

Paolo Prandoni

Prevenzione della PTS

Calze elastiche si o no?

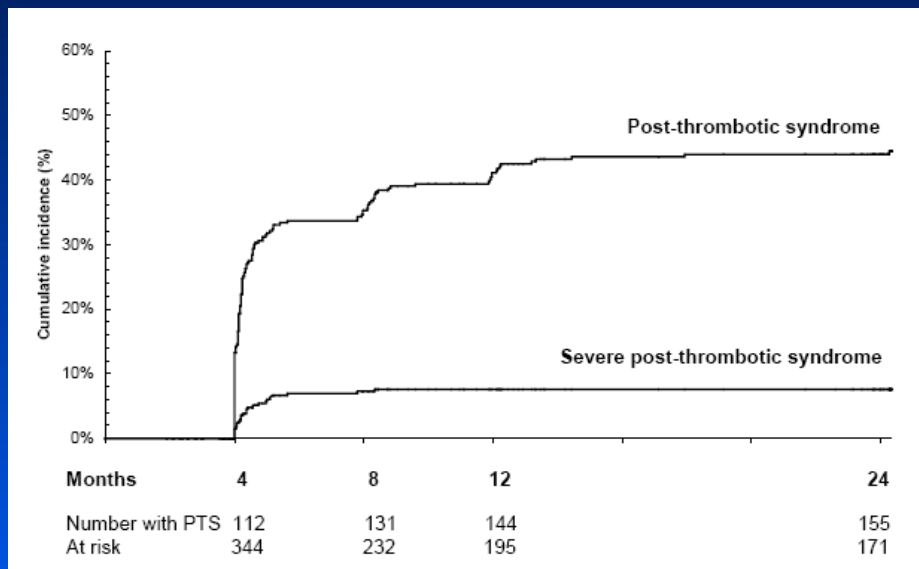


Disclosures of: Paolo Prandoni

Employment	No conflict of interest to disclose
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Speakers bureau	No conflict of interest to disclose
Major stockholder	No conflict of interest to disclose
Patents	No conflict of interest to disclose
Honoraria	No conflict of interest to disclose
Travel support	No conflict of interest to disclose
Other	No conflict of interest to disclose

Presentation includes discussion of the following off-label use of a drug or medical device: N/A

Cumulative risk of the PTS in the study cohort



Kahn et al, Ann Intern Med 2008

Independent predictors of PTS

Baseline parameters

- ❖ Elderly age
- ❖ Varicose veins
- ❖ Obesity
- ❖ Involvement of the ilio-femoral tract
- ❖ Intensity of the initial signs/symptoms

Independent predictors of PTS

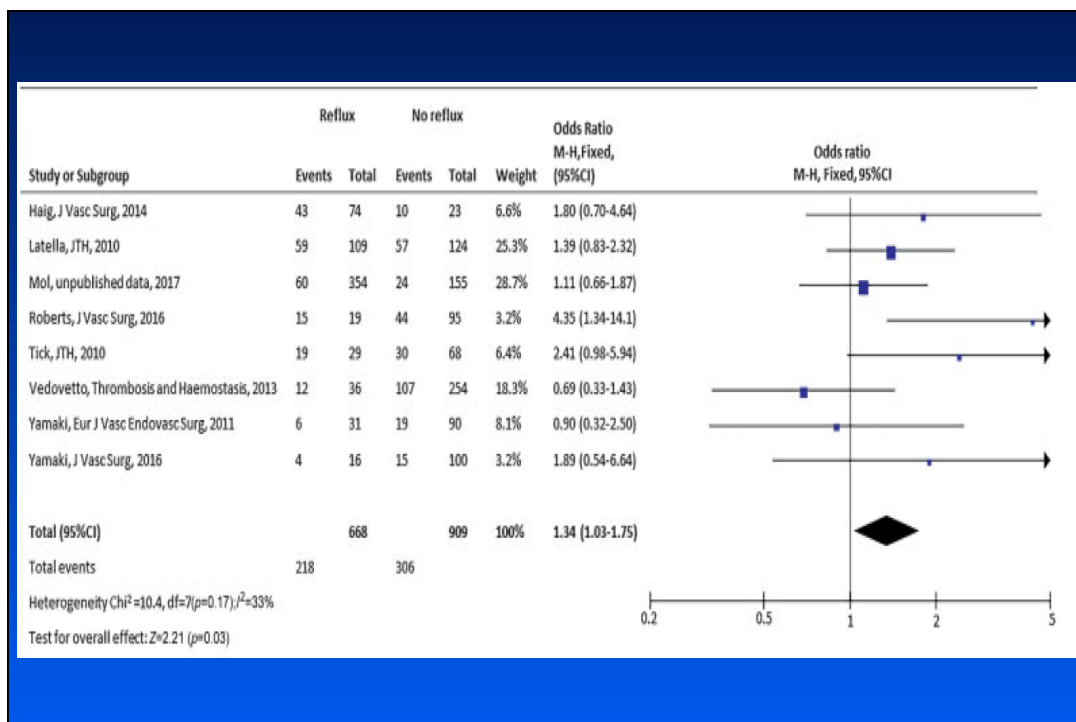
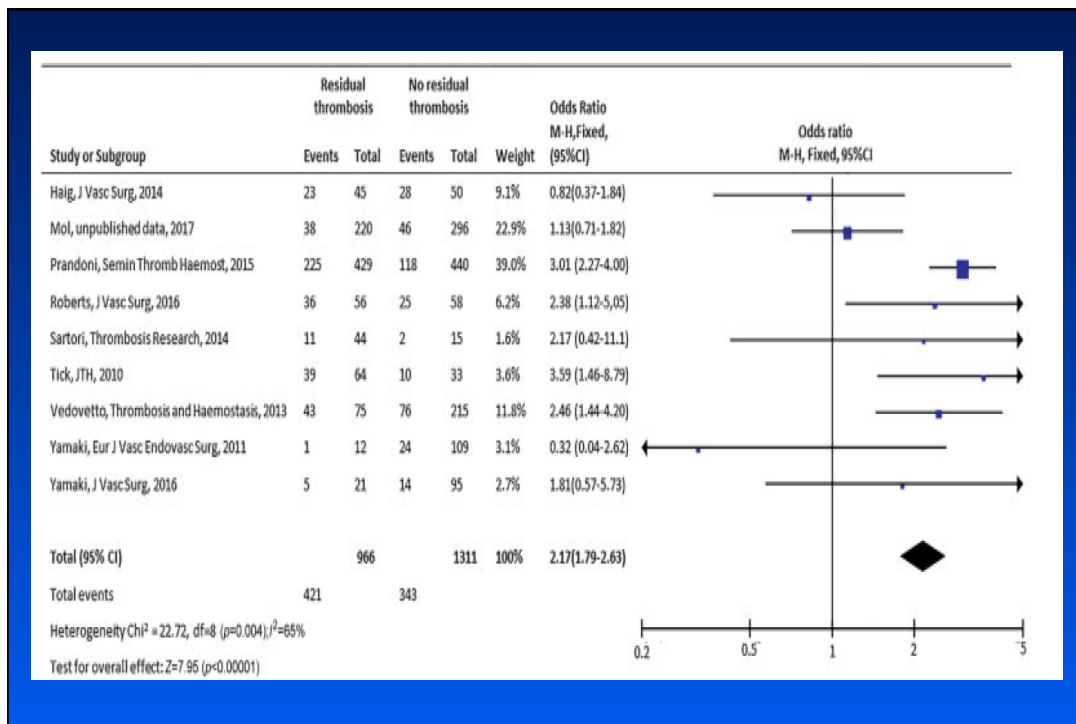
Post-baseline parameters

- ❖ **Positivity of inflammation markers at a variable distance since the initial DVT episode**
- ❖ **Inadequate AVK therapy**
- ❖ **Development of recurrent ipsilateral DVT**
- ❖ **Persistence of residual vein thrombosis**
- ❖ **Development of popliteal valve incompetence**

Predicting Post-Thrombotic Syndrome with Ultrasonographic Follow-Up after Deep Vein Thrombosis: A Systematic Review and Meta-Analysis

C. E. A. Dronkers¹ G. C. Mol² G. Maraziti³ M. A. van de Ree⁴ M. V. Huisman¹ C. Becattini³
F. A. Klok¹

Thromb Haemost 2018



CALZE ELASTICHE

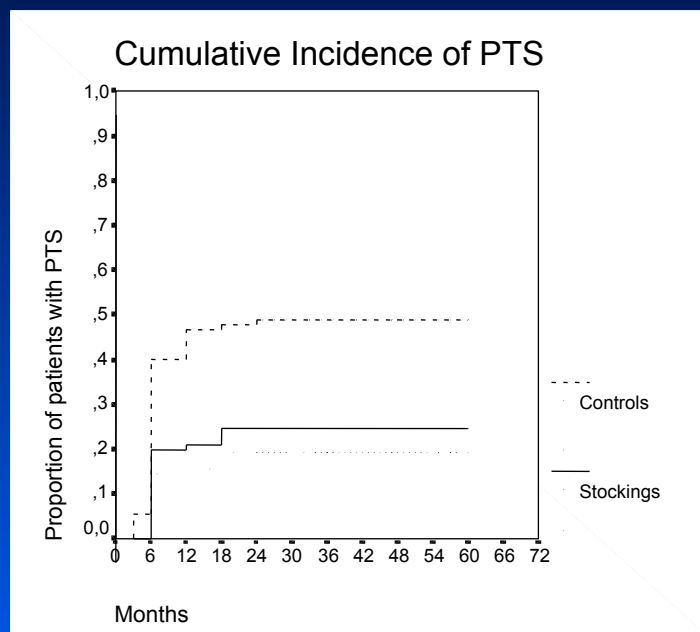
Prandoni P, Frulla M, Marchiori A, et al

Below-knee compression elastic stockings for prevention of PTS in patients with proximal DVT

Ann Intern Med 2004

Patients

• Eligible patients	258
• Patients excluded	78
- life expectancy < six months	34
- previous ipsilateral DVT	20
- pre-existing serious CVI	12
- bilateral DVT	3
- known skin allergy to ES	2
- refusal of consensus	7
• Patients recruited	180



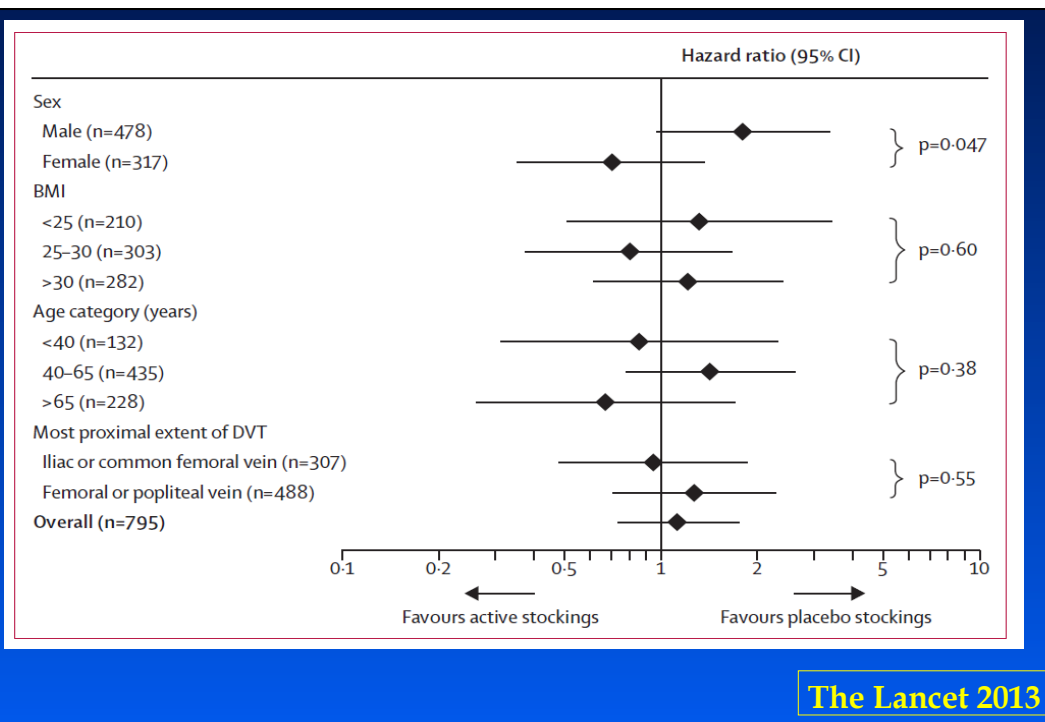
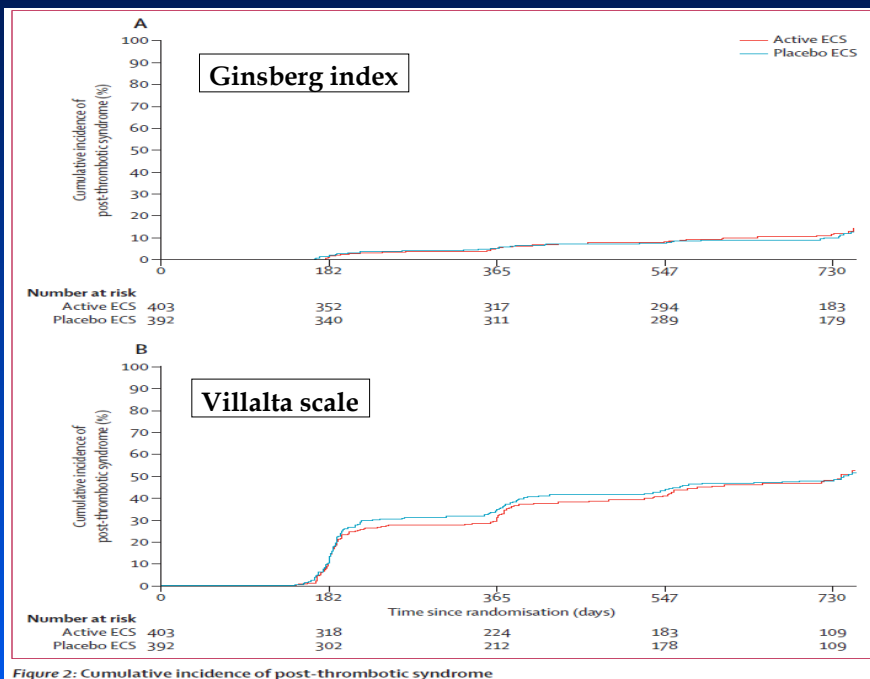
Prandoni et al, ISTH 2003

Compression stockings to prevent post-thrombotic syndrome: a randomised placebo-controlled trial

Susan R Kahn, Stan Shapiro, Philip S Wells, Marc A Rodger, Michael J Kovacs, David R Anderson, Vicky Tagalakis, Adrielle H Houweling, Thierry Ducruet, Christina Holcroft, Mira Johri, Susan Solymoss, Marie-José Miron, Erik Yeo, Reginald Smith, Sam Schulman, Jeannine Kassis, Clive Kearon, Isabelle Chagnon, Turnly Wong, Christine Demers, Rajendar Hanmiah, Scott Kaatz, Rita Selby, Suman Rathbun, Sylvie Desmarais, Lucie Opatrny, Thomas L Ortel, Jeffrey S Ginsberg, for the SOX trial investigators

The Lancet 2013

	Active stockings group (n=409)	Placebo stockings group (n=394)
Age, years	55.4 (15.3)	54.8 (15.8)
Age category		
<40 years	67 (16.4%)	67 (17.0%)
40–65 years	222 (54.3%)	217 (55.1%)
>65 years	120 (29.3%)	110 (27.9%)
Men	255 (62.4%)	228 (57.9%)
Outpatients	355 (86.8%)	344 (87.3%)
White ethnic origin	371 (90.7%)	354 (89.9%)
Body-mass index, kg/m ²	29.0 (6.1)	28.9 (6.1)
Time from DVT diagnosis to randomisation, days	4.8 (4.1)	4.6 (3.8)
Characteristics of DVT		
Right	180 (44.0%)	173 (43.9%)
Left	222 (54.3%)	216 (54.8%)
Bilateral	7 (1.7%)	5 (1.3%)
Most proximal extent of DVT*		
Iliac vein	44 (10.8%)	49 (12.4%)
Common femoral vein	109 (26.7%)	107 (27.2%)
Femoral vein	128 (31.3%)	123 (31.2%)
Popliteal vein	128 (31.3%)	115 (29.2%)
Villalta score at baseline	8.2 (4.4)	8.7 (4.8)

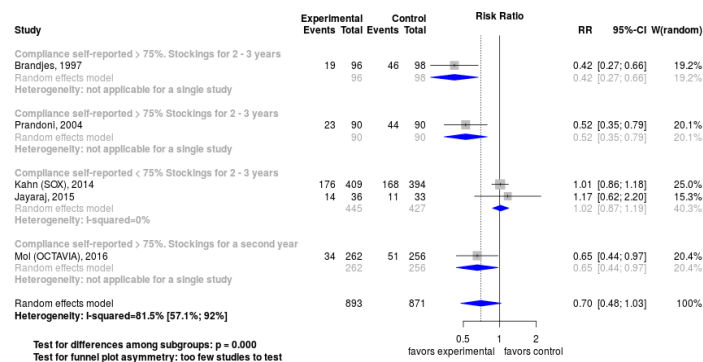


SOCS features

- Compliance lower than 50%
- Allocation to elastic stockings two weeks after the acute episode
- The problem of the “false” elastic stockings
- The substantial (up to 20%) rate of inpatients

Compression Stockings to Prevent Post-phlebotic Syndrome: Open Metanalysis

High pressure compression stockings to prevent post-phlebotic syndrome



www.github.com/openMetaAnalysis/Compression-stockings-to-prevent-post-phlebotic-syndrome/blob/master/README.md

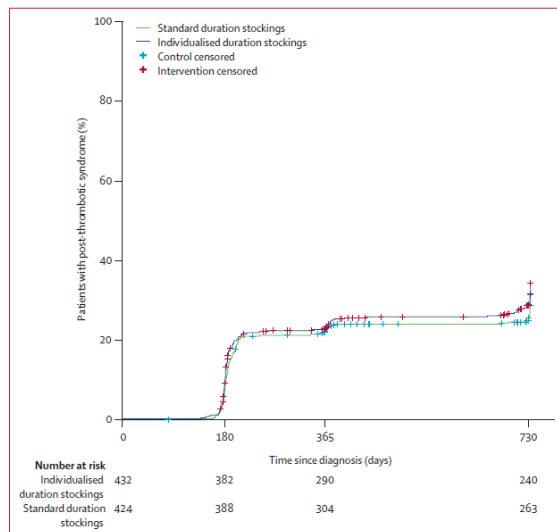
The IDEAL DVT study

Individualised versus standard duration of elastic compression therapy for prevention of post-thrombotic syndrome (IDEAL DVT): a multicentre, randomised, single-blind, allocation-concealed, non-inferiority trial



Arina J ten Cate-Hoek, Elham E Amin, Annemieke C Bouman, Karina Meijer, Lidwine W Tick, Saskia Middeldorp, Guy J M Mostard, Marijke ten Wolde, Simone M van den Heiligenberg, Sanne van Wissen, Marlène HW van de Poel, Sabina Villalta, Erik H Semé, Hans-Martin Otten, Edith HKlappe, Ingrid M Bistervels, Mandy N Lauw, Margriet Piersma-Wichers, Paolo Prandoni, Manuela A Joore, Martin H Prins, Hugo ten Cate, for the IDEAL DVT investigators*

Lancet Hematology 2017



Added value of this study

We found that it is possible to select patients based on their Villalta score to stop treatment as early as 6 months without increasing the incidence of post-thrombotic syndrome at 24 months. This strategy proved to be highly efficient as treatment could be stopped in 55% of patients at 6 months and in an additional 11% of patients at 12 months. No serious adverse events related to individualised duration of treatment occurred.

Implications of all the available evidence

Apart from one negative trial, overall current evidence suggests a beneficial effect of therapy with elastic compression stockings to prevent post-thrombotic syndrome in patients after DVT. Therefore we conclude that individualised therapy duration with elastic compression stockings shortens duration of therapy, is effective, and is likely to reduce health-care costs, although we did not do a formal cost-effectiveness analysis.

LancetHaematol2017

Amin EE, Bistervels IM, Meijer K, et al

(subanalysis of the IDEAL study in a cohort of 592 patients)

**Residual vein occlusion in relation to
immediate compression and post
thrombotic syndrome in deep vein
thrombosis**

Blood 2018 [epub ahead of print]

Main results

- Immediate compression therapy after deep venous thrombosis is associated with a 20% absolute reduction of residual vein occlusion.
- The reduction of residual thrombosis is, in turn, associated with an 8% absolute reduction of PTS at 24 months.

STUDIO DEVICES



NUMERO DI PAZIENTI

320 pazienti che hanno completato un follow-up di sei mesi dopo il primo episodio di TVP prossimale senza sviluppare recidiva di TEV e/o PTS.

CRITERI DI INCLUSIONE

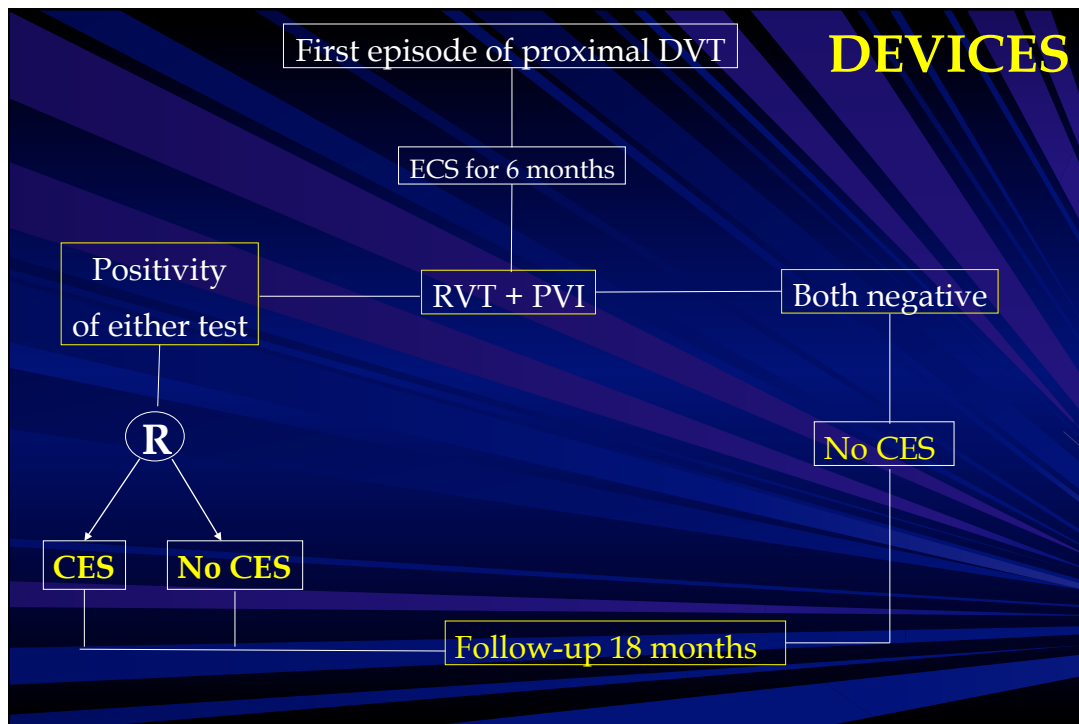
Pazienti con il primo episodio clinicamente sintomatico di TVP prossimale di un arto inferiore, documentato con ecografia venosa.

CRITERI DI ESCLUSIONE

- Ulcera venosa o manifestazioni di insufficienza venosa cronica
- Trombosi bilaterale
- Breve aspettativa di vita (inferiore a due anni)
- Controindicazione alle calze elastiche
- Inaccessibilità al follow-up
- Età inferiore a 18 anni
- Gravidanza o puerperio
- Rifiuto del consenso informato

Vanno poi successivamente esclusi anche i pazienti con:

- Sviluppo di recidiva di TEV e/o PTS nei primi sei mesi successivi all'episodio trombotico (e comunque prima del reclutamento al follow-up successivo)



ENDPOINTS DELLO STUDIO

Endpoints primari:

- Valutare l'efficacia del gambaletto elastico per la prevenzione della PTS in pazienti con RTV e/o IVP
- Paragonare la frequenza della PTS tra pazienti con e senza anomalie venose in assenza di calze elastiche

Endpoints secondari:

- Valutare la frequenza di PTS nei primi sei mesi dopo un episodio di TVP prossimale in pazienti trattati con terapia anticoagulante convenzionale e gambaletto elastico compressivo, e correlarla con lo sviluppo di RVT e/o IVP
- Accertare lo sviluppo di recidive tromboemboliche, mortalità totale e correlate a TEV durante il periodo programmato di follow-up
- Stabilire la compliance alle CE, la loro tollerabilità e la frequenza di sviluppo di eventi avversi correlati con il loro impiego