The Office Based (OB) Chiva Protocol

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Acronyms

US Ultrasound

PW Pulsed Wave

ECD EchoColorDoppler

SFJ Saphenous Femoral Junction

SPJ Saphenous Popliteal Junction

TV Terminal Valve

PTV Pre-Terminal Valve

GSV Greater Saphenous Vein

SSV Shorter Saphenous Vein

CFV Common Femoral Vein

FV Femoral Vein

SVT Superficial Venous Thrombosis

CHIVA Chirurgie Hemodynamique de l'Insufficience Veineuse en Ambulatoire

OB-CHIVA Office Based CHIVA

RDC (Riobamba Draining Crossotomy) G-EV?C-C1

RLDC (Riobamba Laser Draining Crossotomy) G-EVTC-C1

Using several Laser frequencies, RF and Steam

- 808 G-EVTC-(808-Dio)-C1
- 980 G-EVTC-(980-Dio)-C1
- 1470 G-EVTC-(1470-Dio)-C1
- 1470-Radial G-EVTC-(1470-Dio)-R-C1

RLDC-fixed length (Riobamba Laser Draining Crossotomy) G-EVTC-C1-fixed

RXDC (Riobamba eXstensible Draining Crossotomy) G-EVTC-X-C1

RXDC (Riobamba eXstensible Draining Crossotomy + Devalvulation) G-EVTC-X-CDV

RRDC (Riobamba RF draining crossotomy) G-EVTC-RF C1

RMDC (Riobamba mechanical draining crossotomy) G-EVMC-C1

RSDC (Riobamba Steam draining crossotomy) G-EVTC-ST C1

WGD Wire Guided Devalvulation

TD Tributary Disconnection

TA Tributary Access

RET Reflux Elimination Test

The protocol requires a minimal basic knowledge about US venous examination. In addition, a non-detailed knowledge of the Hemodynamic Surgery CHIVA is preferred.

However, everyone will be able to read the text, as any required information is available in the protocol.

CHIVA and OB-CHIVA

A premise is necessary:

CHIVA is a hemodynamic strategy, which requires an adequate tactics. The procedures of the **OB-CHIVA** here described to fit the tactics to the Office environment could show in this experimentation inadequate results, compared to classic CHIVA interventions. In this first application, it's better to declare a substantial difference between CHIVA and OB-CHIVA.

Differences

Some arch tributaries are sacrificed in OB-CHIVA, so that in theory a difference could exist in drainage and recurrence rates.

Using washing vessels leaves a small stump at the SFJ. The use of washing vessels was Introduced for the SSV CHIVA treatment (Passariello, 1991, 1992), but became a standard in SFJ thermal ablation, being practiced almost everywhere. However, no reliable study is available on this issue.

Analogies

LASER closure could be regarded only as a different tactical method to eliminate SFJ reflux with a CHIVA Crossotomy. Other currently available methods to perform a CHIVA Crossotomy are the section-ligature , the isolated ligature, the clip, the TSFL technique (Delfrate, 2010). In analogy with all these methods, a recanalization is possible.

Aim

In this preliminary open study the aim is

- To check on a greater basis the feasibility of the OB-CHIVA, going over the first anecdotal results.
- To set a comparison among detected recurrence rate and data taken from literature about CHIVA recurrence.
- To catch the opportunity to get some data about SFJ stump evolution and the role of washing vessels.
- To check the arch recanalization rate of the procedure.

US Device settings

Steering

No one. Use a rectangular box.

Direction

Set a positive signal (by convention red) for the toward-probe flow and a negative signal (by convention blue) for the away-of-probe flow.

Range

The same range is used for PW and Color Doppler. Set a +/- 5 cm/s or +/- 10 cm/s interval to get a good sensitivity to slow velocities, while higher ones will fall at the limit of the aliasing or over it.

GSV Flow detection

General rules

Transverse cross-section. The probe is directed upward, at 45 degrees with the skin. The probe detects the toward-probe 45 degrees velocity component . A positive signal is a descending/refluxing flow, a negative signal is an ascending/physiologic flow.

GSV trunk

The angle line must be absent or vertical.

SFJ TV

Longitudinal section. No steering. The probe must visualize the CFV and the SFJ. ***Put the sample volume in the CFV just near the SFJ. The angle line must be directed into the SFJ***, as we want to detect SFJ incompetence. Aligning instead with the CFV direction detects only the CFV incompetence. A positive signal is a toward the surface/refluxing flow, a negative signal is a centripetal/physiologic flow.

Transverse cross-section. It's able to visualize the commissural reflux. The probe must visualize the CFV and the SFJ. (two near circles) . ***Put the sample volume in the CFV just near the SFJ. The angle line must be directed into the SFJ.***

SFJ PTV

Same section as for TV. No steering. ***Put the sample volume on the arch, soon after the SFJ. In the longitudinal section the angle line must be aligned with the SFJ arch***. A positive signal is a toward the surface/refluxing flow, a negative signal is a centripetal/physiologic flow.

Reflux detection

Use a ***Valsalva manoeuvre*** elicited by insufflating (systole) into a common drinking straw closed at one terminal with a knot (**Franceschi straw**). In a valid manoeuvre flow must revert to the physiologic direction during rebreathing (diastole).

SFJ Anatomy

Count the number of tributaries you want to use as washing vessels (***#wash***) and measure the max washing caliber (***ϕ wash***), and the distance from the SFJ to the last arch washing tributary (***SFJ-free*** in cm).

Count the number of tributaries you want to use as draining vessels (***#drain***) and measure the max draining caliber (***ϕ drain***), and the GSV ***length to be treated*** (***L*** in cm) from the last washing to the first draining tributary.

Study design

The protocol includes only OB CHIVA cases with Crossotomy performed with alternative methods (LASER, RF, Steam). Foam isn't excluded owing to an "a priori" reason, but only because at the moment foam doesn't seem to be able to get punctual effects on veins.

Exclusion criteria

Deep veins involvement (thrombosis or incompetence).

Previous SVT.

Pelvic shunt. (A Valsalva increase in descending flow in the up-to-down branches of the GSV arch)

Commissural SFJ reflux.

Indications

A correct indication can be achieved synthetically using Shunt definitions. However, the same result is got avoiding the hemodynamic terms as follows.

The prerequisite for treatment is the ***SFJ TV incompetence***.

If this is the case, in order to classify and understand the hemodynamic behavior of the system we need to know

- If the GSV reflux is ***deviated*** or not (***Shunt I***) towards ***at least one incompetent tributary***.
- If this last is the case, does the GSV trunk reflux ***disappear*** (***RET+***, ***Shunt III***) or not (***RET-***, ***Shunt I+II***) while ***pressing the tributaries with a finger*** (with a little help from our friends). (Franceschi, 2009)

This evaluation grid allows the classification and the choice of the therapy. (Flow Chart)

Number of cases

This is an open study. There is no control on the number of cases.

For each patient report the height, the height of the groin and of the re-entry perforator, the Venous Clinical Severity Score (VCSS) and for Quality of Life (QoL) the Aberdeen Varicose Veins Score (AVVQ) and the RAND-36.

RDC Tactics (G-EV?C C1)

RLDC (G-EVTC C1)

Put the tip of the Laser fiber at the end of the last washing tributary, at SFJ-free cm from the junction and treat a L length segment until the first draining tributary. Declare the ***Power*** (***w***), the ***Velocity of Retraction*** of the fiber (***v***) and measure the ***length really treated*** L_T, which generally differs from L. Compute or better measure the administered Energy (***E***) and the ***LEED***=w/v.

For a typical therapy w=14 W, v=0.1 cm/s, LEED=140 J/cm.

Declare if you use or not of a catheter and if you apply the tumescence, declare the temperature, composition and volume of the components: saline, bicarbonate (which %), adopted anesthetics.

Fixed RLDC (G-EVTC C1-fixed)

Starting as described before after the last washing vessel, treat a ***fixed 7 cm length*** of the trunk. This simplification in the procedure doesn't allow to omit the detailed study of the SFJ, as the measures will make it possible to understand if the fixed length method can be really compared to the ultrasound guided detailed study of the GSV arch.

RXDC (G-EVTC-X C1)

The X letter means eXtensible. The RLDC could be extended to other thermal, mechanical and procedures.

RRDC (G-EVTC-RF C1)

RF is a very precise procedure with a fixed length treatment. Probes are of 7 cm length, but recently also 3.5 cm probes are available.

RSDC (G-EVTC-ST C1)

The use of Steam is only a fascinating hypothesis. As the steam jet effect decreases with distance, it could be possible to use a fixed length (i.e. 7 cm from the SFJ-free point) to treat a GSV segment. For this reason The RSDC could be only a fixed length procedure.

RMDC (G-EVMC C1)

Mechanical ablation is a good candidate to compete with LASER for its precision. The procedure could be an ultrasound guided projected crossotomy.

WGD

You can make a classic Devalvulation during a flush phlebectomy or a Wire Guided Devalvulation (WGD)

Use a 18 G needle, a wire guide, a dilatator generally included in the catheter kit.

WGD virtual dissection

If the distance from the GSV access point to the valve is less than the dilatator length, you can use a WGD virtual dissection. Using the same GSV venous access than SFJ treatment, retract the needle until only the tip is inside the vein, then pull the skin upwards, invert the needle direction and push it into the vein and then insert the wire guide.

Only now you can retract the needle completely and stop a while, if you like, releasing the skin. At this moment the wire in inside the vein in the inverted direction.

Pull upwards the skin and insert the dilatator until you reach the valve. Don't release the skin and compress upwards to close the valve. Now push the dilatator and pass through the valve many times. Finally retract the dilatator and release the skin.

You can follow the entire procedure by US, checking the phases in the sequence.

In case you use a catheter as a fiber shield, the start of the procedure is different: remove the fiber (unlock it) and re-insert the wire, before removing completely the shield. Now insert the needle following the wire until the tip enter the vein. The remaining part of the procedure is identical.

Tributary disconnection

Disconnection can be performed classically by a flush phlebectomy, which is an ambulatory/office quick procedure. Anyway, also LASER and Foam could be used with different effects.

Tributary access

The tributary venous access (proposed by Ermini) can be used as an alternate way to reach and treat the SFJ. It can be used with any device. Performing the tumescence when needed, treating and then retracting the device allows to pass through the tributary just before exiting. A new peripheral tumescence and treatment allows then a single access double procedure, which reduces execution time and invasivity.

The method cannot be applied when the reflux isn't deviated into an incompetent tributary, though this case is rare.

In case of a RET+ deviated reflux, a devalvulation strategy could be chosen. However, the TA method doesn't allow the reuse of the same venous access through a WGD virtual dissection, so that you must access the GSV directly in the downward direction.

Informed Consent

To be written.

Ethical considerations

To be written.

No Disclosure Agreement

To be written.

Follow up

Perform a follow up examination soon after the procedure, 1 week, 1 month, 6 months, 1 year and 3 years later.

For each follow up check the GSV reflux, the Tributary reflux, SFJ free, #wash, ϕ wash, #drain, ϕ drain.

In addition, measure the length of the GSV segments of total and partial occlusion above and below the treated zone.

Detect pigmentation and any thrombosis in extra-saphenian segments. Add any notes you consider important and report the VSSS and the Quality of Life (QoL form).

Vasculab Message

To be written.

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