



MEET 2014
MULTIDISCIPLINARY EUROPEAN
ENDOVASCULAR THERAPY

Preservation of Saphenous Trunks: EXTERNAL VALVULOPLASTY

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Faculty disclosure *Sante Camilli MD*

***I am the proposer of the
Stretching Valvuloplasty technique,
but ...***

I have no financial relationships to disclose.

Varicose Veins and SFJ Reflux

What Treatment?

- **Onida S** et Al (UK). Practitioner **2013**;257:21-4.

Improving the management of varicose veins.

"... recommends that **endothermal ablation**, in the form of **RF or Laser treatment**, should be offered as treatment"

- **Carroll C** et Al (UK). Health Technol Assess **2013**;17:1-141.

Clinical effectiveness and **cost-effectiveness** of minimally invasive techniques to manage varicose veins: a systematic review and economic evaluation.

"... **Foam Sclerotherapy** might offer the most cost-effective **alternative to stripping**, within certain time parameters."

Trials with 5 years f-u

(HighLigation+Stripping, EVLAser)

RCT on 137 legs, up to 5 years	HL+S	EVLA
Clinical recurrence	55%	47%
Reoperation	38%	39%
VCSS (Venous Clinical Severity Score)	=	=

Rasmussen L. (DK): J Vasc Surg. 2013;58:421-6

... did not show **any significant difference**
between the two groups

Varicose Veins and SFJ Reflux

Causes of Recurrence

- **Ostler AE et Al (UK). Phlebology 2014. Strip-tract revascularization as a source of recurrent venous reflux following high saphenous tie and stripping: results at 5-8 years after surgery.**

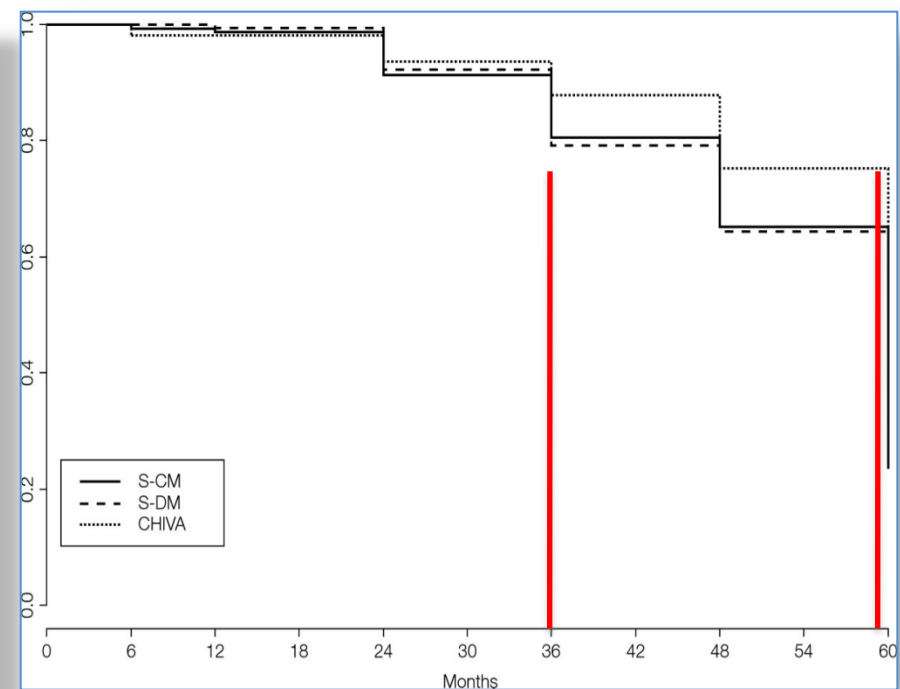
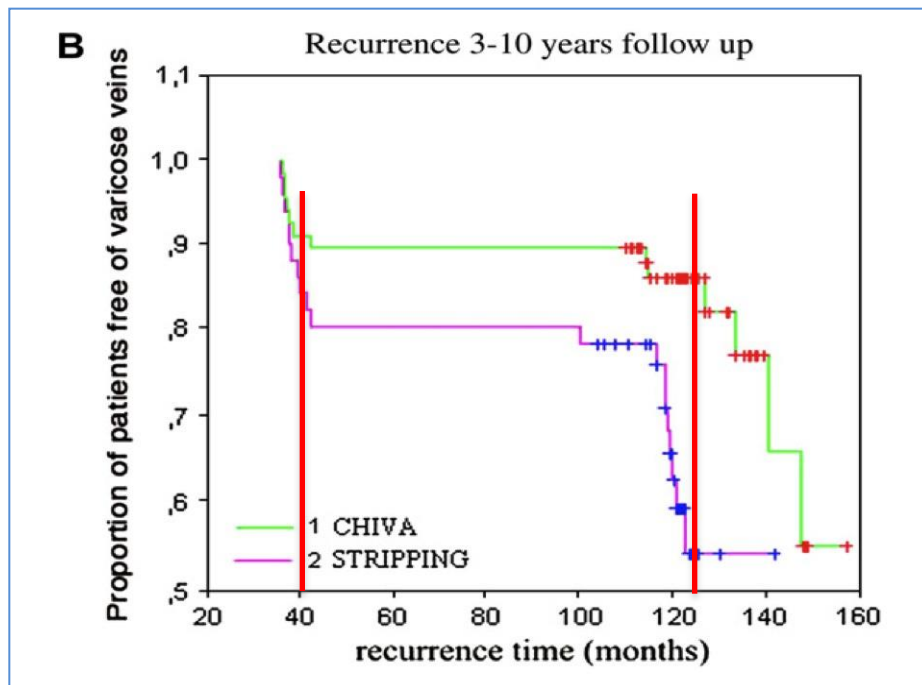
“... 82% of legs of patients showed some strip-tract revascularization and reflux, ... 12% showed total revascularization and reflux of the stripped GSV”

- **Recek C (A). Int J Angiol 2012;21:181–6. The hemodynamic paradox as a phenomenon triggering recurrent reflux in varicose vein disease.**

“... explains why varicose vein and reflux recurrence can occur after any mode of therapy.”

The Matter: VVs Recurrence

Diverging lines after 3 years f-u

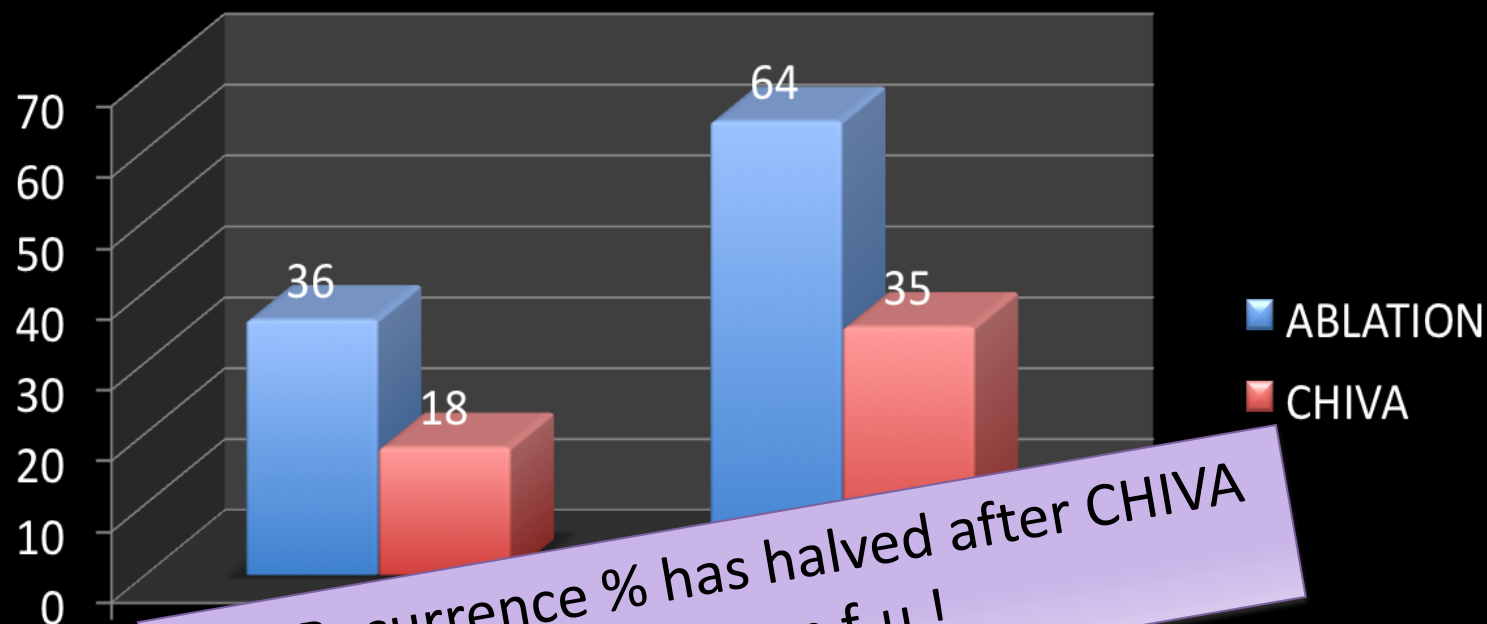


[1] Carandina S. et Al: *Eur J Vasc Endovasc Surg* 2008;35(2):230-7

[2] Parès JO et Al: *Ann Surg* 2010;251(4):624-31

The Matter: VVs Recurrence

Recurrence Rate of Varicose Veins at late F-U after
Ablative Vs. Conservative strategy



The Recurrence % has halved after CHIVA
at long-term f-u !

[1] Carandina S. et Al: Eur J Vasc Endovasc Surg 2008;35(2):230-7

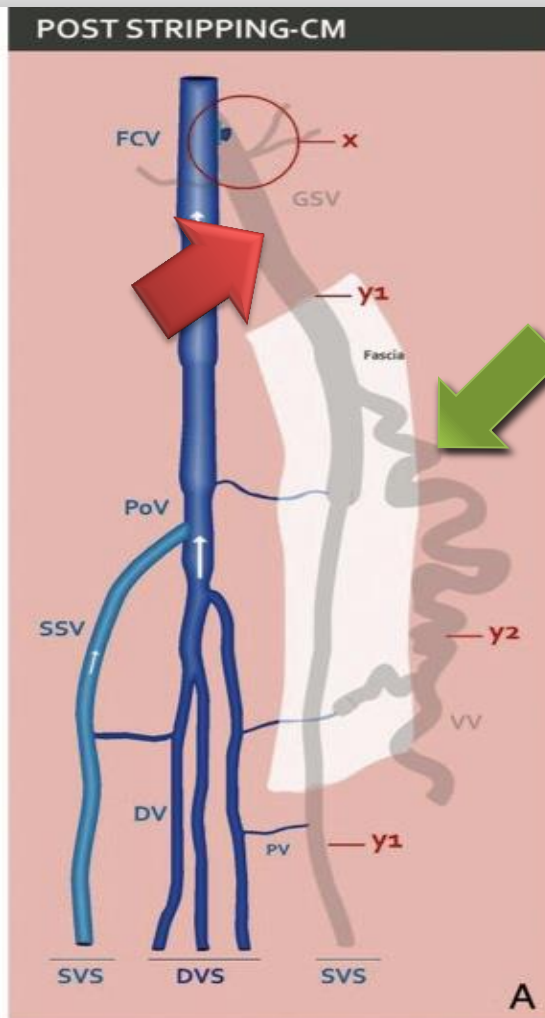
[2] Parès JO et Al: Ann Surg 2010;251(4):624-31

Why the Gap?

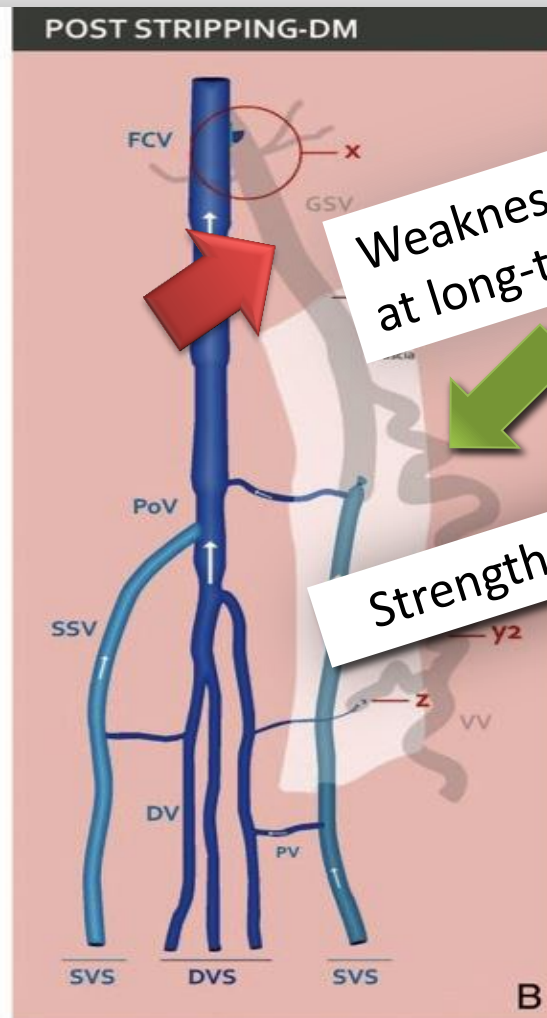
- Ablation Vs CHIVA -

- Each study can be criticized for anything,
but until a more reliable one proves the contrary,
it remains valid
- Between the two strategies, CHIVA shows anatomic
& patho-physiological **peculiar** difference:
the VGS preservation

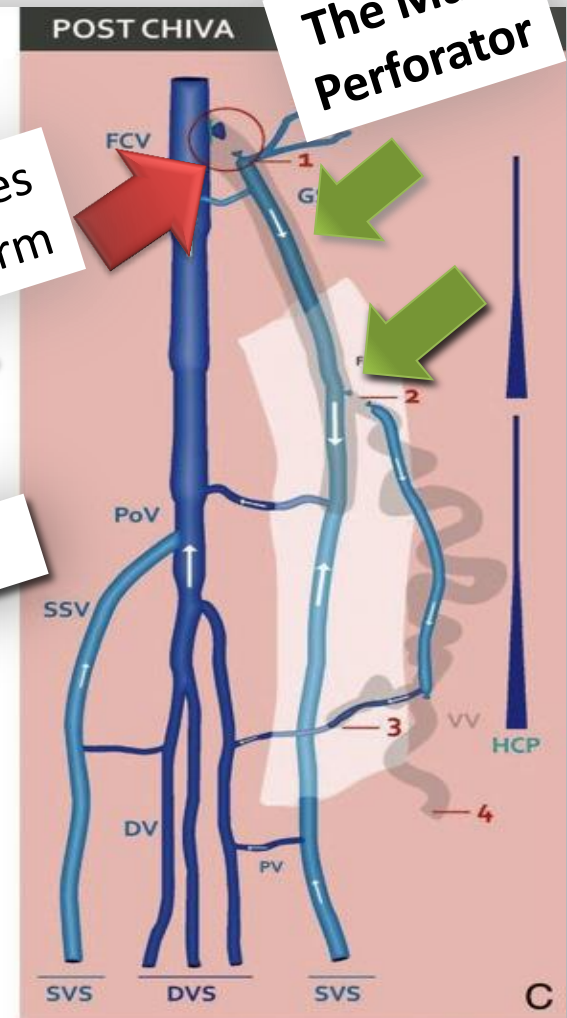
GSV: ablation Vs CHIVA



X: High ligation
Y: Stripping GSV (**y1**), Phlebectomy of tributary VV (**y2**)



X: High ligation
Y: Single Stripping of the incompetent segment GSV (**y1**), Phlebectomy of VV (**y2**)
Z: Subfascial closure of the Re-entry Point (PV)



1: High ligation
2: Disconnection of secondary Reflux Point
3: Preservation of the Re-entry Point (PV)
4: Phlebectomy of non-draining tributary VV

The Main Perforator

Weaknesses at long-term

Strengths

Reflux Patterns in VVs

by: Camilli S. Minerva Angiologica 1992;17:59-62

- from >1.000 descending venographies -

1st Pattern

Typical

2nd Pattern

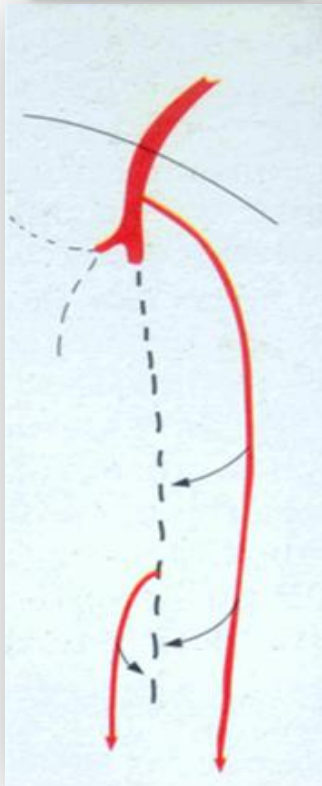
Complex A

Complex B

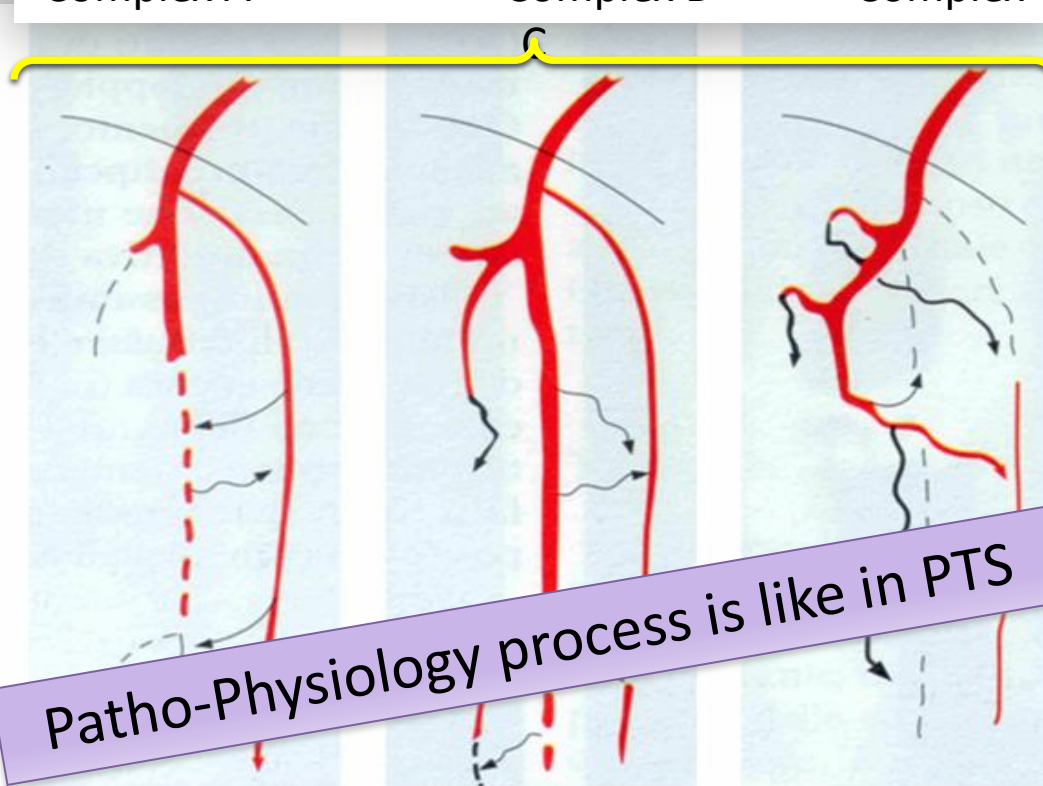
Complex

3rd Pattern

Atypical



≈30%

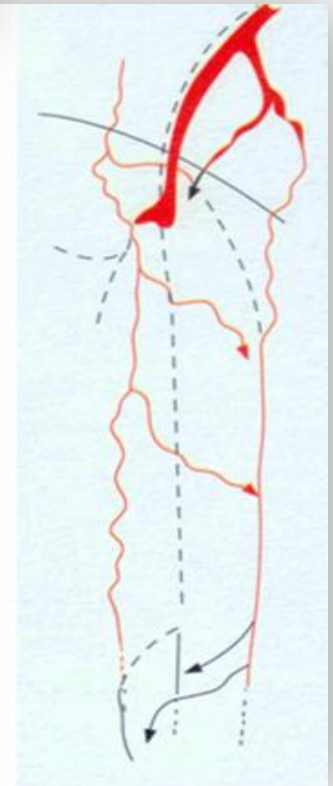


Patho-Physiology process is like in PTS

≈30%

≈10%

≈5%



≈25%

The most of recurrences occur in this group

VVs: Ablative Vs Conservative

*A reasonable
Dream ...*

In case of CVI and VVs,
The best Option should be:

① **Hemodynamic approach** (like in CHIVA) by:

- DUS + Reflux mapping

② **Valvuloplasty** (if eligible) to:

- Valve Repair & Reflux stopping
- Maintain forward drainage

③ **GSV Conservative** techniques by:

- CHIVA, Müller, ASVAL, Sclero-foam, others ...

Valvuloplasty

... on which cases ?

ELIGIBILITY:

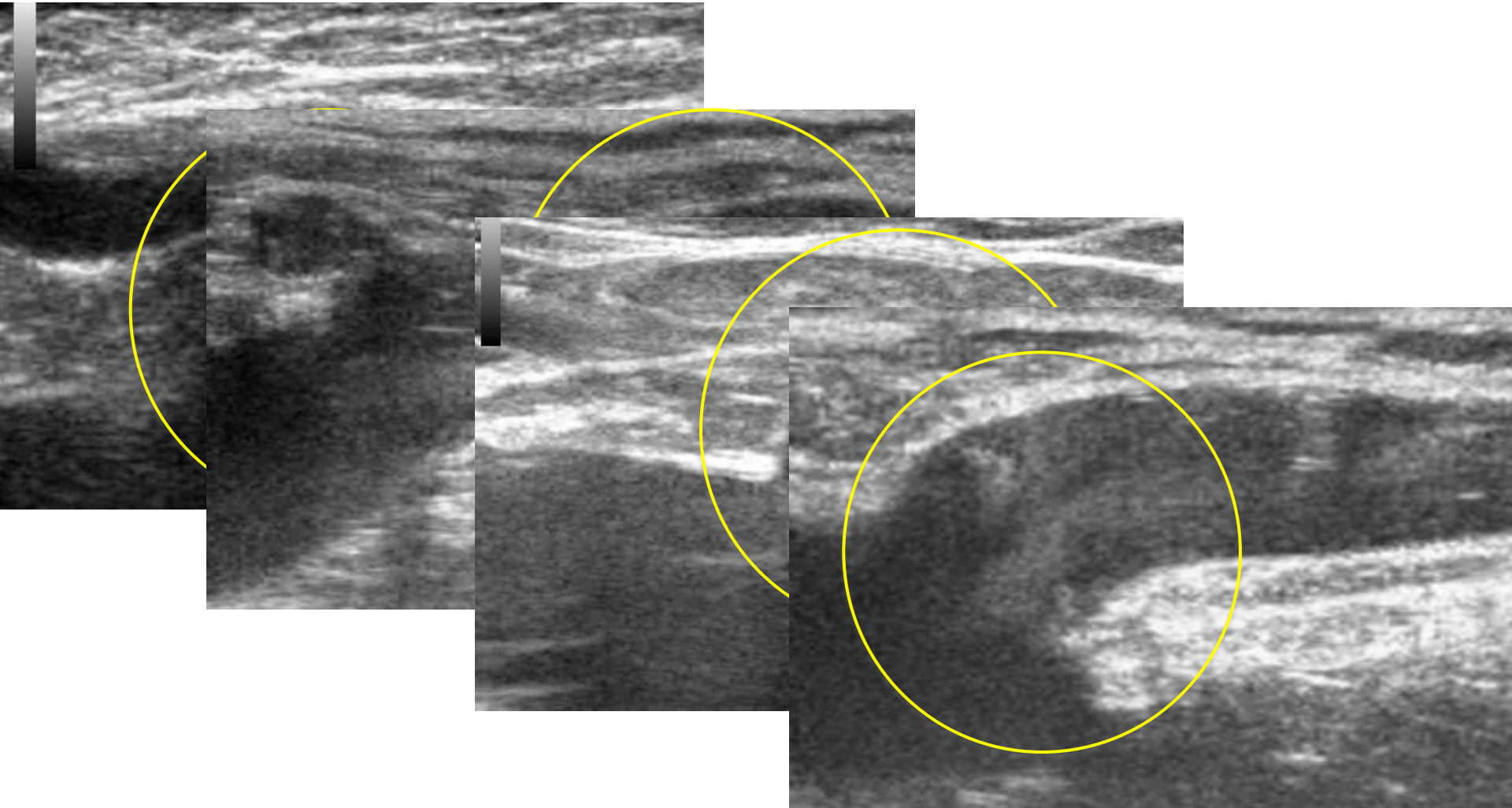
- ✧ VALVE CUSPS, **visible, freely floating, symmetric**
- ✧ GSV, having **segmental (or subtotal) reflux**
- ✧ PATIENT, with **recent VVs (early stage) or young age**

EXCLUSION:

- ✧ VALVE CUSPS, **undetectable, frozen, asymmetric**
- ✧ GSV, with **previous phlebitis**
- ✧ PATIENT, with **severe VVs or aged** (or other excluding conditions)

Valves: Some features

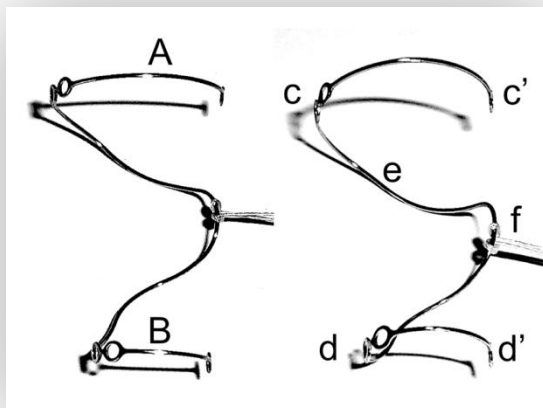
- duplex imaging -



Valvuloplasty

... which Technique ?

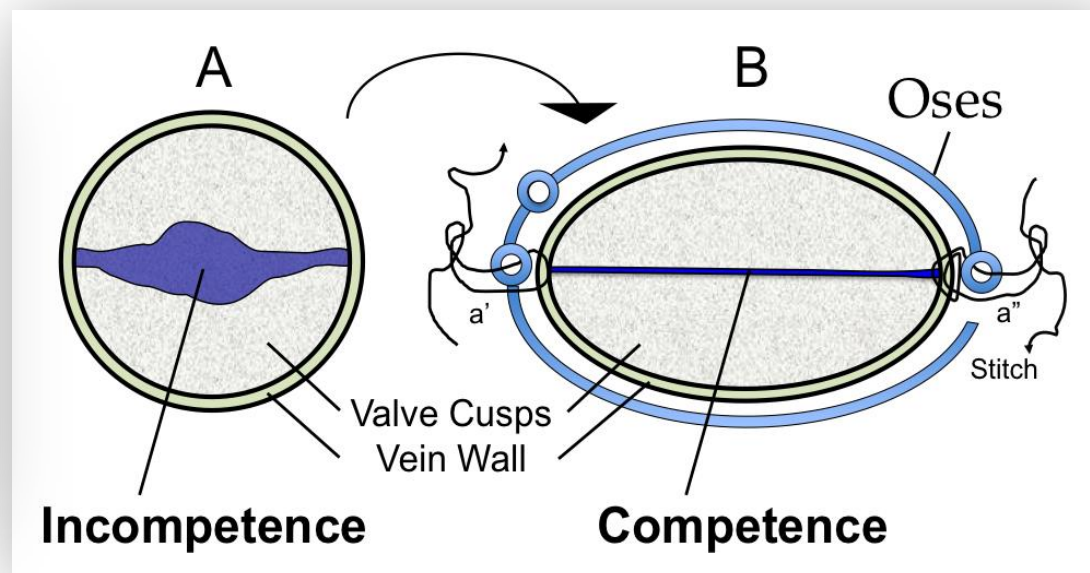
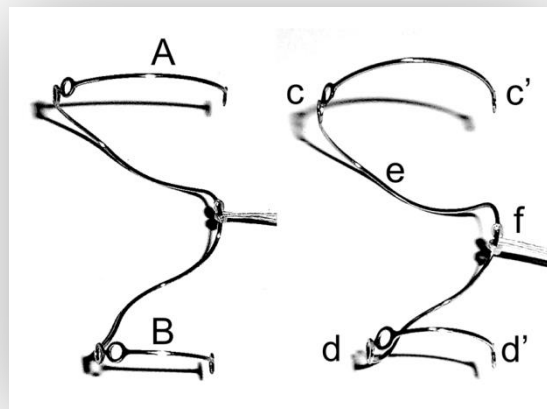
The Stretching Valvuloplasty with OSES device implant (Oval Shaped External Support)



Specifications:

- ✧ material : NiTi alloy (Nitinol)
- ✧ A – B : active elements
- ✧ c/c' – d/d' : eyelets for fixation
- ✧ e : connecting element
- ✧ f : handling means

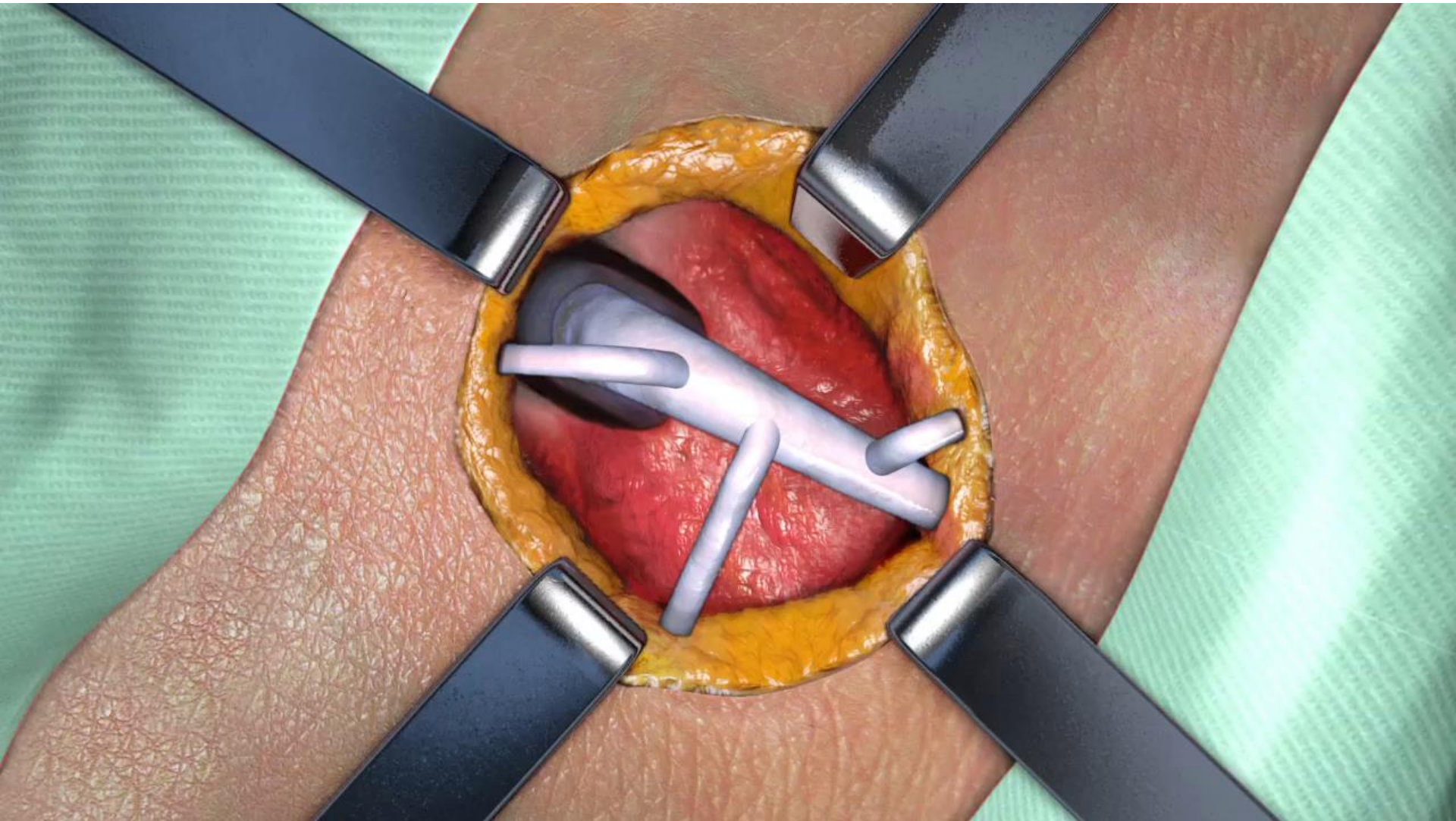
OSES: The Working Concept



The OSES device:

- ✧ must be **oversized (of about +30%)** with respect to the native valve diameter
- ✧ must be **sutured** in correspondence of the intercommissural apices
- ✧ must obtain the **oval shaped valve cross section**

OSES Valvuloplasty: The procedure



Stretching Valvuloplasty

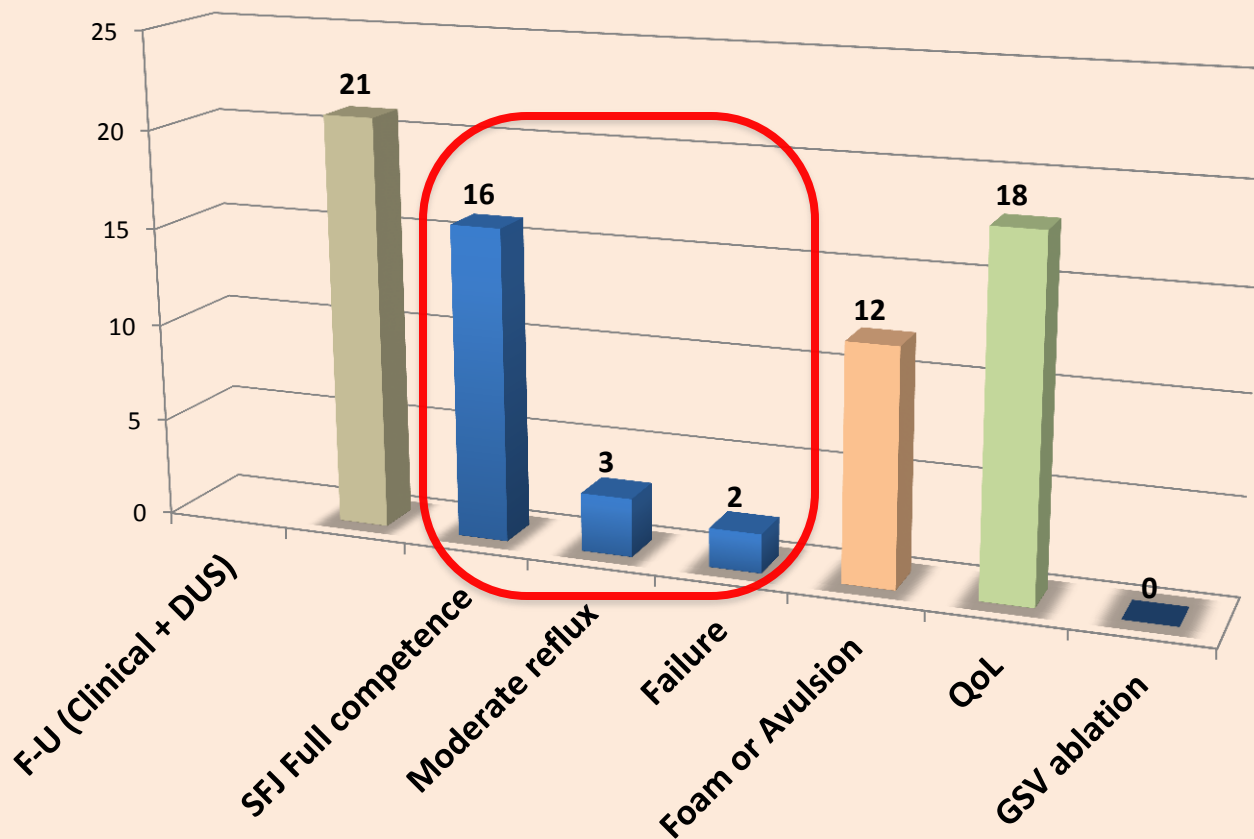
- Personal series on 2014 -

Patology	Cases N°	F-U at 5 aa	Reflux stopped	Reflux reduced	Failure	Post-op. procedures	GSV Stripping
Primary VVs (GSV)	42	21	16	3	2	12	0
Secondary VVs in PTS (GSV)	3	-	3	-	-	3	0
Recurrent VVs + PDVI (SFV)	2	2	2	-	-	2	*
* Bilateral, in a previous time							

A multicentric **DATA REGISTRY** for
STRETCHING VALVULOPLASTY
is being formed

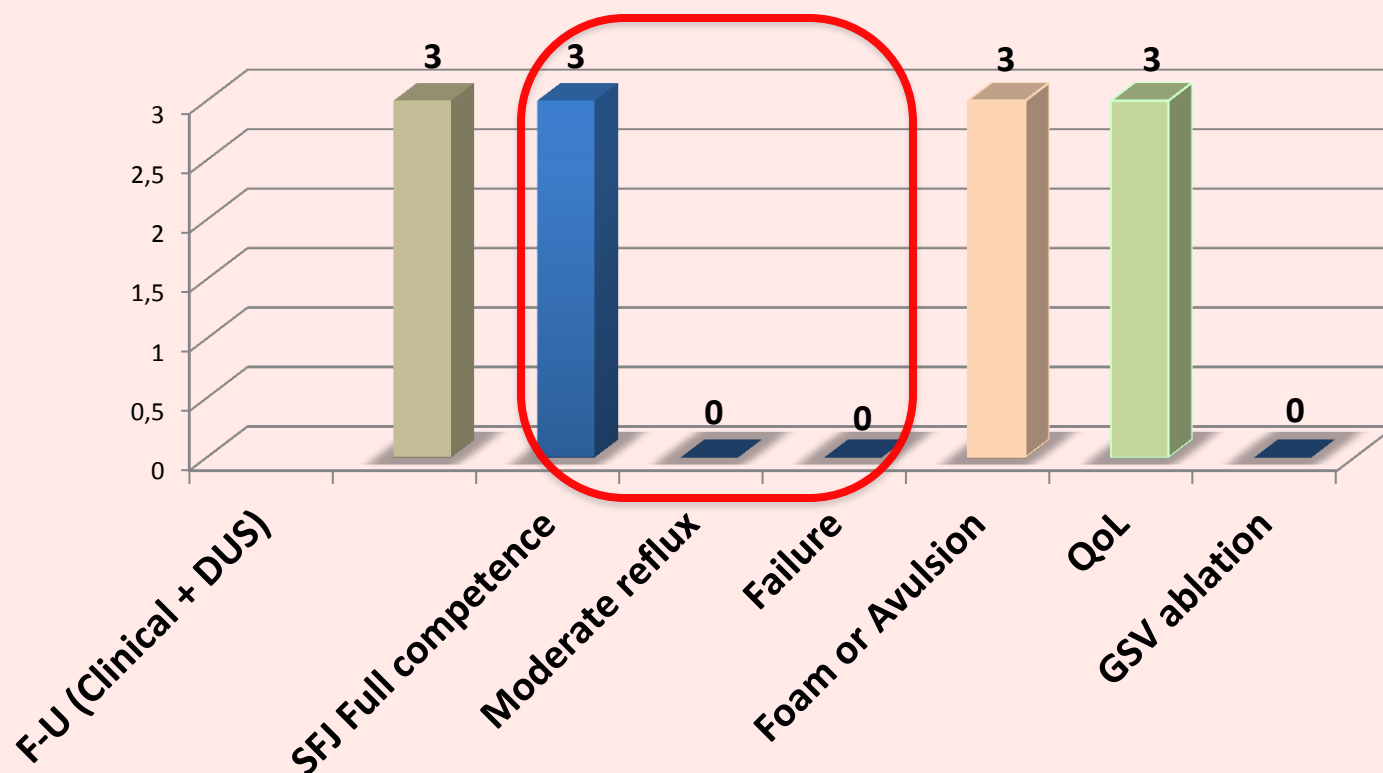
Long-term Results of V-OSES intervention in Primary VVs

No. 21/42 cases at 5 y. FU



Short-term Results of V-OSES intervention in Secondary VVs in PTS

No. 3/3 cases at 20th-18th-3rd mo. FU



Conclusions

Preservation of Saphenous Trunks:
EXTERNAL VALVULOPLASTY
?

Conclusions 1

- AIM: to have better long-term results in VVs -

ReVas PREVENTION :

- ① **Hemodynamic Approach** (like on CHIVA)
 - DUS (deep & superficial) + Reflux mapping
- ② **Valvuloplasty** in eligible cases
 - SFJ Valve Repair & Reflux stopping
 - Maintain forward (as well as backward) drainage
- ③ **GSV Conservative** (any technique?)
 - CHIVA, Müller, ASVAL, Sclero-foam, others ...

Conclusions 2

- we need the S-Valvuloplasty procedure's validation -

For ELIGIBILITY

- Better **knowledge** on venous valves
 - anatomy, DUS, pathology, ...

For EFFICACY

- Larger **Clinical Experience** and **RCT**

A **DATA REGISTRY** is being formed:
If you are **interested** in participating,
you can join by e-mail



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God save the vein!

God Save the Vein !

EXTERNAL VALVULOPLASTY

?

Thanks for your Attention

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