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On which criteria do you select your stent for ilio-femoral obstruction:

European point of view

Marzia Lugli



Hesperia Hospital Modena

www.chirurgiavascolaremodena.it



DVRS Club www.dvrs-club.net

Italian College of Phlebology

FINANCIAL RELATIONSHIP DISCLOSURE: Commercial Interests

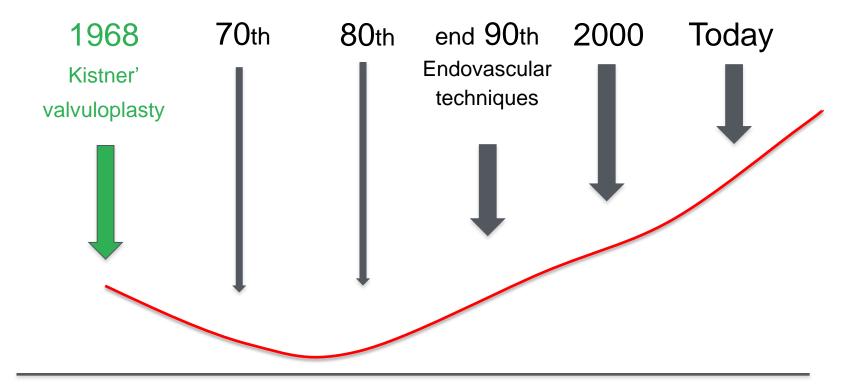
I declare the following commercial interests:

- Jotec Srl
- Volcano Europe BVBA
- BSCI
- Servier International
- Covidien

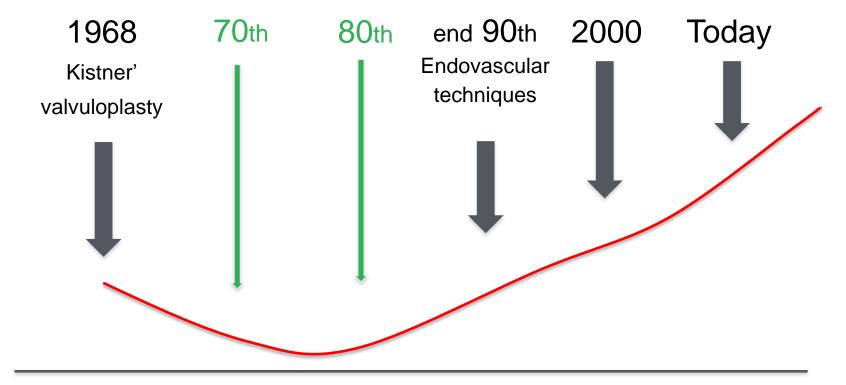
I declare that my presentation will not include commercial contents



Is there a different way to perform venous stenting in Europe and USA?

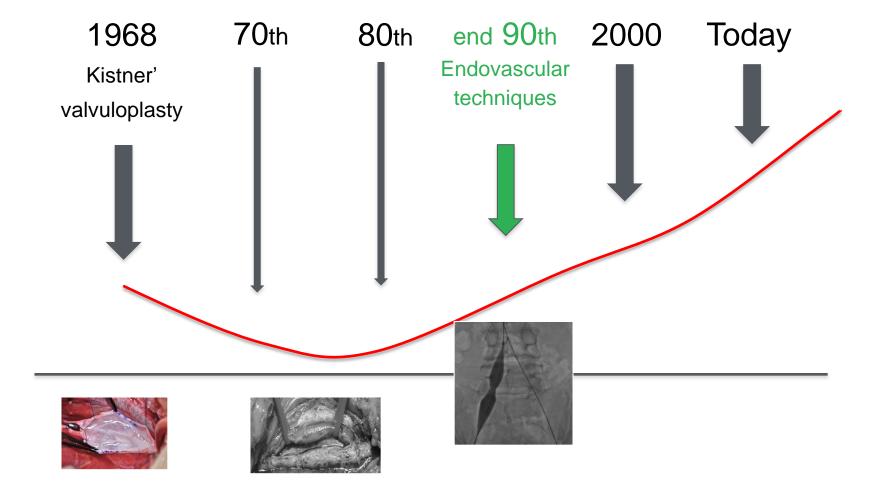


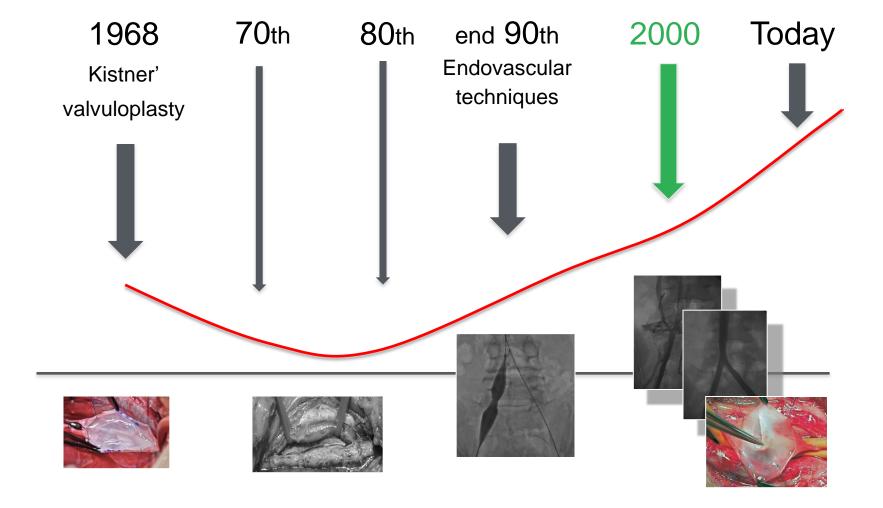


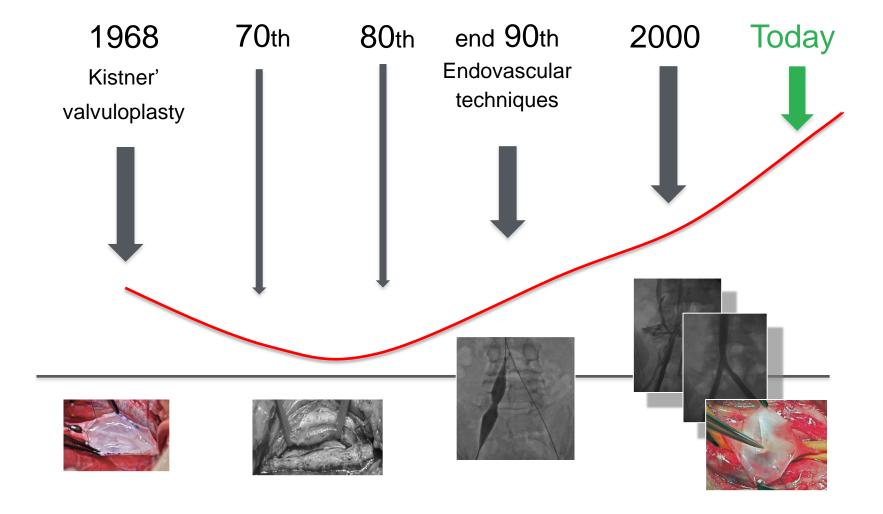












Today

Europe is active in deep venous system as US. but

Extensive Guidelines available in US

(AVF

2011)

Guidelines available in Europe (poor)

(ESVS

2015)

(CIRSE

Venoplasty/stenting technique

there are no significant difference between Europe and US

Available stents in Europe

VENITI is dedicated to providing innovative technologies for the treatment of venous disease.

VENITI VICI VENOUS STENT® System

The VICI VENOUS STENT® System is the first stent designed from inception for use in the venous system. The stent is designed to provide high crush resistance, end-to-end strength and shape with flexibility, and controlled deployment. Since receiving CE marking for the VICI VENOUS STENT® System, in October 2013, VENITI has achieved several important milestones. The product is currently available for commercial use in the European Union, and has received an Investigational Device Exemption (IDE) approval in the United States. VENITI began U.S. clinical trial procedures in the Fall of 2014.



Europe



The VENITI VICI VENOUS STENT® System is CE marked under the European Medical Devices Directive (93/42/EEC) and commercially available in Europe. CAUTION: Investigational device. Limited by United States law to investigational use.

USA

No FDA approval

sinus-Venous

MAXIMUM POWER & FLEXIBILITY

The most powerful stent we have ever built.

The venous system demands high standards of the stent parameters. The sinus-Venous is especially adapted for venous indications and impresses with high radial force. The unique hybrid-design enables the combi-nation of this outstanding power with maximum flexibility.





















Europe

USA

CE mark

No FDA approval

Zilver Vena™ (Cook)



Europe

USA

CE mark

under regulatory by FDA

Wallstent™ (BSCI)



Europe

USA

CE mark

FDA approval



critical issue:

cost of the procedure

European Reimbursement: A Snapshot of Some Healthcare Systems



UK

- 152 Primary Care Trusts
- 105 Foundation Trusts
- 10 Strategic Health Authorities (England)
- HRG (DRG) Prospective payment system

France

- Public & Private centralized decision making
- DRG (T2A) system prospective payment system
- Device specific reimbursement

Spain

- 17 autonomous regions
- High decision making power at hospital level (global budget)

Belgium

- 1 centralized system
- Device specific reimbursement

Denmark

- 5 Counties
- High decision making at hospital level (global budget)

Germany

- 16 counties 134 public & 43 private sickness funds
- High decision making power at hospital level
- G-DRG prospective payment system

Italy

- 21 local health authorities
- High decision power at regional level
- DRG prospective payment system

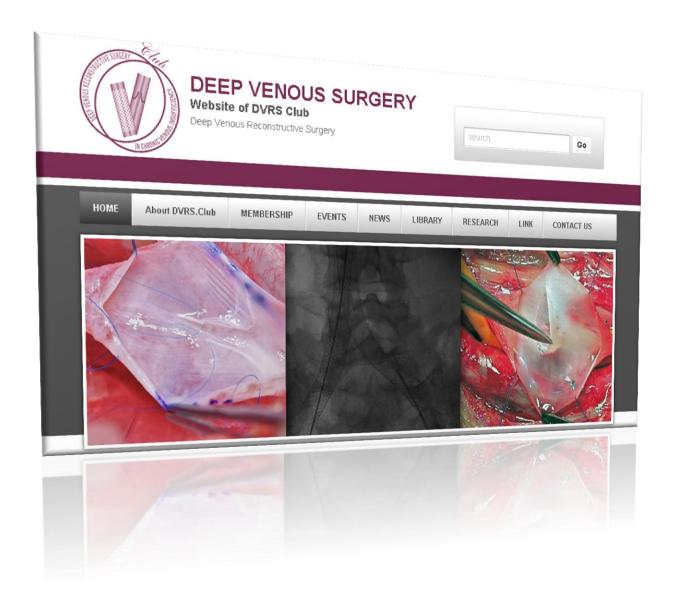
Reimbursement

UK		No dedicated reimbursement for venous stent
France		Reimbursement similar to arterial stent
Germany		No dedicated reimbursement for venous stent
Itay		No dedicated reimbursement for venous stent
Spain		Only private or insurance
IVUS		No reimbursement

In Europe

the most important limits to stenting in deep vein are linked to economic problems.

The cultural gap with US is today to be considered as history



thank you