



# LA GESTIONE DELLE LESIONI DIFFICILI OGGI

## Il punto di vista del chirurgo

P. Bonadeo

Dipartimento di Chirurgia  
Week – Day Surgery  
ASL AL P.O. Tortona

## GESTIONE

*L'insieme delle azioni poste in essere per  
perseguire determinati obiettivi e compiere  
scelte riguardanti persone e tecnologie*

# MANAGEMENT

*Processo di definizione degli obiettivi e di guida della gestione al fine del raggiungimento di tali obiettivi attraverso l'assunzione di decisioni sull'impiego migliore delle risorse disponibili.*

*L'insieme delle persone responsabili del processo (scenari e attori).*

## UN MITO DA SFATARE



**L'ulcera cutanea non esordisce come DIFFICILE ma lo può diventare per diagnosi o assente o errata o tardiva oppure per una gestione non appropriata o per mancanza di risorse umane o economiche e, sempre, per inadeguata formazione.**

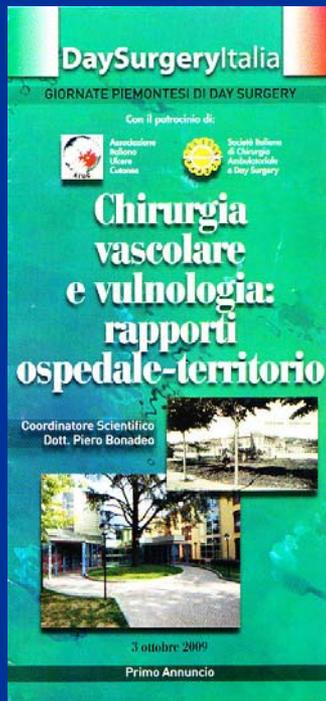
## Evidence Based Medicine (Sackett, 1992)



Processo della individuazione,  
della valutazione e dell'uso sistematico  
dei risultati della ricerca contemporanea  
come base per le decisioni cliniche

## Evidence Based Practice (Sackett)

- Consapevolezza di acquisire nuove informazioni
- Esperienze nella pratica clinica
- Considerazione globale del paziente dal suo punto di vista e nella sua condizione

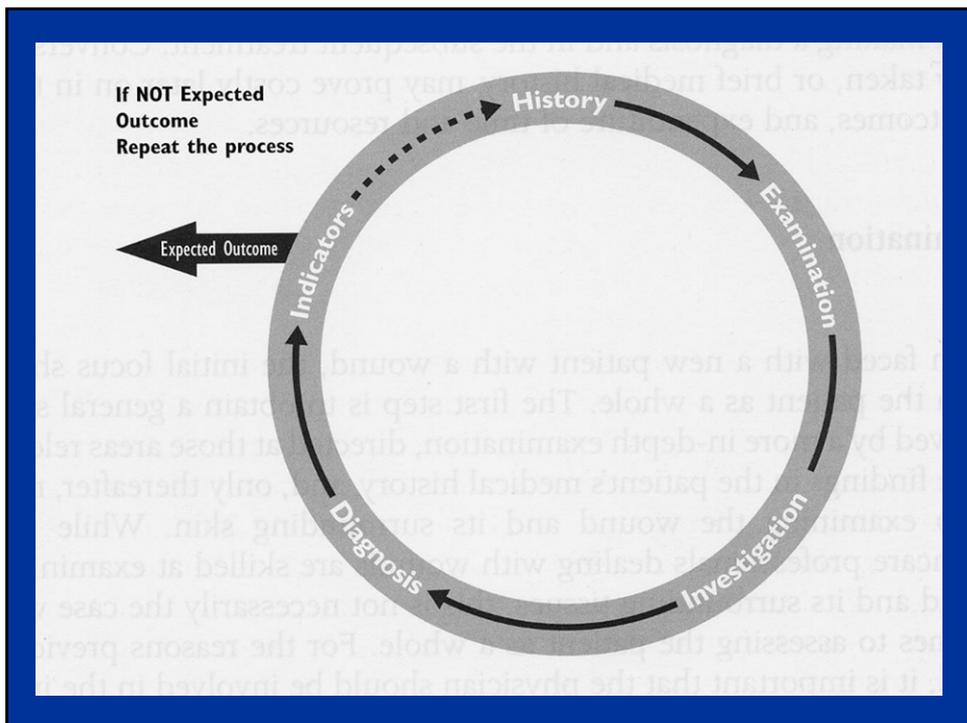


## SEDE di trattamento

- *Domiciliare*
- *Ambulatoriale*  
(dedicato, non dedicato)
- *Ospedaliero*

# PROBLEMI

- **Esattezza della diagnosi**
  - \* oneri per indagini non appropriate
  - \* “nomadismo” dei pazienti
- **Conoscenza e capacità di uso** (maneggevolezza) **dei mezzi a disposizione** (“eclettismo razionale”) = **corrette indicazioni** = **calcolo costo-beneficio favorevole**

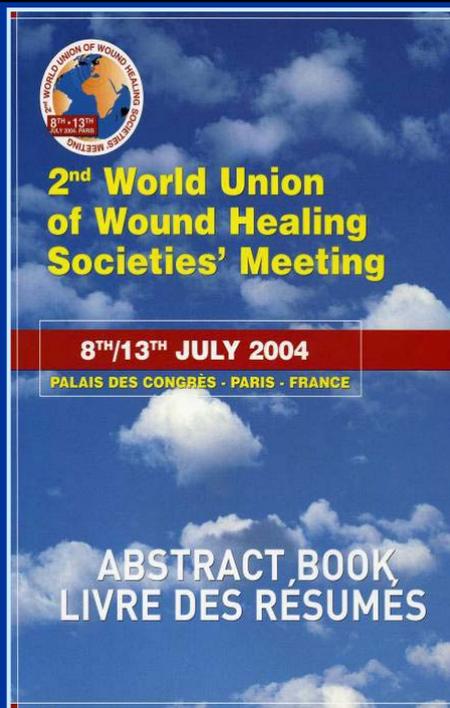


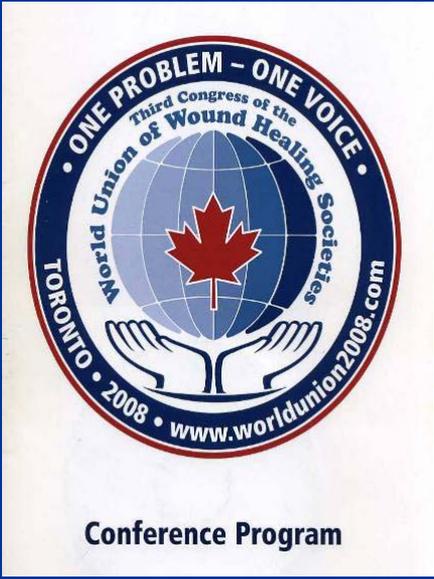
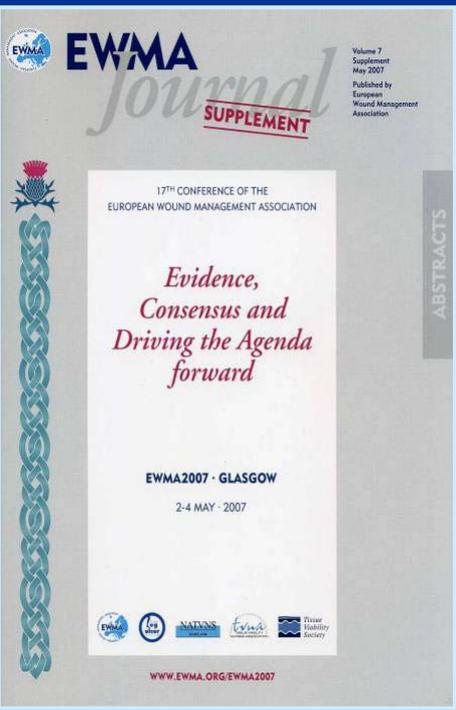
# Multidisciplinarietà

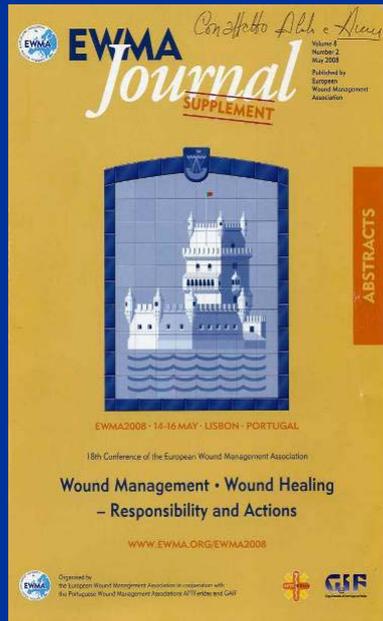
- Chirurgo vascolare
- Chirurgo generale
- Chirurgo plastico
- Chirurgo ortopedico
- Fisiatra
- Nutrizionista
- Psicologo
- Angiologo
- Dermatologo
- Internista
- Diabetologo
- Reumatologo
- Geriatra
- Algologo
- Genetista

Infermiere

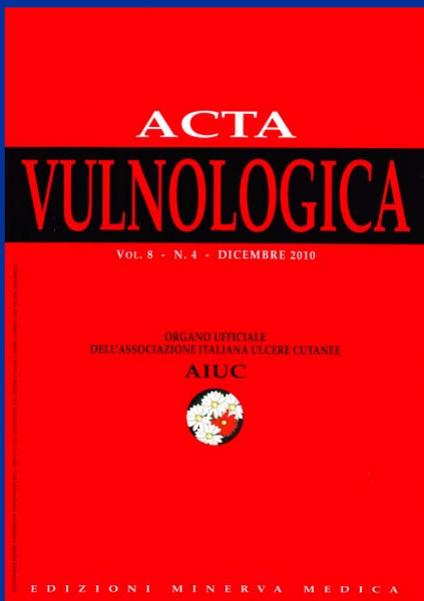
→ Approccio olistico







**K. HARDING**



Associazione Italiana Ulcere Cutanee (AIUC)  
DOCUMENTO DI POSIZIONAMENTO

### La terapia farmacologica e chirurgica dell'ulcera venosa

G. GUARNERA, P. DONADIO, E. SARCHITELLI, A. CRISPÌ

#### PRESENTAZIONE

Onore e piacere nel presentare questa opera letterario-scientifica coordinata dal caro amico Giorgio Guarnera. Questo documento di posizionamento sulla ulcera venosa può sembrare un proseguo del precedente libro "L'ulcera cutanea degli arti inferiori", invece rappresenta una evoluzione, frutto della maturazione del percorso dell'Autore. Dalla costituzione di una Società Scientifica rivolta all'ulcera quale sintomo o segno, esito di una *malpractice* da parte del medico o del paziente verso se stesso, alla critica costruttiva di un esperto in malattie vascolari abituato a domandarsi chi siamo, da dove veniamo, dove andiamo. La lesione trofica, come abbiamo detto, è solo l'esito di una malattia che ne rappresenta la patognomonia e, dunque, sottintende una appropriata e specifica diagnosi e conseguente terapia. La scelta del presidio terapeutico locale e il timing variano, infatti, a seconda della causa che ha prodotto l'esito in ulcera. Per questo, credo che l'apparente limitazione alla patologia venosa sia soltanto il primo numero di un romanzo a puntate che, con garbo, introduce ad un percorso mirato rivolto all'etiopatogenesi e dunque un esplicito e sorridente invito a superare qualcosa di più sulle cause, sul bagaglio culturale globale, sull'essere medico e non tecnico di medicina locale, pur nell'ambito di una reciproca e indissolubile collaborazione con qualsiasi. L'area Guida dunque come raddrizzamento di rotta, passaggio da movimento di opinione a partito strutturato nell'area costituzionale della Medicina. Questa monografia è conseguenzialmente un programma, un invito a un percorso culturale che unisce medico e infermiere nelle stesse problematiche, sia pratiche che cognitive; e fa di questa seconda figura un personaggio qualificato, con un linguaggio tecnico ed un bagaglio di conoscenze finalizzate alla modulazione della patologia ulcervata.

Un complimento agli Autori per il lavoro scientifico e in particolare all'amico Giorgio per il suo noto *fair-play* nel correggere migliorando questo campo di ricerca, il tutto accompagnato da un sorriso complice.

PROF. CLAUDIO ALLERA  
Presidente CIF (Collegio Italiano di Flebologia)

VI. 8. N. 4

ACTA VULNOLOGICA

205

## PRINCIPI FONDAMENTALI

- Diagnosi corretta
- Preparazione del fondo della lesione
- Correzione delle alterazioni emodinamiche
- Strategie preventive della recidiva
- Qualità di vita
- Contenimento dei costi



## ULCERE VASCOLARI

- 📄 Terapia topica
- 📄 Correzione dell'ipertensione e della stasi
  - Elastocompressione
  - Terapia medica
  - Scleroterapia
  - Chirurgia
- 📄 Rivascolarizzazione arteriosa
- 📄 Chirurgia ricostruttiva
- 📄 Esercizio fisico programmato
- 📄 Riabilitazione vascolare



## RECIDIVE - ULCERE VENOSE

- Terapia conservativa 58%
- Innesti cutanei 78%
- Elastocompressione 30%

## CHIRURGIA - ULCERE VENOSE

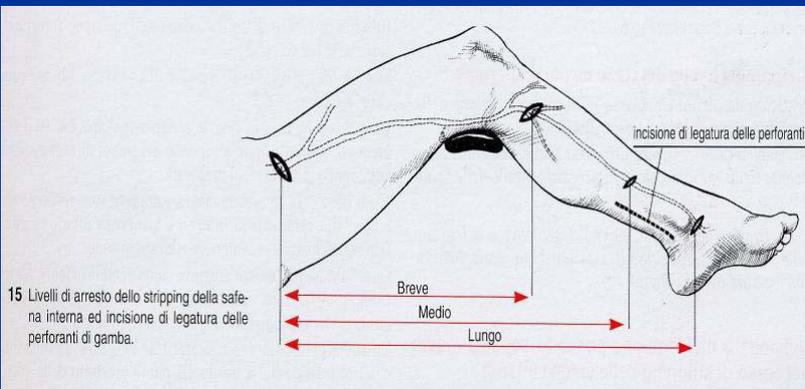
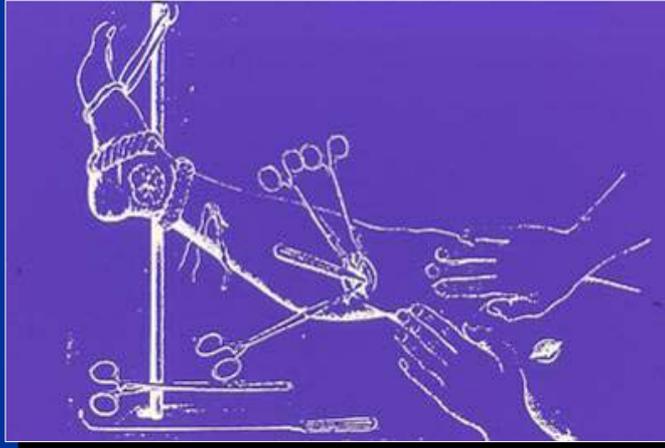
### ☞ Obiettivi :

- Riduzione dell'ipertensione venosa (stasi)
- Riduzione dell'edema (+ Elastocompressione!)
- Riduzione dei tempi di guarigione (?)
- Riduzione del numero delle recidive

## CHIRURGIA - ULCERE VENOSE

### ☞ Chirurgia del sistema venoso superficiale :

- Crossectomia
- Stripping safenico (abolizione reflussi lunghi)  
+ flebectomie
- Legatura vv. perforanti / comunicanti  
incontinenti (tecnica aperta SEPS)  
(abolizione reflussi brevi)
- ELT, occlusione con radiofrequenza
- Flebectomie per transilluminazione



15 Livelli di arresto dello stripping della safena interna ed incisione di legatura delle perforanti di gamba.

# **TERAPIA CHIRURGICA delle VARICI OESCH (1993)**

## **PIN - STRIPPING**

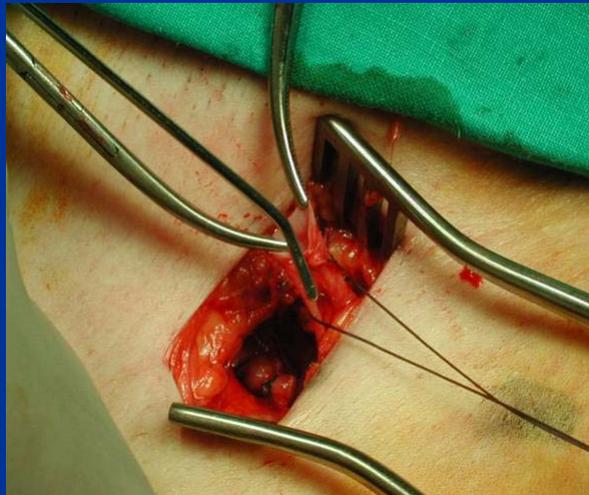
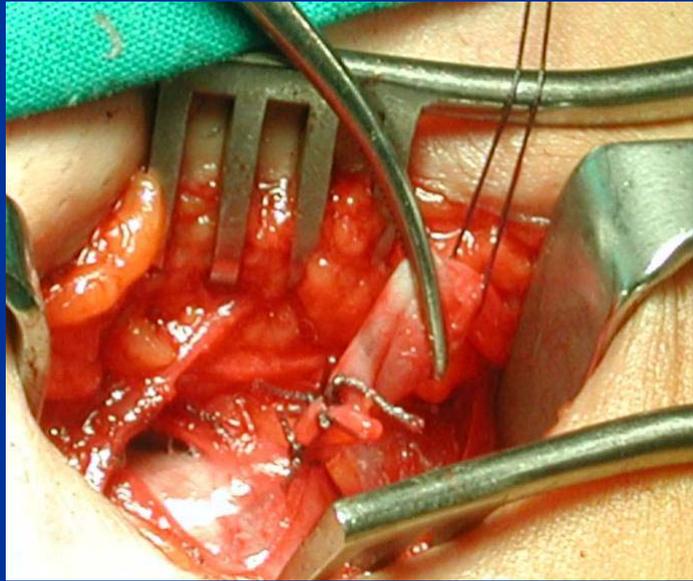
**(stripping per perforazione e invaginazione)**

**Stripping corto mediante strumento rigido con  
estremità**

**distale appuntita e angolata con micro  
controincisione**





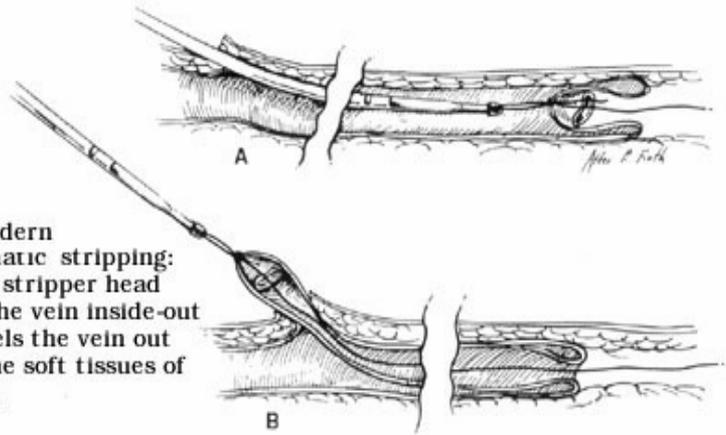








The modern atraumatic stripping: a small stripper head turns the vein inside-out and peels the vein out from the soft tissues of the leg.















# UNCINI PER FLEBECTOMIA

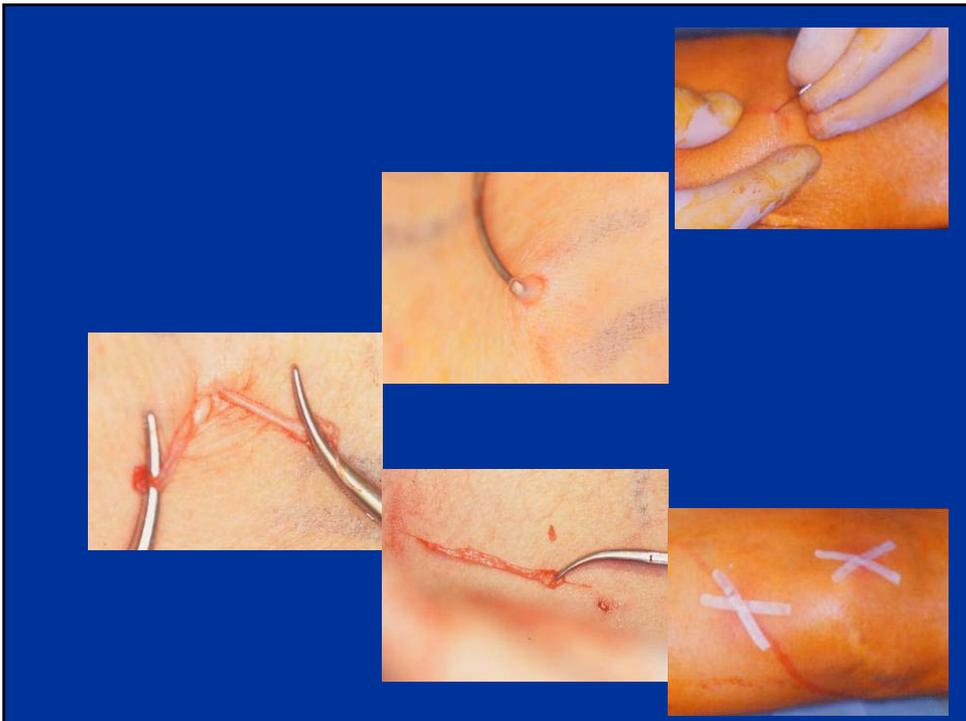
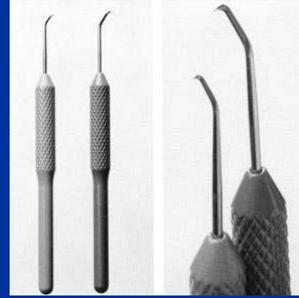
MULLER



OESCH



RAMELET



## CHIRURGIA DELLE VV. PERFORANTI

- N° VARIABILE: 80 – 140 PER ARTO INFERIORE
- ECOCOLORDOPPLER (CONTROVERSIE)
- PATOLOGIA: REFLUSSO > 1.0 SEC; CALIBRO > 2 MM
- SEVERITA' CLINICA: N° PERFORANTI +  
COINVOLGIMENTO MULTISISTEMA
- ULCERE C5 – C6
- DISTROFIE CUTANEE C4

### *Nuove terapie nel trattamento dell'insufficienza venosa cronica degli arti inferiori*

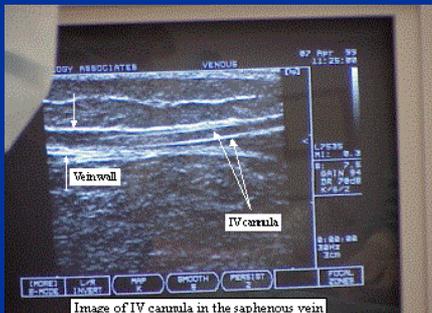
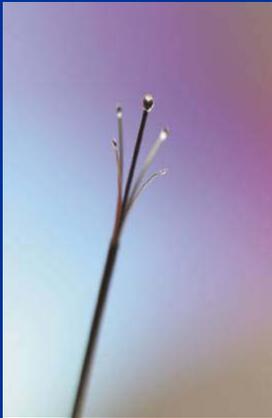
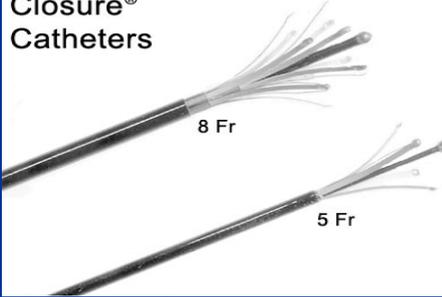
Radiofrequenza

Laser

Scleroterapia ecoguidata  
(scleromousse)

Flebectomie per transilluminazione

# Closure® Catheters



# *Nuove terapie nel trattamento dell'insufficienza venosa cronica degli arti inferiori*

Radiofrequenza

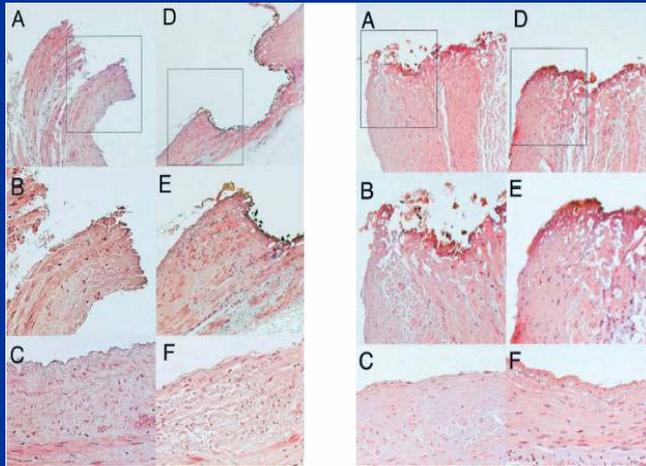
Laser

Scleroterapia ecoguidata  
(scleromousse)

Flebectomie per transilluminazione



# LASER



Proebstle TM: Thermal damage of the inner vein wall during endovenous laser treatment: key role of energy absorption by intravascular blood. *Dermatol Surg.* 2002; 28:596-600.



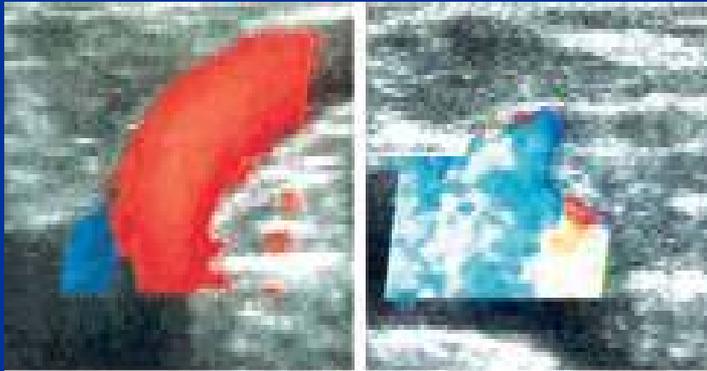
# LASER



Min RJ: Endovenous laser treatment of the incompetent greater saphenous vein. *J Vasc Int Rad* 2001; 12: 1167-1171.



# LASER



Min RJ: Endovenous laser treatment of the incompetent greater saphenous vein. J Vasc Int Rad 2001; 12: 1167-1171.



# LASER



Min RJ: Endovenous laser treatment of the incompetent greater saphenous vein. J Vasc Int Rad 2001; 12: 1167-1171.



# *Nuove terapie nel trattamento dell'insufficienza venosa cronica degli arti inferiori*

Radiofrequenza

Laser

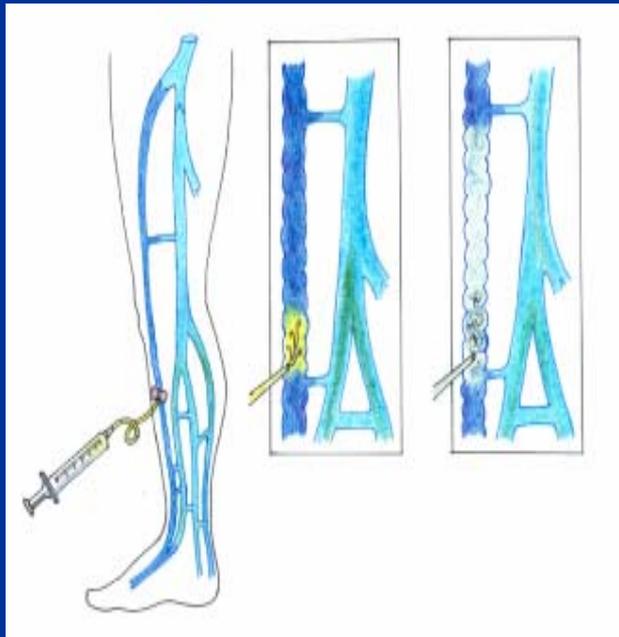
Scleroterapia ecoguidata  
(scleromousse)

Flebectomie per transilluminazione

E.J. ORBACH:

*"Sclerotherapy of  
varicose veins:  
utilization of intravenous  
air block"*.

Am J Surg 1944; 362-  
366





*Nuove terapie nel trattamento  
dell'insufficienza venosa  
cronica degli arti inferiori*

Radiofrequenza

Laser

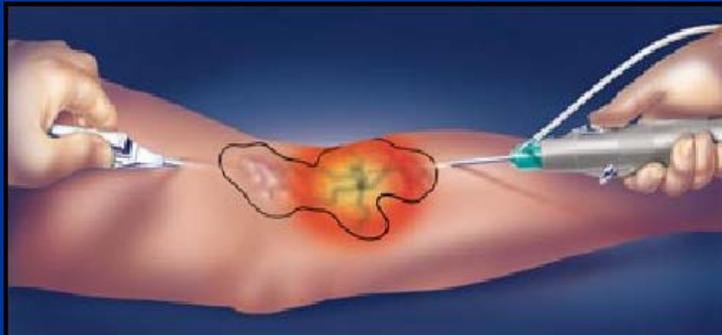
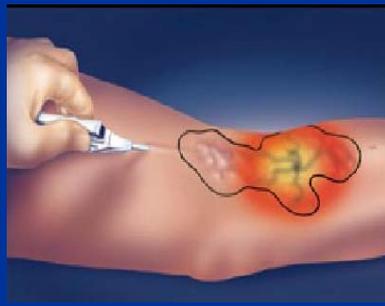
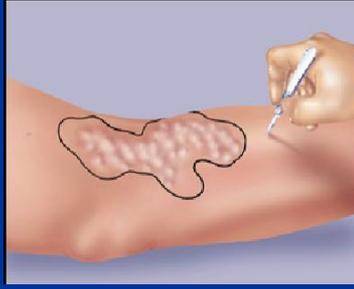
Scleroterapia ecoguidata  
(scleromousse)

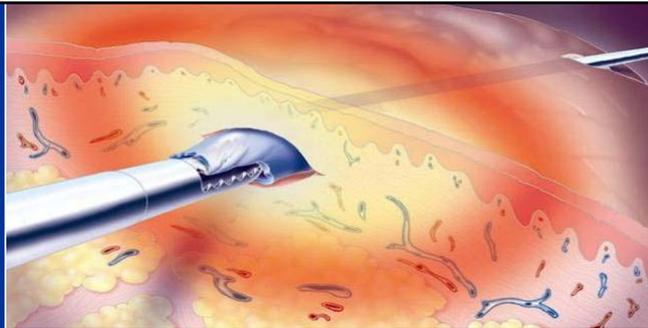
*Flebectomie per transilluminazione*



Illuminatore/Irrigatore

Resettore/Aspiratore





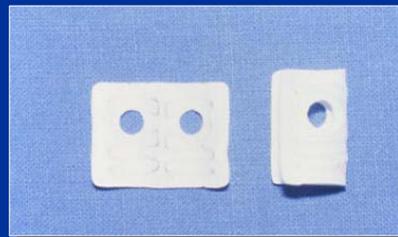
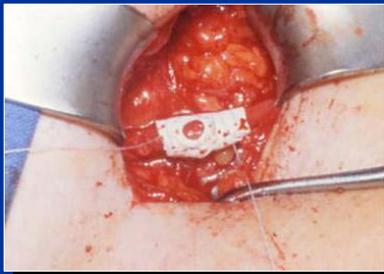
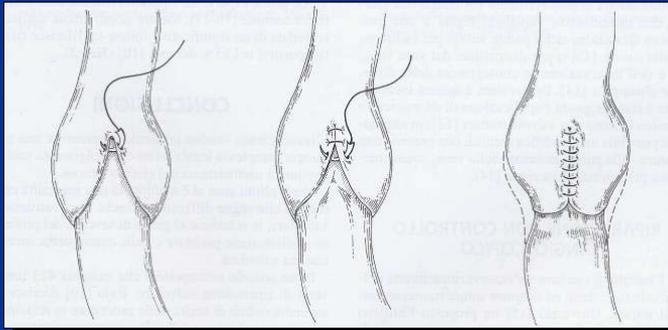
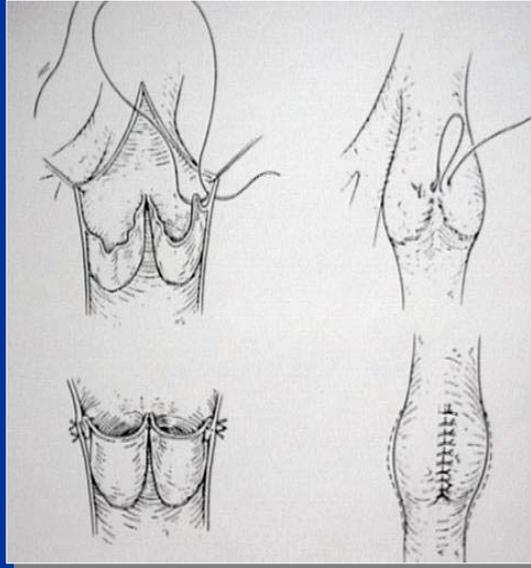


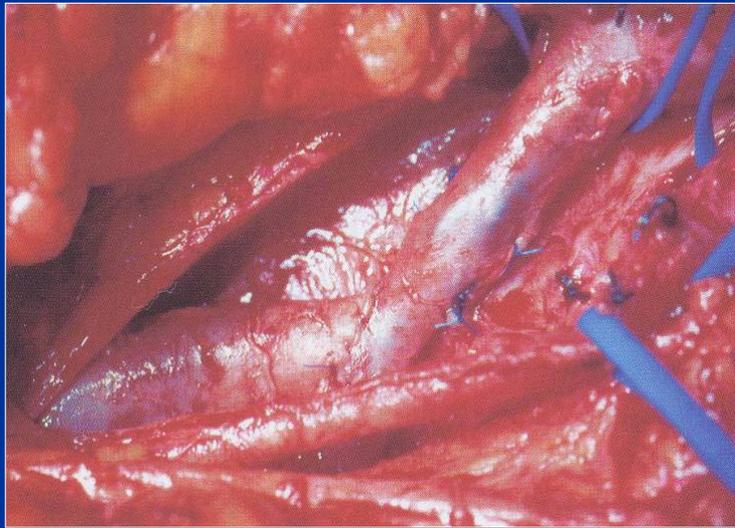
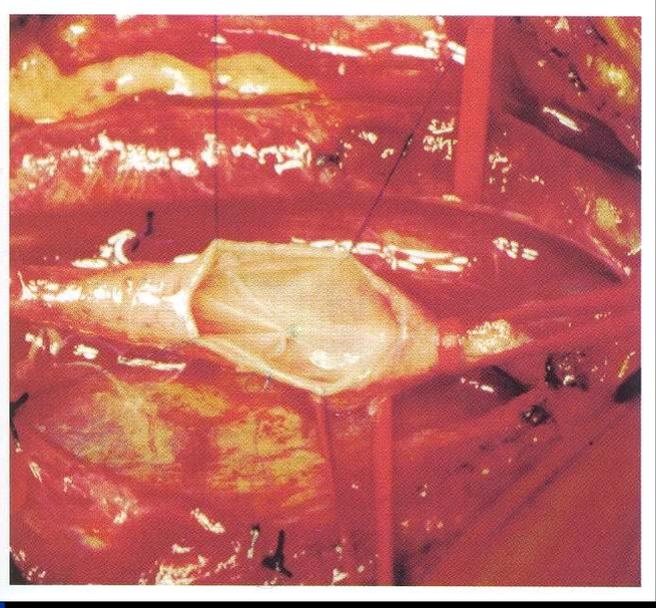
## CHIRURGIA - ULCERE VENOSE

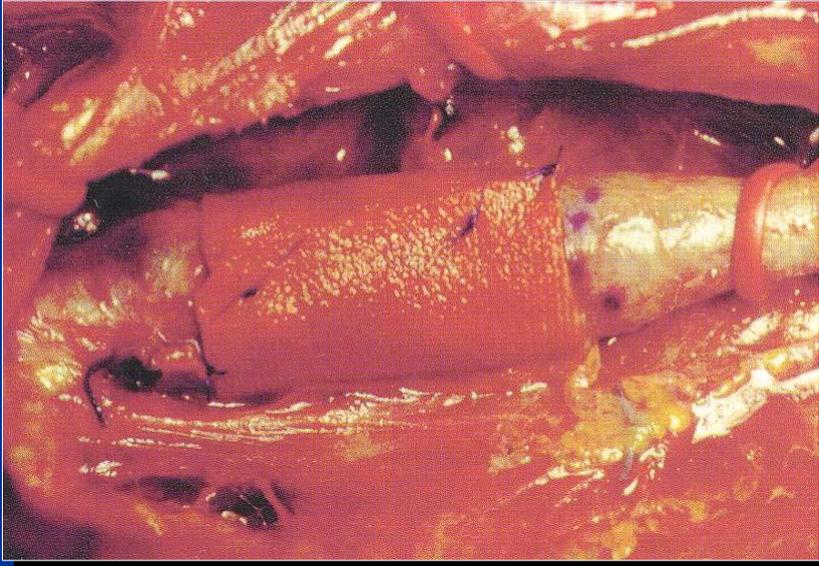
☞ Chirurgia del sistema venoso profondo :

- Trasposizioni valvolari
- Ricostruzioni valvolari
- Sostituzioni con segmenti valvolati
- Bypass venosi
- Valvuloplastiche esterne

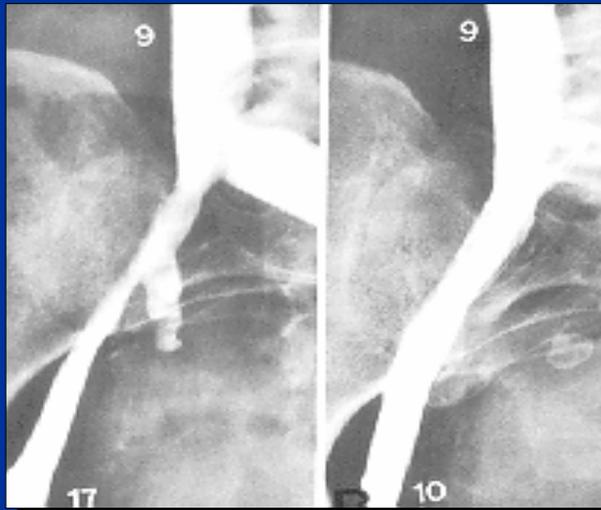
# RICOSTRUZIONI VALVOLARI







## CHIRURGIA ENDOVASCOLARE VENOSA



# CHIRURGIA - ULCERE VENOSE

☞ Risultati :

*Recidive a 4 anni*

• Chirurgia sistema venoso superficiale	10 %
• Legatura isolata VCI	20 %
• SEPS	16 %
• Chirurgia sistema venoso profondo	25 - 60 %

*Istituto di Chirurgia Vascolare e  
Angiologia Università di Milano  
(Direttore: Prof. G. Agrifoglio)*

## Chirurgia del sistema venoso superficiale (varici + ulcere)

	senza chirurgia	con chirurgia
• N° pazienti: 500	298	202
• Guarigione a 12 mesi	37 %	63 %
• Recidive a 36 mesi	39 %	5 %

## Comparison of surgery and compression with compression alone in chronic venous ulceration (ESCHAR study): randomised controlled trial

Jamie R Barwell, Colin E Davies, Jane Deacon, Kate Harvey, Julia Minor, Antonio Sassano, Maxine Taylor, Jenny Usher, Clare Wakely, Jonathan J Earnshaw, Brian P Heather, David C Mitchell, Mark R Whyman, Keith R Poskitt

- Ridotto numero di recidive
- Stabilità di guarigione
- Ridotta sofferenza

BMJ

RESEARCH

### Long term results of compression therapy alone versus compression plus surgery in chronic venous ulceration (ESCHAR): randomised controlled trial

Manjit S Gohel, specialist registrar,<sup>1</sup> Jamie R Barwell, consultant vascular and transplant surgeon,<sup>2</sup> Maxine Taylor, leg ulcer nurse specialist,<sup>3</sup> Terry Chant, vascular nurse specialist,<sup>4</sup> Chris Foy, medical statistician,<sup>5</sup> Jonathan J Earnshaw, consultant surgeon,<sup>6</sup> Brian P Heather, consultant surgeon,<sup>7</sup> David C Mitchell, consultant surgeon,<sup>8</sup> Mark R Whyman, consultant surgeon,<sup>9</sup> Keith R Poskitt, consultant surgeon<sup>10</sup>

#### ABSTRACT

**Objective** To determine whether recurrence of leg ulcers may be prevented by surgical correction of superficial venous reflux in addition to compression.

**Design** Randomised controlled trial.

**Setting** Specialist nurse led leg ulcer clinics in three UK vascular centres.

**Participants** 500 patients (500 legs) with open or recently healed leg ulcers and superficial venous reflux.

**Main outcome measures** Primary outcomes were ulcer healing and ulcer recurrence. The secondary outcome was ulcer free time.

**Results** Ulcer healing rates at three years were 89% for the compression group and 97% for the compression plus surgery group (P=0.73, log rank test). Rates of ulcer recurrence at four years were 54% for the compression group and 37% for the compression plus surgery group (P=0.01). For patients with isolated superficial reflux, recurrence rates at four years were 31% for the compression group and 27% for the compression plus surgery group (P=0.83). For patients who had superficial with segmental deep reflux, recurrence rates at three years were 32% for the compression group and 24% for the compression plus surgery group (P=0.36). For patients with superficial and total deep reflux, recurrence rates at three years were 46% for the compression group and 32% for the compression plus surgery group (P=0.33). Patients in the compression plus surgery group experienced a greater proportion of ulcer free time after three years compared with patients in the compression group (78% v 71%, P=0.002, Mann-Whitney U test).

**Conclusion** Surgical correction of superficial venous reflux in addition to compression bandaging does not improve ulcer healing but reduces the recurrence of ulcers at four years and results in a greater proportion of ulcer free time.

**Trial registration** Current Controlled Trials ISRCTN07549334.

#### INTRODUCTION

In recent years the importance of the effect of venous leg ulceration on healthcare expenses and patients' quality of life has been recognised.<sup>1-4</sup> European studies have reported a prevalence of 1% in the adult population, increasing dramatically in those aged more than 80.<sup>5,6</sup> The precise pathophysiological mechanisms causing ulceration remain debatable, although chronic venous hypertension (usually as a result of venous reflux) is generally accepted to play a major part.<sup>7,8</sup>

Chronic venous hypertension may be treated by high elevation of the leg and multi-layered compression bandaging, applied by trained staff within the setting of a specialist leg ulcer service. Excellent healing rates have been reported with this approach.<sup>9,10</sup> Strategies to prevent ulcer recurrence include patient education and class 2 elastic compression stockings.<sup>11</sup> Stockings are often difficult to put on and uncomfortable, however, resulting in poor patient compliance.<sup>12</sup> Moreover, conservative approaches do little to correct the underlying problem of chronic venous hypertension.

Anatomical studies using colour venous duplex ultrasonography have shown that incompetence in superficial veins (long or short saphenous) is present in most legs with chronic ulceration, sometimes in combination with deep venous reflux.<sup>13,14</sup> Isolated reflux in deep or perforating veins is uncommon.<sup>15,16</sup> Several surgical strategies to correct the underlying venous anatomical abnormalities have been attempted. Deep-vein procedures may be associated with high complication rates, and studies have shown little clinical benefit.<sup>17</sup> However, several studies have suggested that corrective surgery for superficial venous reflux may have clinical benefits for ulcer healing and recurrence.<sup>18,19</sup>

The effect of surgery and compression on healing and recurrence (ESCHAR) study aimed to assess these outcomes in patients with chronic venous leg ulceration. The early results have been published and suggested that compression along with superficial venous surgery may reduce recurrence rates.<sup>20</sup> We present the long term findings.

<sup>1</sup>University General Hospital, Oxford, UK

<sup>2</sup>University Hospital, Oxford, UK

<sup>3</sup>University Hospital, Oxford, UK

<sup>4</sup>University Hospital, Oxford, UK

<sup>5</sup>University Hospital, Oxford, UK

<sup>6</sup>University Hospital, Oxford, UK

<sup>7</sup>University Hospital, Oxford, UK

<sup>8</sup>University Hospital, Oxford, UK

<sup>9</sup>University Hospital, Oxford, UK

<sup>10</sup>University Hospital, Oxford, UK

<sup>11</sup>University Hospital, Oxford, UK

<sup>12</sup>University Hospital, Oxford, UK

<sup>13</sup>University Hospital, Oxford, UK

<sup>14</sup>University Hospital, Oxford, UK

<sup>15</sup>University Hospital, Oxford, UK

<sup>16</sup>University Hospital, Oxford, UK

<sup>17</sup>University Hospital, Oxford, UK

<sup>18</sup>University Hospital, Oxford, UK

<sup>19</sup>University Hospital, Oxford, UK

<sup>20</sup>University Hospital, Oxford, UK

<sup>21</sup>University Hospital, Oxford, UK

<sup>22</sup>University Hospital, Oxford, UK

<sup>23</sup>University Hospital, Oxford, UK

<sup>24</sup>University Hospital, Oxford, UK

<sup>25</sup>University Hospital, Oxford, UK

<sup>26</sup>University Hospital, Oxford, UK

<sup>27</sup>University Hospital, Oxford, UK

<sup>28</sup>University Hospital, Oxford, UK

<sup>29</sup>University Hospital, Oxford, UK

<sup>30</sup>University Hospital, Oxford, UK

<sup>31</sup>University Hospital, Oxford, UK

<sup>32</sup>University Hospital, Oxford, UK

<sup>33</sup>University Hospital, Oxford, UK

<sup>34</sup>University Hospital, Oxford, UK

<sup>35</sup>University Hospital, Oxford, UK

<sup>36</sup>University Hospital, Oxford, UK

<sup>37</sup>University Hospital, Oxford, UK

<sup>38</sup>University Hospital, Oxford, UK

<sup>39</sup>University Hospital, Oxford, UK

<sup>40</sup>University Hospital, Oxford, UK

<sup>41</sup>University Hospital, Oxford, UK

<sup>42</sup>University Hospital, Oxford, UK

<sup>43</sup>University Hospital, Oxford, UK

<sup>44</sup>University Hospital, Oxford, UK

<sup>45</sup>University Hospital, Oxford, UK

<sup>46</sup>University Hospital, Oxford, UK

<sup>47</sup>University Hospital, Oxford, UK

<sup>48</sup>University Hospital, Oxford, UK

<sup>49</sup>University Hospital, Oxford, UK

<sup>50</sup>University Hospital, Oxford, UK

## Minimally Invasive Surgical Management of Primary Venous Ulcers vs. Compression Treatment: a Randomized Clinical Trial

P. Zamboni\*, C. Cisno, F. Marchetti, P. Mazza, L. Fogato, S. Carandina, M. De Palma and A. Liboni

Department of Surgical, Anaesthesiological, and Radiological Sciences, Day-Surgery Unit, University of Ferrara, Italy

**Objectives:** to compare minimally invasive surgical haemodynamic correction of reflux (CHIVA) with compression in the treatment of venous ulceration.

**Design:** prospective randomised study.

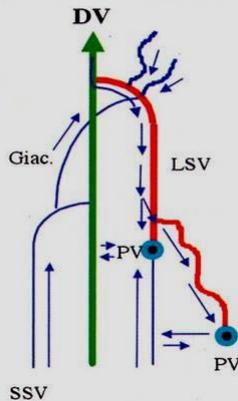
**Materials and Methods:** from a cohort of 80 patients with 87 venous leg ulcers, 47 were randomised to either surgery or compression.

**Results:** at a mean follow-up of 3 years, healing was 100% (31 days) in the surgical and 96% (63 days), in the compression group ( $p < 0.02$ ). The recurrence rate was 9% in the surgical and 38% in the compression group ( $p < 0.05$ ). In the surgical group, all plethysmographic parameters except ejection fraction, had improved significantly at 6 months in the surgical group, and at 3 years residual volume fraction remained in the normal range. Finally, quality of life significantly improved in the operated group.

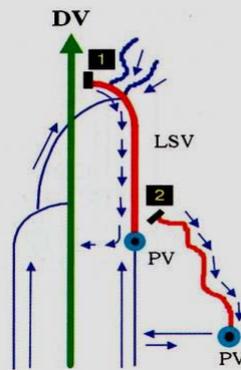
**Conclusions:** this study supports the effectiveness of surgical therapy for leg ulceration secondary to superficial venous reflux.

**Key Words:** Primary venous ulcers; Minimally invasive surgery; Venous haemodynamics; CHIVA; Compression; Quality of life.

### Deviazione di tipo I



### Correzione emodinamica CHIVA 1



## Surgery for venous leg ulcers

Can reduce recurrence, but will have little impact on prevalence



### RESEARCH, p 83

**Charles H McCollum**, professor of surgery, Education and Research Center, University Hospital of South Manchester, Manchester M20 9LT, [cmcc@manchester.ac.uk](mailto:cmcc@manchester.ac.uk)

Competing interests: None declared. Provenance and peer review: Commissioned; not externally peer reviewed.

BMJ 2007;335:65-6  
doi:10.1136/bmj.33504.02005.07

Venous leg ulcers are painful, malodorous sores that impact quality of life and are difficult to treat.<sup>1</sup> An estimated 5-8% of the world's population have venous disease, and 1% have venous ulcers at some time in their life.<sup>2</sup> The cost to healthcare services is best known for the United Kingdom, where active ulcers affect 1.7% of the elderly population, at a cost to the NHS of around £500m (€800m, \$1200m) a year.<sup>3</sup> Available evidence suggests costs are high throughout Europe, the United States, and Australia. These ulcers are caused by sustained high venous pressures due to venous disease, obesity, immobility associated with arthritis, or even old age itself.

Compression using four layer bandaging is the mainstay of treatment—it completely heals ulcers in a mean of 7.8 weeks when delivered by trained leg ulcer nurses in the community.<sup>4,5</sup> The efficacy of four layer bandaging is not influenced by the underlying venous abnormality.<sup>6</sup> Whether novel “biologically active” dressings can improve these healing rates remains uncertain, as does the role of venous surgery.

In this week's *BMJ* Gohel and colleagues report the long term results from the ESCHAR trial, which compared compression alone with compression plus superficial venous surgery in patients with open or recently healed leg ulcers and superficial venous incompetence.<sup>7</sup> This trial was adequately powered and reported on ulcer healing, ulcer recurrence, and ulcer-free time over three or four years. Most previous trials either ignored the role of compression therapy or compared surgery with compression, which is inappropriate as both are effective treatments that should be complementary.<sup>8,9</sup>

ESCHAR clarifies the role of superficial venous surgery in people willing or able to have an operation.<sup>8</sup> The trial found no significant difference between compression alone and compression plus surgery on ulcer healing at three years—but recurrence, which otherwise happens in a quarter of patients each year, was almost halved. This beneficial effect was most obvious in patients who have incompetence affecting only the superficial veins or those with “segmental” deep venous incompetence, in which reflux is found in limited segments of the deep veins without widespread

valve failure. The authors' use of “isolated superficial” where the deep veins are normal, “segmental deep,” and “total deep” incompetence is unfortunate as most “segmental deep” incompetence is reflux within the common femoral or popliteal vein emptying into the incompetent long or short saphenous vein; valve failure is largely confined to the superficial veins.<sup>10</sup>

The finding of reduced ulcer recurrence after superficial vein surgery in patients with “total deep” incompetence is surprising as valve failure causes widespread deep venous reflux in such patients. However, early results from the ESCHAR study showed that ablating incompetent superficial veins improves deep venous function.<sup>10</sup> This does not mean that all patients with combined superficial and deep incompetence would benefit from superficial surgery. Preoperative assessment in ESCHAR was by duplex imaging, which describes the anatomy of venous disease but not the function. Ambulatory venous pressures would be a more reliable measure of venous function, with a narrow tourniquet obstructing the superficial veins.<sup>11</sup> Many surgeons do not use ambulatory venous pressure measurement because it requires cannulation of the foot, even though it is the only direct measure of venous pressures.

The encouraging results of surgery on ulcer recurrence rates in the ESCHAR trial will sadly have little influence on overall ulcer prevalence. Patients were recruited from specialist, hospital based leg ulcer clinics, whereas many elderly people in the community refuse to attend hospitals for either venous investigation or surgery.<sup>12</sup> Even among the hospital clinic patients screened for ESCHAR, over a third refused to be randomised and a further 20% refused surgery despite consenting to the study.<sup>8</sup> In the community, our experience is that less than half the patients would attend for investigation and perhaps a third would consider surgery, simple pinch skin grafting being an exception as it can be done in the community by specialist nurses, under local anaesthetic, and speeds the healing of large ulcers.<sup>13</sup>

What does this mean for general practitioners looking after people with leg ulcers? Firstly, people should be referred to a specialist leg ulcer service for investigation of arterial disease before four layer bandaging, if appropriate.

## TERAPIA CHIRURGICA delle ULCERE VENOSE

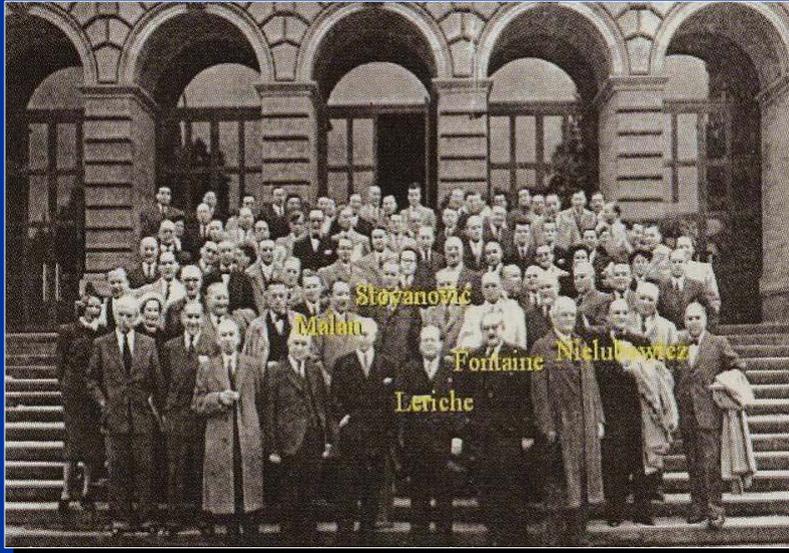
- Si in casi selezionati (indicazione relativa)
- Si sul sistema venoso superficiale
- Attento studio morfologico ed emodinamico
- Sindrome post-trombotica: risultati peggiori

## LAVORI SCIENTIFICI - Limiti attuali

- Non dati sulle caratteristiche di pazienti che non guariscono nonostante una terapia conservativa attuale
- Non dati sufficienti su pazienti guariti ma a rischio di recidiva
- “ End Point ”: “ guarigione “ dell’ulcera
- E le recidive a distanza ?







## CLASSIFICAZIONE DI LERICHE E FONTAINE

- **I STADIO:** preclinico o subclinico, senza manifestazioni funzionali, evidenziato da un esame clinico sistematico.
- **II STADIO:** claudicatio intermittens, non dolori a riposo, esordio progressivo o acuto.
  - A. intervallo libero > 200 m
  - B. intervallo libero < 200 m
- **III STADIO:** dolori a riposo, arto in posizione antalgica declive, edematoso e/o cianotico.
- **IV STADIO:** lesioni trofiche (gangrene, ulcere).

(Fontaine, Kim, Kieny, 1954 mod.)

# ISCHEMIA CRITICA CRONICA

**III + IV STADIO di Fontaine  
Dolori a riposo  $\pm$  lesioni trofiche**

**Jamieson C. et al.: The definition of critical ischaemia of a limb. *Br. J. Surg.* 1982**

- “Limb-threatening ischaemia”
- No diabetici
- P. caviglia (Doppler) > 40 mmHg - dolori a riposo  
> 60 mmHg - ulcere, gangrene
- “Critical” = elevata probabilità di perdita d’arto
- Tentativo di rendere più aderente possibile alla realtà clinica il principio di IC critica.

## DOLORE ISCHEMICO A RIPOSO

- **Dolore severo non controllato da analgesici**
- **Sede: avampiede, dita, ulcere**
- **Scatenato o peggiorato dall'elevazione, notturno**
- **AP < 40 mmHg; TP < 30 mmHg**

## “NON-HEALING ISCHEMIC ULCER”

**Insufficiente perfusione arteriosa ⇒  
risposta infiammatoria non adeguata ⇒ no  
cicatizzazione.**

# **IERD !**

**In caso di Ischemia Critica  
Cronica l'indicazione alla  
chirurgia di rivascularizzazione  
arteriosa  
è assoluta**

# ULCERE VASCOLARI

## Terapia topica

## Correzione dell'ipertensione e della stasi

- Elastocompressione
- Terapia medica
- Scleroterapia
- **Chirurgia**

## **Rivascolarizzazione arteriosa**

## Chirurgia ricostruttiva

## Esercizio fisico programmato

## Riabilitazione vascolare



## PRINCIPI FONDAMENTALI

- Diagnosi corretta
- Preparazione del fondo della lesione
- Correzione delle alterazioni emodinamiche
- Strategie preventive della recidiva
- Qualità di vita
- Contenimento dei costi

Tessuto necrotico  
Edema  
Infezione  
Alterazioni emodinamiche



Sbrigliamento  
Antibiotici  
**Chirurgia**

# COME?

## Basi razionali della chirurgia

- Lesioni steno-ostruttive su base prevalentemente aterosclerotica
- Clinica correlata all'estensione delle lesioni, allo sviluppo del circolo collaterale ed al coinvolgimento dei punti nodali di rientro

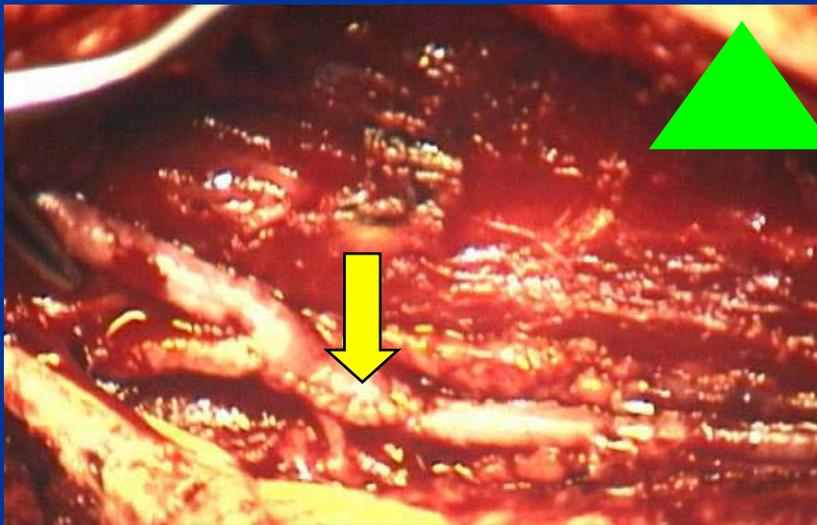
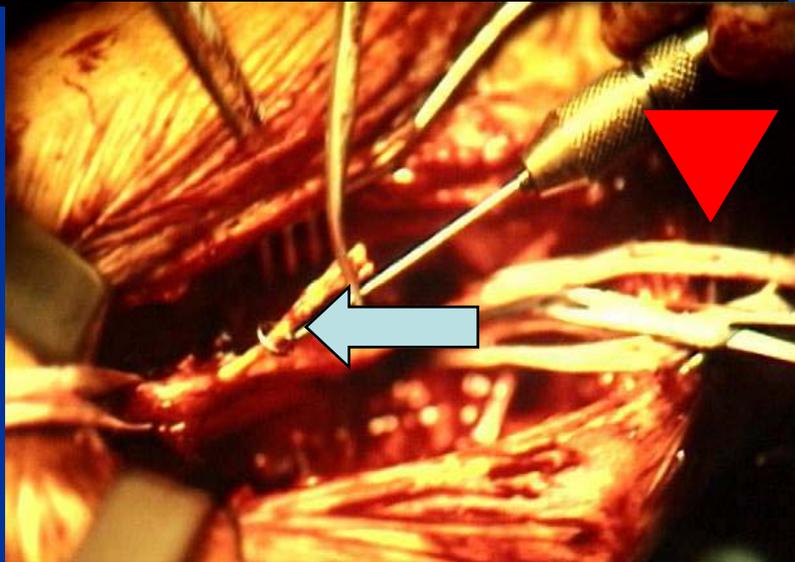
## **TERAPIA CHIRURGICA delle ULCERE ISCHEMICHE**

- Obiettivi:
  - rivascularizzazione distale
  - riduzione sintomatologia dolorosa
  - controllo infezioni (gangrena umida)
  - riparazione delle lesioni
  - contenimento della perdita di sostanza
  - riduzione dei livelli di amputazione

### **Chirurgia di rivascularizzazione arteriosa**

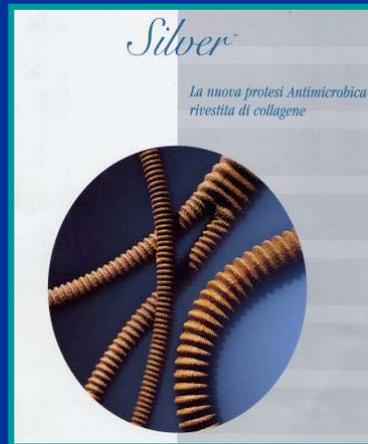
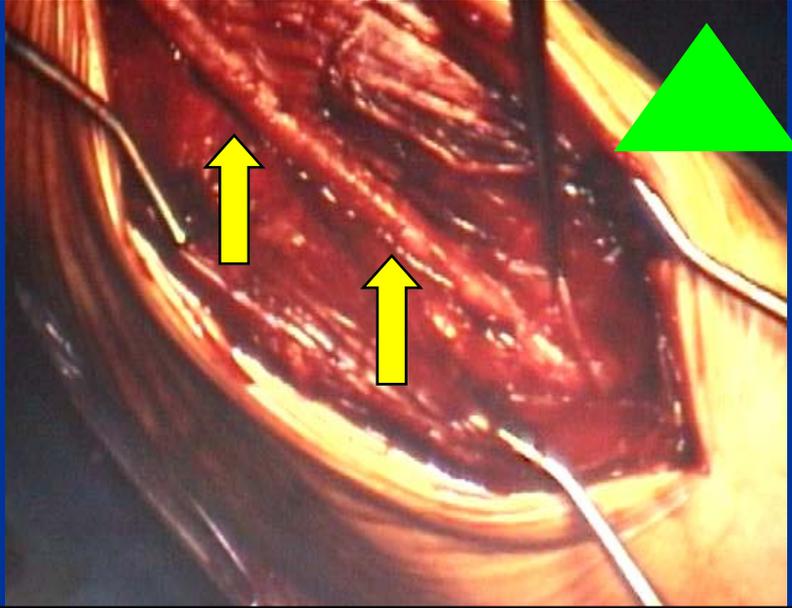
- **Tromboendoarteriectomia (TEA)**
- **Bypass**
- **Chirurgia Endovascolare**
- **Simpaticectomia**
- **Spinal Cord Stimulation (SCS)**

## TEA femoro-poplitea

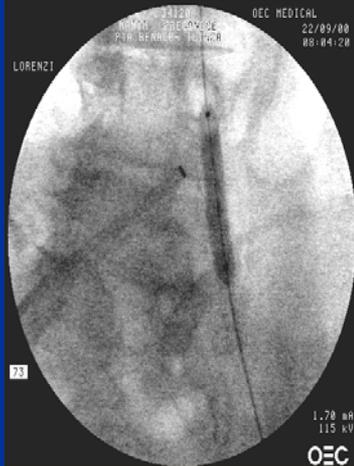


**Bypass femoro-distale  
in vena grande safena "in situ"**

# Bypass femoro-distale in bioprotesi



# CHIRURGIA ENDOVASCOLARE

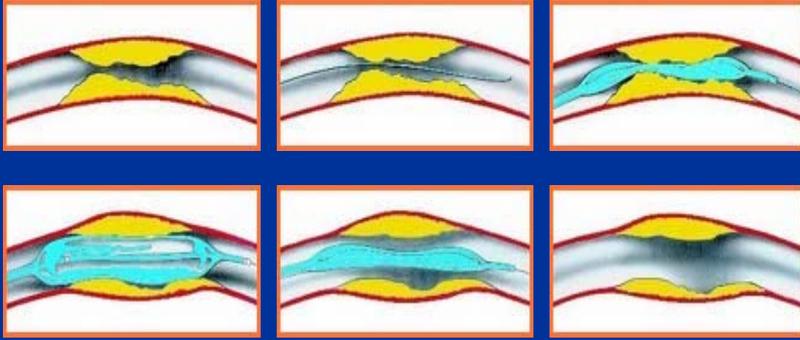


- MINI-INVASIVITA'
- ELEVATA PERCENTUALE DI SUCCESSI TECNICI
- ALTA PERVIETA' A DISTANZA
- BASSA INCIDENZA DI COMPLICANZE
- RIDUZIONE TEMPI DI DEGENZA
- POSSIBILITA' DI ASSOCIAZIONE CON LA CHIRURGIA VASCOLARE CONVENZIONALE

# CHIRURGIA ENDOVASCOLARE

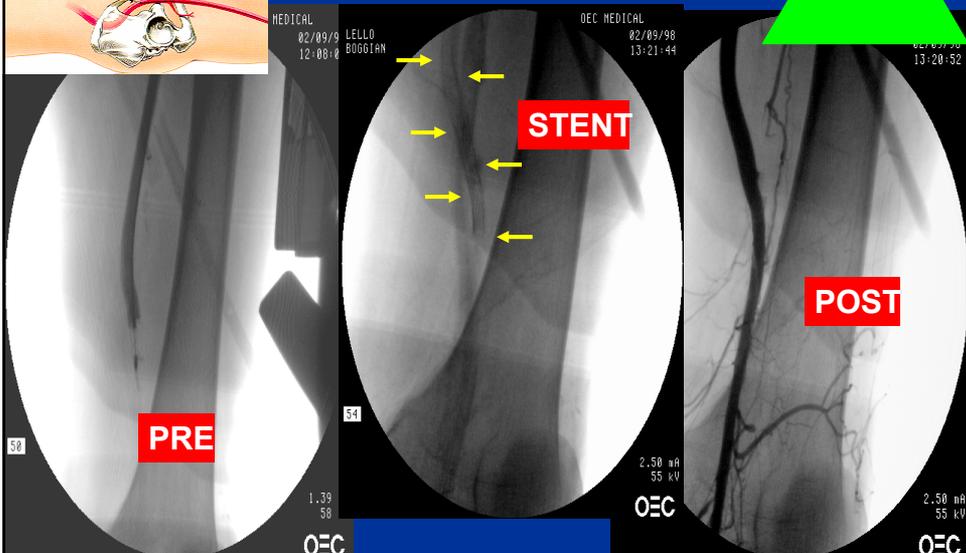
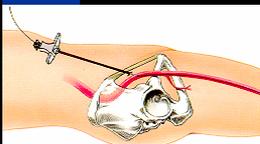
- PTA
- STENTING
- LASER ANGIOPLASTICA
- ENDOPROTESI
- ATERECTOMIA
- TROMBOLISI

## ANGIOPLASTICA PERCUTANEA TRANSLUMINALE



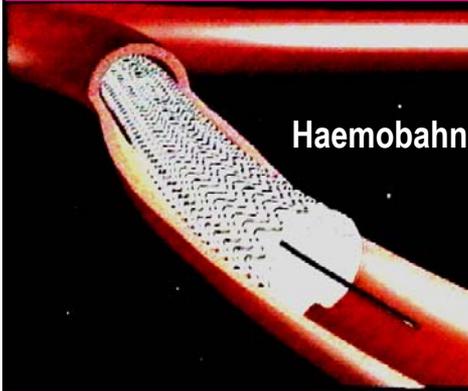
STIRAMENTO FIBRE ELASTICHE E CELLULE MUSCOLARI LISCE  
FRATTURA LONGITUDINALE DELLE TUNICHE INTERNE AMMALATE  
SPOSTAMENTO MATERIALE ATEROMASICO  
RIPARAZIONE FIBROSA  
FORMAZIONE STRATO NEO-INTIMALE

## Chirurgia endovascolare Stenting femorale



## CHIRURGIA ENDOVASCOLARE

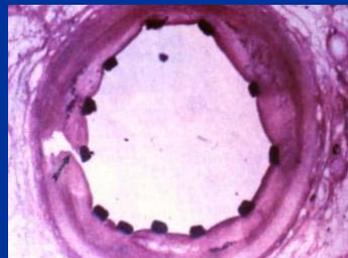
### Endoprotesi

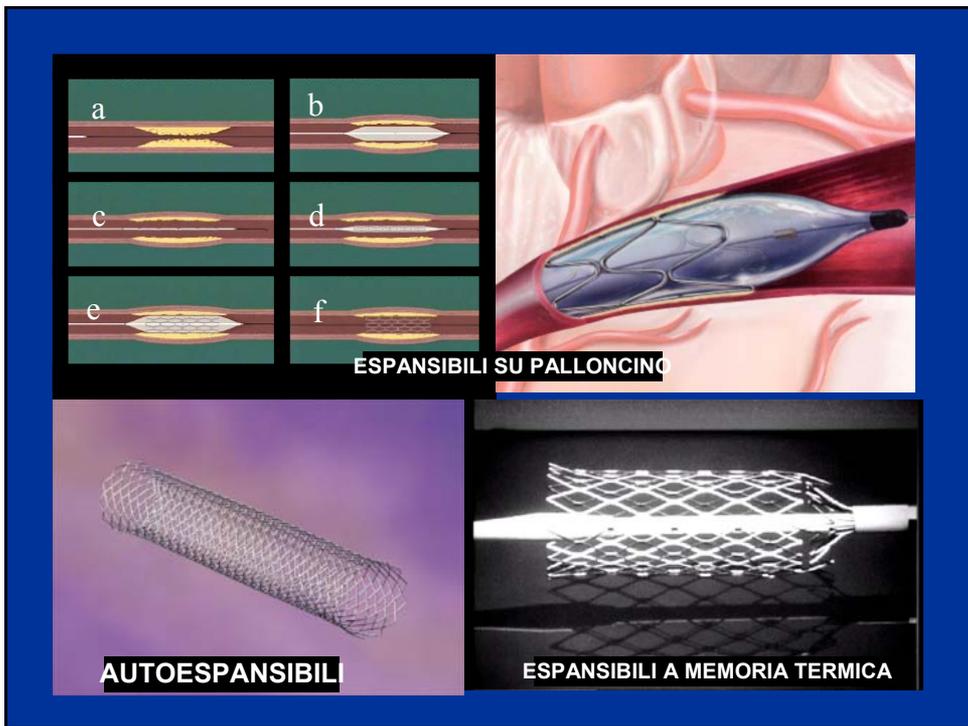


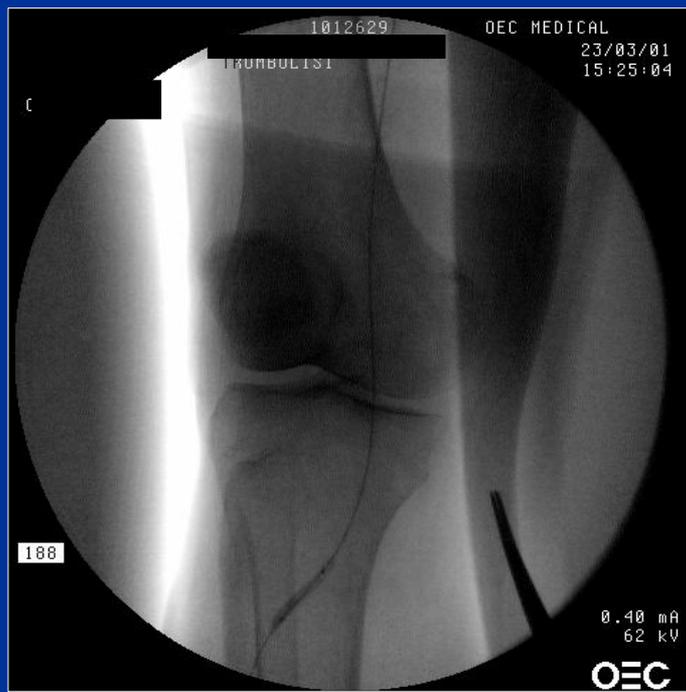
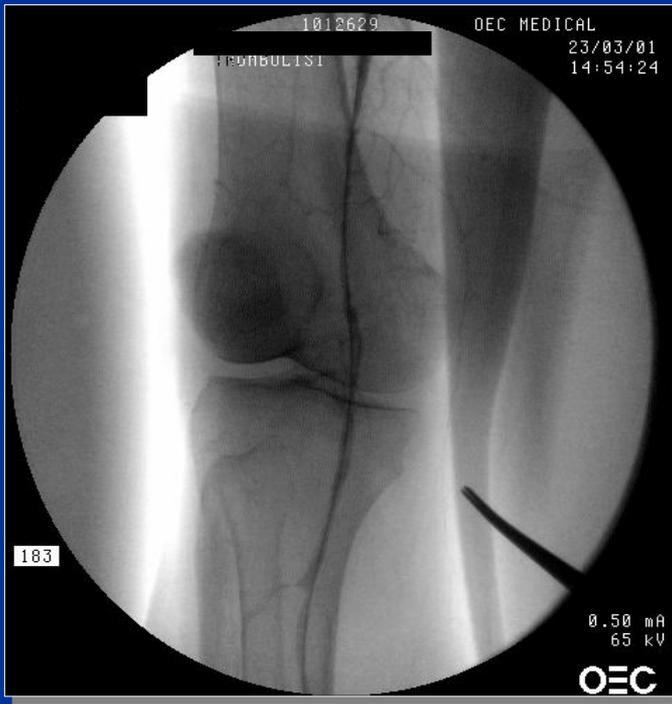
## CHIRURGIA ENDOVASCOLARE

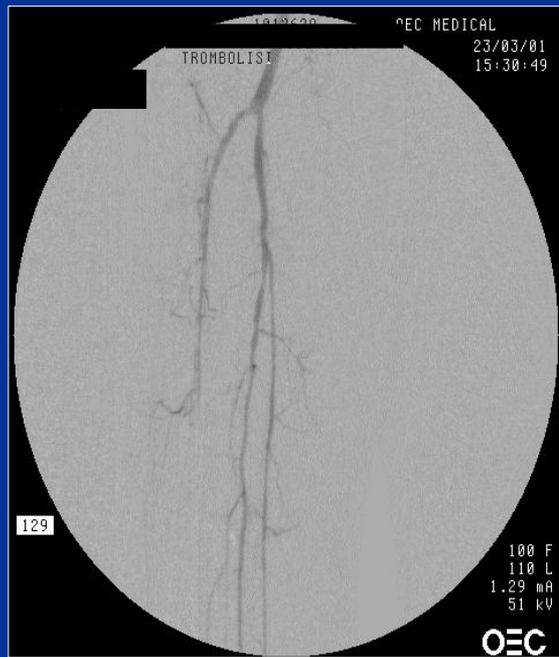
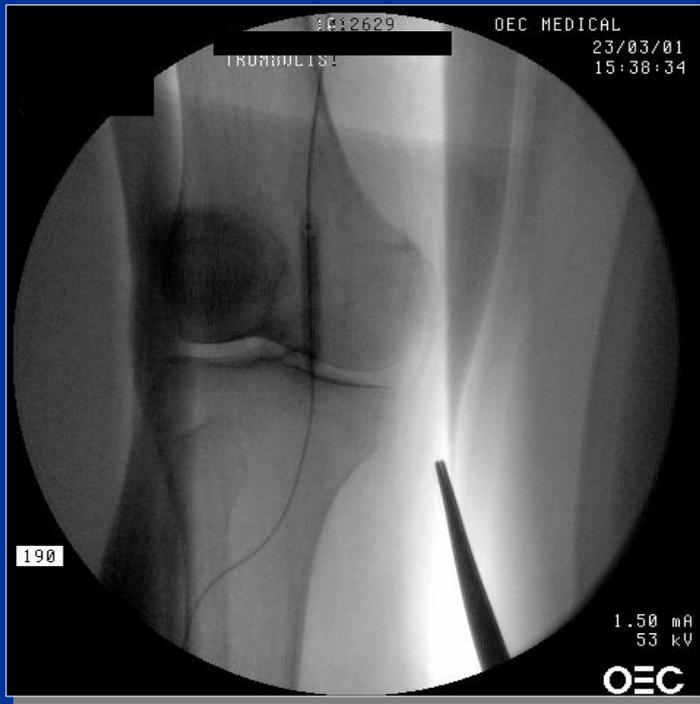
### • STENTING

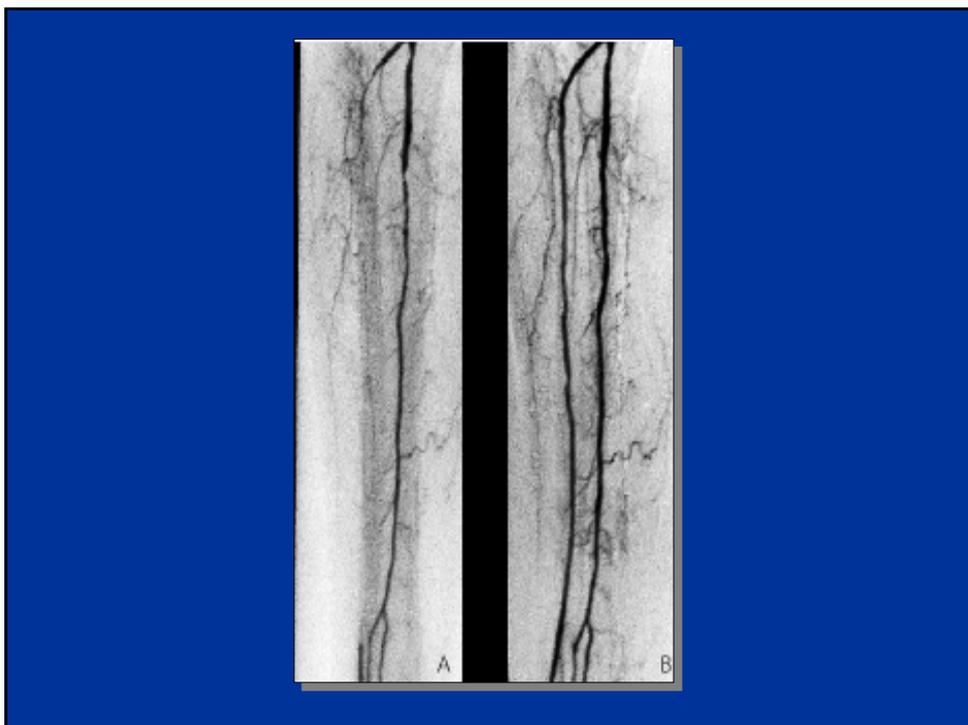
- STABILIZZA LA PLACCA
- PREVIENE RITORNO ELASTICO
- PREVIENE EMBOLIZZAZIONE DI MATERIALE











## La nostra esperienza

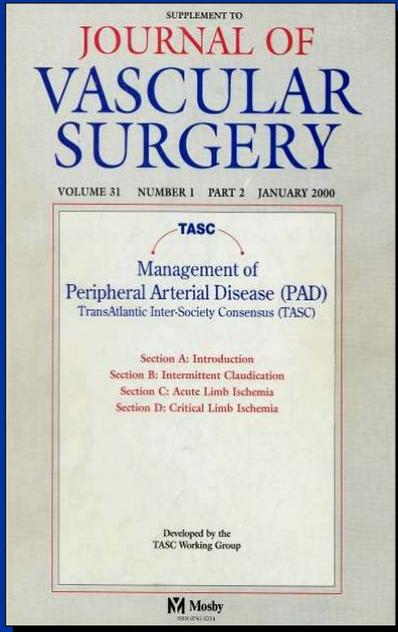
- Stima su ultimi 70 casi di Bypass femoro-distale
- Follow up → 36 mesi

### Risultati

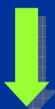
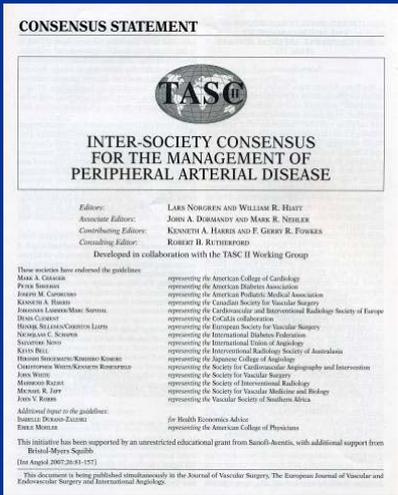
- Pervietà primaria: 74.3% dei pontaggi venosi  
23% di protesi alloplastiche
- Salvataggio d'arto: 83.7% con buon run off  
51.8% con un solo

## Endovascolare

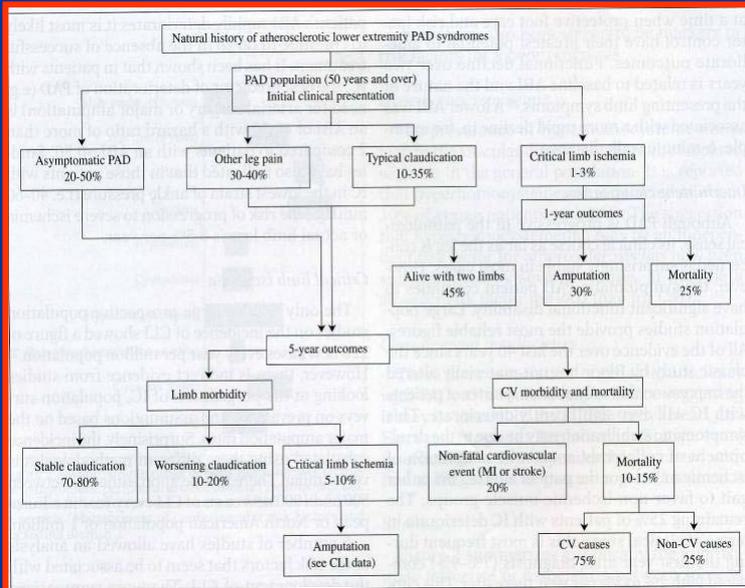
- Tecniche endovascolari nel distretto popliteo-tibiale in corso di validazione.
- Successo tecnico → 90%
- Salvataggio d'arto a 2 anni: 52-86%
- Pervietà a 5 anni: 50-60% se run off accettabile



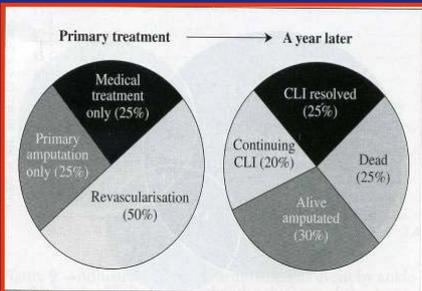
2007



**TASSO DI AMPUTAZIONE**

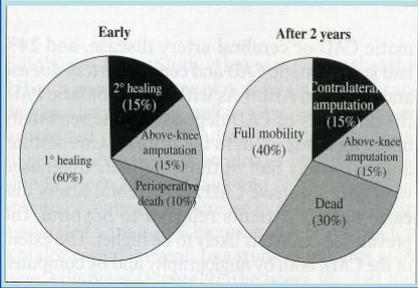


Storia naturale di pz con claudicatio a 5 anni

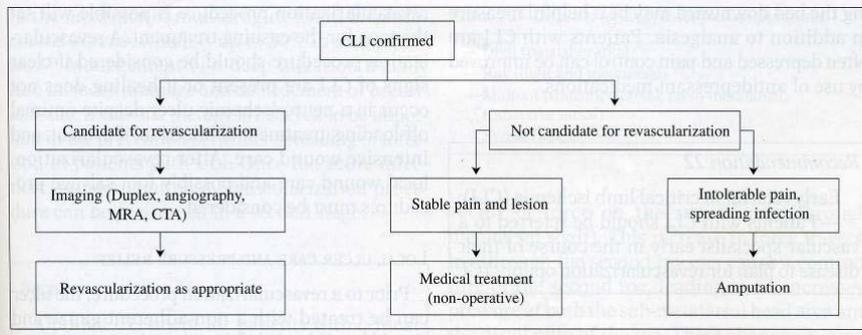


Storia naturale di pz con ICC

Storia naturale di pz amputato di gamba



## Algoritmo per il trattamento di ICC



### *Recommendation 22*

Early referral in critical limb ischemia (CLI):  
— Patients with CLI should be referred to a vascular specialist early in the course of their disease to plan for revascularization options [C].

### *Recommendation 23*

Multidisciplinary approach to treatment of critical limb ischemia:  
— A multidisciplinary approach is optimal to control pain, cardiovascular risk factors and other co-morbid disease [C].

*Recommendation 24*

Optimal treatment for patients with critical limb ischemia (CLI):  
— Revascularization is the optimal treatment for patients with CLI [B].

*Recommendation 26*

Multidisciplinary care in critical limb ischemia (CLI):  
— Patients with CLI who develop foot ulceration require multidisciplinary care to avoid limb loss [C].

*Recommendation 27*

Amputation decisions in critical limb ischemia (CLI):  
— The decision to amputate and the choice of the level should take into consideration the potential for healing, rehabilitation and return of quality of life [C].



**Bypass surgery for chronic lower limb ischaemia (Review)**

Leng GC, Davis M, Baker D



**THE COCHRANE  
COLLABORATION®**

This is a review of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in The Cochrane Library  
2007, Issue 3

<http://www.thecochranelibrary.com>



Bypass surgery for chronic lower limb ischaemia (Review)  
Copyright © 2007 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd

## ABSTRACT

### Background

Surgical bypass of an occluded arterial segment is the mainstay of treatment for patients with critical limb ischaemia. As with many surgical interventions, however, it was introduced without formal evaluation.

### Objectives

The objective of this review was to determine the effects of bypass surgery in patients with chronic lower limb ischaemia.

### Search strategy

The reviewers searched the Cochrane Peripheral Vascular Diseases Group trials register, MEDLINE, EMBASE, reference lists of relevant articles, and contacted principal trial investigators.

### Selection criteria

Randomized controlled trials of bypass surgery versus control or versus one other form of treatment.

## Authors' conclusions

There is limited evidence for the effectiveness of bypass surgery and further large trials are required.

Trials involved a total of just over 700 patients, two trials comparing bypass surgery with angioplasty (PTA), and one with each of thromboendarterectomy, thrombolysis, exercise, and spinal cord stimulation. Four trials included patients with a range of disease severity (intermittent claudication and critical limb ischaemia), one was restricted to claudicans only and another to only critical limb ischaemia. The type of bypass procedure performed in each trial was similar: vein grafts for distal reconstructions; synthetic prostheses for aorto-iliac or ilio-femoral bypasses. The outcome measures varied, but four of the six trials included mortality and operative failure. In general the quality of the trials was good, but none was blinded because of the nature of the intervention.

There were no clear differences between bypass surgery and PTA. Mortality and amputation rates did not differ significantly, although primary patency was significantly higher in the bypass group after 12 months (Peto OR 1.6, 95% CI 1.0, 2.6) but not after four years ( $p=0.14$ ). Compared with thrombolysis, amputation rates were significantly lower in the bypass group (Peto OR 0.2, 95% CI 0.1, 0.6), but mortality rates did not differ. Compared with thromboendarterectomy, restoration of blood flow was significantly greater in the bypass patients (Peto OR 9.2, 95% CI 1.7, 50.6), but mortality and amputation rates did not differ. Bypass did not differ significantly from exercise or spinal cord stimulation.

### Authors' conclusions

There is limited evidence for the effectiveness of bypass surgery and further large trials are required.

### Bypass surgery for chronic lower limb ischaemia (Review)

Copyright © 2007 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd

## Natural history of limbs with arterial insufficiency and chronic ulceration treated without revascularization

William A. Marston, MD, Stephen W. Davies, BS, Brian Armstrong, BS, Mark A. Farber, MD, Robert C. Mendes, MD, Joseph J. Fulton, MD, and Blair A. Keagy, MD, Chapel Hill, NC

**Objective:** The natural history of limbs affected by ischemic ulceration is poorly understood. In this report, we describe the outcome of limbs with stable chronic leg ulcers and arterial insufficiency that were treated with wound-healing techniques in patients who were not candidates for revascularization.

**Methods:** A prospectively maintained database of limb ulcers treated at a comprehensive wound center was used to identify patients with arterial insufficiency, defined as an ankle-brachial index (ABI)  $<0.7$  or a toe pressure  $<50$  mm Hg. Patients were treated without revascularization when medical comorbidity or anatomic considerations did not allow revascularization with acceptable risk. Ulcers were treated with a protocol emphasizing pressure relief, debridement, infection control, and moist wound healing. Risk factors analyzed for their effect on healing and amputation risk included age, gender, diabetes mellitus, chronic renal insufficiency (serum creatinine  $> 2.5$  mg/dL), severity of ischemia measured by ABI or toe pressure, wound grade, wound size, and wound location.

**Results:** Between January 1999 and March 2005, 142 patients with 169 limbs having arterial insufficiency and full-thickness ulceration were treated without revascularization. Mean patient age was  $70.8 \pm 4.5$ . Diabetes mellitus was present in 70.4% of limbs and chronic renal insufficiency in 27.8%. Toe amputations or other foot-sparing procedures were performed in 28% of limbs. Overall, limb loss occurred in 37 patients. By life-table analysis, 19% of limbs required amputation  $\leq 6$  months of initial treatment and 23% at 12 months. Complete wound closure was achieved in 25% by 6 months and in 52% by 12 months. Statistical analysis showed a correlation between ABI and the risk of limb loss. In patients with an ABI  $<0.5$ , 28% and 34% of limbs experienced limb loss at 6 and 12 months, respectively, compared with 10% and 15% of limbs in patients with an ABI  $>0.5$  ( $P = .01$ ). The only risk factor associated with wound closure was initial wound size ( $P < .005$ ).

**Conclusions:** Limb salvage can be achieved in most patients with arterial insufficiency and uncomplicated chronic nonhealing limb ulcers using a program of wound management without revascularization. Healing proceeds slowly, however, requiring more than a year in many cases. Patients with an ABI  $<0.5$  are more likely to require amputation. Interventions designed to improve outcomes in critical limb ischemia should stratify outcomes based on hemodynamic data and should include a comparative control group given the natural history of ischemic ulcers treated in a dedicated wound program. (J Vasc Surg 2006;44:108-14.)

## REVIEW

### Complete Ulcer Healing as Primary Endpoint in Studies on Critical Limb Ischemia? A Critical Reappraisal

U. Hoffmann,<sup>1\*</sup> K.-L. Schulte,<sup>2</sup> H. Heidrich,<sup>3</sup> H. Rieger<sup>4</sup> and S. Schellong<sup>5</sup>

<sup>1</sup>Division of Angiology, Ludwig-Maximilians-University Hospital Munich, Germany,

<sup>2</sup>Vascular Center Berlin, Ev. Hospital KEH, Academic Teaching Hospital of the Charité, Germany,

<sup>3</sup>Formerly Franziskus Hospital, Berlin, Academic Teaching Hospital of the Charité, Germany,

<sup>4</sup>Formerly Aggertal Hospital, Engelskirchen, Germany, and

<sup>5</sup>Division of Angiology, University Hospital Carl Gustav Carus, Dresden, Germany

**Objectives.** Although complete ulcer healing is the mandatory primary efficacy criterion in current European guidelines for drug trials in critical limb ischemia (CLI), the appropriateness of this endpoint has been questioned for some time. We carried out a systematic review to assess the value of this endpoint in studies on reconstructive measures, considered to be the standard of care for CLI.

**Methods.** A computerized literature search (1985–2005) was performed to track down clinical studies on endovascular and surgical interventions by using the search terms CLI and ulcer healing and their synonyms.

**Results.** 1,914 papers on revascularization in CLI were identified. Complete ulcer healing was reported in 17 studies (0.9%). Among these, there were no randomized controlled trials, five prospective cohorts on endovascular procedures, and six retrospective cohorts for endovascular and surgical procedures, respectively. If healing rates or time to ulcer healing were available, they differed greatly between the studies without consistent correlation to types of therapy.

**Conclusions.** In past and current literature, complete ulcer healing is not a consistently reported criterion for success of revascularization in CLI. Thus, its appropriateness for efficacy assessment of drug studies in CLI patients has to be questioned.

# CHI ?

→ **Chirurgo Vascolare**

→ **Radiologo Interventista**

→ **Cardiologo Emodinamista**

### **Chirurgia riparativa - rigenerativa**

- Innesti cutanei (omologhi, autologhi)
- Sostituti dermici
- Cute ingegnerizzata
- Cellule staminali
- ...



Integra® (Integra Life Science Corporation, Plainsboro, New Jersey)

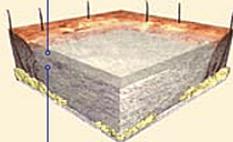


1. Silicone
2. Collagene e glicosaminoglicani

### How it works

#### Semi-permeable silicone membrane

- controls water vapor loss
- provides a flexible adherent covering
- adds increased tear strength



#### Collagen-glycosaminoglycan biodegradable matrix

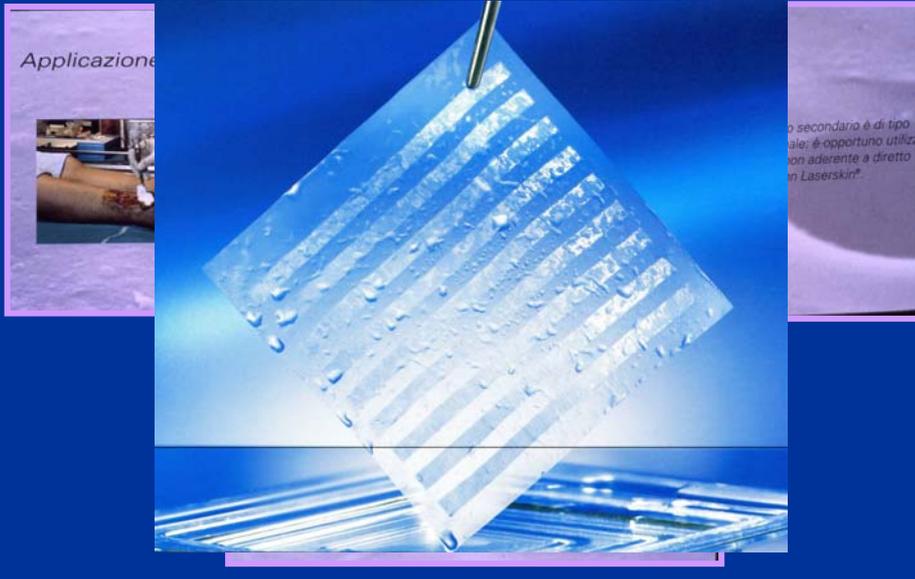
- provides a scaffold for cellular invasion and capillary growth
- scaffold is eventually remodeled as the patient's cells rebuild the damaged site



Laserskin™99 (Fidia Advanced Biopolymers, Italy) commercializzata anche come Vivoderm™99 dalla Squibb & sons Inc.



1. Cheratinociti autologhi cresciuti in coltura
2. Acido ialuronico perforato con il laser



## PROBLEMI APERTI

Trials clinici randomizzati per lo studio della terapia chirurgica delle ulcere

Quante u. possono guarire col solo trattamento conservativo ?

La chirurgia ha un ruolo sia nell'incrementare le guarigioni dove la terapia è fallita sia nel prevenire le recidive ?

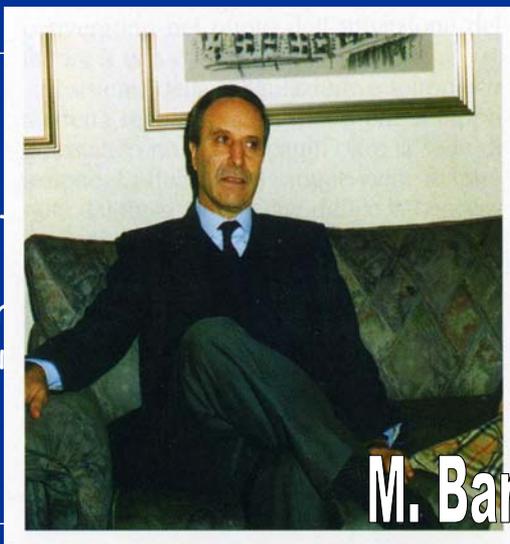
Come confrontare le tecniche di chirurgia vascolare con la chirurgia locale dell'ulcera ?

Quali e quanti pazienti richiederanno un ricovero ad un dato momento del proprio programma terapeutico ?

## Conclusioni

Fondamentale l'aspetto  
profilattico, preventivo e la  
precocità del percorso  
diagnostico-terapeutico

"...nell'at  
dovrebbe  
occorren  
qu



ando si  
si quando  
terapia  
."

M. Bartolo

"Confidiamo  
di una cura  
con un trat  
chirurgia cont  
efficace sa  
che signif  
morte di un  
tuttora do  
salvare la vita e



speranza  
sca il male  
ad allora la  
to sicuramente  
mputazione  
inarsi alla  
a alla quale  
entire per  
pili sofferenze"

**E. Malan** Malan, 1949



***Sfida aperta ed estrema***



SUPERARE

Incomunicabilità

Incomprensione



# TEAM

**T**ogether

**E**veryone

**A**chieve

**M**ore





