Treatment of Severe Varicose Veins: Surgery vs. Medical Therapy.

Surgical Argument

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Definition

Varicose Veins—Permanent dilatation and tortuosity of a vein.

*Stedman’s Concise Medical Dictionary

http://www.dornier.com
Prevalence  

One of the most prevalent medical disorders in the U.S.

- Almost 40 million people
- Prevalence close to Diabetes in western countries
Symptoms

- Most are Asymptomatic
- Displeasure of Cosmetic Appearance
- Tiredness, Heaviness of leg
- Dull aching, Burning pain
  - Worse with standing or with hot weather
Complications

- Recurrent Superficial Thrombophlebitis (20-50%)
- Cellulitis
- DVT 3x more likely in people with Varicose Veins
- Hemorrhage/Bleeding from traumatized varicosities
- Varicose Eczema
  - Extravasation of RBC’s, and breakdown in the skin
Risk Factors 2, 17

- Sex
- Aging
  - Incidence in women/men in 5\textsuperscript{th} decade of life approx. 41%/24% and increases to 72%/43% by the 7\textsuperscript{th} decade
- Tall stature
- Obesity
- Standing for long periods of time
- Restrictive clothing
- Marfan’s Syndrome
- Ehlers-Danlos Syndrome
- Family History
- Pregnancy
- OCP’s
Classification

- C, E, A, P Classification of Chronic Lower Extremity Venous Disease.
Classification

- **C: Clinical Signs**
  - Class 0: No visible/palpable signs of venous disease
  - Class 1: Telangiectasias, reticular veins, malleolar flare
  - Class 2: Varicose Veins
  - Class 3: Edema w/o skin changes
  - Class 4: Skin changes ascribed to venous disease (pigmentation, venous eczema)
  - Class 5: Skin changes defined above with healed ulceration
  - Class 6: Skin changes defined above with active ulceration

- --Moderate to advance CVI is class 3-6
Classification

- **E: Etiologic**
  - Congenital
  - **Primary**—defect is the absence or incompetence of the saphenofemoral valve and other valves in the greater and lesser saphenous system
  - Secondary—occur as a result of trauma or phlebitis or the venous systems that has damaged the valvular system
Classification

- A: Anatomic Distribution\(^2\)
  - Superficial
  - Deep
  - Perforator
  - Alone or in any combination of above
Classification

P: Pathophysiological Dysfunction²

- Reflux
- Obstruction
- Alone or in combination
Greater Saphenous Vein (GSV) begins anterior to the medial malleolus and rises obliquely and posterior as it crosses the anteromedial surface of the tibia. At the knee joint—joined by the posterior arch vein. The GSV rides on top of the fascia to join common femoral vein at the foramen ovale. 17
Anatomy

Lesser Saphenous Vein (LSV): Begins posterior to the lateral malleolus and courses upward. In the middle third of the calf it turns midline and enters the deep fascia in the upper third of the calf. In 60% of pts., the LSV enters the popliteal vein directly. The remainder joins the GSV at the knee level.

http://healthlibrary.epnet.com
Anatomy

Blood drains from smaller veins close to the surface into larger, deeper veins.

Great saphenous vein
Deep vein
Small saphenous vein
Skin
Reticular vein
Superficial vein
Perforating vein
Deep vein

Back View
Side View

http://www.richmondveincenter.com
Pathogenesis

- In healthy veins:
  - One-way valves direct flow of venous blood from the superficial venous capillaries → larger superficial veins → deep veins → IVC → heart.
  - Perforating Veins allow blood to move from the superficial venous system to the deep venous system.
In the muscle compartments of the leg and thigh, blood is pushed upward through the one-way valves of the veins. Pressures can be as high at 5 atm’s.—the fascia surrounding the deep veins prevent excessive dilatation.  

http://www.richmondveincenter.com
Pathogenesis

- Superficial veins normally encounter pressures that are much lower than the deep system, and exposure to persistently high pressures can cause dilatation and create varicosities.\(^\text{22}\)
  - Most valve failure is secondary to elevated pressures—with continued exposure of elevated venous pressure, the veins dilate so much that their valve leaflets no longer meet.

[Diagram of normal and dilated veins]

http://www.veininovations.com
Pathogenesis

- When a single venous valve fails, it creates a local high pressure area and local dilatation
  - which then leads to adjacent valve failure and more regional dilatation of the vein “a recruitment phenomenon”\textsuperscript{22}
Women: vein walls and valves periodically become more distensible with the cyclic increases in progesterone.

- Pregnancy increases this susceptibility due to the hormonal changes that lead to increased distensibility of vein walls and soften valve leaflets.
  - Also increase in blood volume.
  - Later in pregnancy—gravid uterus presses on IVC-causing further venous pressures.
  - Varicose veins of pregnancy may or may not go away after delivery.
Diagnosis

- **Physical Exam**:  
  - Arranged in an organized manner  
    - Distal to proximal, front to back  
    - May find cutaneous ulceration, telangiectasias, eczema, brown spots, prominent varicose veins.  
    - Healthy veins are typically only visibly distended at the foot and ankle—distension at other levels usually imply venous disease.  
    - Darkened, discolored, stained skin are usually signs of chronic venous stasis.
Diagnosis

- Palpation\textsuperscript{22}: dilated veins may be palpable even if not visible.
  - new varices sit on the surface of muscle or bone.
  - chronic varices erode into the underlying muscle or bone making them feel “boggy” or “spongy”.
Diagnosis

- Perthes Maneuver\textsuperscript{22}
  - A test designed to distinguish antegrade flow from retrograde flow in superficial varices.
  - Antegrade flow indicates that the system is a bypass pathway around a deep vein obstruction and should not be ablated.
Diagnosis

- Place a tourniquet over the proximal part of the varicose leg. Have the patient walk or do toe-stands to activate the calf-muscle pump.
- The muscle pump normally causes varicose veins to be emptied.
- but if deep system obstruction exists, then activating the calf-muscle pump causes paradoxical increase in the size of the varicose vein.
Diagnosis

- Trendelenburg Test\textsuperscript{17}: 
- Distinguish patients with superficial venous reflux from those with incompetent deep venous valves.
- Place patient in supine position and elevate the leg to drain the blood—a tourniquet is then applied to the leg.
- Results based on the biphasic response after the patients stands.
Diagnosis

- First response tells of the competency of the perforator veins valves of the lower leg
- The second response tells of the competency of the saphenofemoral valve after the tourniquet is removed.
Diagnosis

• **Negative-Negative:** Normal response—saphenofemoral valve is intact and perforating veins are intact

• **Negative-Positive:** Incompetent saphenofemoral valve, but competent perforators

• **Positive-Negative:** Competent saphenofemoral valve, but incompetent perforators

• **Positive-Positive:** Incompetent saphenofemoral valve and perforators.
Diagnosis

- Duplex Ultrasound: gold-standard for assessing venous competence, and allows measurement of flow through valves and identification of the sources of venous reflux.

- Doppler—probe at 45 degree angle to skin. Compression of the vein causes forward flow and gives an audible cue. When pressure is released, backward flow can also be heard. Competent valves should not have backward flow and thus no sound should be heard when pressure is released.

- Plethysmography: provides an indirect measurement of venous obstruction—readily available in most settings.
  - compares the systolic blood pressure of the lower to upper extremity, to help rule out disease that blocks the arteries in the extremities.
Differential Diagnosis

- Intermittent Claudication
- Deep Vein Thrombosis
- Nerve Root Compression
Medical Treatments 21, 22

- Life-Style changes
  - Weight loss
  - Wear less constrictive clothing
  - Be on feet less
  - Elevate lower extremities

- Compression Stocking

- Sclerotherapy
  - Causes inflammation of the vein’s intima and thrombus formation—development of fibrous tissue and obliteration of vein
  - Sodium Tetradecyl (DIC, DVT)
  - Morrhaue Sodium (PE, Valvular incompetency, vascular collapse, thrombosis)
    - Injection site reactions, permanent discoloration at injection site, extravasation, Hypersensitivity Reactions

- Radiofrequency/Laser Obliteration
Radiofrequency Ablation of the Saphenous Vein

- Use of Radiofrequency (RF) energy-mediated heating of the vein wall to destroy the intima and denature collagen in the media with resulting fibrous occlusion of the vein
  - Laser energy can also be used

Figure 1. Diagrammatic representation of endoluminal laser treatment of the greater saphenous vein.
Surgical Treatments

- Vein Stripping
- Ambulatory Phlebectomy (Removal of Branch Varicosities)
- Endoscopic (TriVex)
- Subfascial Endoscopic Perforator Vein Surgery
Indications for Surgery

- Dependent on:
  - Symptoms
  - Clinical Stage
  - Pt’s willingness to make lifestyle changes
  - Cosmetic reasons alone
Indications for Surgery

Figure 1 Evaluation and management of chronic venous insufficiency.

* Cameron
Vein Stripping

- Removal of the varicose vein in the OR with multiple incisions.
- High Ligation and Stripping of the GSV
  - “Gold Standard” of invasive procedures.
Vein Stripping\textsuperscript{21}

- Performed through a short, oblique incision at the groin crease—starting just medial to the femoral pulse and extending medially for 2-3 cm.
- Saphenofemoral junction is located and all tributaries are ligated and divided.
Vein Stripping

- Trunk of the GSV is dissected and then a flexible, disposable (Codman) vein stripper is introduced into the cut end of the vein at the groin and passed through the GSV to a 1 cm incision at the medial aspect of the popliteal space.

- Vein in the groin is then ligated around the stripper with nonabsorbable suture.

- Stripper is then inverted into the GSV and the vein is stripped from above downwards—the inverted vein come out of the knee incision and is ligated there.
Vein Stripping

- High Ligation and Stripping of the Lesser Saphenous Vein
  - Performed in the same manner as the GSV procedure but with more anatomical variation—prudent to use US to mark the saphenopopliteal junction pre-op.
Vein Stripping

- **Risks**: 
  - Damage to the saphenous nerve—resulting sx in up to 47% of patients.
    - Approx 7% of patients have sx that affect their quality of life
    - Recurrence

- **Benefits**: 
  - Complete removal of varicosity decreases recurrence rates.
  - Relieves leg pain
  - Improves cosmetic appearance.
  - Prevents complications of venous stasis—skin/pigment changes, ulcers, etc...
Ambulatory phlebectomy is indicated for disease not at the saphenofemoral and saphenopopliteal junctions.

- Branch varicosities of the greater saphenous vein
- Pudendal veins in the groin
- Reticular varices in the popliteal fold or lateral part of the thigh.
Ambulatory Phlebectomy
(Removal of Branch Varicosities)$^{21}$

- Removal of varicose veins through small (1-2 mm) incisions in the skin.

- Vein clusters are marked pre-operatively with the patient in the standing position.

- Incision usually done vertically to minimize lymphatic channel, except at the knee or ankle where the incision is transverse at the skin crease.

http://treatveins.com
Ambulatory Phlebectomy

- Varicosity is grasped with a crochet or hook—pulled out of the incision and grasped with a clamp.
- As much of the varicosity is then pulled out of the incision.
- Ligation of the ends of the veins not necessary—hemostasis is achieved by limb elevation and local pressure.
- Incisions are closed with steri-strips.

http://www.dermatologytimes.com
Ambulatory Phlebectomy

- **Risks:**
  - Bleeding
  - Hematoma
  - Sensory Nerve Damage
  - Chronic Foot Edema

- **Benefits:** can be performed in an outpatient setting.
  - Wounds leave very little, if any, scarring.

- **Considerations:**
  - Need to wear compressions garments after surgery
  - Does not prevent recurrence
TriVex²⁶

- Uses 2-3 incisions
- 1ˢᵗ instrument illuminates the varicose vein through the skin using fiber optics
- 2ⁿᵈ instrument is a vein resector that is guided next to the vein underneath the skin. Suction draws the vein into the tip of the vein resector where a rotating blade effectively removes the leg vein.

http://endo.smith-nephew.com
TriVex

http://endo.smith-nephew.com
Subfascial Endoscopic Perforator Vein Surgery (SEPS) 21

- Perforating veins in the calf connect the superficial to the deep venous systems and have valves that provide a one-way flow towards the deep system.

- The medial calf perforators—Cockett Perforators—do not originate from the GSV
  - Posterior arch vein to the paired posterior tibial veins
  - Stripping and removal of the GSV will not affect these perforators.
Subfascial Endoscopic Perforator Vein Surgery (SEPS) 21, 22

- Cockett I perforator is located **posterior** to the medial malleolus.

- Cockett II and III are located in the **distal calf** 2-4 cm posterior to the medial edge of the tibia.

- Presence if incompetent perforator in patients with advanced CVI is an indication for perforator ligation.

Gloviczki P, Yao, JST, eds. Handbook of Venous Disorders, 2nd ed. London: Arnold, 2001:18, Fig. 2.9.)
Subfascial Endoscopic Perforator Vein Surgery (SEPS) ²¹

- The “two-port” technique of SEPS is used in the U.S.: one port for the camera, and a separate ports for the instruments.
- Limb is first exsanguinated and a tourniquet is placed to provide a bloodless field.
- CO₂ is insufflated into the subfascial space.
- Subfascial space is explored and all perforator encountered are divided with harmonic scalpel, electrocautery, or clips.

http://www.njsurgery.com
Studies

- Belcaro et al, Angiology July 2000
  - Evaluated Sclerotherapy vs. Surgery vs. Surgery with Sclerotherapy
    - Randomized Control Trial with 10-year follow-up
Belcaro 2000

- Group B: 40—Surgery alone.
- Group C: 42—Surgery and Sclerotherapy.
Inclusion Criteria: 40-60 with simple superficial venous incompetence (uncomplicated by phlebitis, hemorrhage, or ulcers).

Excluded: DVT, superficial thrombophlebitis, obesity, diabetes other clinically significant diseases, or patients previously treated with surgery/sclerotherapy in the past.
Incompetence was evaluated with color duplex scanning. Patients were then evaluated every 2 years for 10 years with color duplex and AVP measurements.
# Table II

**Proximal (Saphenofemoral) and Distal (Thigh and Below-Knee) Venous Incompetence at 10 Years**

<table>
<thead>
<tr>
<th></th>
<th>No. Included Patients</th>
<th>Dropouts</th>
<th>Incompetence After 10 Years</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Saph-Fem</td>
</tr>
<tr>
<td>Endovascular sclero</td>
<td>39</td>
<td>7</td>
<td>6/32</td>
</tr>
<tr>
<td>Surgery + sclero</td>
<td>40</td>
<td>9</td>
<td>0/31</td>
</tr>
<tr>
<td>Surgery only</td>
<td>42</td>
<td>9</td>
<td>0/33</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>121</strong></td>
<td><strong>25</strong></td>
<td><strong>6/96</strong></td>
</tr>
</tbody>
</table>

Saph-Fem = sapheno-femoral, sclero = sclerotherapy.
Belcaro 2000

- At one year all treated patients were occluded.

- At later follow up (4-10 years) 6 patients became incompetent at the SFJ with Sclerotherapy alone.
Belcaro 2000

- **Conclusion:**
  - Sclerotherapy alone is an effective solution to varicose veins
  - But in the long term (10+ years) surgery is superior.
  - Surgery and Sclerotherapy is best.
Studies

- RCT comparing sclerotherapy and ambulatory phlebectomy.
De Roos 2003

- September 1996 to October 1998
- 49 patients were randomly assigned
to compression sclerotherapy.
- 49 to ambulatory phlebectomy.
- Doppler Ultrasound evaluated GSV incompetence.
De Roos 2003

1 year later:
- Sclerotherapy—12/49 (25%) recurred
- Surgery—1/49 (2.1%)

2 years later:
- Sclerotherapy—18/49 (37.5%)
- Surgery—1/49 (2.1%)
De Roos 2003

- Surgery is the treatment of choice for varicose veins.

- If sclerotherapy is chosen, and is unsuccessful after 2 treatments, surgery should be next step.
Studies

- 9 RCT trials with 3313 patients in the trials comparing sclerotherapy vs. surgery
“Trade-off between lower cost and fewer serious complications with sclerotherapy showing better early outcomes but surgical treatment showing more durable long-term benefits.”

“The exact lines between the use of one or the other are unclear.”
Randomized into 2 groups
- Group 1: 15—Endovenous Closure
- Group 2: 13—Vein stripping
Pt were evaluated with color duplex ultrasound to show GSV reflux.
After procedures, patients reported pain at rest, on standing, and walking with a 0 to 10 scale
A short term RAND-36 generic health-related quality of life questionnaire was given at 1 and 4 weeks post-op.

Patients were reexamined 7 to 8 weeks post-op with color duplex US.

Patients were also asked how much time off was needed and asked if they were satisfied with the procedure.
Cost was analyzed:

- Direct costs (surgery, hospital costs, etc.)
- Indirect costs (value of loss of productivity from work).
## Rautio 2002

<table>
<thead>
<tr>
<th>Condition</th>
<th>Closure (n=15)</th>
<th>Stripping (n=13)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saphenous nerve Paresthesia</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Clinical thrombophlebitis</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Local hematoma</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Thermal skin injury</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>7</strong></td>
<td><strong>7</strong></td>
</tr>
</tbody>
</table>
Rautio 2002

- Post-op pain score
  - Rest
    - 0.7 SD 0.5—Endovascular
    - 1.7 SD 1.3—Surgery
  - Standing
    - 1.3 SD 0.7—Endovascular
    - 2.6 SD 1.9—Surgery
  - Walking
    - 1.8 SD 0.8—Endovascular
    - 3.0 SD 1.8—Surgery
Sick Leave:
- 6.5 days SD 3.3—Endovascular
- 15.6 SD 6.0—Surgery

Direct Costs
- $794—Endovascular
- $360—Surgery

Indirect Costs (number of days lost x avg salary in Finland + 50% nonwage costs)
- $607—Endovascular
- $1566—Surgery
Rautio 2002

- **Total Cost:**
  - $1401 for Endovascular
  - $1926 for Surgery

- Difference of $525
- Investment of the VNUS Closure Generator
  - $3400 plus the catheter
Rautio 2002

Conclusion

- Endovascular easier on patient’s post-op pain when compared to surgery.
- More expensive for the hospital.
- Less expensive for society in general.
- Recommend long term study for varicose vein recurrence.
Lurie 2003

- 85 patients from 5 sites
  - France-2
  - Austria-1
  - US-2

- S&L group: 36
- RFO group: 44
Follow-up
- 72hrs
- 1 week
- 3 weeks
- 4 months.

Patients underwent CIVIQ2 quality-of-life questionnaire and ultrasound duplex scanning.
Results

- 36/36 of S&L were free of reflux or flow through the GSV at 72 hrs

- 36/43 were free of flow at 72 hrs in RFO group.
Complications were negligible at 4 months follow up.

**Table V. Complications and adverse findings reported through 3-week follow-up**

<table>
<thead>
<tr>
<th>Complications and adverse findings</th>
<th>72 h</th>
<th></th>
<th>1 wk</th>
<th></th>
<th>3 wk</th>
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<tr>
<td></td>
<td>RFO</td>
<td>S&amp;L</td>
<td>RFO</td>
<td>S&amp;L</td>
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<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>None</td>
<td>19</td>
<td>43.2</td>
<td>6</td>
<td>16.7</td>
<td>&lt;.05</td>
<td>15</td>
</tr>
<tr>
<td>Infection</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>5.6</td>
<td></td>
<td>0</td>
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<tr>
<td>Superficial venous thrombosis</td>
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<td>0</td>
<td>1</td>
<td>2.8</td>
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<td>1</td>
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<tr>
<td>Tenderness</td>
<td>2</td>
<td>4.5</td>
<td>9</td>
<td>25.0</td>
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<td>5</td>
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<tr>
<td>Lymphocele</td>
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<td>0</td>
<td>0</td>
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<td></td>
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<tr>
<td>Bleeding from stab wound</td>
<td>3</td>
<td>6.8</td>
<td>3</td>
<td>8.3</td>
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<td>0</td>
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<tr>
<td>Ecchymosis</td>
<td>12</td>
<td>27.3</td>
<td>19</td>
<td>52.8</td>
<td>&lt;.05</td>
<td>14</td>
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<tr>
<td>Erythema</td>
<td>6</td>
<td>13.6</td>
<td>3</td>
<td>8.3</td>
<td></td>
<td>2</td>
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<tr>
<td>Hematoma</td>
<td>7</td>
<td>15.9</td>
<td>14</td>
<td>38.9</td>
<td>&lt;.05</td>
<td>6</td>
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<tr>
<td>Paresthesia</td>
<td>5</td>
<td>11.4</td>
<td>2</td>
<td>5.6</td>
<td></td>
<td>10</td>
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<tr>
<td>Hyperpigmentation</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
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</tbody>
</table>

RFO, Radiofrequency obliteration; S&L, stripping and ligation.
Lurie 2003

- Time to return to normal activities
  - 1.15 days – RFO
  - 3.89 days – S&L

- Return to work
  - 4.7 days – RFO
  - 12.4 days – S&L

- Less pain reported by RFO vs. S&L
Two year follow-up, Eur J Endovasc Surg, 2005

- Recurrence rate was 14.3% for RFO and 20.9% with S&L
- Recurrence rate was numerically lower in the RFO group at 2 years but not to the level of statistical significance (CI 0.7-28)
28 patients were randomized

- 15 RFO group
- 13 Stripping group

Follow up at 7-8 weeks, and also at 3-year follow up.
At 3-year follow up

- Recurrence was detected by surgeon
  - 5/15 (33%) in RFO
  - 2/13 (15%) in Stripping group

- Recurrence was noticed by patient
  - 4/15 (27%) in the RFO
  - 2/13 (15%) in stripping group
Perala 2005

- Conclusion
  - “somewhat less satisfactory results with radiofrequency endovenous obliteration method compared to the conventional stripping operation with SFJ ligation along with its tributaries.”
Conclusions

- Lifestyle changes must first be offered for patients with moderate disease.

- Surgery is the treatment of choice for severe varicose veins when compared to sclerotherapy in the long term (5-10+ years post-op).

- When compared to RFO:
  - RFO more expensive for hospital.
  - RFO less pain post-op and quicker recovery time.
  - RFO may or may not have increased rate of recurrence of varicose veins when compared to surgery—more studies need to be done.
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