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Original article

The effectiveness of thread embedding acupuncture in reducing wrinkles at nose and mouth

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Abstract: Introduction: Beauty need is a growing demand these days; thus, the search for non-invasive beautifying methods that effectively and safely reduce the wrinkles on the face is of great need. Thread embedding acupuncture (TEA) has been proven to be effective in rejuvenating the facial skin and consists of advantages such as little invasion, few side-effects. **Methods:** The study was a single-arm pre-post study, 20 female volunteers, aged 35-60. TEA is conducted on Daying (ST5), Jiache (ST6), Dicang (ST4), Yingxiang (LI20), and Hegu (LI4) with mono-filament Polydioxanone (PDO). The participants were monitored and evaluated after 1, 2 and 3 months. The variables are Nasolabial fold (NF), Marionette line (ML), Alexiades-Armenakas laxity scale (AALS), Global aesthetic improvement scale (GAIS). **Results:** Both sides NF, ML and AALS after 1 month TEA, 2 months TEA, 3 months TEA compared to pre-intervention showed decrease of statistical significance. NF, ML of both sides after 1 month TEA, 2 months TEA compared to the previous 1 month showed decrease of statistical significance. However, after 3 months, compared with 2-month threshold, difference has no statistical significance. AALS after 2 months and 3 months TEA, differences have no statistical significance. There were 17 persons “improved” (85%), 3 persons “unchanged” (15%) according to GAIS. No side effect of any kind was recorded. **Conclusions:** This research proved TEA method is effective on the acupuncture points that the research used in facial wrinkle reduction treatment. However, a RCTs (Randomized Controlled Trial study) is needed to confirm effectiveness.

Keywords: Thread embedding acupuncture, aesthetic acupuncture, monofilamentous Polydioxanone, facial rejuvenation.

1. INTRODUCTION

According to statistics provided by International Society of Aesthetic Plastic Surgery (ISAPS), the number of cosmetic surgery and beautifying procedures around the world in 2017 has a total increase of 9% compared with 2016. Among that number, surgery methods increase by 8% and non-surgical cosmetic procedures by 10% [1]. Therefore, the need for beauty is essential; beauty treatments, especially effective, safe and non-invasive facial rejuvenation and wrinkle reduction treatment are more and more desired. Aesthetic medicine, as a result, becomes continuously developed and gives birth to many non-invasive beauty methods such as fat

graft, filler injection, botulinum toxin injection, laser usage... [2], [3].

For Traditional Medicine, aesthetic acupuncture has been a long-standing method (from 475-221 BC); this method was exclusive to the queens and royal concubines to rejuvenate, prolong their lives and improve their health [4]. According to Traditional Medicine, skin care was mentioned in Huang Di Nei Jing Ling Shu, chapter 9 “終始”; chapter 64 “陰陽二十五人” also discussed the relationship between meridian system and physical conditions of skin and hair [5]. Therefore, meridian system and acupuncture points play an important

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role in skin care. As a result, injecting at accurate position of acupuncture points is essential for the initiation of acupuncture mechanics: balancing Yin Yang and fostering circulation. Nowadays, TEA proved to be effective in rejuvenating the face with many advantages such as non-invasion, short treatment and recovery, few side effects, simple procedures, saving time, and economy. TEA's mechanic has similar effects to acupuncture: helping retain stimulation to balance Yin Yang and foster the circulation thanks to the threads at acupuncture points; additionally, there are the effects of melting thread: enhancing the regeneration of collagen and elastin fibers at the dermis [6].

Certain other research utilizing PDO thread in reducing wrinkles were referred to. A notable example is Antonella Savoia and et al' research (2014) on rejuvenation with thread lift method. The research was conducted on 37 female patients, aged 37-65. Equipment utilized was double thread with cogs, length 120–230 mm and long straight needle, 90 or 150 mm in length, size 24G. Insertion position is the cheekbone, lower jaw and eyebrow. Comparisons were made 25 days, 2 months, 6 months and 12 months after treatment. The result is 33 patients (89%) satisfactory including 24 patients (65%) with excellent results, 9 patients (24%) with a good result, and 4 patients (11%) unsatisfactory [7].

Arora Gulhima and et al' research (2019) on thread lift method to rejuvenate the neck was conducted on 20 female patients. Threads in use were PDO mono, cogs, screw, thread and Poly L-lactic acid thread with bidirectional cones. Each patient was inserted 48-64 needles. Measured with Visual analog scale (VAS), the result obtained was 75% of the patients reached 4+ point, 50% –75% reached 3+, 25% –50% reached 2+ and 0% –25% reached 1+. Pre-intervention neck weights were 3.65 and 2.45, post-intervention weights decreased to 1.4 and 1.1; these differences are of statistical significance ($p < 0.001$) [8].

As can be seen, the above researchs share one common trait that is the utilization of double, cog, screw thread, thread with cone shape, focusing more on lifting mechanism than tissue regeneration mechanism. Thread injection positions are not determined according to acupuncture points but mainly according to mechanical principle. Younghee Yun and et al' research (2017) carried out injection at acupuncture points but only utilized acupuncture points abiding by local principles and injected many adjacent non-acupuncture point positions as well [9]. Therefore, each participant has to be injected numerous needles; there are occasional post-injection side-effects recorded: painful facial swellings and increased infection risk; as a result, the use of backup antibiotics might be needed.

In Vietnam, TEA and aesthetic acupuncture are growing more popular by the day. However, there has yet to be actual research on TEA with regards to aesthetic medicine in general and wrinkle reduction treatment in particular. The new trait in our study is that it not only used acupuncture points according to local principles Daying (ST5), Jiache (ST6), Dicang (ST4), Yingxiang (LI20) but also applied specific facial acupuncture point: Hegu (LI4); this aims to increase treatment effectiveness, limit the number of facial needles and reduce the side-effects such as swelling, straining, pain on patients.

The objectives of the study were to evaluate the effectiveness of TEA in reducing wrinkles at nose and mouth, in general facial skin improvement, and to evaluate the side effects of TEA.

2. MATERIALS AND METHOD

2.1. Study design and participants

The study was a single-arm pre-post study. This study was performed at Faculty of Traditional Medicine, University of Medicine and Pharmacy at Ho Chi Minh City from December 2021 to June 2022. Volunteers had to meet requirements as follows (all criteria are to be fulfilled): gender is female; aged 35 – 60; Glogau photoaging scale level II, III, IV; agreement on not receiving any other kind of treatment during the whole research. Exclusions criteria (if any one of these filled): pregnant or breastfeeding; using botulinum toxin, fillers, or any kind of injection within 6 months prior to the research; keloid scar (natural or not); history of being diagnosed with Herpes simplex; skin allergies; history of allergies with anaesthetics or acupuncture needles; history of diabetes mellitus; currently using anticoagulant.

The information and method of the study are presented according to the STRICTA (Standards for Reporting Interventions in Clinical Trials of Acupuncture) 2010 checklist [10].

2.2. Sample size and sampling

$$n = \frac{C}{(ES)^2} = \frac{C}{(s)^2}$$

With $C = 7.85$ ($\alpha = 0.05$ and $\beta = 0.2$), $d = 11.15$ and $s = 17.48$, we can calculate $n = 20$.

2.3. Research procedures

2.3.1. Research subject reception

Participants were recruited and explain the procedures. Then, they signed the form “Information and consent form for research participant”.

2.3.2. Equipment

Threads in use are mono-filament PDO, length 30-50 mm. Needles in use: 10 needles per person, size 31G - 29G; lidocaine solution 10%; povidone-iodine solution 10%; sterile absorbent cotton, sterile gloves, adhesive bandage; anti-shock medicine box.

2.3.3. TEA process

Doctor check the pulse, blood pressure, body temperature and respiratory rate of the participant. Then, doctor wash hands, wear sterile gloves; determine the acupuncture points, apply lidocaine solution 10%, sterilize the acupuncture points with povidone-iodine 10%. The needles were inserted quickly through the skin and push it slowly to the dermis. Place sterile gauze on the needle-inserted area, press and then pull the needle out, apply adhesive bandage on the area. Doctors perform TEA method have at least 10 years of experience in acupuncture and has a license for thread implantation.

Acupuncture points applied: Daying (ST5) with needle directed to Jiache (ST6), Jiache (ST6) directed to Xiaguan (ST7), Dicang (ST4) directed to Juliao (ST3), Yingxiang (LI20) directed to Sibai (ST2), and Hegu (LI4). Daying (ST5), Jiache (ST6), Dicang (ST4), Yingxiang (LI20) are used according to local principles. Hegu (LI4) is used according to special principles. The reason Hegu (LI4) was chosen is because it belongs to the Liu Zong Xue group, including 6 special acupuncture points and Hegu (LI4) specifically used

in treatments for facial and head diseases. Besides, certain studies have proven that Hegu (LI4) helps foster facial blood circulation, increasing facial temperatures, especially the areas surrounding the lips [11], [12].

2.3.4. Care and monitoring

Participants lie down relaxing, observed for 30 minutes; apply ice compress for 10 minutes. Within 2 weeks after TEA, participants should not make excessive facial movements such as yawning, laughing loudly, chewing aggressively or massaging the face, sleeping in a supine position is recommended.

2.4. Outcomes

Nasolabial fold is quantitative variable, measured from the sides of the nose to the corner of the mouth, and calculation unit is millimeter (mm).

Marionette line is quantitative variable, measured from the corners of the mouth to the lower jaw, and calculation unit is millimeter (mm).

Alexiades-Armenakas laxity scale is a quantitative variable with grades from 0 to 4 (grades are inversely proportional to the elasticity of the facial skin) (Table 1).

Global aesthetic improvement scale (GAIS) is a qualitative variable with 5 values (Table 2).

Table 1. Skin laxity grading scale according to AALS

Grade	Descriptive parameter	Laxity
0	None	None
1	Mild	Localized to nasolabial folds
1.5	Mild	Localized, nasolabial folds and early melolabial folds (Marionette lines)
2	Moderate	Localized, nasolabial folds/ Marionette lines, early jowls, early submandibular
2.5	Moderate	Localized, prominent nasolabial folds/ Marionette lines, jowls and submandibular
3	Advanced	Prominent nasolabial folds/ Marionette lines, jowls and submandibular, early neck strands
3.5	Advanced	Deep nasolabial folds/ Marionette lines, prominent jowls and submandibular, prominent neck strands
4	Severe	Marked nasolabial folds/ Marionette lines, jowls and submandibular, neck redundancy and strands

Table 2. Scale describing aesthetic improvement according to GAIS

	Degree	Description
1	Exceptional improvement	Excellent corrective result
2	Very improved	Marked improvement of the appearance, but not completely optimal
3	Improved	Improvement of the appearance, better compared with the initial condition, but a touch-up is advised
4	Unchanged	The appearance substantially remains the same compared with the original condition
5	Worsened	The appearance has worsened compared with the original condition

Unwanted symptoms include swellings, ecchymosis, straining, pain, infection and others are qualitative variables with 2 values of “Yes” or “No” that were examined by doctors and asked participants.

2.5. Measuring the outcomes

Outcomes include NL, ML, AALS were measured multiple times at 4 time points: before TEA (T0), after 1 month TEA (T1), after 2 months TEA (T2), after 3 months TEA (T3). GAIS was evaluated after 3 months TEA. Side effects were evaluated immediately post-intervention, after 1 month TEA, after 2 months TEA, after 3 months TEA. Doctor is person who measures and monitors these outcomes.

2.6. Statistical analysis

Statistics were collected using Microsoft Excel 2010 and analyzed with SPSS 20 for Windows Student Version. Statistics represent variables: mean, median, standard deviation, standard error. We used one way ANOVA repeated measurement with Greenhouse-Geisser correction. Post hoc analysis with Bonferroni adjustment was used to compare variables at 4 time points before TEA (T0), after 1 month TEA (T1), after 2 months TEA (T2), after 3 months TEA (T3).

3. RESULTS

3.1. Participants

20 women, average age 48.4, from 38 to 57 years of age, satisfying the criteria. There were 2 people with Glogau photoaging scale level II (10%), 17 people level III (85%), 1 person level IV (5%). All participants undergone TEA and were monitored after 1, 2 and 3 months.

3.2. Changes in facial wrinkles at nose and mouth

1 month after TEA, both sides nasolabial folds and both sides Marionette lines witnessed statistically significant decrease ($p < 0.05$). 2 months after TEA, both sides nasolabial folds and both sides Marionette lines witnessed statistically significant decrease ($p < 0.05$). 3 months after TEA, both sides nasolabial folds and both sides Marionette lines witnessed statistically significant decrease ($p < 0.05$) (Table 4).

A repeated measures ANOVA with a Greenhouse-Geisser correction determined that mean Right NF differed statistically significantly between time points ($F(1.873, 35.588) = 103.087, P < 0.0005$). Post hoc analysis with a

Bonferroni adjustment revealed that Right NF was statistically significantly decreased from T0 to T1 (0.67 (95% CI, 0.26 to 1.09) mm, $p = 0.01$), and from T1 to T2 (1.10 (95%

CI, 0.89 to 1.30) mm, $p < 0.0005$), but not from T2 to T3 (0.12 (95% CI, -0.11 to 0.36) mm, $p = 0.811$) (Table 5).

Table 3. Changes of NF and ML

	T0	T1	T2	T3
	Mean \pm SD	Mean \pm SD	Mean \pm SD	Mean \pm SD
Right NF (mm)	46.40 \pm 5.82	45.72 \pm 6.04	44.62 \pm 6.01	44.50 \pm 6.06
Left NF (mm)	45.15 \pm 6.32	44.50 \pm 6.48	43.92 \pm 6.35	43.75 \pm 6.31
Right ML (mm)	15.65 \pm 4.91	15.17 \pm 4.82	14.67 \pm 4.91	14.57 \pm 4.93
Left ML (mm)	16.10 \pm 5.03	15.70 \pm 4.87	15.25 \pm 4.79	15.17 \pm 4.86

Table 4. Changes of NF and ML after 1 month TEA, 2 months TEA, 3 months TEA compared to pre-intervention

	T0-T1		T0-T2		T0-T3	
	Mean difference	p	Mean difference	p	Mean difference	p
Right NF (mm)	0.67 \pm 0.14	0.01	1.77 \pm 0.15	0.000	1.90 \pm 0.16	0.000
Left NF (mm)	0.65 \pm 0.12	0.000	1.22 \pm 0.12	0.000	1.4 \pm 0.14	0.000
Right ML (mm)	0.47 \pm 0.10	0.01	0.97 \pm 0.12	0.000	1.07 \pm 0.13	0.000
Left ML (mm)	0.40 \pm 0.10	0.05	0.85 \pm 0.10	0.000	0.92 \pm 0.09	0.000

Table 5. Changes of NF and ML at time points compared to the previous 1 month

	F	T0-T1		T1-T2		T2-T3	
		Mean difference	p	Mean difference	p	Mean difference	p
Right NF (mm)	103.087	0.67 \pm 0.14	0.01	1.10 \pm 0.07	0.000	0.12 \pm 0.08	0.811
Left NF (mm)	54.343	0.65 \pm 0.12	0.000	0.57 \pm 0.11	0.000	0.17 \pm 0.06	0.092
Right ML (mm)	37.752	0.47 \pm 0.10	0.01	0.50 \pm 0.12	0.03	0.10 \pm 0.06	0.622
Left ML (mm)	44.880	0.40 \pm 0.10	0.05	0.45 \pm 0.09	0.01	0.07 \pm 0.04	0.497

A repeated measures ANOVA with a Greenhouse-Geisser correction determined that mean Left NF differed statistically significantly between time points ($F(2.087, 39.646) = 54.343$, $P < 0.0005$). Post hoc analysis with a Bonferroni adjustment revealed that Left NF was statistically significantly decreased from T0 to T1 (0.65 (95% CI, 0.29 to 1.01) mm, $p < 0.0005$), and from T1 to T2 (0.57 (95% CI, 0.25 to 0.9) mm, $p < 0.0005$), but not from T2 to T3 (0.17 (95% CI, -0.02 to 0.37) mm, $p = 0.092$) (Table 5).

A repeated measures ANOVA with a Greenhouse-Geisser correction determined that mean Right ML differed statistically significantly between time points ($F(2.035, 38.673) = 37.752$, $P < 0.0005$). Post hoc analysis with a Bonferroni adjustment revealed that Right ML was statistically significantly decreased from T0 to T1 (0.47 (95% CI, 0.16 to 0.79) mm, $p = 0.01$), and from T1 to T2 (0.50 (95% CI, 0.15 to 0.85) mm, $p = 0.03$), but not from T2 to T3 (0.10 (95% CI, -0.07 to 0.27) mm, $p = 0.622$) (Table 5).

A repeated measures ANOVA with a Greenhouse-Geisser correction determined that mean Left ML differed statistically significantly between time points ($F(2.193, 41.660) = 44.880$, $P < 0.0005$). Post hoc analysis with a Bonferroni adjustment

revealed that Left ML was statistically significantly decreased from T0 to T1 (0.40 (95% CI, 0.11 to 0.69) mm, $p = 0.05$), and from T1 to T2 (0.45 (95% CI, 0.17 to 0.73) mm, $p = 0.01$), but not from T2 to T3 (0.07 (95% CI, -0.05 to 0.19) mm, $p = 0.497$) (Table 5).

3.3. General improvement of facial skin

Alexiades-Armenakas laxity scale showed decrease of statistical significance after 1 month TEA, 2 months TEA, 3 months TEA compared to pre-intervention ($p < 0.05$). However, after 2 months, compared with 1-month threshold, and after 3 months, compared with 2-month threshold, the differences were of no statistical significance ($p > 0.05$).

According to GAIS among 20 participants, after 3 months TEA there isn't any person was estimated "Exceptional improvement", "Very improved" and "Worsened", 17 persons were labelled "improved", accounting for 85% and 3 persons "unchanged" accounting for 15%.

3.4. Unwanted symptoms

No symptom such as swelling, ecchymosis, straining, pain, infection or others was recorded during the research.

Table 6. Changes of AALS at different time points

	Mean difference	p
T0-T1	0.22 \pm 0.05	0.05
T0-T2	0.27 \pm 0.05	0.01
T0-T3	0.30 \pm 0.05	0.000
T1-T2	0.05 \pm 0.03	0.975
T2-T3	0.02 \pm 0.02	1.000

Table 7. Description the ratio of unwanted symptoms

	Immediately post-intervention	After 1 month TEA	After 2 months TEA	After 3 months TEA
Swelling (%)	0	0	0	0
Ecchymosis (%)	0	0	0	0
Straining (%)	0	0	0	0
Pain (%)	0	0	0	0
Infection (%)	0	0	0	0
Others (%)	0	0	0	0

4. DISCUSSION

Both sides nasolabial folds after 1 month TEA, 2 months TEA, 3 months TEA compared to pre-intervention showed decrease of statistical significance ($p < 0.05$). 1 month after TEA, left-side nasolabial fold decrease 0.65 ± 0.12 mm, right-side nasolabial fold 0.67 ± 0.14 mm. 2 months after TEA, compared with 1-month threshold, nasolabial folds of both sides continued to show decrease of statistical significance; left-side nasolabial fold decrease 0.57 ± 0.11 mm, right-side nasolabial fold decrease 1.10 ± 0.07 mm. However, after 3 months, compared with 2-month threshold, nasolabial folds of both sides showed difference of no statistical significance (Table 4, Table 5). To make comparison, in Younghee Yun and et al' research (2017) conducted on 14 patients, only 1 week after TEA, right-side nasolabial folds decrease 11.15 ± 17.48 mm, left-side nasolabial folds decrease 17.08 ± 33.87 mm; the differences were of statistical significance [9].

Marionette lines of both sides after 1 month TEA, 2 months TEA, 3 months TEA compared to pre-intervention showed decrease of statistical significance ($p < 0.05$). After 1 and 2 months TEA compared to the previous 1 month, both sides Marionette lines showed decrease of statistical significant ($p < 0.05$). Right-side Marionette lines decreased 0.47 ± 0.10 mm 1 month after TEA and continued additional reduction 0.50 ± 0.12 mm after 2 months; the left Marionette lines decreased 0.40 ± 0.10 mm after 1 month and continued additional reduction 0.45 ± 0.09 mm after 2 months. However, after 3 months, compared with 2-month threshold, the difference was of no statistical significance (Table 4, Table 5).

According to Alexiades-Armenakas laxity scale, after 1 month, there was decrease of statistical significance: 0.22 ± 0.05 ($p < 0.05$). After 2 and 3 months compared to the previous 1 month, the differences were of no statistical significance (Table 6). Compared with the study of Younghee Yun and et al' research, after 1 week TEA, AALS decreased 0.27 ± 0.27 ($p < 0.05$).

GAIS had 17 people "Improved" and 3 people "Unchanged", no person "Worse" but also no person "Exceptional improvement" or "Very Improved". Compared with the study of Antonella Savoia et al' (2014) performed on 37 participants, evaluation immediately after intervention have GAIS: "Exceptional improvement" 29.8% (11 people), "Very improved" 35.1% (13 people), "Improved" 24.3% (9 people), "Unchanged" 10.8% (4 people). After 6 months intervention the results were: "Exceptional improvement" 54.1% (20 people), "Very improved" 43.2% (16 people), "Improved" 2.7% (1 person), "Unchanged" 0%. Younghee Yun's study, the evaluation results after 1 week of implantation were only "Very improved" 64.3% (9 people), "Improved" 35.7% (5 people), the study did not follow up and evaluate longer time.

In this study, there aren't any symptom such as swelling, ecchymosis, straining, pain, infection or others (Table 7). In the study of Antonella Savoia et al' (2014), the most frequent complication was small ecchymosis in 23 patients (62%), mild erythema was noticed in 15 patients (41%). Mild esthesia was encountered in two patients (5%). Mild post-operation tumefaction was observed in 15 patients (41%).

In comparison with Younghee Yun and et al' research, our research took a longer time to produce post-TEA effects and the differences before and after TEA are also smaller. The reason re-evaluation only took place at least 1 month after TEA is because the thread in use is monofilamentous PDO, length 30 – 50 mm while Younghee Yun's research makes use of not only PDO mono thread but also screw thread, double thread with cogs, length 30 – 110mm, intended for physical stretch. Because in this research, only monofilament was utilized, there was barely any physical mechanism involved; thread was inserted into acupuncture points to enhance capillary system, foster the regeneration of protein, especially collagen and elastin fibers at the dermis [6]. Therefore, our result took a longer time span to produce results. Besides, in our research, each participant was only injected 10 needles including 8 on the face and 2 on the hands; Younghee Yun's research makes use of 68 needles for two sides of the face. These are likely the factors affecting the effectiveness of TEA in our study [9].

In the study of Antonella Savoia et al' (2014), there was a visible reduction in facial wrinkles immediately after the intervention and continued to be maintained after 6 months of thread implantation. Research shows that the lifting effect of facial skin is guaranteed and reinforced by the fibrotic reaction that occurs along the length of the thread, and that remains effective and stable even when threads were fully absorbed [7]. In this research, TEA indicated its effectiveness in reducing nasal and oral wrinkles, this improvement did not grow larger over time. Even though the threads have not completely absorbed after 3 months, the improvement showed no sign of increasing. Thus, in order to reach higher effectiveness, 1-2 more TEA procedures could be added, and acupuncture points in formula may be replaced with adjacent acupuncture points in case old threads have not been absorbed completely.

Conclusion

The TEA method on the acupoints of this study is effective in reducing wrinkles in the nose and mouth area and improving the elasticity of the facial skin. However, the effect is not maintained and increases over time. The advantage of the study is that the method does not cause side effects because it uses a small number of acupoints (10 acupoints).

Nevertheless, this is a pilot study, so we only conducted on 1 group and compared before and after the intervention, without a control group. Therefore, the results of this study can be used as a basis for further studies with modified procedures such as increasing sample size, adding courses of treatment and having a control group to conduct RCTs.

ETHICAL STATEMENT

The research was approved by the Ethics Council of the University of Medicine and Pharmacy Ho Chi Minh City on December 06, 2021, according to Decision No. 770/ĐHYD-HĐĐĐ.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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AUTHORS' CONTRIBUTION

Designing the study: Dieu Thuong Thi Trinh and Binh Minh Thi Pham; Methodology: Dieu Thuong Thi Trinh; Validation: Binh Minh Thi Pham; Writing original draft: Binh

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