). Nevertheless, improvement of this value was seen during follow-up. However, there appeared to be one patient with a very influential outlying EQ-5D index value at baseline, which affected the outcome of the follow-up data. Remarkably, when excluding this patient from analysis, EQ-5D index showed no significant improvement during follow-up. Also, there was only a slight association between EQ-5D index and DLQI. Considering these findings, the EQ-5D index and DLQI obviously

capture different aspects of health-related QoL, which was also concluded by Norlin et al. (39). We agree with their hypothesis that the DLQI may be more sensitive to detect change in QoL of psoriasis patients, as the DLQI is dermatology specific whereas the EQ-5D measures health-related QoL for health-economic analyses. Additionally, sexual health is completely missing in the EQ-5D measurement, notwithstanding the fact that it is frequently affected in psoriasis patients. It is important to realise the purpose of using a health measurement tool, avoiding that such a tool is randomly selected.

Although this study reveals a number of interesting points regarding the care for patients with genital psoriasis, certain limitations have to be acknowledged. As patients were members of the Dutch Psoriasis Society or visited a tertiary care facility, it may be argued that the study population does not represent a random sample of psoriasis patients. It is also possible that response bias i.e. wanting to meet the expectations of the researcher influenced the answers given by patients to some extent. Besides, we acknowledge that life events and the natural course of psoriasis may have influenced the outcome. As blinding was not feasible, observer bias could have influenced the severity scores. Only a limited number of patients participated in this study. Nevertheless, the significant results found in the current small study group are supportive for the validity of our findings. The introduction of a control group would have provided more insight in the real value of intensified care compared to standard daily clinical practice. However, it is hardly possible to monitor daily clinical care for genital psoriasis without the knowledge of patients and physicians of being studied.

To conclude, this study showed that genital psoriasis, though devastating for QoL and (particularly in women) for sexual health, can be treated relatively easy within limited time exposure. Prompt and simple adjustments in the provided care are enough to accomplish this. Routine attention for possible genital psoriasis and accompanying impact on (S)QoL is imperative. Therefore, we highlight the need for well-trained and motivated clinicians.

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