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METHODOLOGY

Office based conservative hemodynamic correction of venous insufficiency protocol

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Fausto Passariello[1]
Stefano Ermini[2]
Erika Mendoza[3]
Massimo Cappelli[4]
Roberto Delfrate[5]
Claude Franceschi[6]

[1]Centro Diagnostico Aquarius, Napoli, Italy; [2]Private Practice, Grassina, Italy; [3]Private Practice, Wunstorf, Germany; [4]Private Practice, Firenze, Italy; [5]Casa di Cure Figlie di Maria, Cremona, Italy; [6]Hopital St Joseph, Paris, France

Abstract: The office based (OB)-conservative hemodynamic correction of venous insufficiency (CHIVA) protocol is aimed at transferring CHIVA procedures to an office environment. The protocol will check the feasibility of OB-CHIVA, data pertaining to recurrence, and will offer the opportunity to study saphenous femoral junction (SFJ) stump evolution, the role of the washing vessels and the arch recanalization rate, and gather new data about the effect of the length of the treated saphenous vein. This simplified diagnostic procedure will allow an essential ultrasound examination of the venous net while a schematic and easily readable algorithm guides therapeutic choices. The Riobamba draining crossectomy (RDC) tactic is composed of a set of OB procedures. While some of these procedures are, at the moment, only proposals, others are already applied. Devices generally used in ablative procedures such as LASER, RF, steam, and mechanical devices are used in this context to serve as conservative interventions for CHIVA. New techniques have also been proposed for devalvulation and tributary disconnection. Detailed follow-up is necessary in order to determine the effects of therapy and possible disease evolution. Finally, information is added about the informed consent and the ethical considerations of OB-CHIVA research.

Keywords: CHIVA, office based procedures, LASER, RF, steam

History and anecdotal cases

The Riobamba laser draining crossectomy (RLDC) protocol was designed in 2009 by Passariello in the city of Riobamba, Ecuador. Some cases were performed following the present protocol on Shunt I and I+II configurations, in collaboration with the surgical team of Morrison and later of King.

The need for an office based (OB)- conservative hemodynamic correction of venous insufficiency (CHIVA) intervention arose because only simplified resources are available in non-typical surgical settings. The OB procedure was introduced in order to reduce the required resources and generic surgical risk, especially risks associated with CHIVA crossectomy. In addition, this protocol tries to answer the "often faced but never solved issue" of a minimally invasive surgical CHIVA intervention.

The objective of an OB-CHIVA protocol is to ensure that it is quick and easy (or hopefully a little bit quicker and easier) than the currently available OB ablative procedures. This procedure was presented to the II Hemodynamic Conference in Phoenix in 2009,[1] to the American College of Phlebology Meeting in Palm Desert, California also in 2009,[2] and to the XI Meeting of the Association Europea de Chiva (AECH) in Puerto Madryn, Argentina in 2010;[3,4] the OB-CHIVA issue was also chosen as a topic for the next meeting in Hannover.

Correspondence: Fausto Passariello
Centro Diagnostico Aquarius, Napoli
Italy

The actual version of the protocol is essentially a thorough detailed extension that allows the treatment of other network configurations. In addition, a modified format will accept also cases made using a different technique proposed by other groups, in particular RF cases presented by Erika Mendoza in Hannover in 2012.

The protocol requires a minimal basic knowledge of ultrasound venous examination. In addition, non-detailed knowledge of hemodynamic surgery CHIVA is preferred. However, everyone should be able to read the text, as all required information is available in the protocol.

CHIVA and OB-CHIVA

Premise

CHIVA is a hemodynamic strategy that requires an adequately skilled technician. The OB-CHIVA procedures were designed to be appropriate for an office environment and the goal is to determine if this experimentation produced adequate results compared to classic CHIVA interventions. However, it is best first to define the substantial differences between CHIVA and OB-CHIVA.

Differences

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

Tributaries of the greater saphenous vein (GSV) arch have great variability, but generally it is possible to divide them in two groups (Table 1):

- The near to saphenous femoral junction (SFJ) group is composed of the epigastric, pudendae, and iliac circumflex tributaries (often a common trunk with the epigastric).
- The far from SFJ group. Apart from the near incompetent tributaries (which must always be sacrificed), only the far group is a candidate to be eliminated using the endovenous procedure.

Using washing vessels leaves a small stump at the SFJ. The use of washing vessels was introduced for the shorter saphenous vein (SSV) CHIVA treatment,[5,6] but became a standard in SFJ thermal ablation, and is practiced almost everywhere. However, no reliable study is available on this issue.

LASER closure can only be regarded as a different tactical method to eliminate SFJ reflux with a CHIVA crossectomy (Figure 1A–C). Other currently available methods to perform CHIVA crossectomy are section-ligature, isolated ligature, the clip, and triple saphenous flush ligation (TSFL) technique; with all these methods, recanalization is possible.[7]

Aim

In this preliminary open study the aim is:

- To check on a greater basis the feasibility of the OB-CHIVA, by reviewing the first anecdotal results.
- To set a comparison among detected recurrence rates and data taken from the literature regarding CHIVA recurrence.
- To gather data regarding SFJ stump evolution and the role of washing vessels.
- To determine the arch recanalization rate of the procedure.

Ultrasound (US) device settings

Steering

None; a rectangular box is used.

Table 1

	CHIVA	OB-CHIVA
Washing	No one in GSV, sometimes used in SSV	Always
Draining	All the arch tributaries (no one is ligated)	Some tributaries downward the treated arch segment
Stump	Absent (flush ligation)	Small stump with washing vessels
Sacrificed arch tributaries	Only SFJ incompetent tributaries	Generally the far group of SFJ tributaries or all the ones lower than an incompetent one, if any
Invasivity	Surgical	Endovenous
Environment	Ambulatorial	Office based

Abbreviations: CHIVA, conservative hemodynamic correction of venous insufficiency; GSV, greater saphenous vein; OB, office based, SFJ, saphenous femoral junction; SSV, shorter saphenous vein.

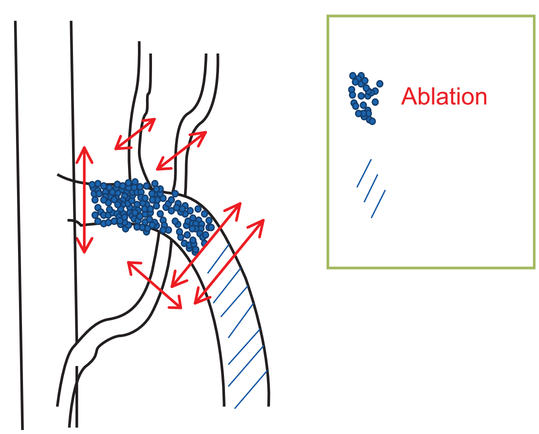

Figure 1 Differences between several methods for treating the saphenous arch: (**A**) traditional crossectomy; (**B**) CHIVA crossectomy; (**C**) RLDC Crossectomy (LASER).

Abbreviations: CHIVA, conservative hemodynamic correction of venous insufficiency; LASER, ; RLDC, Riobamba laser draining crossectomy.

Direction

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

Range

The same range is used for pulsed wave (PW) and color Doppler. In order to get good sensitivity at slow velocities, set a ±5 cm/second or ±10 cm/second interval, while higher values will either 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 to the skin. The probe detects the toward-probe 45 degree velocity component. A positive signal is a descending/refluxing flow, while a negative signal is an ascending/physiologic flow.

GSV trunk

The angle line must be absent or vertical.

SFJ terminal valve (TV)

The longitudinal section requires no steering: the probe must visualize the common femoral vein (CFV) and the SFJ. This can be accomplished by putting 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 CFV incompetence. A positive signal is toward the surface/refluxing flow, a negative signal is a centripetal/physiologic flow.

Transverse cross-section is able to visualize the commissural reflux. The probe must visualize the CFV and the SFJ (two near circles). This can be accomplished by putting the sample volume in the CFV just near the SFJ. The angle line must be directed into the SFJ.

SFJ pre-terminal valve

For this technique, the same section is used as for TV. No steering is required; the sample volume is put on the arch, immediately after the SFJ. In the longitudinal section, the angle line must be aligned with the SFJ arch. A positive signal is toward the surface/refluxing flow, a negative signal is a centripetal/physiologic flow.

Reflux detection

Use the Valsalva maneuver elicited by insufflating (systole) into a common drinking straw closed at one terminal with a knot (Franceschi straw, Figure 2). In a valid maneuver, flow must revert to the physiologic direction during rebreathing (diastole).

SFJ anatomy

Count the number of tributaries to be used as washing vessels (#wash) and measure the max washing caliber (ϕwash), and the distance from the SFJ to the last arch washing tributary (SFJ-free in cm).

Count the number of tributaries to be used as draining vessels (#drain) and measure the max draining caliber (ϕdrain), and the GSV length (L) to be treated (in cm) from the last washing to the first draining tributary. Draining and washing vessels are defined as part of the project before the intervention. During the intervention, the surgeon tries to respect the project.

During the follow-up, the ultrasonographer detects if the draining and washing vessels are still open, their number, and their caliber.

Study design

The protocol includes only OB-CHIVA cases with crossectomy performed with alternative methods (LASER, RF, and steam). Foam was excluded because, at the moment, foam doesn't seem to be able to get punctual effects on veins.

Exclusion criteria

Exclusion criteria were: deep vein involvement (thrombosis or incompetence); previous SVT; pelvic shunt (a Valsalva increase in descending flow in the up-to-down branches of the GSV arch); and commissural SFJ reflux.

Inclusion criteria

A correct indication can be achieved synthetically using shunt definitions. However, the same result is obtained by avoiding the hemodynamic terms as follows:

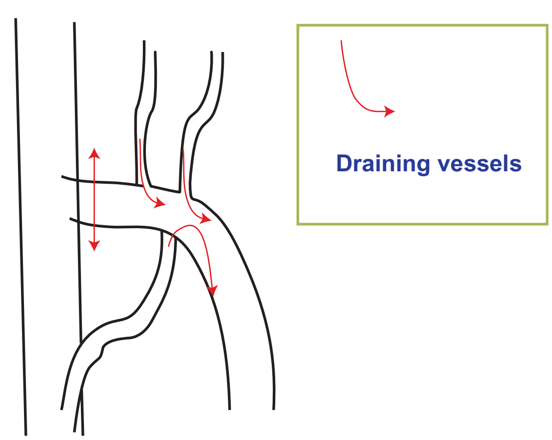

Figure 2 (Above) A drinking straw, (Below) A Franceschi straw (make a knot).

The prerequisite for treatment is 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; and if the latter is the case, does the GSV trunk reflux disappear (reflex elimination text [RET]+, Shunt III) or not (RET-, Shunt I+II) while pressing the tributaries with a finger.[8]

This evaluation grid permits the classification and choice of the therapy (Figure 3).

Number of cases

This is an open study; there is no control on the number of cases. The protocol will end when at least one of the two following conditions are satisfied: 500 treated cases or 1-year from the official publication. The analysis of the results will then be a guide for setting up a more robust protocol (with the same or a modified method) or will suggest abandoning the study.

For each patient the height, the height of the groin and of the re-entry perforator, the venous clinical severity score (VCSS), quality of life (QoL), the Aberdeen varicose veins score (AVVQ) and the RAND-36 will all be reported.

Riobamba draining crossectomy (RDC) tactics

Riobamba laser draining crossectomy (RLDC; G-EVTC C1)

For RDC,[9] the tip of the laser fiber is placed at the end of the last washing tributary, 1 (SFJ-free) cm from the junction and one L length segment is treated until the first draining tributary. The power (w) and the velocity of retraction of the fiber (v) are recorded, and the length treated (L_T), which generally differs from L, is measured. Finally, the administered energy (E) and the LEED = weight/volume are computed or, even better, recorded.

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

Also, the use or lack of use of a catheter and the tumescence, the temperature, composition, and volume of the components (saline or bicarbonate; including the percentage), and adopted anesthetics should all be determined.

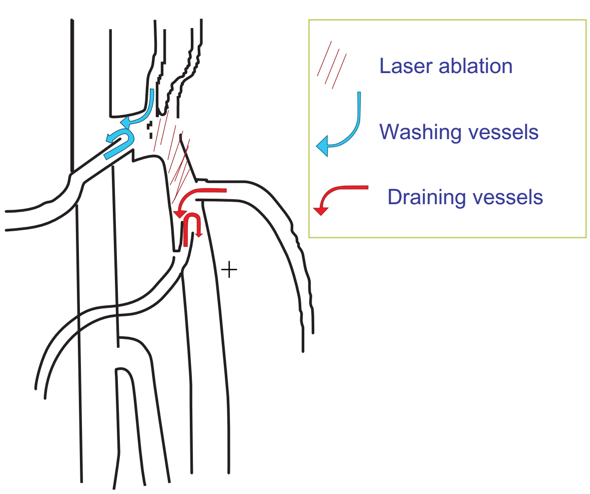

Figure 3 The flow chart of the RDC algorithm.
Abbreviation: RDC, Riobamba draining crossectomy.

Fixed RLDC (G-EVTC C1-fixed)

Starting as described before after the last washing vessel, a fixed 7 cm length of the trunk is treated. This simplification in the procedure does not permit omission of a detailed study of the SFJ, as the measurements will make it possible to understand if the fixed length method can really be compared to the US guided detailed study of the GSV arch.

RXDC (G-EVXC-C1)

The "X" letter stands for extensible. The RLDC can be extended to other thermal and mechanical procedures.

RRDC (G-EVTC-RF C1)

RF is a very precise procedure with a fixed length treatment. RF works in cycles of 20 seconds, reaching a target temperature of 120°C. During catheter pullback, the device automatically regulates the emitted power to maintain the temperature. Planning the therapy requires only choosing the number of cycles per segment and the number of segments.

The electrode at the tip of the catheter is 7 cm long, though a new device provides a length of 3 cm. Sequential electrode positions can usually overlap for 0.5 cm and the treated segments are almost 6.5 cm long.

In OB-CHIVA, only one segment near the SFJ is treated for a length of 7 cm (no overlap). Thus, the only variable to be fixed is the number of cycles; ie, the overall time length. RF use in OB-CHIVA was proposed and performed by Erika Mendoza in 2012.

RSDC (G-EVTC-ST C1)

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

Wire guided devalvulation (WGD)

For this procedure, you make a classic devalvulation during a flush phlebectomy or a WGD, using a 18 gauge 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, a WGD virtual dissection can be used. Using the same GSV venous access as 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. Next, retract the needle completely and stop if needed, releasing the skin. At this moment, the wire inside the vein is in the inverted direction. Next, pull the skin upward and insert the dilatator until the valve. Don't release the skin and compress upward to close the valve. Now, push the dilatator and pass through the valve many times. Finally, retract the dilatator and release the skin. The entire procedure should be followed by US, checking the phases in the sequence.

If a catheter is used as a fiber shield, the start of the procedure is different: remove the fiber (unlock it) and re-insert the wire before completely removing the shield. Now, insert the needle following the wire until the tip enters the vein. The remaining part of the procedure is identical as previously mentioned.

Tributary disconnection

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

Tributary access

The tributary venous access (proposed by Ermini) could be used as an alternate way to reach and treat the SFJ and it can be used with any device. Performing the tumescence when needed, treating and then retracting the device allows passage 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. This method cannot be applied when the reflux is not deviated into an incompetent tributary, though these cases are rare.

In case of a RET+ deviated reflux, a devalvulation strategy could be chosen. However, the tributary access method does not allow the reuse of the same venous access through a wire guided virtual dissection; thus, the GSV is accessed directly in the downward direction.

Follow-up

A follow-up examination will be performed soon after the procedure at the 1-week, 1-month, 6 months, 1-year, and 3-year mark.

For each follow-up check, the GSV reflux, the tributary reflux, SFJ free, #wash, ϕwash, #drain, and the ϕdrain should be recorded.

In addition, the length of the GSV segments of total and partial occlusion above and below the treated zone should be measured and the state of the phlebectomies should be reported.

Pigmentation and any thrombosis in extra-saphenian segments should be detected and any notes considered important as well as the VCSS, the AVVQ, and RAND-36 scores should be reported.

Informed consent

Informed consent consists of a general part common to other procedures cited in the protocol and a specific one, which deals with the choice of the procedure. Essentially, the patient should be aware of the advantages and disadvantages of classic CHIVA surgery, the proposed OB-CHIVA, and the other procedures, including ablative (foam) and conservative (ASVAL). Another issue involves the type of OB-CHIVA procedure to be applied. Generally, as the OB-CHIVA protocol is open also to small centers where only a limited number of procedures are available, it can be assumed that only a few methods are proposed, although the information provided in the informed consent must be complete.

Essentially CHIVA and OB-CHIVA share the same strategy, apart from the differences already highlighted. However, they differ strongly instead in the tactical choices. Thus, adequate information should be provided in order for the patient to make an educated choice.[10]

The patient should also be informed about the loss or preservation of the saphenous heritage, its potential use in cardiac or arterial diseases, and the availability and cost of new materials for arterial grafts.

Ethical considerations

Though some RCTs[11] comparing stripping and CHIVA, LASER and CHIVA, and so on, are available at the moment, no clear recognized superiority is assigned to any one procedure.

OB-CHIVA is a slightly modified CHIVA procedure designed to use some technical facilities adopted in ablative procedures. The only difference is the reduced length of saphenous treatment (almost 5 cm), much less than the length generally treated in laser procedures (25–35 cm).

However, no reliable study is available about the length of treatment of the saphenous trunk. Thus, this study does not oblige an irrational technical choice and instead could help clarify the effect of the venous length on the treatment.

Unlike CHIVA but similar to LASER and RF, OB-CHIVA leaves some tributaries of the arch and uses them as washing vessels. This cannot constitute an ethical issue as it is a technical choice commonly practiced in several procedures. Thus, the protocol is ethically acceptable and could serve to study the evolution of SFJ stumps.

These ethical considerations should be submitted to an Ethical Committee, if needed in the health structure where the protocol is applied, whether in a public, accredited, or partially/totally private institution.

Local changes are required to comply with local laws and common uses. A translation of the current text could be required, according to local laws.

Finally, essential help should be given locally to centers that join the protocol.

No disclosure agreement

During the experiment, this research will have a public content, ie, published in a scientific magazine and on a website, and a private website, disclosed only to joining centers and supporting companies, consisting of details, forms, and organization texts and partial results and conclusions, as well as partial changes to the procedures to assure better management of the research.

People, centers, and companies joining the protocol will be requested to sign a non-disclosure agreement in order to avoid the diffusion of private contents, just before the final publication, and must accept to pay a fee in case they break the non-disclosure rule.

Disclosure

The authors report no conflicts of interest in this work.

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