

# HEPARIN PROPHYLAXIS IN MAJOR SCLEROTHERAPY (THE PROSCLEP STUDY)

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## ASSESSMENT OF THROMBOTIC ADVERSE EVENTS AND TREATMENT PATTERNS ASSOCIATED WITH VARICOSE VEIN TREATMENT

- retrospective study was conducted with health care claims data
- 40 million insured lives
- subjects aged  $\geq 18$  years with a new diagnosis of varicose veins who had received at least one invasive treatment
- 985,632 unique subjects diagnosed with varicose veins

## DVT INCIDENCE

- RADIOFREQUENCY..... 4.4%
- LASER ABLATION ..... 3.1%
- SURGERY ..... 2.4%
- SCLEROTHERAPY ..... 0.8%

## PE INCIDENCE

- RADIOFREQUENCY..... 0.3%
- LASER ABLATION ..... 0.3%
- SURGERY ..... 0.3%
- SCLEROTHERAPY ..... 0.2%

## THROMBOTIC COMPLICATIONS OF SCLEROTHERAPY

- TWO DIFFERENT CONDITIONS:
  - 1) PROGRESSION OF THE SCLERUS IN THE DEEP VENOUS SYSTEM
  - 2) OCCLUSION OF A DEEP VEIN NOT IN CONTINUITY WITH THE SCLERUS

## 1) PROGRESSION OF THE SCLERUS IN THE DEEP VENOUS SYSTEM

- USUALLY A SELF LIMITED CONDITION
- USUALLY ASYMPTOMATIC
- VERY RARELY TOTAL OCCLUSION
- USUALLY FULL RESOLUTION
- USUALLY RESOLVES AFTER A SHORT TREATMENT WITH LMWH

POSTE

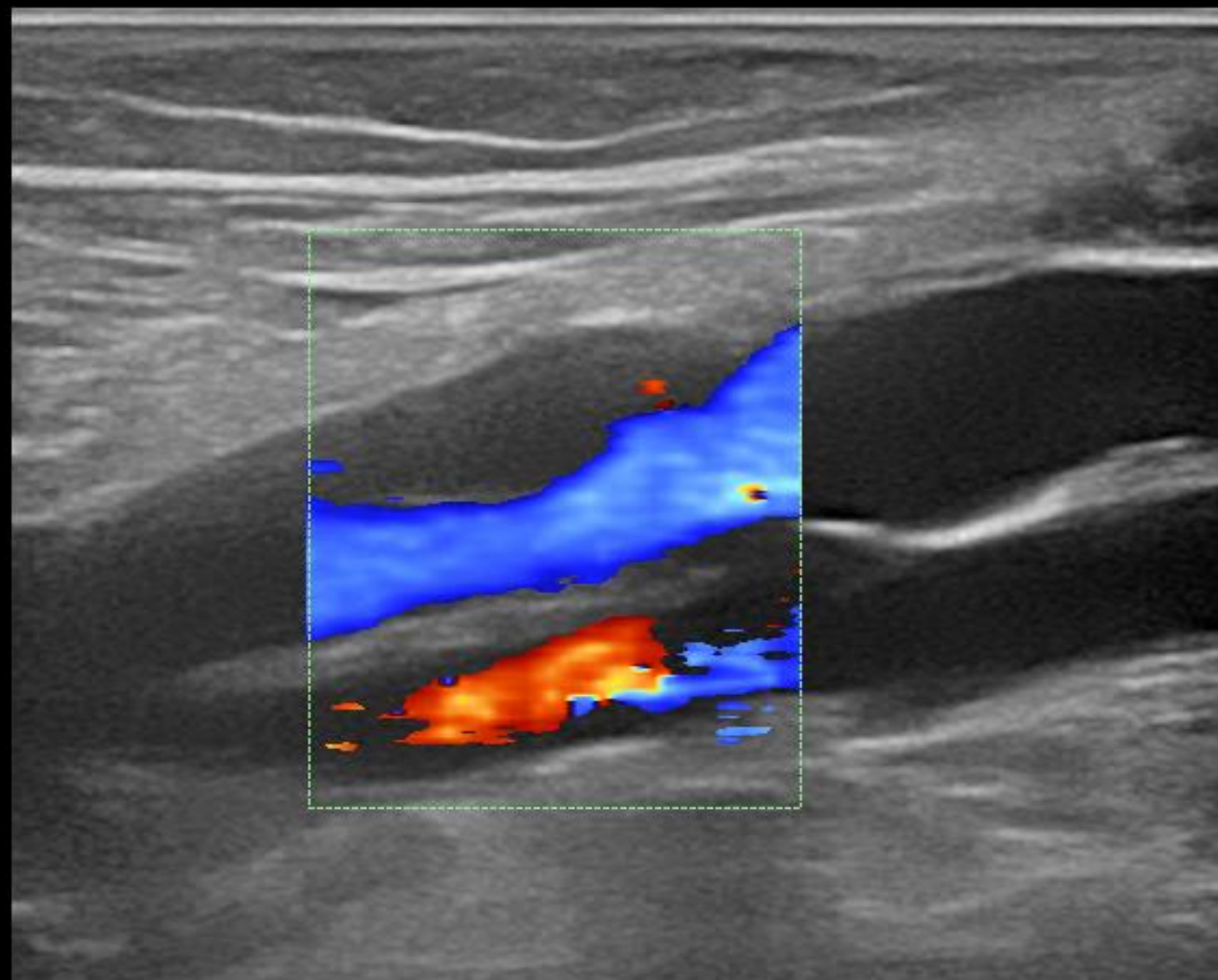
POst Sclerotherapy Transient  
Extension

(PASTE = Post Ablation Superficial Thrombus Extension)



B	RIS-A	G	—	CFM F	6.3 MHz	G	—
TEI	D 44 mm	XV/M	+7/1	PRF	1.2 kHz	FP	3
	PRC 10/2/1/2	PRS	2	PRC	M/1	PRS	3

3 /VASCOLARE  
GL1543 VENOSO PERIFERICO



0  
1  
2  
3



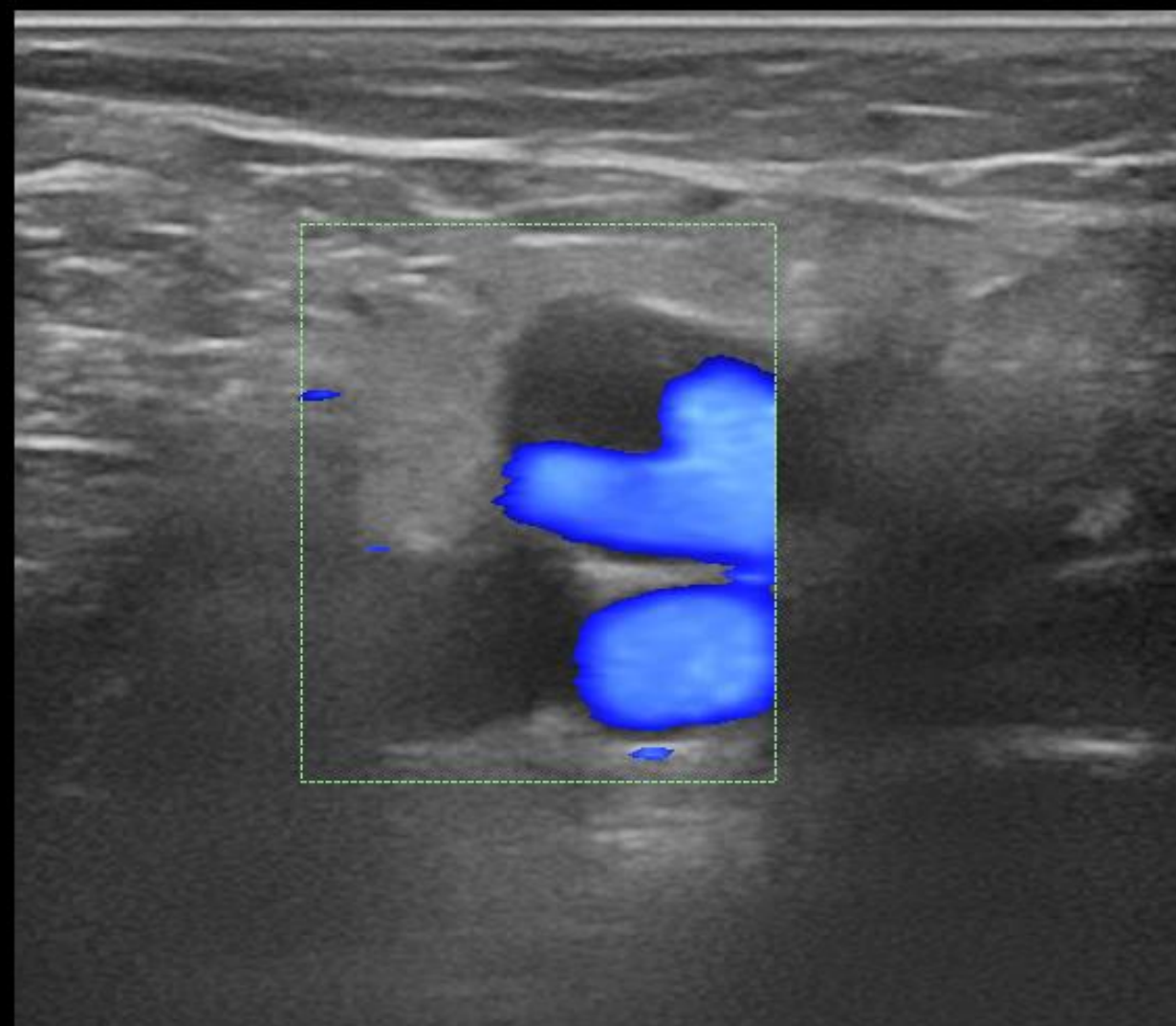
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P 80% MI 1.3  
TIS 0.4



B TEI  
RIS-A D 44 mm XV/M +7/1  
G --- PRS 2  
CFM F 6.3 MHz PRF 1.2 kHz PRC M/1  
G --- FP 3 PRS 3

/ASCOLARE  
SL1543 VENOSO PERIFERICO

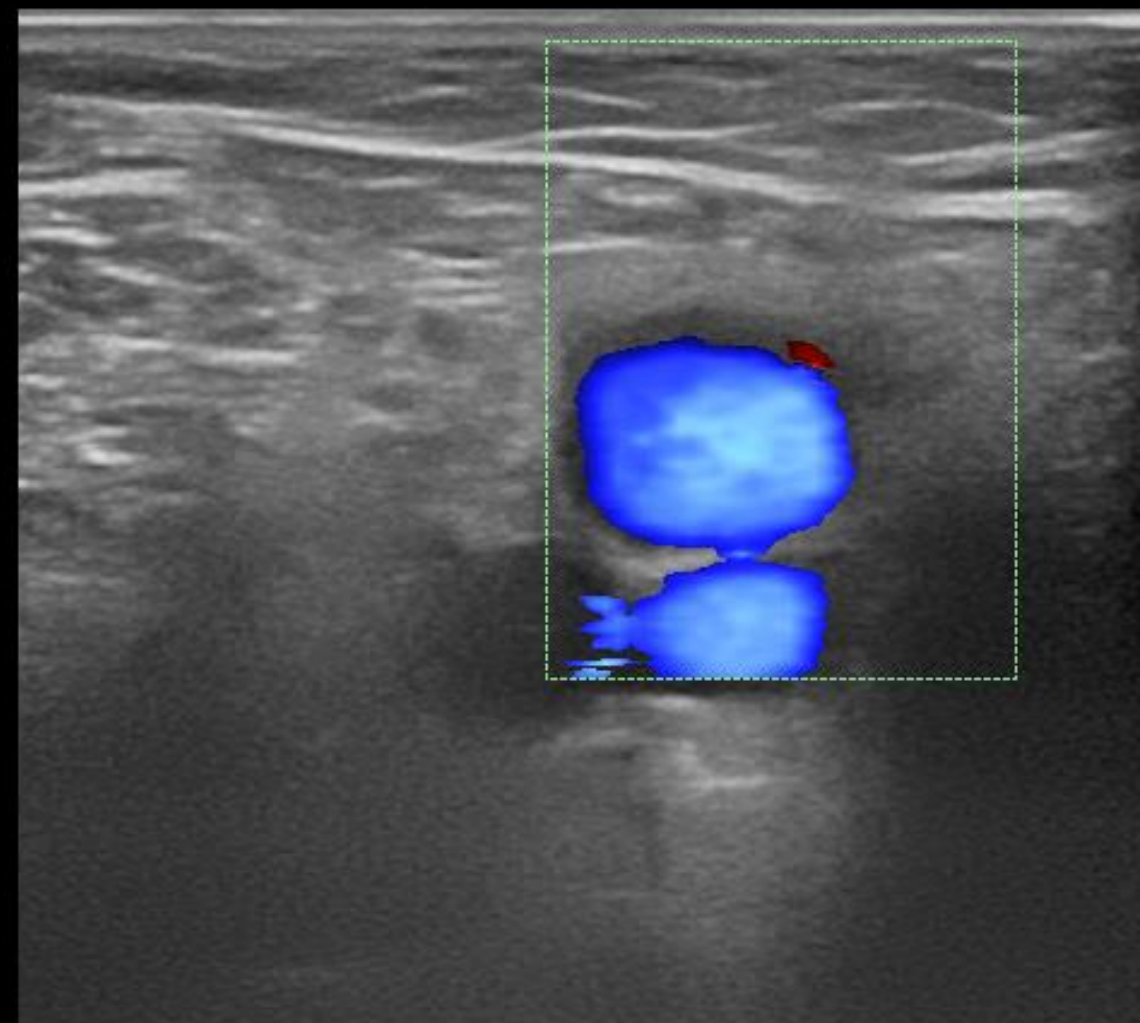


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P 80% MI 1.3  
TIS 0.4

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ASCOLARE  
L1543 VENOSO PERIFERICO

B TEI D RIS-A G — CFM F 6.3 MHz G —  
PRC 10/2/1/2 PRS 2 PRF 1.2 kHz FP 3  
PRS 3



0  
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3

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P 80% MI 1.3  
TIS 0.4

3 13  
/ASCOLARE  
SL1543 VENOSO PERIFERICO

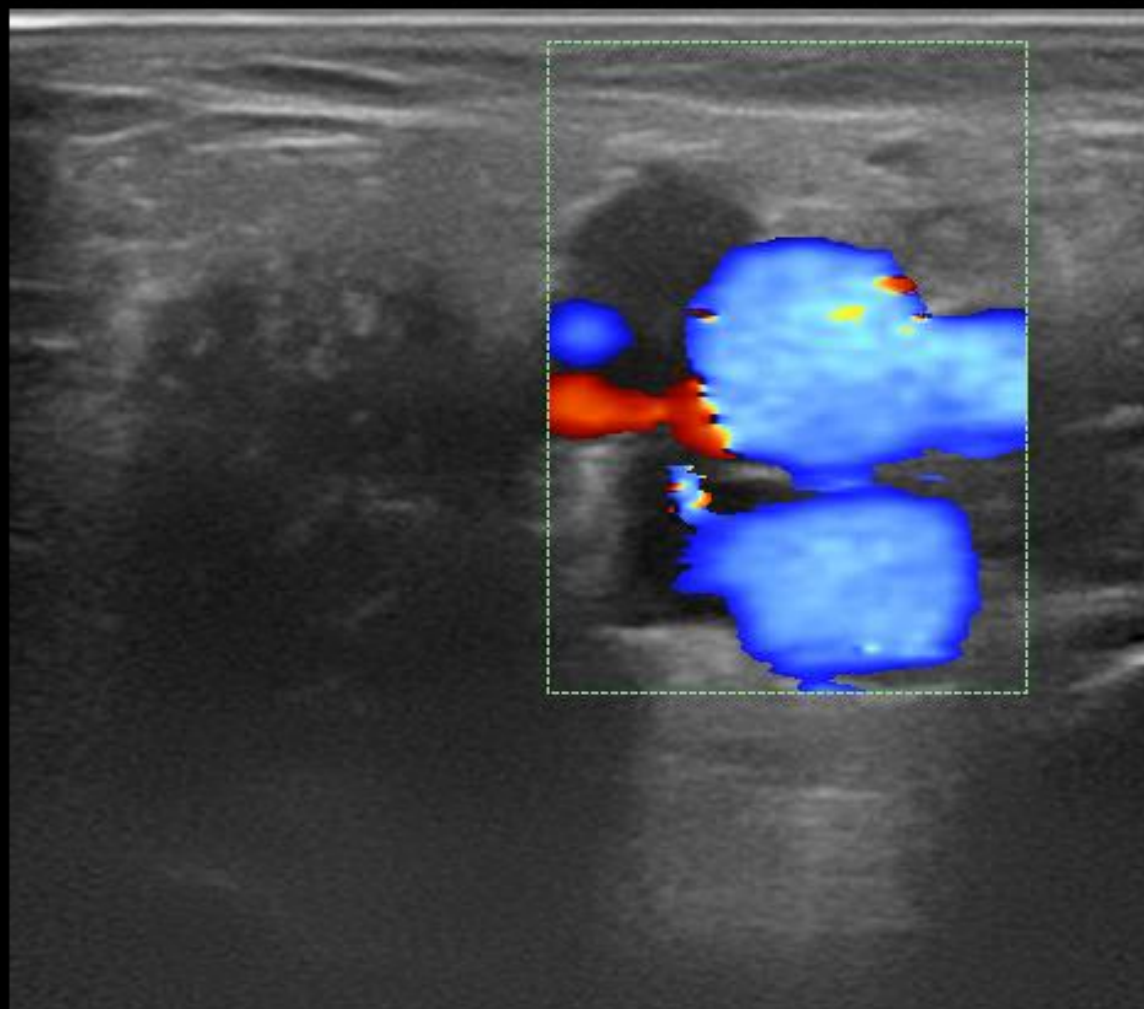
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TEI	D 52 mm	XV/M	+7/1	PRF	1.2 kHz	FP	3
	PRC 10/2/1/2	PRS	2	PRC	M/1	PRS	3



0.08



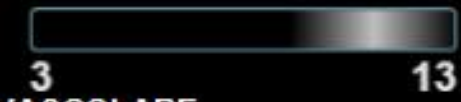
-0.08  
m/s





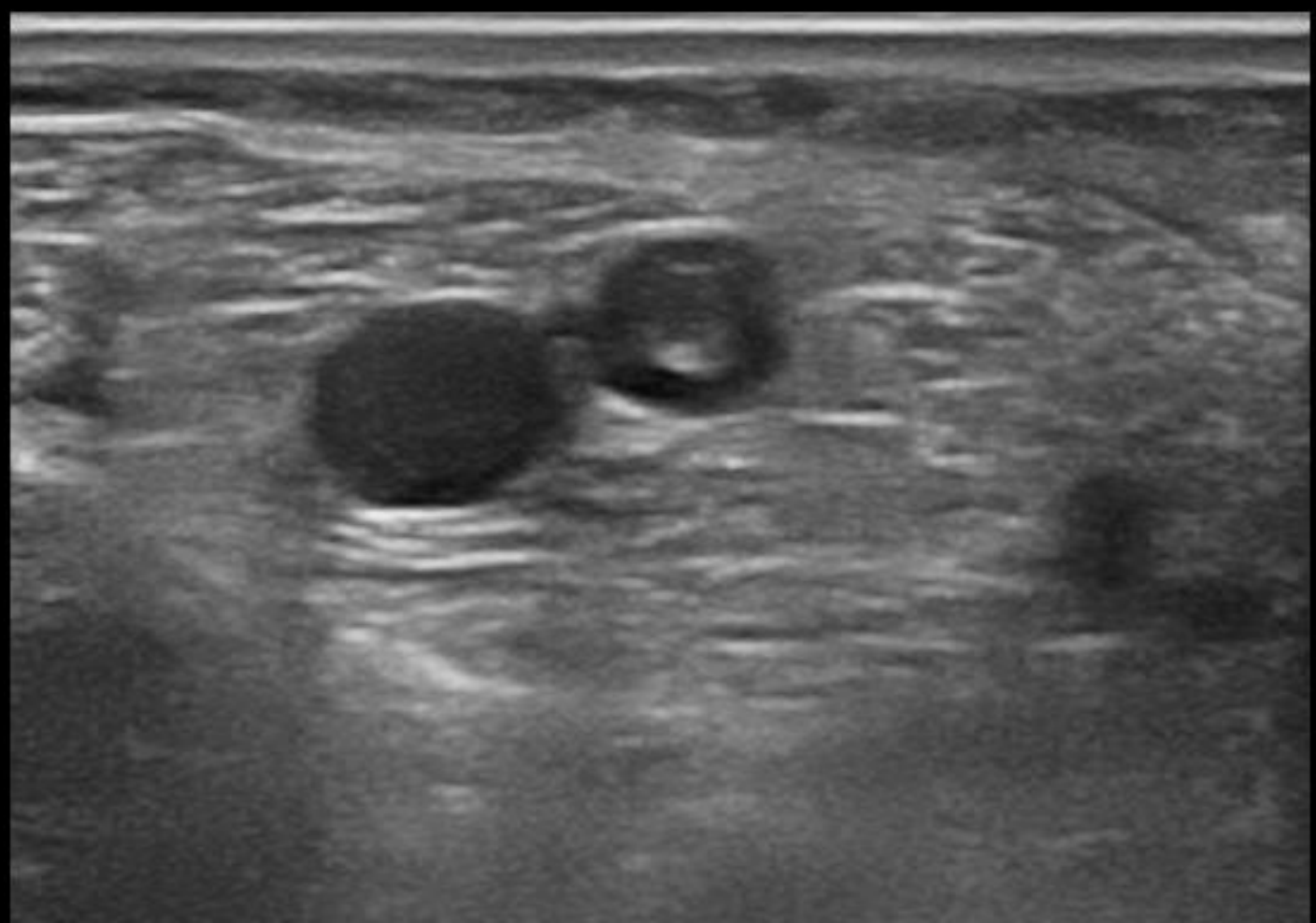
2) OCCLUSION OF A DEEP VEIN NOT IN CONTINUITY WITH THE SCLERUS

- USUALLY OCCLUSION OF A MUSCOLAR VEIN
- LESS TENDENCE TO SPONTANEOUS RESOLUTION
- OFTEN PAINFUL



VASCOLARE  
SL1543 VENOSO PERIFERICO

B	RIS-A	G	—
TEI	44 mm	XV/M	+7/1
D	PRC 10/2/1/2	PRS	2





THROMBOTIC COMPLICATION AFTER  
SCLEROTHERAPY MAY HAVE NO OR POOR  
CLINICAL EVIDENCE



SUCH COMPLICATIONS DO NOT  
AFFECT THE QUALITY OF  
SCLEROTHERAPY

# THE PROSCLEP STUDY

PROphylaxis in SCLerotherapy with hEParin



# PROSCLEP STUDY GROUP



- A.FRULLINI FIRENZE
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## PROSCLEP STUDY

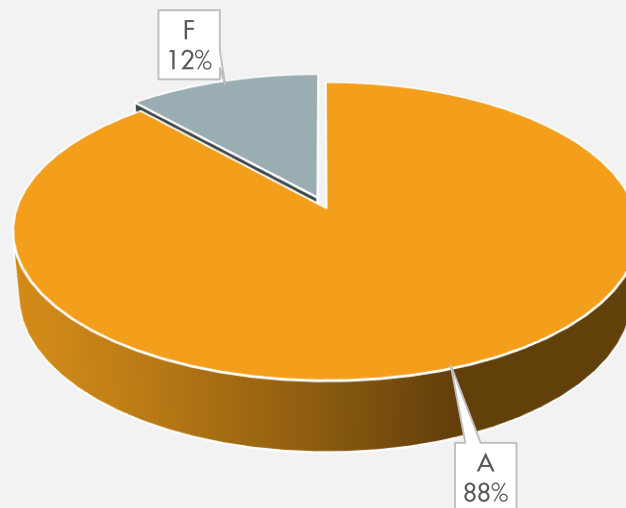
- **study promoted by AFI (registry)**
- **16 vein centers (multicentric)**
- **Sclerotherapy conducted as usual**
- **Some centers routinely used prophylaxis and some centers didn't**
- **Common tool for data collection (Excel file)**

# PROSCLEP: INCLUSION CRITERIA

- **Major insufficient veins**
  - **GSV**
  - **SSV**
  - **AASV**
  - **RECURRENCES**
  - **PERFORATORS**
  - **LARGE TRIBUTARIES**

## PROSCLEP: INCLUSION CRITERIA

**- SCLEROTHERAPY WITH POL OR STS 1-3% (LIQUID OR FOAM)**



## PROSCLEP: EXCLUSION CRITERIA

- CONTRAINDICATION TO SCLEROTHERAPY
- CONCOMITANT PHLEBOLOGIC PROCEDURE (SURGERY, THERMAL ABLATION, GLUE ETC) BUT MULLER PHLEBECTOMY WAS ADMITTED
- RECENT THROMBOSIS

## MATERIALS & METHODS

- **2489 sessions in 2010 patients**
- **No prophylaxis in 1087 sessions 43,7 %**
- **Heparin prophylaxis in 1402 sessions 56,3 %**
- **Liquid 1%**
- **Foam 99%**
- **Mean volume 4,9 ml**
- **Pol 88,3 % STS 11,6 %**

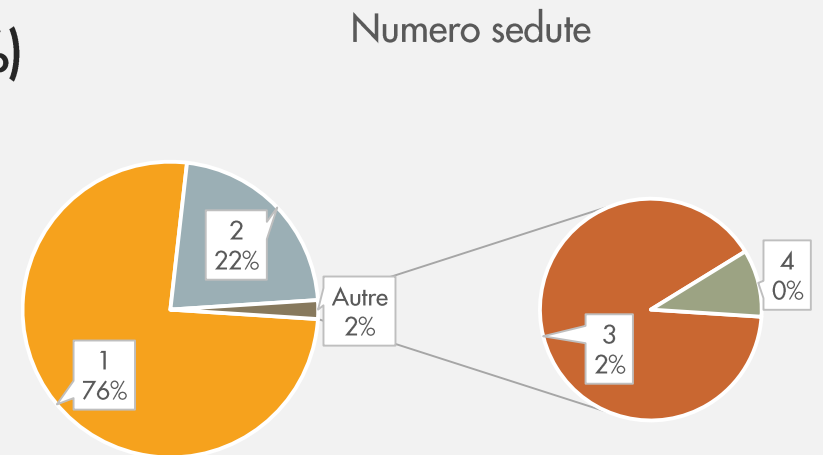


## MATERIALS & METHODS

- **PROPHYLAXIS WAS PERFORMED USING LMWH FOR 3-6 DAYS STARTING BEFORE THE FIRST SESSION (NADROPARINE 3800 UI OR ENOXAPARIN 4000 UI)**
- **COMPRESSION WAS ALWAYS USED WITH K1 OR K2 STOCKINGS (ONLY A 12 TREATMENT WITH ELASTIC BANDAGE)**

# MATERIALS & METHODS

- **How many session per patient?**
- **1..... 1887 (75,8%)**
- **2 ..... 551 (22,1%)**
- **3 .....45 (1,8%)**
- **4 .....5 (0,2%)**



# SESSIONS BY SITE

- GSV PROF..... 956
- GSV NO PROF ..... 314
- SSV PROF ..... 150
- SSV NO PROF .....106
- PERF PROF .....66
- PERF NO PROF ..... 24
- RECURR PROF ..... 184
- RECURR NO PROF ..... 132
- TRIB NO PROF ..... 40
- ASV PROF ..... 103
- ASV NO PROF ..... 54

## NO INDICATION ON TREATMENT

- THIS IS A REGISTRY AND DOCTORS WERE ASKED TO PERFORM SCLEROTHERAPY AS USUAL
- PATIENTS WERE INCLUDED CONSECUTIVELY, NO ONE EXCLUDED
- INDICATIONS WERE GIVEN ON THE TECHNIQUE OF DUPLEX SCANNING

## RESULTS

- WE OBSERVED 13 MINOR THROMBOTIC COMPLICATIONS ON 2489 SESSIONS **0,52 %**
- **8 POSTE – 5 GASTROCNEMIUS**
- NO SEVERE DVT OR PE WERE REGISTERED

## DVT AFTER GSV SCLERO

WITH PROPHYLAXIS..... 0,31 %

WITHOUT PROPHYLAXIS..... 1,91 %

p= 0,009 **SIGNIFICANT**

DVT AFTER SSV SCLERO

WITH PROPHYLAXIS..... 2 %

WITHOUT PROPHYLAXIS..... 1,88 %

NOT SIGNIFICANT

DVT AFTER PERFORATOR SCLERO

WITH PROPHYLAXIS..... 1,5 %

WITHOUT PROPHYLAXIS..... 0 %

NOT SIGNIFICANT



DVT AFTER SCLERO

NO COMPLICATIONS WERE  
OBSERVED AFTER SCLERO OF  
ASV, RECURRENCES AND LARGE  
TRIBUTARIES

## CONCLUSIONS 1

- SCLEROTHERAPY CARRIES A VERY LOW RISK OF THROMBOTIC COMPLICATIONS

## CONCLUSIONS 2

- HEPARIN PROPHYLAXIS IS ADVISED IN SCLEROTHERAPY OF GSV AS SIGNIFICANTLY REDUCES THE RISK OF THROMBOTIC COMPLICATIONS

## CONCLUSIONS 3

- THERE ARE NO ENOUGH DATA ON THE ROLE OF HEPARIN PROPHYLAXIS FOR PERFORATORS AND SSV SCLEROTHERAPY

## CONCLUSIONS 4

- THERE IS NO NEED FOR HEPARIN PROPHYLAXIS IN SCLEROTHERAPY OF RECURRENCES, LARGE TRIBUTARIES AND ASV

## CONCLUSIONS 5

- THIS STUDY CONFIRMS THAT THROMBOSIS AFTER SCLERO IS A RARE AND MINOR COMPLICATION THAT RESOLVES AFTER A SHORT COURSE OF ANTICOAGULATION

## CONCLUSIONS 6

- TWO KINDS OF THROMBOTIC COMPLICATION AFTER SCLERO CAN BE IDENTIFIED
  - POSTE
  - ISOLATED THROMBOSIS

VALET CONFERENCE

BOLOGNA

2020

11-12 SETTEMBRE  
SEPTEMBER | سبتمبر

XVI SCLEROTHERAPY  
& VENOUS ABLATION

LINGUE UFFICIALI | OFFICIAL LANGUAGES | اللغات الرسمية

ITALIANO | INGLESE | ARABO  
ITALIAN | ENGLISH | ARABIC  
العربية | الإنجليزية | الإيطالي





THANK YOU FOR YOUR  
ATTENTION

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