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## Results of operative therapy of diabetic foot purulent complications using programmed sanitation technologies // Ergebnisse der chirurgischen Behandlung von eitrigen diabetischen Komplikationen am Fuß unter Verwendung von Hygiene-Technologien

Sergeev VA, Glukhov AA

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# Results of operative therapy of diabetic foot purulent complications using programmed sanitation technologies

V. A. Sergeev[1], A. A. Glukhov[2]

**Kurzfassung: Ergebnisse der chirurgischen Behandlung von eitrigen diabetischen Komplikationen am Fuß unter Verwendung von Hygiene-Technologien.** Ziel der Studie war es, die Ergebnisse der chirurgischen Behandlung von Patienten mit diabetischen nekrotisch-abszedierenden Komplikationen (NAK) am Fuß (Diabetischer Fuß, DF) ohne kritische Ischämie unter Verwendung von Hygiene-Technologien (HPT) zu bewerten: Ultraschall, Vakuum, programmgesteuerte Spülung und Aspirationshygiene (PSAH).

Es wurden die Ergebnisse der Behandlung von 106 Patienten mit NAK-DF ohne kritische Ischämie im Alter von 52–63 Jahren analysiert. Alle Patienten mit DF wurden in zwei Gruppen eingeteilt. In der Kontrollgruppe wurde eine normale Sanierung durchgeführt. In der Studienbehandlungsgruppe wurde die chirurgische Behandlung von Eiterherden (HBEH) mit Ultraschall ergänzt, nach der Operation wurde eine programmgesteuerte Spülung in Kombination mit Vakuumtechnologien verwendet, wobei das Originalgerät AMP01 eingesetzt wurde. Dieses Gerät ist mit einem Drucksensor ausgestattet und ermöglicht, automatisch ein bestimmtes Vakuum in der eitrigen Kaverne aufrechtzuerhalten.

Es gibt plausible Nachweise, dass die Alkalisierung der Wundflüssigkeit (pH > 6,5–6,6) und Reduzierung des Proteingehalts im Wundexsudat unter die Schwellenwerte bei Patienten der therapeutischen Gruppe früher als bei Patienten der Versuchsgruppe erfolgte (p < 0,001). Eine Abnahme der Bakterienbelastung unter kritische Werte wurde in der therapeutischen Gruppe früher als in der Versuchsgruppe festgestellt (p < 0,001). Die postoperative Mortalität in der therapeutischen Gruppe betrug 5,5 %, in der Kontrollgruppe 9,8 %. Die Anzahl der eitrigen Komplikationen war signifikant geringer (p = 0,014), in einem größeren Prozentsatz der Fälle war es viel einfacher, die Unterstützung des Beins in der therapeutischen Gruppe (p = 0,023) als in der Kontrollgruppe aufrechtzuerhalten. Es gab auch eine signifikante Überschreitung der Häufigkeit hoher Amputationen in der Kontrollgruppe im Vergleich zur therapeutischen Gruppe (p = 0,026), die Dauer der stationären Behandlung von Patienten in der therapeutischen Gruppe verringerte sich um das 1,3-Fache.

*Ergebnisse:* Die operative Behandlung der Patienten mit NAK-DF ohne kritische Ischämie in Kombination mit der programmgesteuerten Hygiene, dem Ultraschall und Vakuumtechnologien kann die Qualität der Hygiene eitriger Kavernen erheblich verbessern, die Dauer des Krankenhausaufenthalts reduzieren und Behandlungsergebnisse optimieren.

**Schlüsselwörter:** diabetische Komplikationen am Fuß, nekrotisch-abszedierenden Komplikationen, programmgesteuerte Spülung und Aspirationshygiene

**Abstract:** The purpose of the study was to evaluate the results of operative therapy of patients with purulo-necrotic complications (PNC) of diabetic foot (DF) without critical ischemia using programmed sanitation technologies (PST): ultrasound, vacuum, programmed irrigation and aspiration sanitation (PIAS).

The results of treatment of 106 patients with PNC of DF without the phenomena of critical ischemia at the age of 52 to 63 years are analyzed. All DF patients were divided into two groups. In the experimental group, the conventional sanitation was carried out. In the treatment group of the study, surgical debridement of the purulent foci (SDPF) was supplemented with ultrasound, and after the operation, programmed sanitation was used in combination with vacuum technologies, where the original device AMP01 was used. This device is equipped with a pressure sensor and allows to automatically maintain a certain level of vacuum in the purulent cavity. Alkalization of the wound fluid (pH 6.5–6.6) and a decrease in the protein content in the wound effluent below threshold values in patients of the treatment group reliably occurred earlier than in the experimental group (p < 0.001). A decrease in the level of bacterial load below critical values was reliably noted earlier in the treatment group than in the experimental group (p <0.001). Operative mortality in the treatment group was 5.5%, in the experimental group 9.8%. The number of purulent complications turned out to be significantly less (p = 0.014), and it was significantly possible to maintain foot support ability in a larger percentage of cases in the treatment group (p = 0.023) than in the experimental group. There was also a significant increase in the frequency of high amputations in the experimental group in relation to the treatment group (p = 0.026), and the inpatient treatment time for patients in the treatment group decreased by 1.3 times.

Results: Operative therapy of patients with PNC of DF without critical ischemia in combination with programmed sanitation, ultrasound, and vacuum technologies can significantly improve the quality of purulent foci sanitation, helps to reduce hospitalization and improve treatment outcomes. **Z Gefäßmed 2020; 17 (3): 13–7.**

**Key words:** diabetic foot, purulo-necrotic complications, programmed irrigation and aspiration sanitation.

## Introduction

Diabetic foot (DF) is one of the most formidable complications of diabetes mellitus (DM), which causes painful suffering for the patient, and which places a significant financial burden on the Healthcare Service of any country in the world and society as a whole [1–8]. Thus, the financial costs of the National Health Service of England and Wales for the hospitalization and treatment of patients with complicated forms of DF for 2010–2011 amounted to approximately 639–662 million pounds [9]. Annually, up to 54,000 lower limb amputations are performed in the United States due to DF complications, and mortality after such operations is up to 20–30% [10]. According to European researchers, mortality after below-knee amputation with DF for 1 year is 24.6%, for the first 5 years 66.3%; after hip amputation, mortality during the year was noted in 43.3% of cases, five-year mortality was 83.3% [11]. The solution to the problems of mortality and disability due to DF is to adopt and adhere to a strategy that covers the prevention and implementation of an interdisciplinary approach to the treatment of diabetic foot trophic and purulent lesions [12, 13].

The subject of further study and discussion continues to be questions of the general strategy for operative therapy of purulo-necrotic foci in DF, as well as specific questions regarding the determination of the volume and radicalism of operative therapy [12–15]. International DF experts emphasize the

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From the [1]Department of Specialized Surgical Disciplines, Medical Institute, Oryol State University named after I.S. Turgenev, Orel, Russian Federation, and the [2]Department of General Surgery, Institute of Surgical Infection, Voronezh State Medical University named after N.N. Burdenko, Voronezh, Russian Federation

**Correspondence to:** Vladimir A. Sergeev, MD, Department of Specialized Surgical Disciplines, Medical Institute, Oryol State University named after I.S. Turgenev, 302026, 95 Komsomolskaya Str., Orel, Russian Federation; e-mail: sergeev5320@murdoch.in

importance of chronic wounds operative therapy in diabetes over any topical preparations [16–18]. The healing of wound defects in diabetes is characterized by a longer duration of the inflammation phase, a decrease in the activity of macrophages producing growth factors [19–21]. The role of matrix metalloproteases has been proved, significantly slowing the reparative processes in people with diabetes due to remodeling of the extracellular matrix and increasing the timing of collagen network organization [22, 23]. The issues of determining the readiness of the diabetic foot tissues for reconstructive operations remain relevant [18, 24]. The unfailing interest in the development of new methods for intra- and postoperative sanitation of DF purulent foci is still topical [25–28].

The purpose of the study was to evaluate the results of operative therapy of patients with purulo-necrotic complications (PNC) of DF without critical ischemia using programmed sanitation technologies (PST): ultrasound, vacuum, programmed irrigation and aspiration sanitation (PIAS).

## Materials and Methods

The immediate results of treatment of 106 patients with PNC of DF without the phenomena of critical ischemia who were treated for 2008–2016 at State-funded health institution "Oryol Regional Clinical Hospital" of the city of Oryol were analyzed. The study was conducted with the approval of the ethics committee of the State Budgetary Institution of Higher Professional Education "Voronezh State Medical University named after N.N. Burdenko" of the Ministry of Public Health of the Russian Federation (Minutes No. 2 dated March 29, 2012).

**Inclusion criteria:** patients with type 1 and type 2 diabetes; the absence of critical ischemia at $TcPO_2$ values of at least 30 mm Hg, the degree of damage to the tissues of the foot according to F. W. Wagner (1979) of degree II–IV, signed informed consent. **Exclusion criteria:** patients age less than 18 years; concomitant diseases in the stage of decompensation, circulatory inefficiency and degree III respiratory failure; endocrine-metabolic and hypothalamic obesity; $TcPO_2$ value in the skin of the foot below 30 mm Hg, the degree of damage to the foot tissues according to F. W. Wagner's (1979) classification of degrees I and V.

Depending on the methods of sanitizing purulent foci, all patients were divided into two groups. The treatment group consisted of 54 patients, the experimental group of 51 patients. In the experimental group, patients after surgical debridement of the purulent foci (SDPF) received conventional topical treatment (tamed iodine solutions, polyethyleneglycol ointments), and after stopping the inflammatory process, foot plastic reconstruction (FPR) was performed or the wound healed by secondary intention. In the study treatment group, SDPF was supplemented by ultrasonic cavitation using the Soring Sonoca 185 apparatus, the wound was drained by tube drainages that were discharged through counterpunctures. The wound was then sutured tightly, and after the operation, the PIAS method was used with the original АМП-01 device (utility patent No. 2539165 dated November 27, 2014). Using the control panel of the device, the program sanitation mode was set (3 hours), while the sequential cycles of antiseptic injection into the wound cavity, its exposure and evacuation of the spent solution were switched on sequentially. Programmed sanitation was replaced by the constant evacuation mode (1 hour)

**Table 1.** Characteristics of patients of the treatment group and the experimental group

| Indicator | | Treatment group (n = 55) | Experimental group (n = 51) | p |
|---|---|---|---|---|
| Mean age *(M ± σ)* | | 59 ± 8 | 60 ± 9 | 0.26* |
| Sex | Men (abs.,%)<br>Women (abs.,%) | 25 (45.5%)<br>30 (54.5%) | 23 (45.1%)<br>28 (54.9%) | 1.00** |
| Type of diabetes | Type 1<br>Type 2 | 5 (9.1%)<br>50 (90.9%) | 4 (7.8%)<br>47 (92.2%) | 1.00** |
| DF form | neuropathic<br>neuroischemic | 32 (58.2%)<br>23 (41.8%) | 31 (60.8%)<br>20 (39.2%) | 0.66** |

Note: *according to the Mann-Whitney U test; **according to the two-tailed Fisher's exact test

**Table 2.** Characteristics of patients in the studied groups depending on the nosological entity of DF purulo-necrotic complications and the volume of the lesion in accordance with the classification of F. W. Wagner (1979)

| Nosological entity of the foot purulo-necrotic process | Volume of the lesion in accordance with the classification of F. W. Wagner (1979) | Treatment group (n = 55) | | Experimental group (n = 51) | | Total |
|---|---|---|---|---|---|---|
| | | Abs. | % | Abs. | % | |
| Deep ulcer | 2 | 5* | 9.1 | 4* | 7.8 | 9 |
| Deep ulcer + Toe chronic osteitis | 3 | 3* | 5.5 | 3* | 5.9 | 6 |
| Toe phlegmon + foot phlegmon | 2 | 5* | 9.1 | 6* | 11.8 | 11 |
| Toe osteitis + foot phlegmon | 3 | 8* | 14.5 | 9* | 17.6 | 17 |
| Suppurative wound after toe amputation or foot resection, previously performed in other medical institutions | 3 | 14* | 25.5 | 13* | 25.5 | 27 |
| Dry gangrene of one or more toes | 4 | 12* | 21.8 | 9* | 17.6 | 21 |
| Humod gangrene of toe + foot phlegmon | 4 | 8* | 14.5 | 7* | 13.7 | 15 |
| Total: | | 55 | 100 | 51 | 100 | 106 |

Note: *according to the Pearson $\chi$2-test (for 50% of groups the expected frequencies are less than 5) there are no differences between the groups (p = 0.989).

created by the AMP01 device in the "aspiration" mode. The device is equipped with a pressure sensor, with which the vacuum level in the purulent cavity was maintained at a level of 60–80 mm Hg. This technique was used for 5-8 days of treatment, and then they switched to active aspiration.

The composition of the patients in the studied groups was comparable by age, gender, type of diabetes and the DF clinical form (Tab. 1).

According to the prevalence of foot PNC, all patients of the study groups were distributed according to the degree of damage according to F. W. Wagner (1979) (Tab. 2).

In the treatment group of patients with a neuropathic form, radical surgical debridement and foot plastic reconstruction (FPR) were performed in one stage. With the neuroischemic form, stage-by-stage sanitation of the purulent focus was performed, and after stopping the inflammation, FPR was performed. In the postoperative period, in all cases after wound suturing, the PIAS method was used.

Patients of the study groups received complex therapy, which included complete unloading of the foot, insulin therapy with intermittent administration of adequate doses of the drug under the control of glycaemia, causal antibiotic therapy, anticoagulants and immunomodulators were prescribed according to indications. Primary surgical operations in patients in the study groups are presented in Table 3.

The treatment results of the groups were studied during the entire period of inpatient treatment with assessment points on the day of admission, as well as on the 3rd, 5th, 7th, 9th, 12th day from the start of treatment. The effectiveness of sanitation of purulo-necrotic foci in patients with DF was assessed by the level of bacterial load, the pH measurement of the wound fluid and the determination of the quantitative protein content in it. The immediate results of treating patients with PNC of DF were evaluated by the terms of inpatient treatment, the rate of operative mortality, the number of purulent complications and high amputations, as well as by the assessment of cases of maintaining the foot support ability. All patients underwent Duplex sonography of arteries and transcutaneous oximetry using a TCM 400 device (Radiometer medical, Denmark). The sensors were superimposed at standard points on the rear foot.

The work was done in the design of a simple randomized comparative controlled trial in parallel groups. The following statistical methods were used in the study: calculated mean, standard deviation, median, interquartile range (25th and 75th quartiles), absolute and relative risks, Mann-Whitney U-test (Wilcoxon-Mann-Whitney), distribution comparison Pearson $\chi^2$-test, Fisher's exact test. Significant differences were considered at $p < 0.05$.

**Table 3.** Primary operations in patients of the studied groups

| Primary operations | Treatment group (n = 55) | | Experimental group (n = 51) | | Total |
|---|---|---|---|---|---|
| | Abs. | % | Abs. | % | |
| Surgical debridement | 9* | 16.4 | 9* | 17.6 | 18 |
| Phlegmon incision | 13* | 23.6 | 18* | 35.3 | 31 |
| Toe amputation | 9* | 16.4 | 6* | 11.8 | 15 |
| Distal foot amputation | 12* | 21.8 | 8* | 15.7 | 20 |
| Transmetatarsal amputation of the foot | 12* | 21.8 | 10* | 19.6 | 22 |
| Total: | 55 | 100 | 51 | 100 | 106 |

Note: * according to the Pearson $\chi^2$-test (expected frequencies are greater than 5), there are no differences between the groups (p = 0.72).

## Results and Discussion

According to the pH measurement of wound effluent during surgery, patients of the treatment group had wound acidosis (median and interquantile range) 5.2 from 5 to 5.4, in the experimental group 5.2 from 5 to 5.6; by the Mann-Whitney test p = 0.99. During treatment, alkalization of wound fluid (pH above 6.5–6.6) in patients of the treatment group was

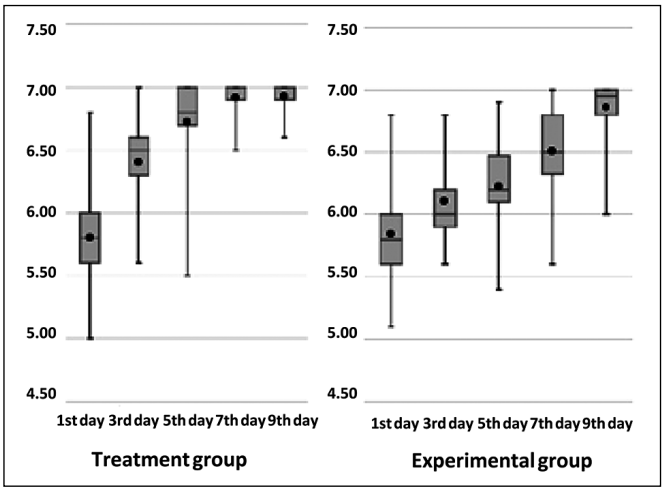


**Figure 1.** Dynamics of pH measurement results in patients with DF purulo-necrotic complications of the treatment group and the experimental group.

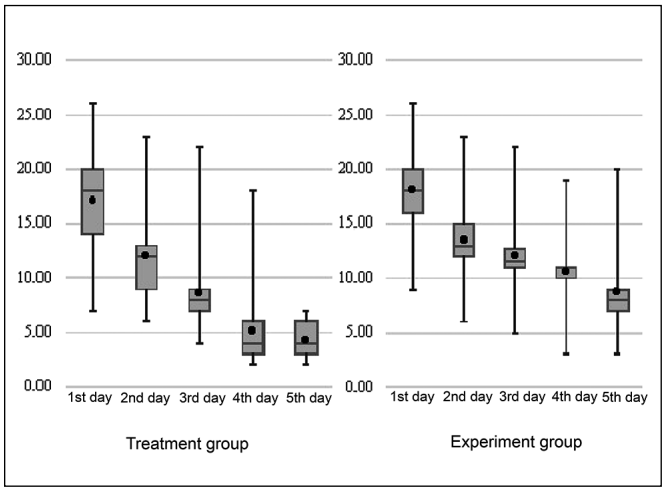


**Figure 2.** Dynamics of quantitative protein content in patients with DF purulo-necrotic complications of the treatment group and the experimental group

**Table 4.** Immediate results of treatment of patients with DF purulo-necrotic complications in the studied groups

| | | There is an outcome | No outcome | AR | RR | CI RR | OR | CI OR | F |
|---|---|---|---|---|---|---|---|---|---|
| Operative mortality | Treatment group | 3 | 52 | 0.055 | 0.556 | 0.140 | 0.531 | 0.098 | 0.477 |
| | Experimental group | 5 | 46 | 0.098 | | 2.211 | | 3.899 | |
| Purulent complications | Treatment group | 5 | 50 | 0.091 | 0.357 | 0.137 | 0.292 | 0.064 | 0.037 |
| | Experimental group | 13 | 38 | 0.255 | | 0.930 | | 0.744 | |
| Amputation | Treatment group | 4 | 51 | 0.073 | 0.285 | 0.099 | 0.229 | 0.072 | 0.016 |
| | Experimental group | 13 | 38 | 0.255 | | 0.819 | | 0.842 | |
| Foot support ability preserved in discharged patients | Treatment group | 45 | 7 | 0.865 | 1.327 | 1.047 | 3.429 | 1.260 | 0.017 |
| | Experimental group | 30 | 16 | 0.652 | | 1.681 | | 9.331 | |

Note: AR: absolute risk, RR: relative risk, CI RR: 95% confidence interval for relative risk, OR: odds ratio, CI OR: 95% confidence interval for odds ratio, F: value of the two-tailed Fisher's test

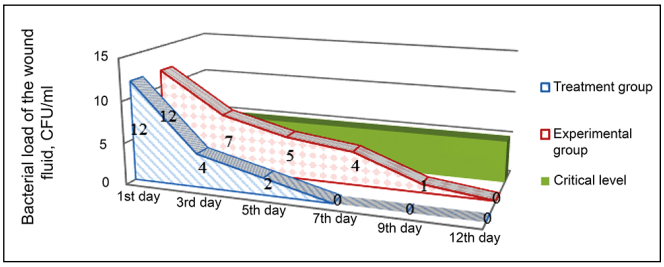


**Figure 3.** The dynamics of bacterial load of the wound fluid in patients with DF purulo-necrotic complications in the compared groups

observed on days 4th–5th (according to the Wilcoxon test, the results differ, p <0.001), and in patients of the experimental group the same results are achieved on 8th– 9th day after surgery (Fig. 1).

The patients of the treatment group, by 4–5 days after surgery, had a decrease in the quantitative protein content in wound effluent lower than 10 g/l, the median was 9 [8, 9] g/l (differences in protein content in wound effluent in the treatment group before surgery and after 5 days are statistically significant according to the Wilcoxon test, p < 0.001). In patients of the experimental group, the same data were observed by day 8th–9th (Fig. 2).

The median of microbial load of wounds upon admission in patients of the treatment group was $50\times10^{10}$ CFU/ml of wound fluid (interquartile range from $40\times10^{10}$ to $65\times10^{10}$ CFU/ml of wound fluid), in the experimental group $50\times10^{10}$ CFU/ml of wound fluid (interquartile range from $40\times10^{10}$ to $60\times10^{10}$ CFU/ml of wound fluid, p = 0.57). Five days after SDPF, in patients of the treatment group, the median microbial load of the wounds was $6\times10^{3}$ CFU/ml of wound fluid (interquartile range from $5\times10^{3}$ to $7.5\times10^{3}$ CFU/ml of wound fluid). In the treatment group, according to the Wilcoxon test, statistically significant differences were found between the results for this indicator, p < 0.001. In the experimental group, on the 5th day, the median of microbial load of the wounds was $5\times10^{5}$ CFU/ml of wound fluid (interquartile range from $3\times10^{5}$ to $6\times10^{5}$ CFU/ml of wound fluid) (Fig. 3).

In the treatment group, the length of stay in hospital for patients with PNC of DF (median and interquartile range) was 21 bed days (from 21 to 23 bed days), in the experimental group 29 bed days (from 27 to 30 bed days, p < 0.001 based on the Mann-Whitney U test). The nearest treatment results were analyzed in 106 operated patients (Tab. 4).

Operative mortality in the treatment group of patients was 5.5%, in the experimental group 9.8%. All fatal cases were noted after high amputations. At the significance level p = 0.477, the hypothesis was accepted that there were no differences between groups in the number of fatal cases. Purulent complications were observed in the treatment group of patients in 5 cases (9.1%), and in the experimental group in 13 cases (25.5%, p = 0.037). The foot support ability was preserved in 45 discharged patients (86.5%) in the treatment group, and in the comparison group in 30 patients, which amounted to 65.2% (p = 0.017).

High amputations were performed in patients of the treatment group in 4 cases (7.3%), of which at the level of midleg in two cases, and at the level of the thigh in two cases as well. In the experimental group, amputation was performed in 13 cases (25.5%, p = 0.016), of which amputation of the lower leg was performed in 5 cases, and hips in 8 cases.

It has been proven that wounds in DF are characterized by a longer course of the inflammation phase, a decrease in the activity of cells involved in inflammation, especially macrophages that produce local growth factors [19–21]. The role of matrix metalloproteases, which significantly inhibit the regeneration processes in diabetes due to a slowdown in the production of extracellular matrix and an increase in the organization time of the collagen network, has been proven [22, 23]. To date, various methods of intra- and postoperative sanitation of DF purulent foci have been proposed.

## Conclusions

The study showed the effectiveness of an integrated approach in the treatment of patients with PNC of DF without critical ischemia compared with conventional methods. The use of ultrasound in the surgical debridement of purulent foci, early closure of the wound, the use of programmed sanitations in the postoperative period in combination with vacuum technologies allowed improving the results of treatment of patients of this nosology. During the study, it was reliably proved that faster purification of purulent foci from microbial bodies with DF in the treatment group (p < 0.001), and the inpatient treatment time for patients with PNC of DF in the treatment group decreased by 1.3 times. There was a significant decrease in the number of purulent complications (p = 0.037), a decrease in the number of high amputations (p = 0.016), and the likelihood

of maintaining foot support ability in patients of the treatment group was also higher (p = 0.017).

Operative therapy in combination with programmable debridement, ultrasound, and vacuum technologies has a significant advantage over conventional methods in treating patients with purulo-necrotic complications of diabetic foot without critical ischemia. Its use statistically significantly accelerates the time of cleansing wounds from purulo-necrotic tissues, microbial bodies, stimulates regenerative processes, which helps to reduce hospitalization and improve immediate treatment results.

## Conflict of interest

None.

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