

**PROPHYLAXIS OF
NEUROLOGICAL AND VISUAL
DISTURBANCES AFTER
SCLEROTHERAPY
(*PROCOMET STUDY*)**

**A Frullini, D. Guarnaccia, A. Guastini,
O.W. Loparco, D. Maurano, S.Paradiso, P.
Pavei, A.M. Previtera, M.Rendace
(**PROCOMET STUDY GROUP**)**

DISCLOSURE

Consultant for:

- Baldaccilab

**IN GENERAL FOAM
SCLEROTHERAPY HAS
SIMILAR COMPLICATIONS TO
LIQUID SCLEROTHERAPY**

**BUT VISUAL AND NEUROLOGICAL
DISTURBANCES ARE MORE
FREQUENT**

NEUROLOGICAL AND VISUAL DISTURBANCES AFTER LS AND FS

- NEUROLOGICAL DISTURBANCES: Forlee, Bush
- **VISUAL DISTURBANCES:**
The frequency of occurrence : 0% - 14 %
average rate : 1.4%

*Jia X: Systematic review of foam
sclerotherapy for varicose veins, BJS 2007*

**OUR HYPOTESIS IS THAT
VASOACTIVE SUBSTANCES ARE
RELEASED AFTER SCLEROTHERAPY
FROM THE DAMAGED
ENDOTHELIUM**

- **Endothelin 1 and retinal vasospasm**
- **Endothelin and migraine**
- **Endothelin and cerebral ischemia**

- **Non-ST-elevation myocardial infarction following foam ultrasound-guided sclerotherapy**
- **A hypothesis of post sclerotherapy release of endothelin-1leading to sustained coronary artery spasmis suggested**

R Stephens R Dunn

Phlebology **May 3, 2013**

doi: 10.1177/0268355513481765

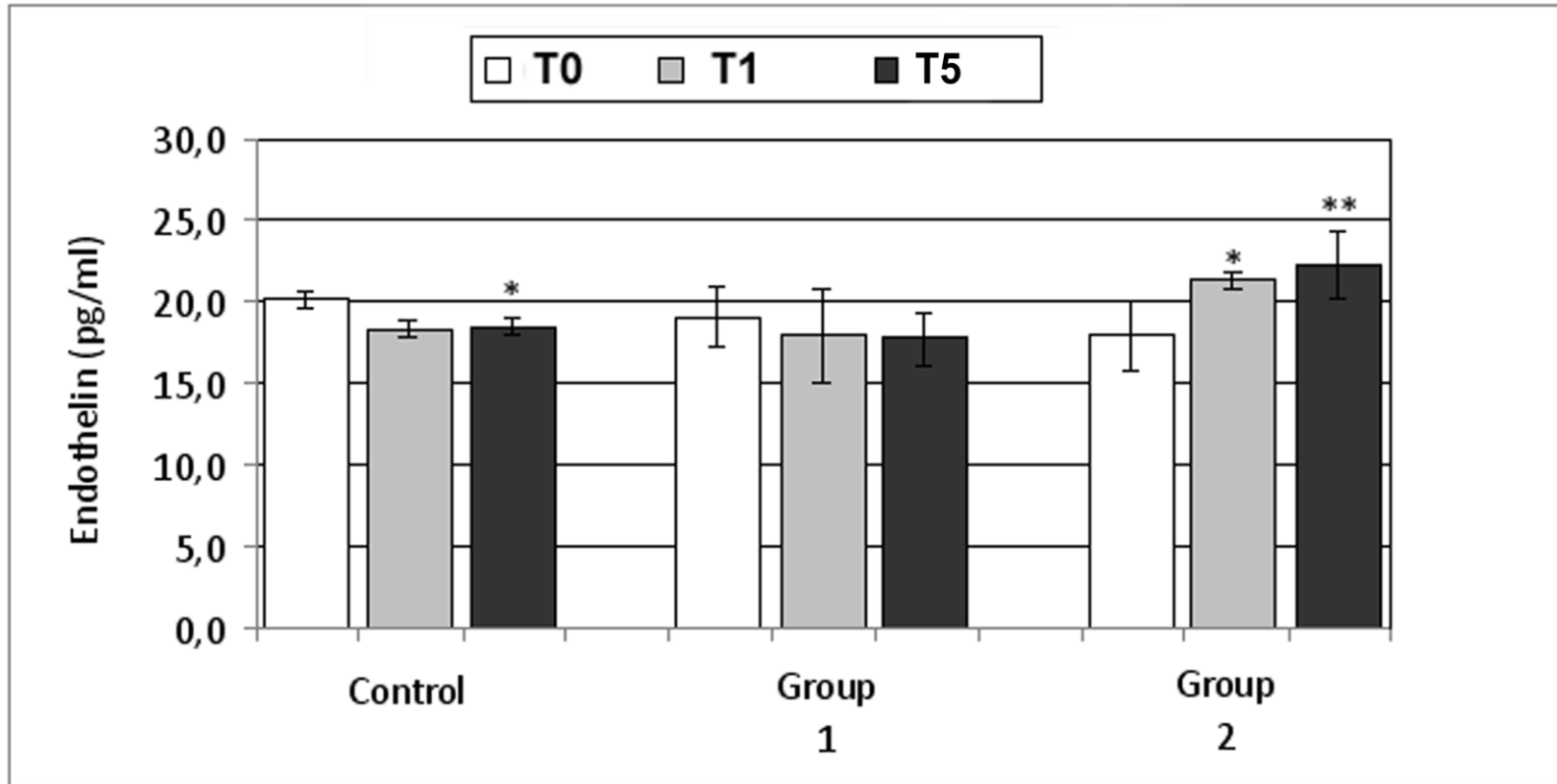
**WHY WITH FOAM SCLEROTHERAPY THE
INCIDENCE OF VISUAL AND
NEUROLOGIC COMPLICATIONS IS
HIGHER?**

**FOAM SCLEROTHERAPY HAS A
LONGER AND MORE POWERFUL
ACTION ON THE ENDOTHELIUM**

- **High production of endothelin after foam sclerotherapy: a new pathogenetic hypothesis for neurological and visual disturbances after sclerotherapy**
- **A Frullini et al**
- *Phlebology, August 2011; vol. 26, 5: pp. 203-208.*



Results with POL



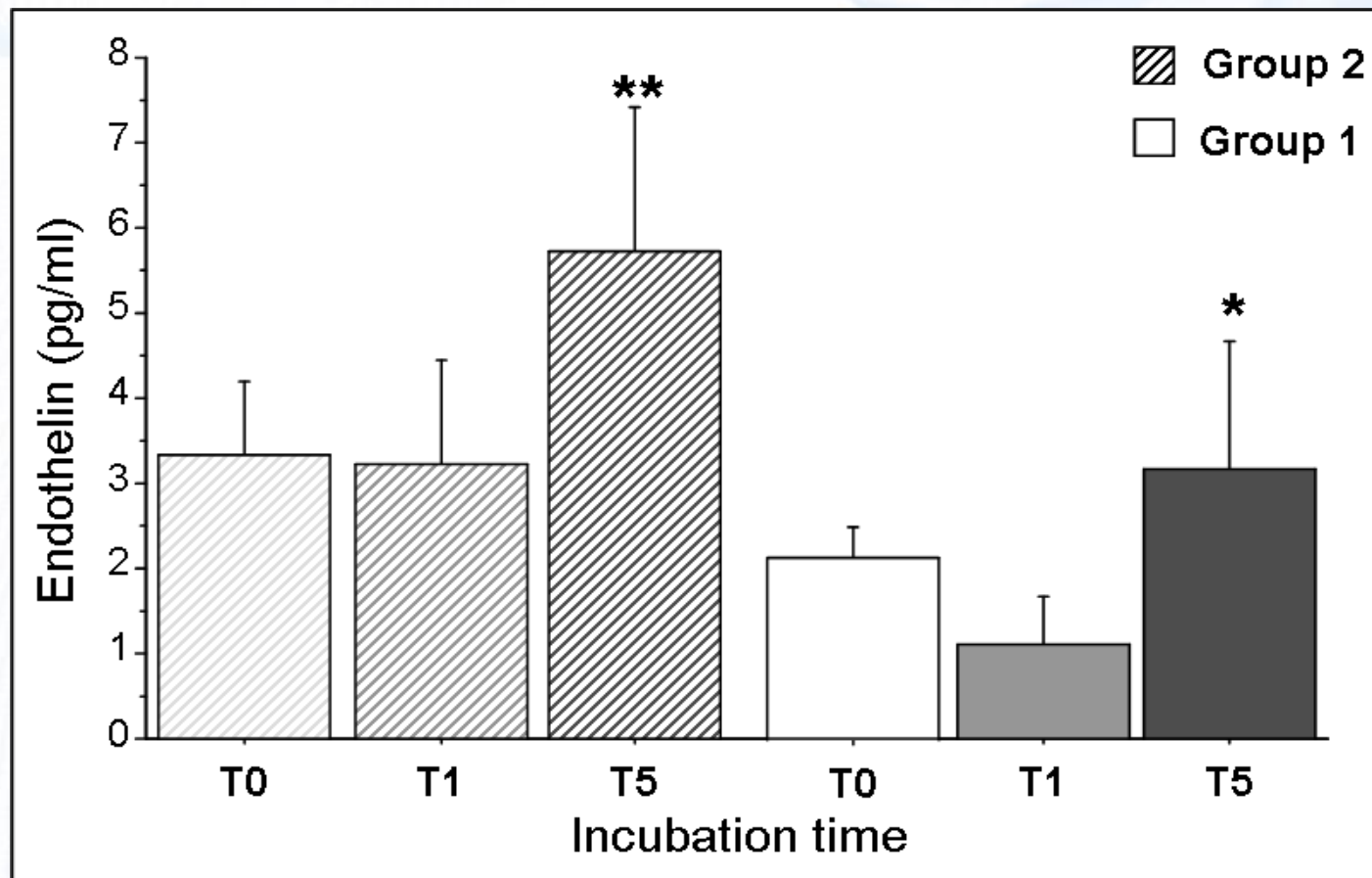
- GROUP 1 – ESSAY AT 1 AND 5 MINUTES AFTER INJECTION OF POL LIQUID
- GROUP 2 – ESSAY AT 1 AND 5 MINUTES AFTER INJECTION OF POL FOAM

*** p < 0.05 vs. at T1 / p < 0.01 at T5**

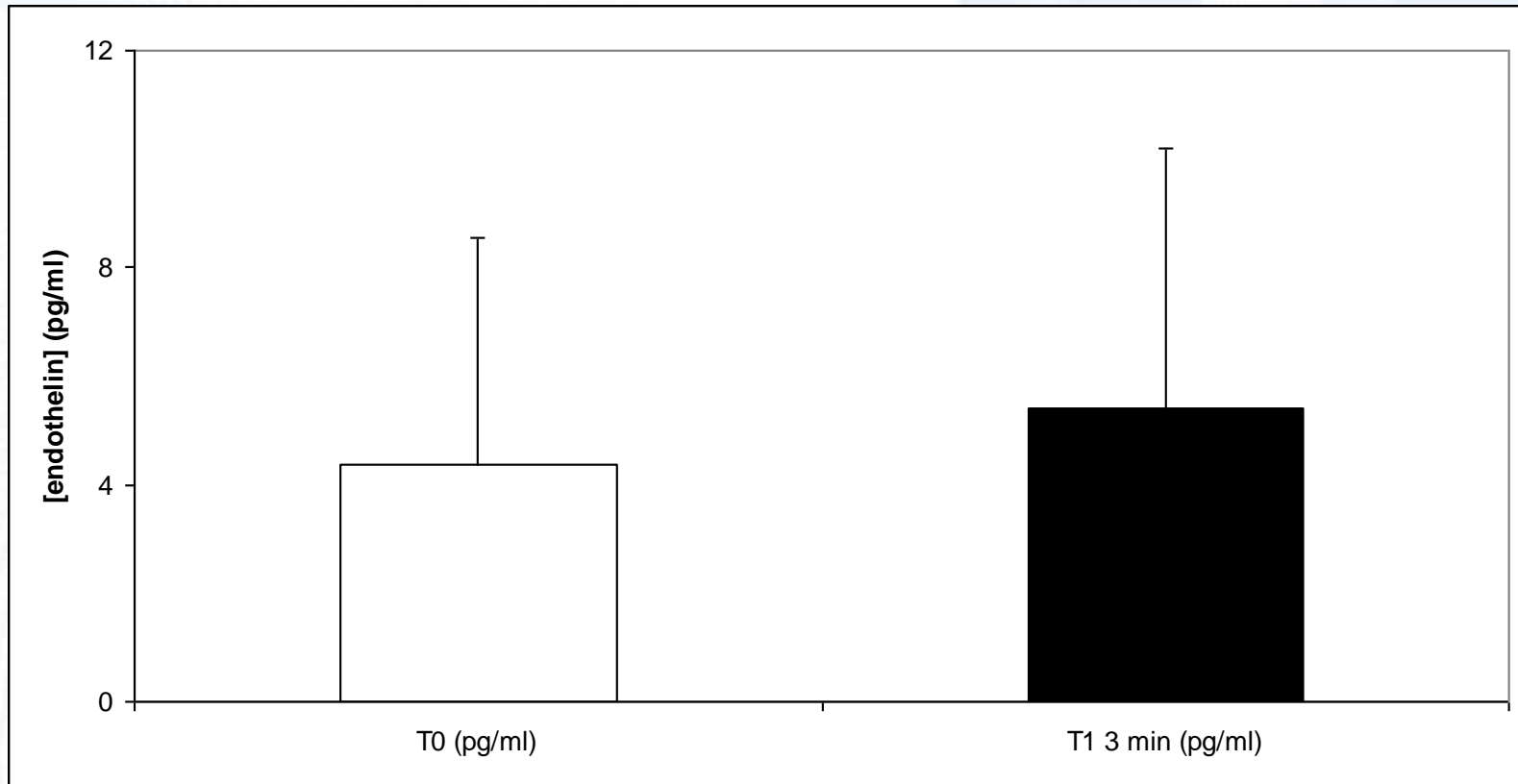
- **Significant Endothelin Release in Patients Treated with Foam Sclerotherapy**
- **A.Frullini et al. Dermatologic Surgery**
- **[Volume 38, Issue 5, pages 741–747, May 2012](#)**



Results with STS



ET 1 after FS in VV patients



T0: 4.35 ± 4.20 pg/ml vs. T1: 5.41 ± 4.79 pg/ml, p < 0.05

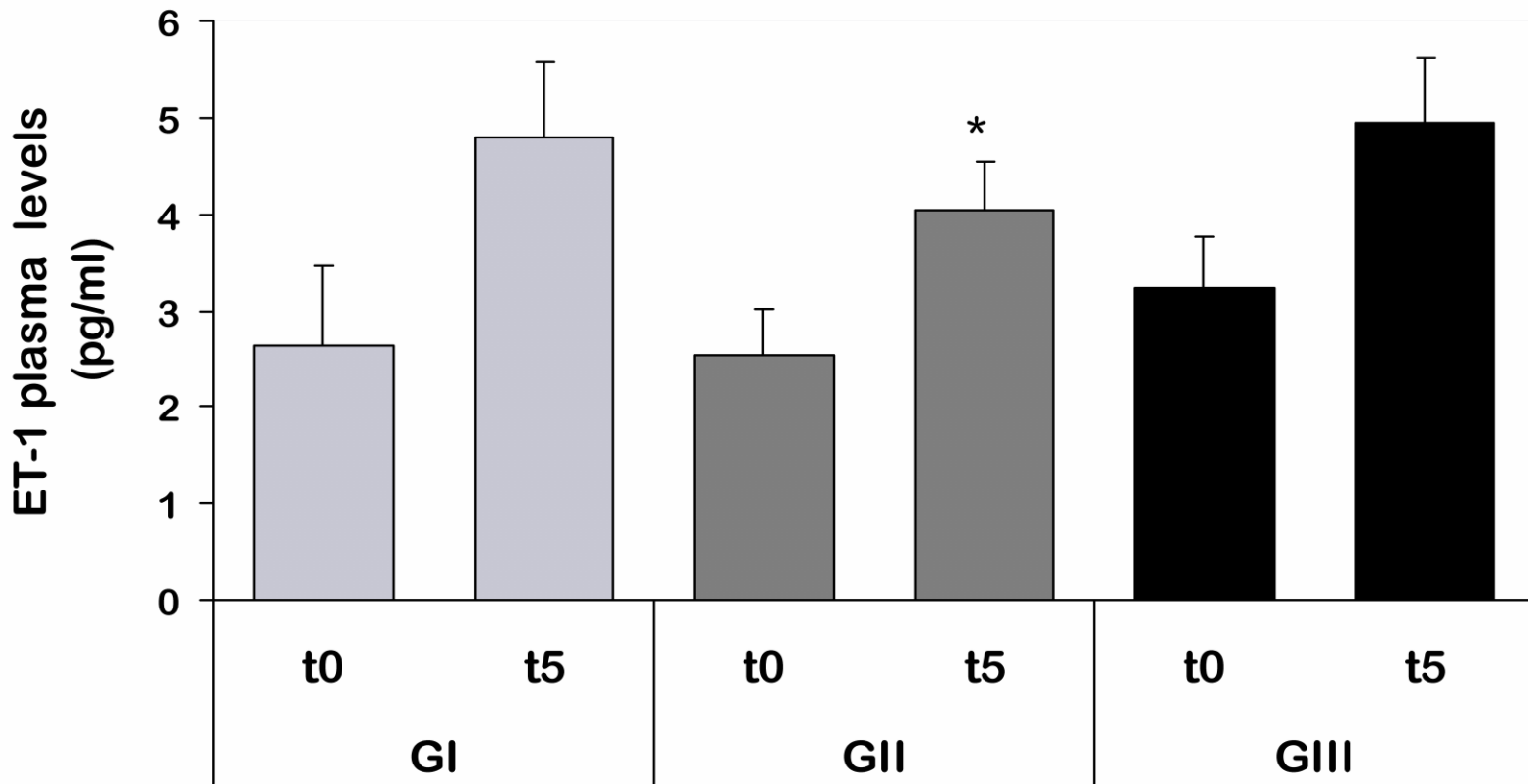
- Prevention of excessive Endothelin-1 release in sclerotherapy: in-vitro and in-vivo studies
A.Frullini et al. Dermatologic Surgery 2014



FOAM SCLEROTHERAPY IN RATS WITH ANTI-ENDOTHELIN PRETREATMENT (aminaphtone)

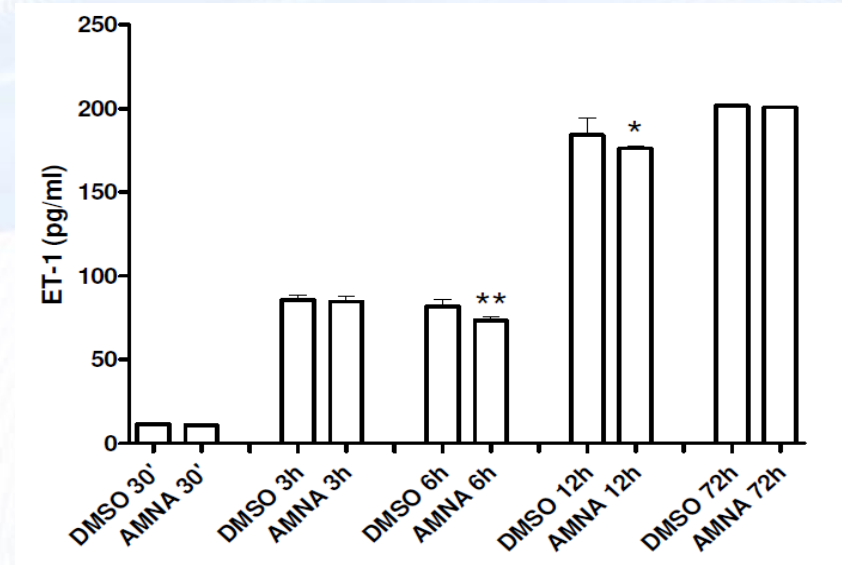
- 3 groups
 - C: control
 - G1: oral AMNA 30mg/kg/die
 - G2: oral AMNA 150mg/kg/die

ET-1 levels after sclerotherapy



Sclerotherapy on HUVEC CELLS:results

- After AMNA pre-treatment and POL treatment, ET 1 cellular release was significantly lower after 6 (p<0.01) and 12 hours (p<0.05) in respect to control without AMNA



PRO.COM.ET study

(**PRO**phylaxis **COM**plications **ET** 1 related)

- **A.FRULLINI –FIRENZE**
- **D.GUARNACCIA-
AFRAGOLA**
- **S.PARADISO-TRANI**
- **D.MAURANO COSENZA**
- **M.RENDACE- RENDE**
- **A.M. PREVITERA-
CATANIA**
- **A.GUASTINI- CHIAVARI**
- **O.W. LOPARCO
PESCARA**
- **P.PAVEI-PADOVA**

Aims

TO EVALUATE IF PRETREATMENT WITH AMINAPHTHONE (AMNA) WAS ABLE TO AFFECT THE INCIDENCE OF NEUROLOGICAL OR VISUAL DISTURBANCES IN PATIENTS TREATED WITH SCLEROTHERAPY FOR CHRONIC VEIN DISEASE

PROCOMET STUDY design

- **Retrospective**
- **Similar protocol for data collection**
- **Sclerotherapy conducted as usual and according to guidelines**
- **Aminaphtone is commonly used in venous patients (75mg/bid starting at least 3 days before sclerotherapy)**

PROCOMET STUDY

- **TOTAL SESSIONS1642**
- **TOTAL SESSIONS WITH LIQUID.....430**
- **TOTAL SESSION WITH FOAM.....1212**

PROCOMET STUDY

NUMBER OF PTS

540

(406 AMNA/134 NO AMNA)

ADVERSE EVENTS

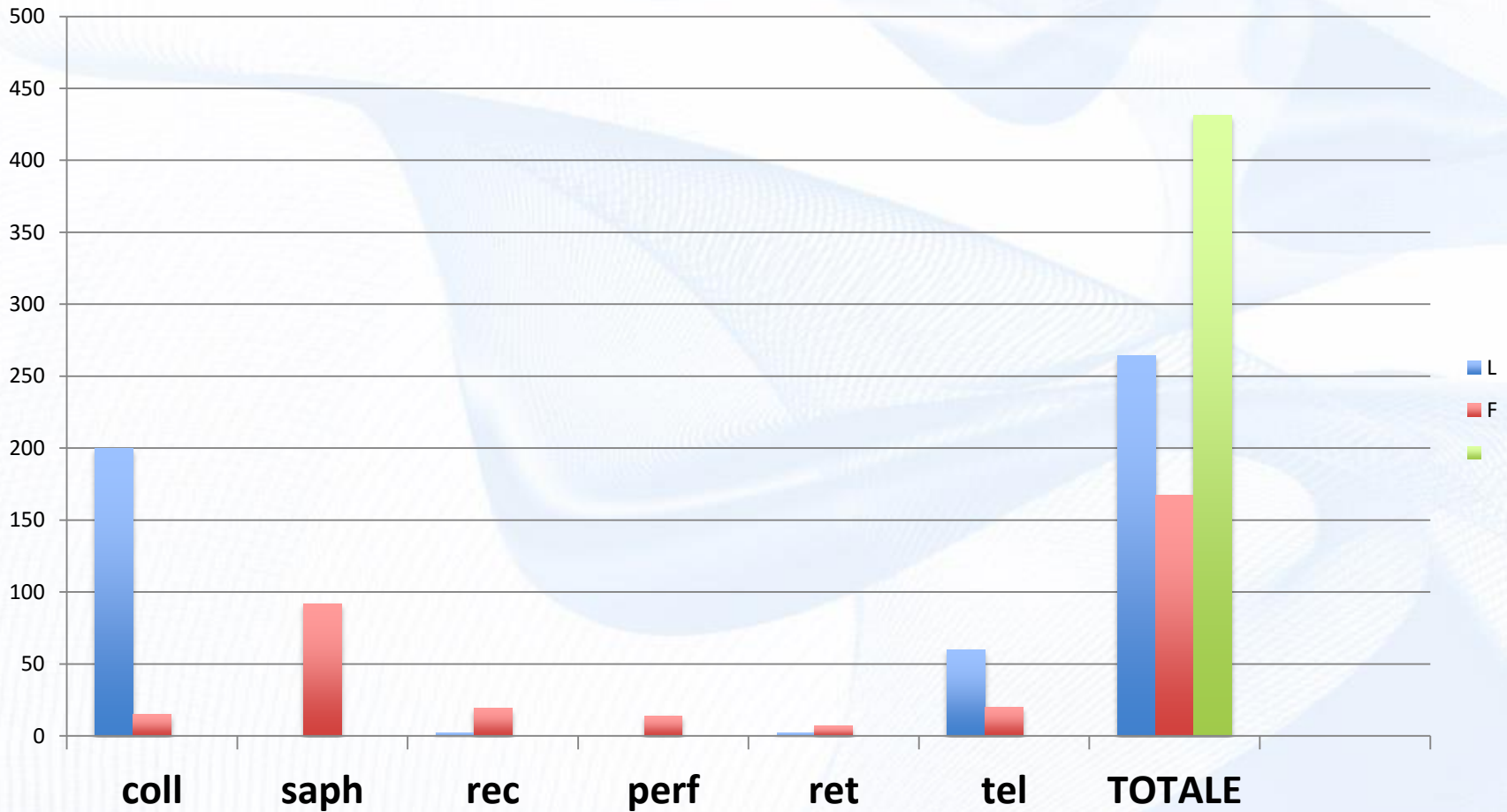
- **MIGRAINE**
- **TRANSIENT VISUAL DISTURBANCE**
- **TRANSIENT NEUROLOGICAL DISTURBANCE**

MEAN CONCENTRATION

- **NO AMNA.....1,78 %**
- **AMNA.....2,6 %**

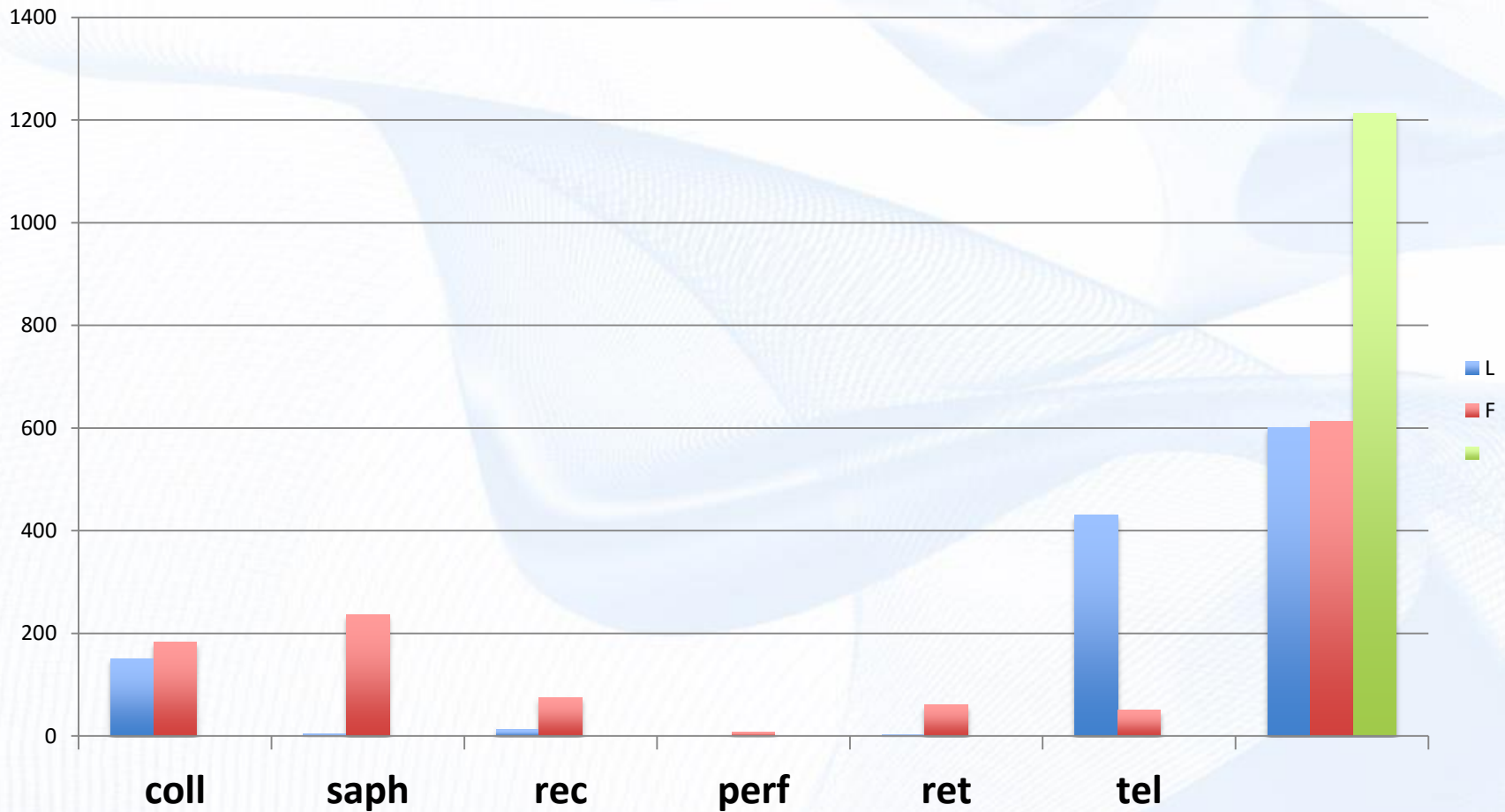
PROCOMET STUDY

disease distribution NO AMNA



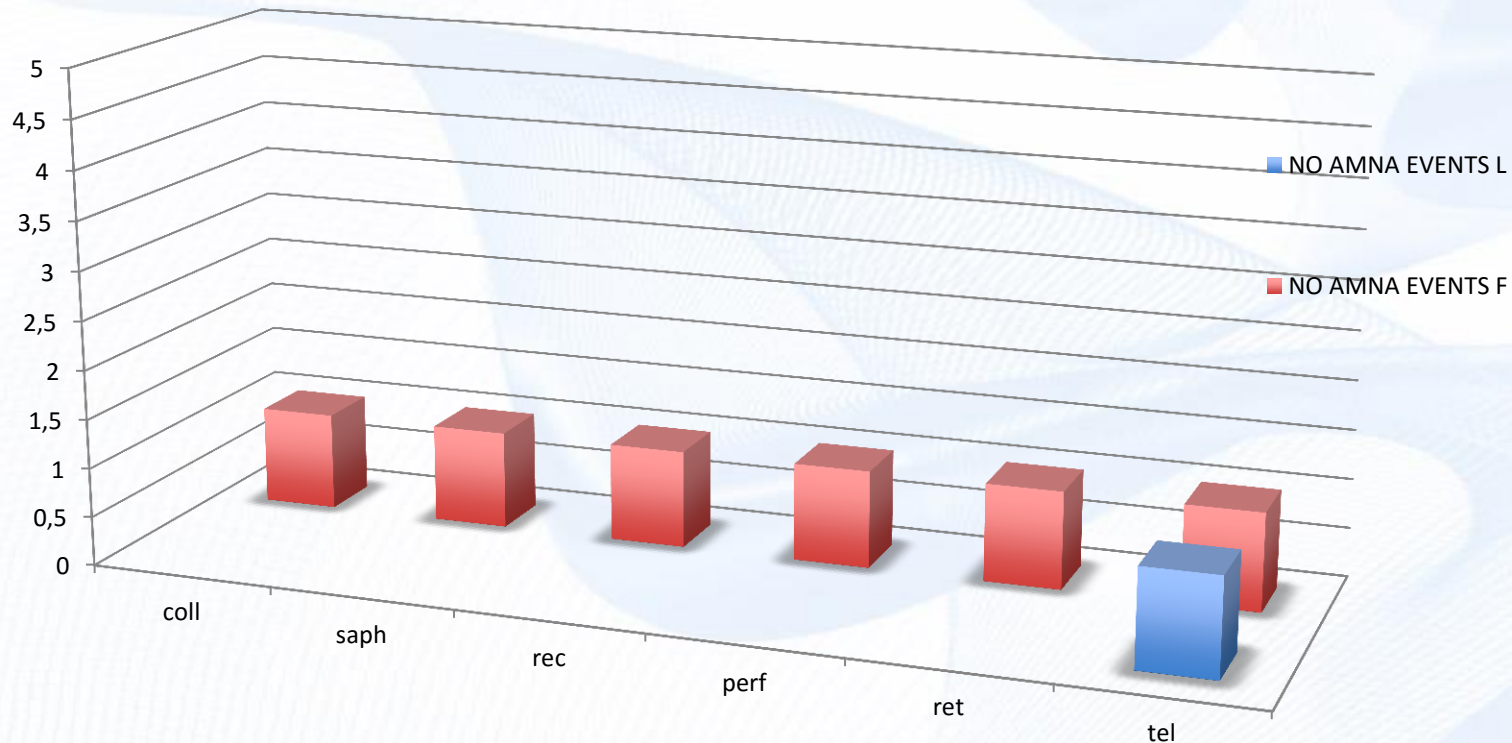
PROCOMET STUDY

disease distribution AMNA



PROCOMET

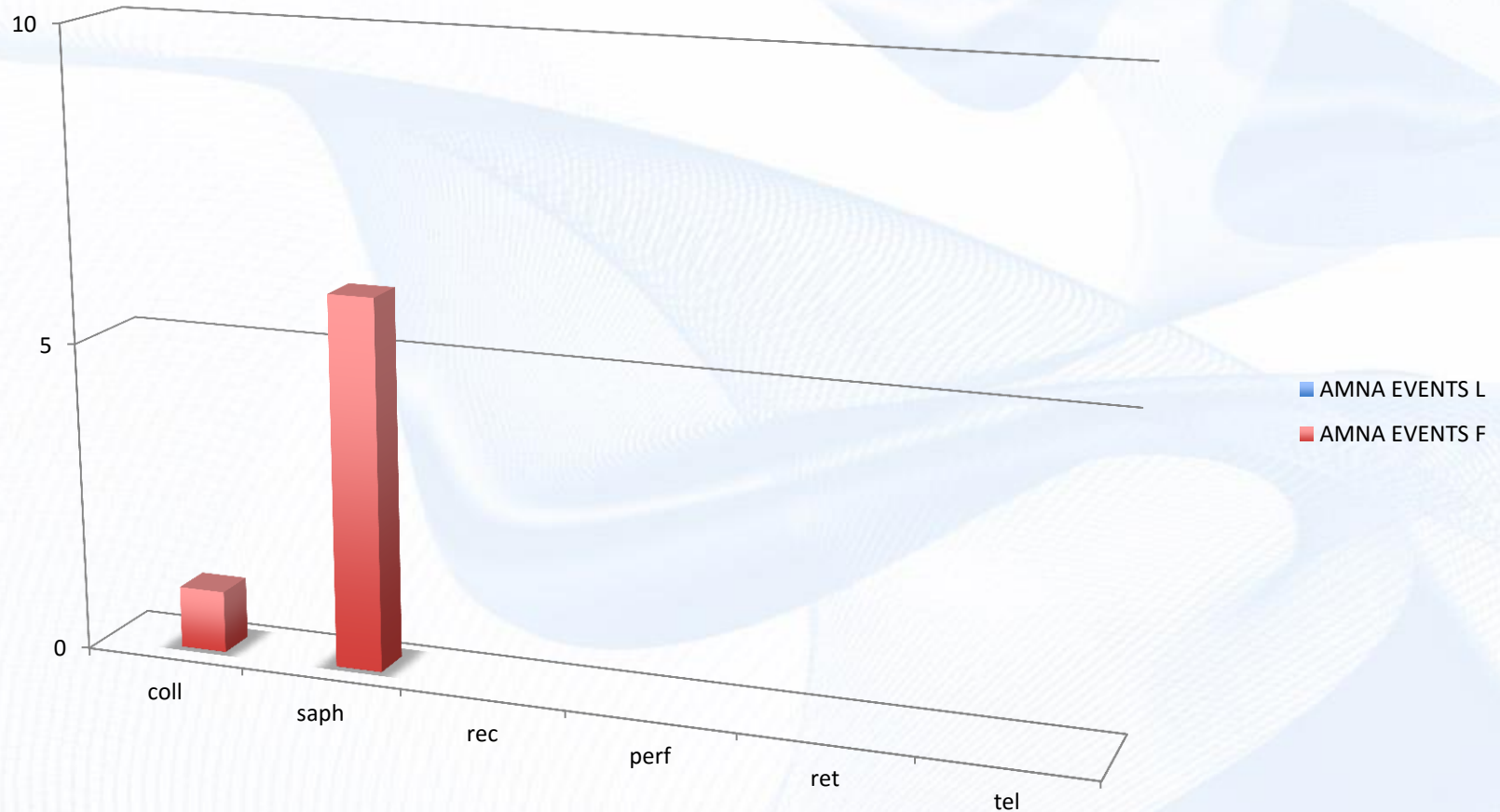
adverse events NO AMNA



7/430 = 1,62%

PROCOMET

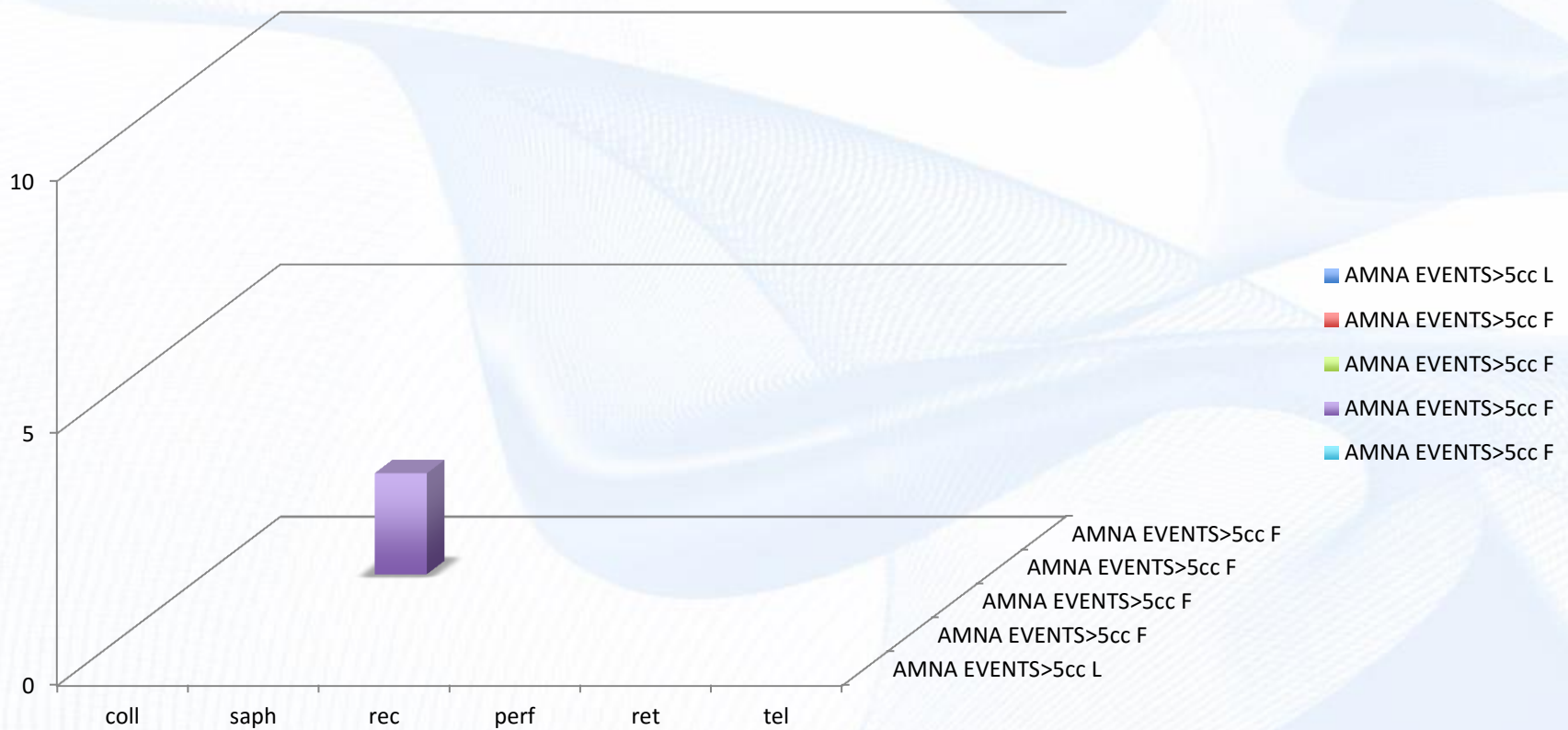
adverse events AMNA



7/1212 = 0,57%

PROCOMET

adverse events AMNA <5cc foam



2/1076 = 0,18%

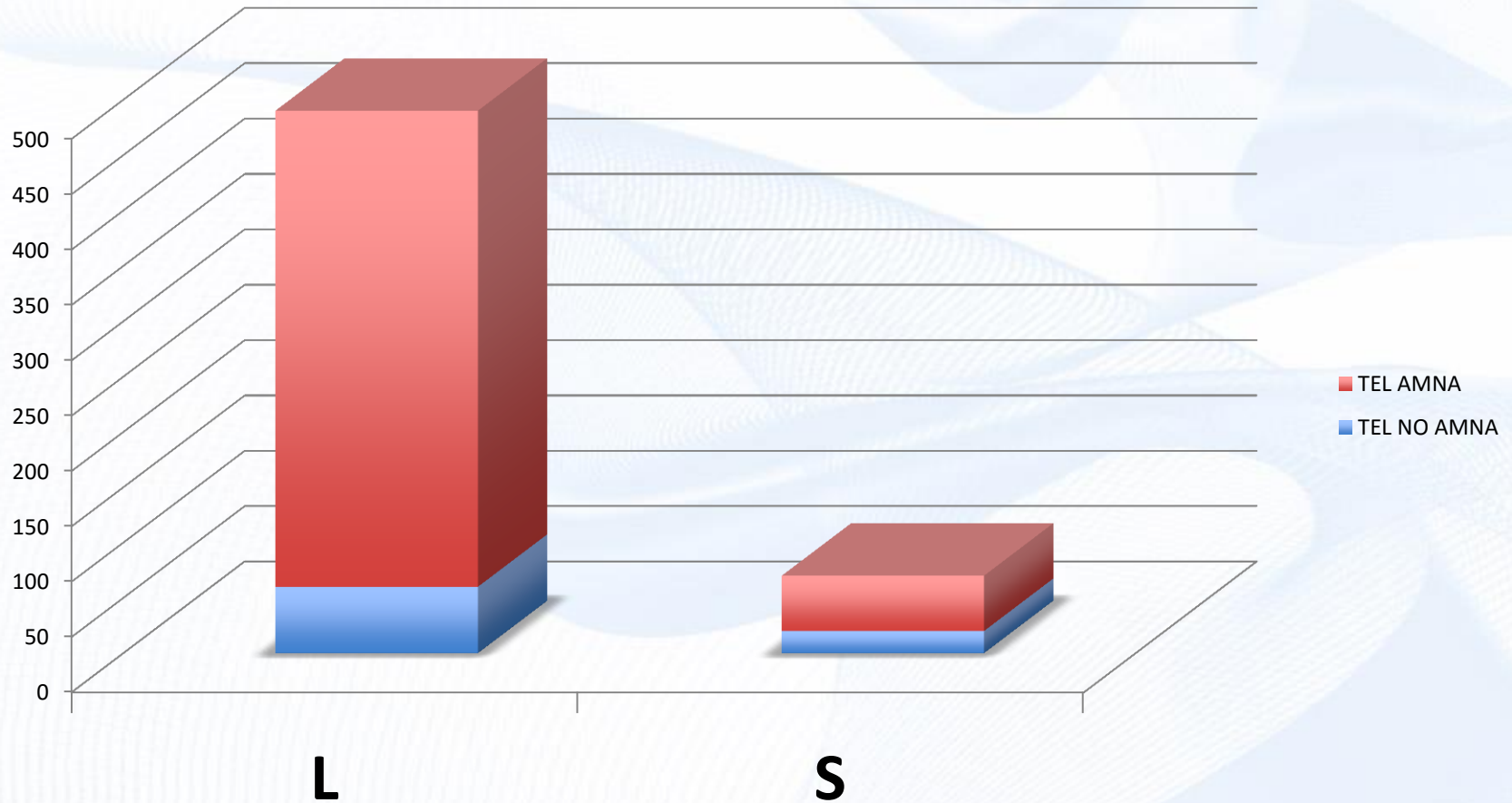
PROCOMET

adverse events **TOTAL**

- **NO AMNA PROPHYLAXIS** **1,62%**
- **AMNA PROPHYLAXIS** **0,57%**
- **AMNA PROPHYLAXIS > 5CC foam** **0,18%**

p=NS

PROCOMET TELEANGECTASIAS

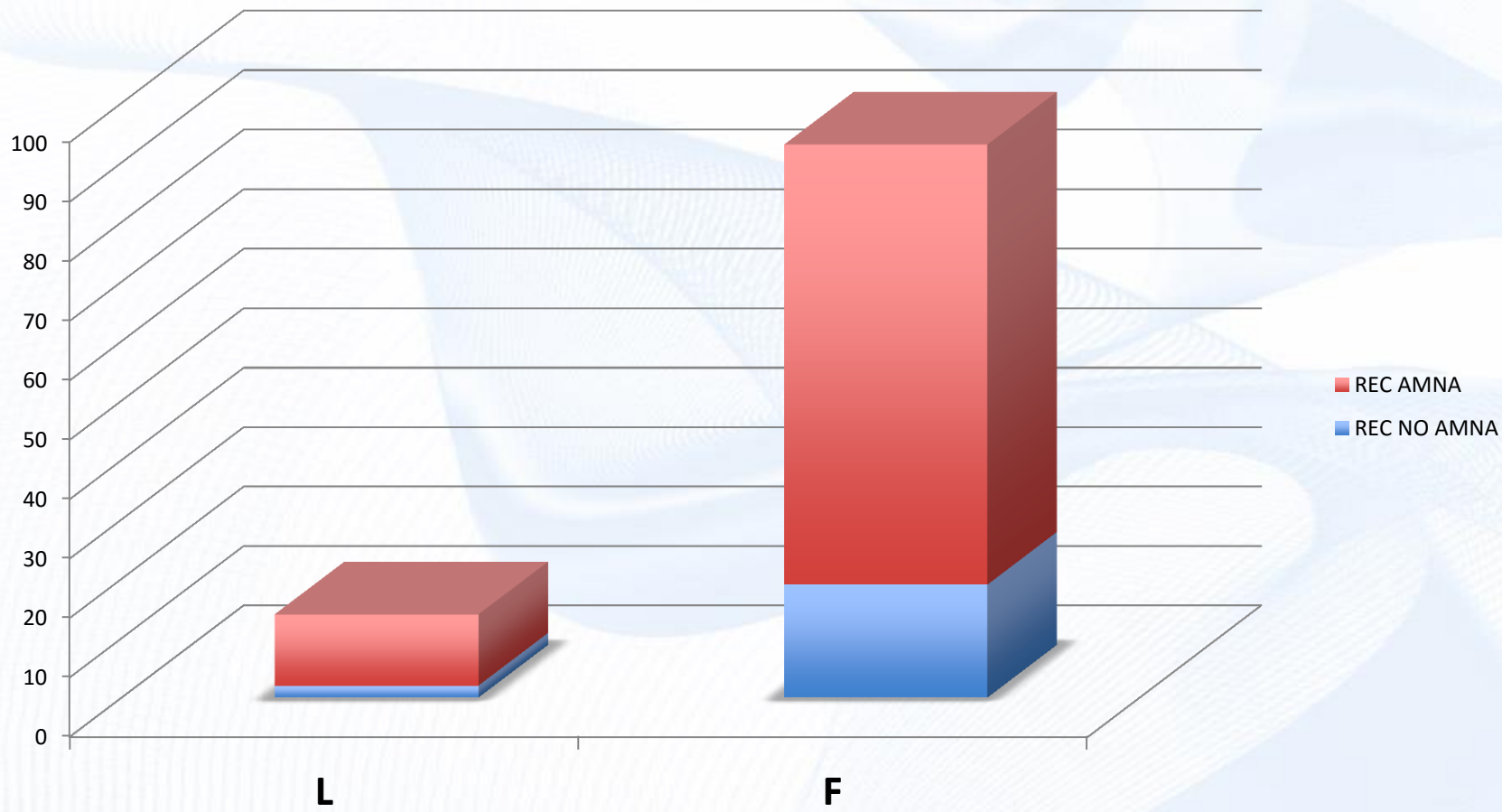


PROCOMET TELEANGECTASIAS

- **NO AMNA PROPHYLAXIS** **2,43 %**
**VISUAL OR NEUROLOGIC
ADVERSE EVENTS**
- **AMNA PROPHYLAXIS** **0%**

p= 0,02

PROCOMET RECURRENCIES



PROCOMET RECURRENCIES

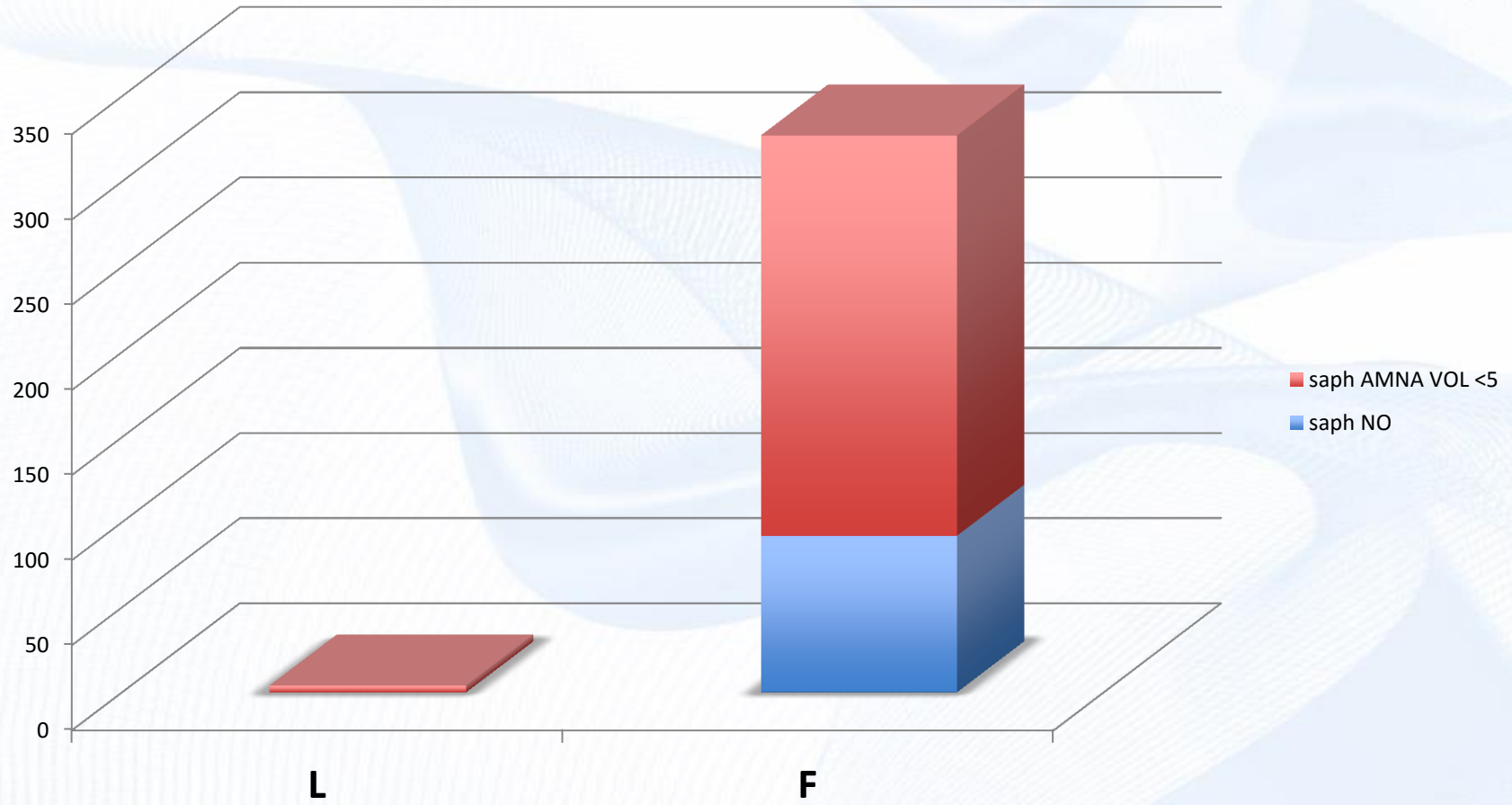
- NO AMNA PROPHYLAXIS

ADVERSE EVENTS 4,7%

- AMNA PROPHYLAXIS 0%

p=NS

PROCOMET SAPHENS

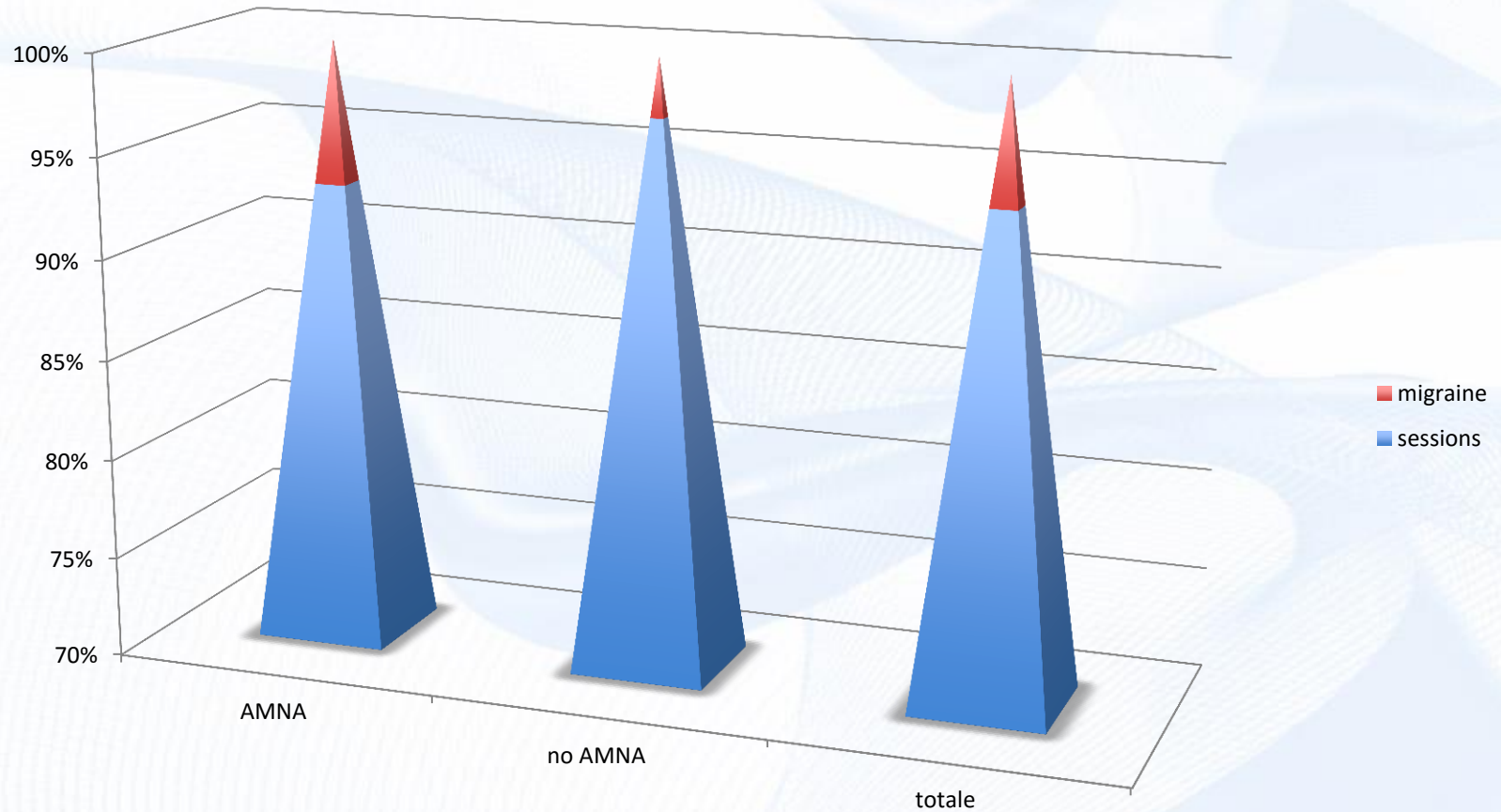


PROCOMET

SAPHENS < 5 cc foam

- NO AMNA PROPHYLAXIS
adverse events 1,08%
- AMNA PROPHYLAXIS
 - Adverse events 0,95%
 - **Statistically NS**

Complications & headache



Complications & headache

NO AMNA

- PERCENTAGE OF SESSIONS IN HEADACHE PATIENTS 3,0%

AMNA

- PERCENTAGE OF SESSIONS IN HEADACHE PATIENTS 7,6%

Complications & headache

- **NO AMNA PROPHYLAXIS IN HEADACHE PATIENT:
38,4 % PROBABILITY ADVERSE EVENT**
- **AMNA PROPHYLAXIS IN HEADACHE PATIENT:
3,2% PROBABILITY ADVERSE EVENT**

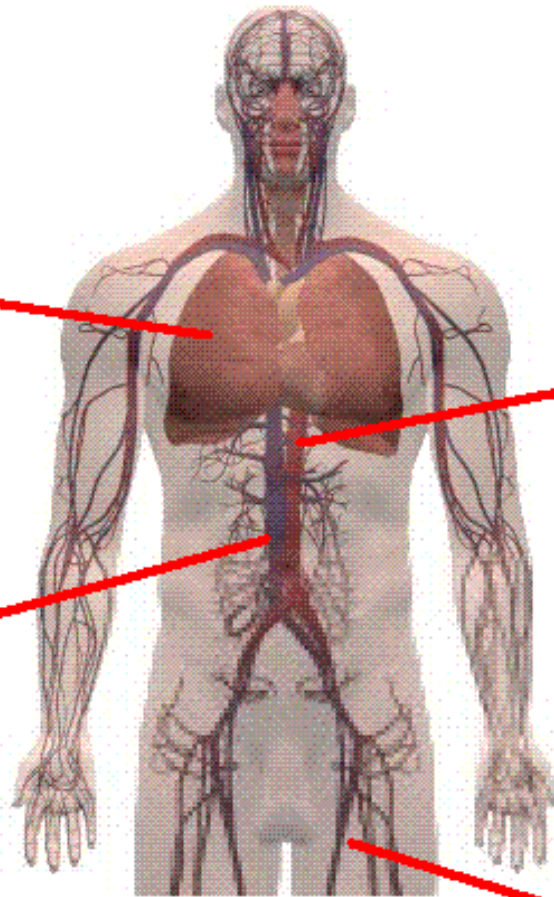
p=0,002

**NO PFO
ET 1 TO
LUNGS**

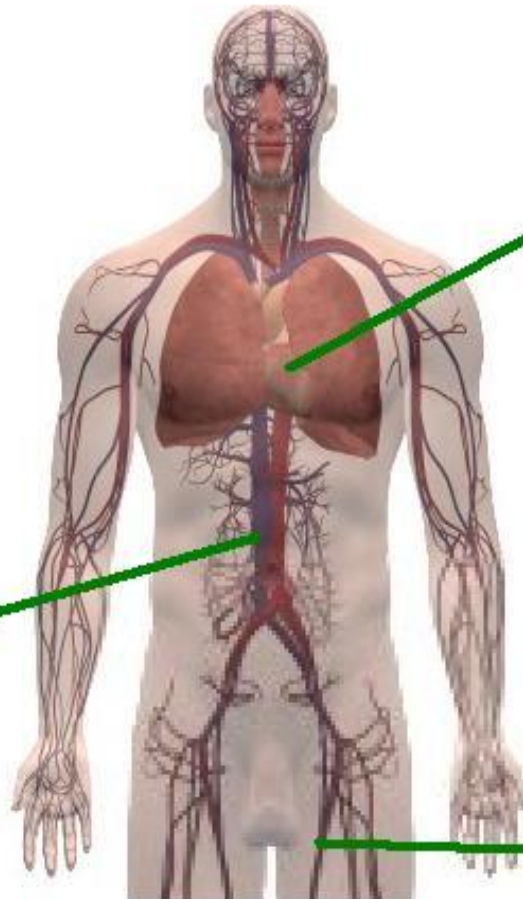
**LOW ET 1
SYSTEMIC
CIRCULATION**

**HIGH
ET 1**

**FOAM
INJECTION**



**HIGH
ET 1**



**PFO:
SHUNT TO LEFT
HEART OF ET 1
RICH BLOOD**

**FOAM
INJECTION**

CONCLUSION 1

**MICRO-BUBBLES COULD
NOT BE THE CAUSE OF
SUCH COMPLICATIONS**

CONCLUSION 2

**AMINAPHTONE SIGNIFICANTLY
REDUCE THE RISK OF
NEUROLOGICAL AND VISUAL
DISTURBANCES DURING
SCLEROTHERAPY OF
TELEANGECTASIAS**

CONCLUSION 3

**AMINAPHTONE PROTECTS
MIGRAINE PATIENTS FROM
NEUROLOGICAL AND VISUAL
DISTURBANCES WHEN
SUBMITTED TO SCLEROTHERAPY**

CONCLUSION 4

- **THERE IS AN INTERESTING TREND IN PROTECTION FROM VISUAL AND NEUROLOGICAL COMPLICATIONS FOR LARGER VEINS SCLEROTHERAPY**
- **A STUDY WITH A LARGER NUMBER OF SESSIONS IS REQUIRED IN ORDER TO CONFIRM THIS DATA**

CONCLUSION 5

**THERE IS A TREND FOR
BETTER SAFETY OF <5 CC
VOLUMES OF FOAM**

CONCLUSION 6

**IN CONSIDERATION OF THE
EXCELLENT SAFETY PROFILE OF
AMINAPHTONE SUCH
PROPHYLAXIS IS NOW USED IN MY
PRACTICE OF SCLEROTHERAPY**

**GRAZIE PER LA VOSTRA
ATTENZIONE**

