# "MEDITRACK" RANDOMIZED CONTROL STUDY

## Role of the recommendations to improve patient compliance in using compression stockings

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25 sept 2016

ICC
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# Conflict of interest:

This study was sponsored by MEDI Bayreuth

# BACKGROUND

Patient compliance is the cornerstone of compression therapy success.

However, there was no mean to assess it other than patient self-report, which is not reliable.

# BACKGROUND (2)

- Several studies* have reported patient´s compliance as low as 30 to 50% after 3 months of compression stocking use.
- Patient's lack of education# seems to be at the root of this noncompliance.
- To our knowledge no one has objectively assessed the true (or real) compliance.

* *Raju et al. Ann Vasc Surg. 2007 ; 21(6):790-5.*
*# *Ziaja et al. Phlebology. 2011;26:353-360*

# OBJECTIVES

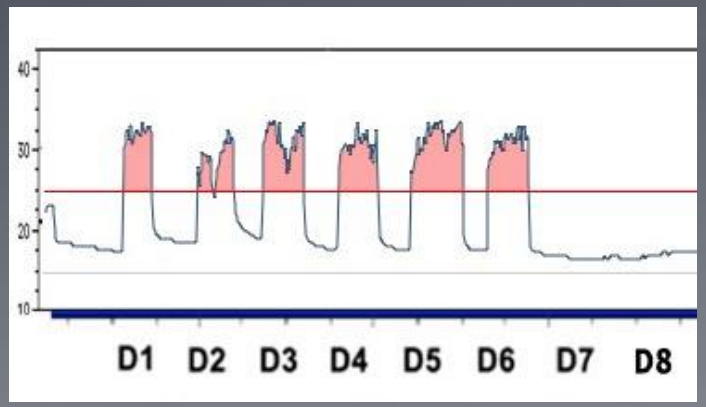
- To accurately measure the real compliance in using compression stockings by using a thermal probe ( Thermotrack device* )
- To assess the role of the recommendations to improve the patient compliance.

** Thermotrack online www.progesplus.com*

# METHODS : the thermotrack « spy » device

Thermal probe included in the compression stockings


It is a small disk recording the temperature every 20 minutes during 4 weeks I.E 4096 measurements readable on a PC (accuracy 1 ° C)



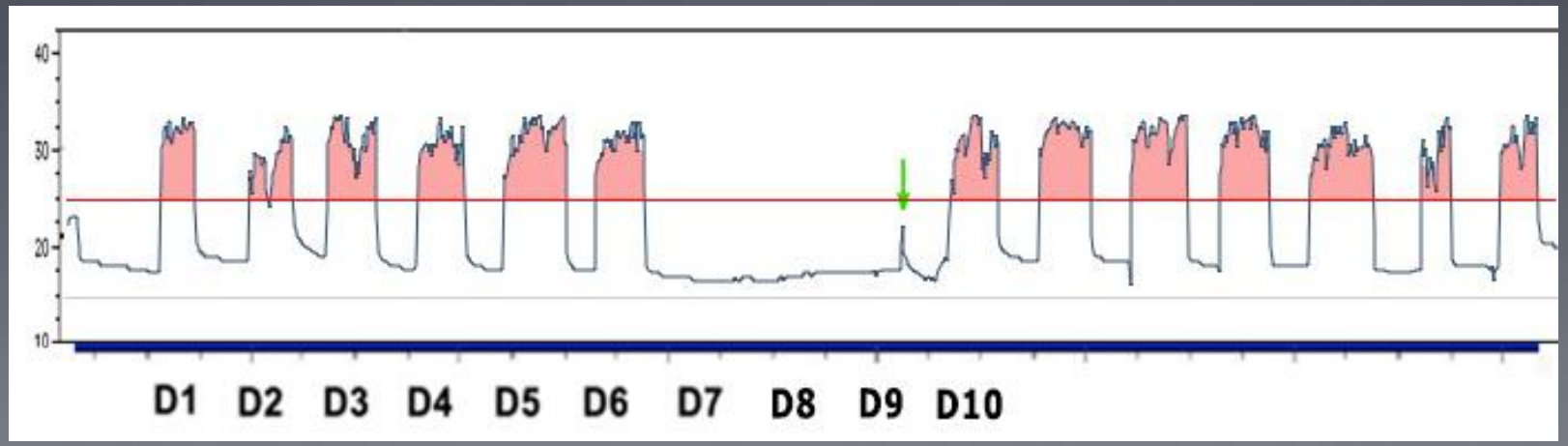

THERMAL CURVE

USB probe reader

# METHODS (2)

- MEDI Stockings / socks were used including the probe and providing a pressure of 15-20 mmHg at the ankle (B1 point).

- TEMPERATURE RECORDING through the thermotrack probe every 20 minutes during 4 weeks. The accurate wearing time was computed* with excel® from the daily temperature curve.




* *A validation study has been achieved before, and presented at the AVF and ICC*

# INCLUSION CRITERIA

- Active Females between 20 and 65 Y
- with a primary CVD classified C2S
- Venous symptoms imputability score > 2
- Free personnal choice  for stockings or socks
- Cellular phone + written consent to participate

The patients were told to participate to a study for the quality of the stockings, not for their compliance +++

# MATERIAL & METHODS (3)

Monocentric study

40* selected women were randomized into

2 groups of 20 :

- Group 1: receiving minimal recommendations about stockings use by their physician at the office.

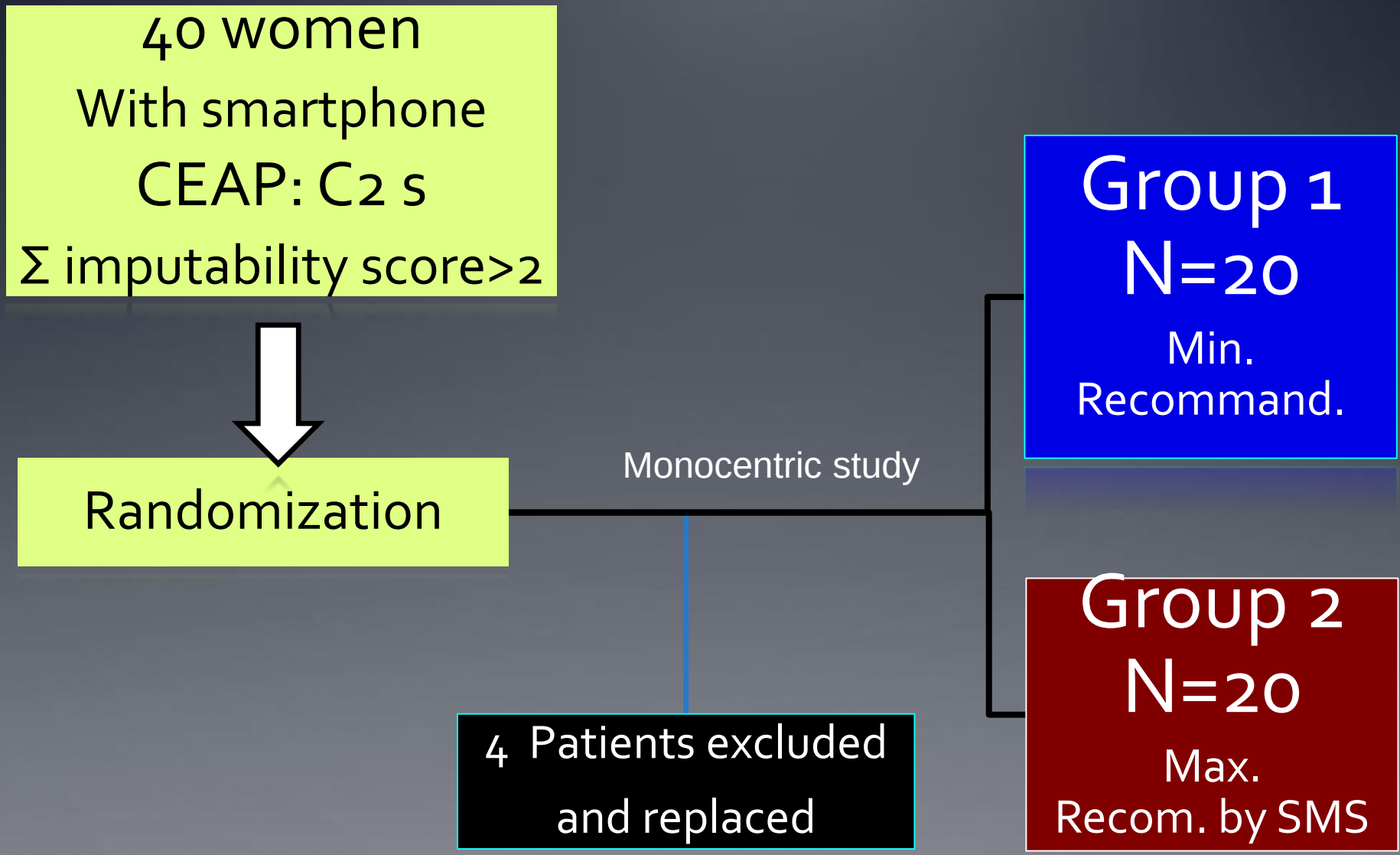
- Group 2: receiving detailed explanations reinforced by SMS or smartphone recommendations repeated weekly.

* 44 women were selected but 4 were excluded and replaced

# 4 patients were discarded and replaced

- In 2 cases the bouton was not readable (5%)
- In 1 case the curve was too difficult to analyse
- 1 patient of group 2 was eliminated (not reachable by phone for recommandations)

# STUDY DESIGN



# EVALUATION CRITERIA

At the beginning of the study:

1/ Podiatric examination – Djian angle measurement

2/ Assessment the "venous" symptoms with a VAS

3/ Auto questionnaire QOL (CIVIQ)

4/ Venous symptoms imputability score*

5/ Basic CEAP (Computerized venous registry**)

6/ Color Duplex

At the end of the study: Auto-questionnaire QOL (CIVIQ)

TEMPERATURE CURVE

* *Carpentier PH et al. JVS 2007;46:991-6.)*

** *Uhl J.F et al. Int. Angiology 2005; 21 N° 3 supp 2 p7*

# Patients characteristics

| CEAP C2 S | Group 1<br>Minimal recom<br>Average (sd) | Group 2<br>Max recom.<br>Average (sd) | t of Student test |
|---|---|---|---|
| AGE (years) | 53 (14) | 53,5 (16) | NS |
| Body Mass Index | 23,9 (4,2) | 23 (2,9) | NS |
| Imputability score (0-5) | 3,8 (1,5) | 3,9 (1,2) | NS |
| Pain score (VAS 0-10) | 3,6 (1,4) | 4,1 (1,2) | NS |
| Heavy legs (VAS 0-10) | 1,4 (0,5) | 1,3 (0,8) | NS |
| | | | Chi $^2$ |
| Socks / Stockings % | 65/35 | 56/44 | NS |

# RESULTS:

## Real wearing time compared in the 2 groups

| | Group 1 R - | Group 2 R+SMS | increase | t test of Student |
|---|---|---|---|---|
| Hours / day | 5,6 ( 3.7) | 8 ( 3.6) | +33% | p= 0.02 |
| Days / week | 3.4 (2) | 4.9 (1.7) | +33% | p= 0.01 |

Recommandations increase wearing time by 33%

# RESULTS:
## compared real wearing time in the 2 groups

| | Group 1<br>R - | Group 2<br>R + SMS | increase | t test of Student |
|---|---|---|---|---|
| Hours / day | 5,6 ( 3.7) | 8 ( 3.6) | +33% | p= 0.02 |
| Hours / wearing day | 11,1 (3) | 11,6 (1.7) | +4% | NS |
| Days / week | 3.4 (2) | 4.9 (1.7) | +33% | p= 0.01 |

Recommandations increase wearing time by 33%

# Discussion

**We propose to assess the compliance only by the wearing days according to our results. Why ?**

**Because if worn, the average H/day is the same in the 2 groups**

For example: 3 days/week makes a compliance of 3/7 = 43%

# Discussion (2)

-Good comfort

-Reliability of the device ( 7% issues )

-Computation of wearing time can be automatized. by an excel formula using the sparkling curves (average cut-off 26° C)

-Main limitation: an external temperature > 28° C makes it difficult to use +++

# Conclusion

- This is the first study assessing the REAL compliance for the wear of compression stockings +++
- Average observance is high (60%) due to the confidence for the practitionner and inclusion in a RCT.

# Conclusion (2)

Recommandations given by the practitionner are a important factor of good observance of the wear of compression stockings/socks:

in fact, weekly recommandations by SMS were found to improve observance by 33% .

Another study on 3-6 months should confirm the results of this small study.

# Thank you for your attention !