

CONTROVERSES ET ACTUALITÉS EN CHIRURGIE VASCULAIRE  
CONTROVERSIES & UPDATES IN VASCULAR SURGERY

JANUARY 19-21 2017

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PARIS, FRANCE



# Does heparin-bonded ePTFE graft improve BTK bypass patency?

Carlo Pratesi

*Vascular Surgery*  
*University of Florence*





## Disclosure

Speaker name:

CARLO PRATESI MD

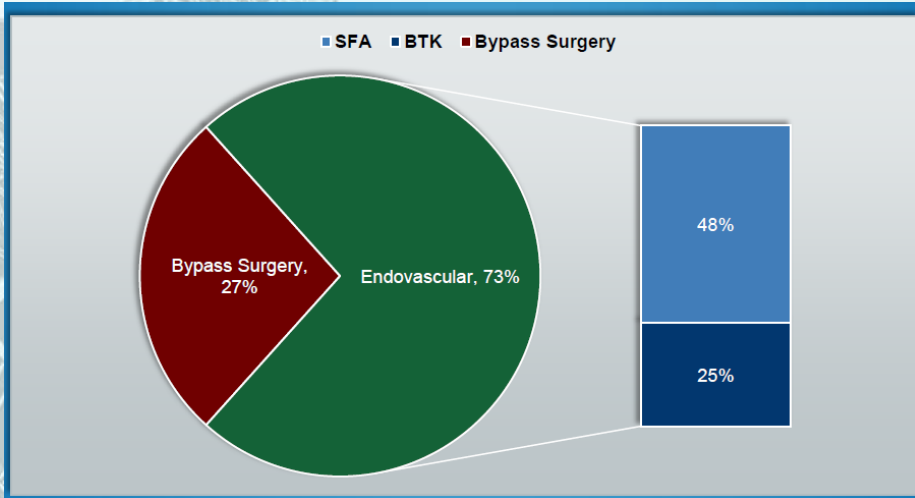
- I have the following potential conflicts of interest to report:
  - Consulting
  - Employment in industry
  - Shareholder in a healthcare company
  - Owner of a healthcare company
  - Other(s)
- I do not have any potential conflict of interest

# Femoro-popliteal procedures (EVEM panel)

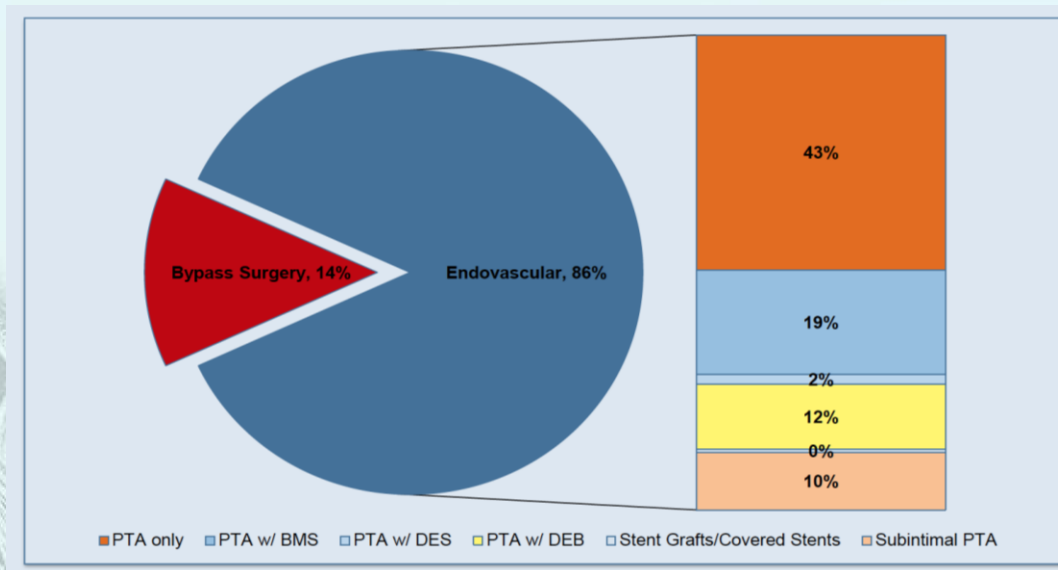
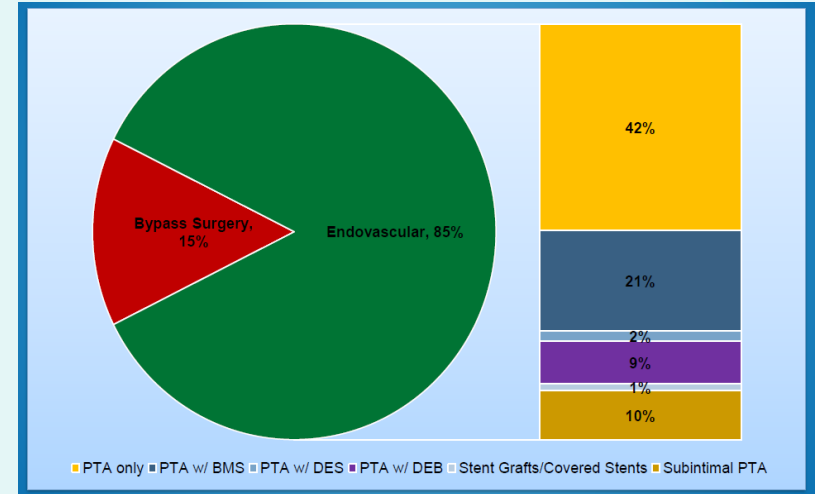


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Q3-2012



Q3-2014



Q3-2015

# Critical appraisal of surgical revascularization for critical limb ischemia

Michael S. Conte, MD, *San Francisco, Calif*

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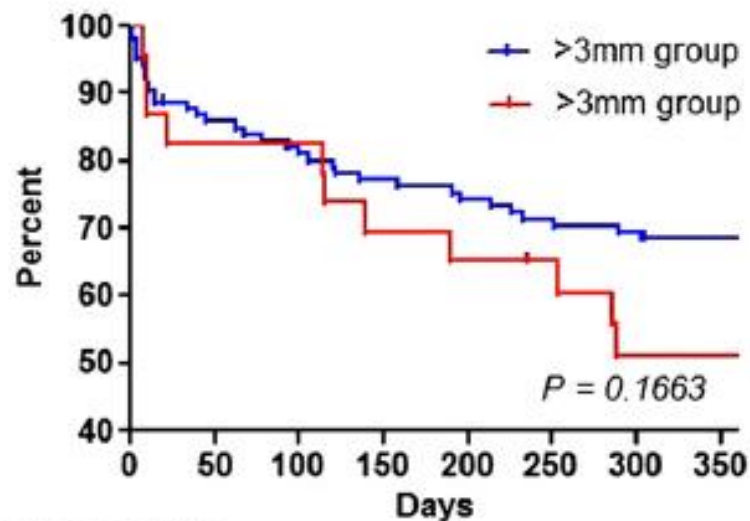
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**An adequate caliber, good quality great saphenous vein (GSV) is the optimal graft for distal bypass in the leg.**

**The availability of such a conduit is a relevant limitation of lower extremity bypass surgery: good ipsilateral greater saphenous vein may be lacking in up to 40% of the patients, and the strong relationship between vein diameter and graft failure makes autologous saphenous vein **unsuitable** in some **25% of the patients with critical limb ischemia**.**



# Outcome of infra-inguinal bypass grafts using vein conduit with less than 3 millimeters diameter in critical leg ischemia



Numbers at risk

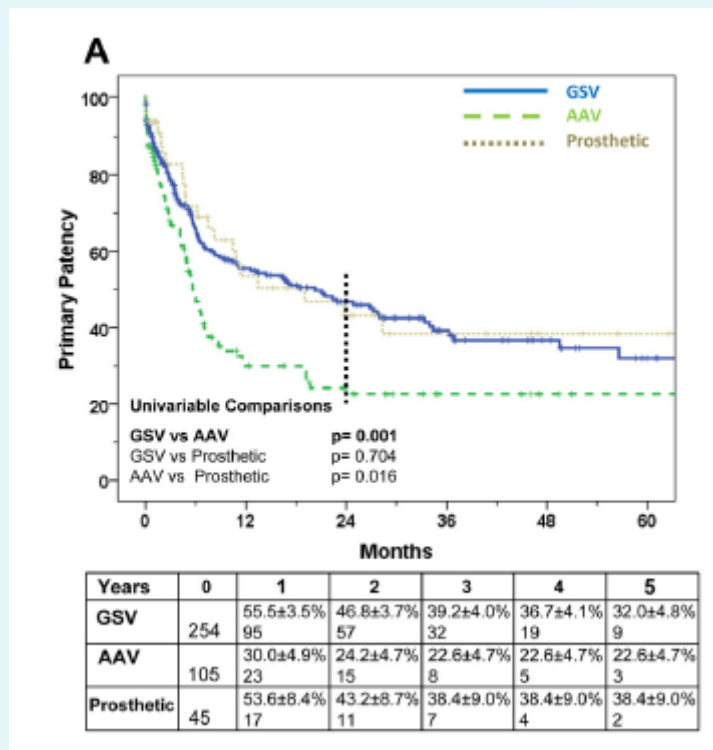
>3mm	92	84	79	74	70
<3mm	21	19	16	14	11

Fig 1. Primary patency rates in both groups.

**(Slim et al., J Vasc Surg 2011)**



# Autologous alternative veins may not provide better outcomes than prosthetic conduits for below-knee bypass when great saphenous vein is unavailable

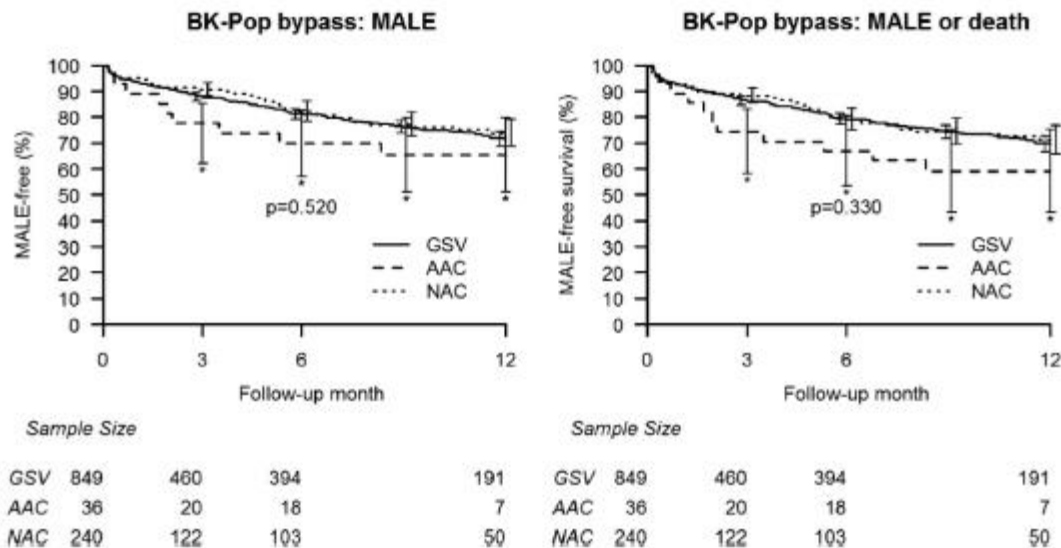


**Conclusions:** AAV conduits may not offer a significant patency advantage in midterm follow-up over prosthetic bypasses. (J Vasc Surg 2015;62:385-91.)

**(Avgerinos et al., J Vasc Surg 2015)**



# Alternative conduit for infrageniculate bypass in patients with critical limb ischemia

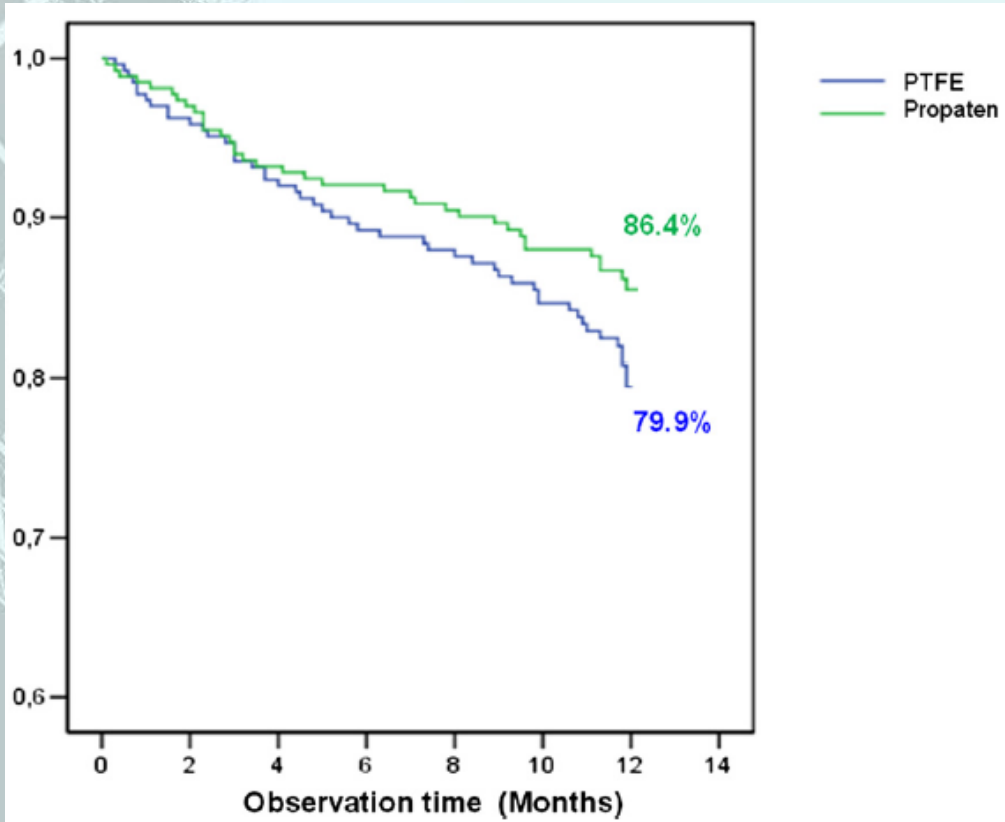


**Conclusions:** Conduit type does not affect outcomes in BK-Pop bypass. In the absence of single-segment GSV, the use of AAC for IPA bypass does not appear to confer any additional benefit of MALE, MALE-free survival, or graft patency compared with prosthetic grafts at 1-year follow-up. (J Vasc Surg 2016;64:131-9.)

**(Moreira et al., J Vasc Surg 2016)**

# The Scandinavian Propaten<sup>®</sup> Trial – 1-Year Patency of PTFE Vascular Prostheses with Heparin-Bonded Luminal Surfaces Compared to Ordinary Pure PTFE Vascular Prostheses – A Randomised Clinical Controlled Multi-centre Trial<sup>☆</sup>

J.S. Lindholt<sup>a,\*</sup>, B. Gottschalksen<sup>b</sup>, N. Johannesen<sup>c</sup>, D. Dueholm<sup>d</sup>, H. Ravn<sup>e</sup>, E.D. Christensen<sup>f</sup>, B. Viddal<sup>g</sup>, T. Flørenes<sup>h</sup>, G. Pedersen<sup>i</sup>, M. Rasmussen<sup>j</sup>, M. Carstensen<sup>k</sup>, N. Grøndal<sup>a</sup>, H. Fasting<sup>a</sup>

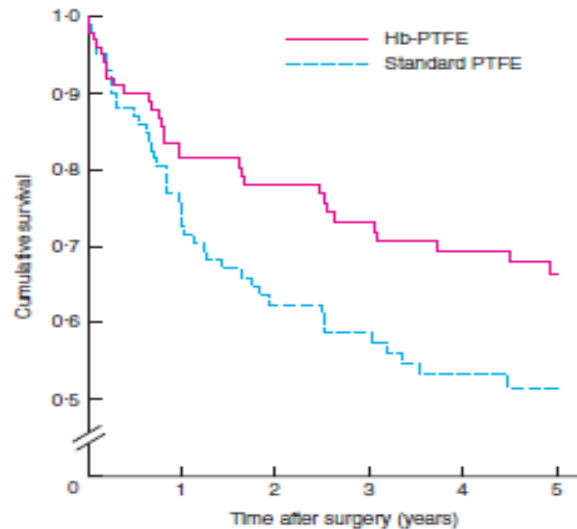


- The Hb-PTFE graft significantly reduced the overall risk of primary graft failure by 37%.
- Risk reduction was 50% in fem-pop bypass cases and in patients with CLI.





# Five-year outcomes following a randomized trial of femorofemoral and femoropopliteal bypass grafting with heparin-bonded or standard polytetrafluoroethylene grafts



No. at risk	0	1	2	3	4	5
Hb-PTFE	100	75	67	58	50	36
PTFE	100	66	53	44	33	27

**Fig. 3** Subgroup analysis of patients with critical ischaemia: 5-year primary patency of standard polytetrafluoroethylene (PTFE) and heparin-bonded PTFE (Hb-PTFE) grafts

	Hazard ratio	P	Variables adjusted for
Primary patency			
All patients*†	0.95 (0.71, 1.28)	0.748	CLI, type of bypass
Critical ischaemia	0.63 (0.40, 0.99)	0.049	Type of bypass
Femorofemoral bypass	0.74 (0.37, 1.48)	0.398	None
Femoropopliteal bypass	0.56 (0.31, 1.01)	0.055	None
Intermittent claudication	1.28 (0.89, 1.85)	0.192	Type of bypass
Femorofemoral bypass*‡	3.15 (1.49, 6.65)	0.003	None
Femoropopliteal bypass	0.87 (0.56, 1.37)	0.553	None
Amputation	1.23 (0.60, 2.53)	0.579	CLI and type of bypass
Death	0.87 (0.66, 1.16)	0.344	CLI, type of bypass, age

**Conclusion:** In this study there was no difference in primary graft patency between Hb-PTFE and standard PTFE grafts. Patients receiving Hb-PTFE grafts for critical limb ischaemia were more likely to have a patent graft at 5 years than those with standard PTFE grafts.

*(Lindholt et al., Br J Surg 2016)*

# Italian Registry: participants centres

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# External validation obtained (2009-2013)



Associazione Professionale  
**Castalia**  
I.C.T. & Quality Management

## OVERVIEW ON PROPATEN DATABASE CONTROL PROCEDURES

The results of the control procedure to verify Propaten database (DB) validity and coherence are presented in this paper.

### a) PREMISES

1. the total number of clinical cases (follow-up parameters included) collected in linear records was N=477;
2. data to be submitted to control has been "cleaned" by means of filters in order to confirm the coherence and completeness of the selected variables, previously analysed (in the details: months of follow-up / thrombosis / amputation / age - considered if >0)
3. after a random sorting on patients initials (anonymous during the whole procedure) a casual sample was extracted - Spss (Software Package for Statistical Sciences) SAMPLE function - which took out n = 50 subjects from the total available cases (this significant sample numerosity can be reasonably verified by re-examining diagnostic investigations and clinical files)
4. the error was estimated, in the errors concentration evaluation, as follows:  
$$err = \sqrt{(N / n - 1) / (N - 1)} = 0,013 \rightarrow \pm 13\%$$

### b) ELABORATION

Hereby tables report the elaborations carried out on sample check after medical examinations (descending order frequencies obtained using Spss)

### Total errors, per patient, on all the 44 clinical variables considered

	Frequencies	Rates	Valid rates	Cumulative rates
Valid none	37	74,0	75,5	75,5
1 error / patient	9	18,0	18,4	93,9
2 error / patient	2	4,0	4,1	98,0
3 error / patient	1	2,0	2,0	100,0
Total	49	98,0	100,0	
Missing	1	2,0		
Total	50	100,0		

### Overall errors, per patient, on the sample control variable: MONTHS OF FOLLOW UP

	Frequencies	Rates	Valid rates	Cumulative rates
Valid None	49	98,0	100,0	100,0
Missing	1	2,0		
Total	50	100,0		

### Overall errors on the sample control variable: THROMBOSIS MONTHS

	Frequencies	Rates	Valid rates	Cumulative rates
Valid None	46	92,0	93,9	93,9
1 error	3	6,0	6,1	100,0
Total	49	98,0	100,0	
Missing 2	1	2,0		
Total	50	100,0		

### Overall errors on the sample control variable: AMPUTATION MONTHS

	Frequencies	Rates	Valid rates	Cumulative rates
Valid None	49	98,0	100,0	100,0
Missing 2	1	2,0		
Total	50	100,0		

In conclusion, referring to the clinical variables reported and considering the numerical confirmation of the completeness of the others, the DB integrity can be reasonably validated and it can represent a fundamental basis for the scientific extrapolations already produced and for the elaborations in progress (with respect to the opportune significance estimations).

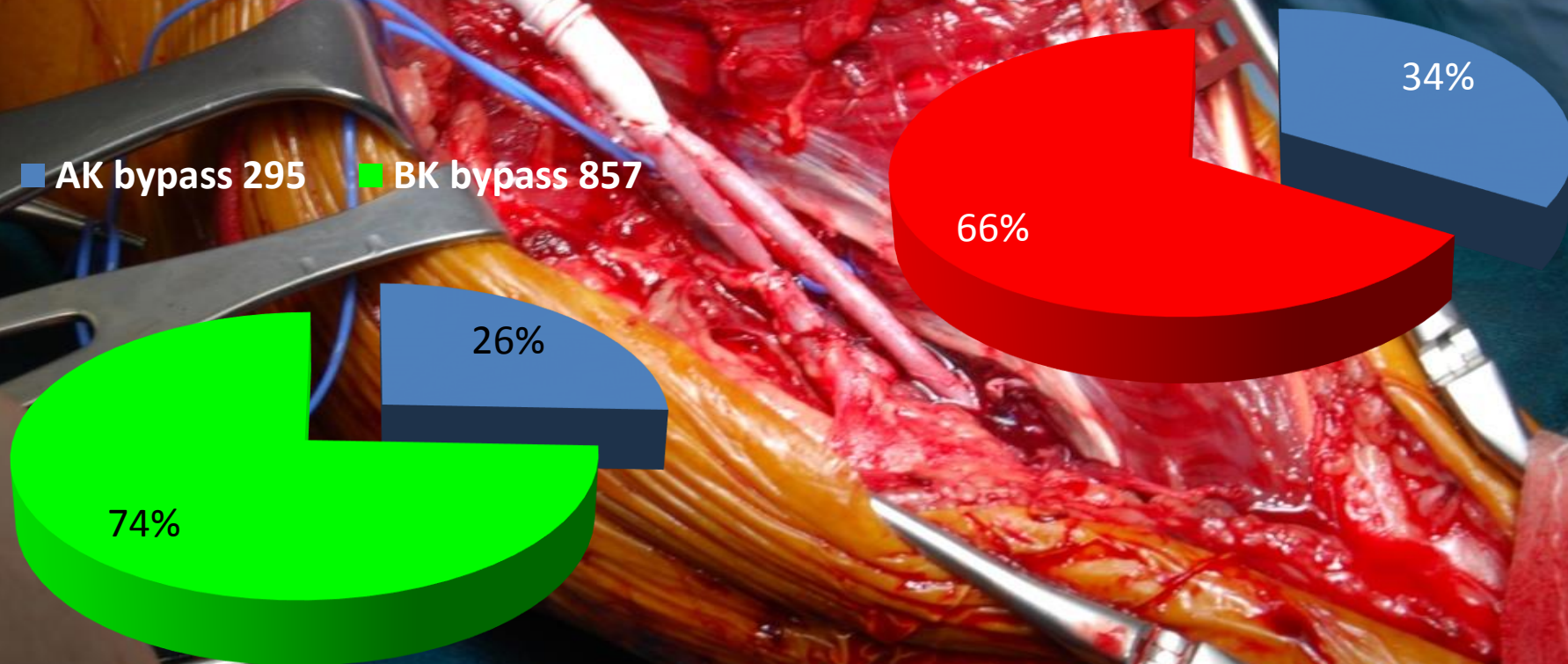
# PROPATEN ITALIAN REGISTRY GROUP

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## UPDATE - 2015

■ Claudicants 388   ■ CLI 764

■ AK bypass 295   ■ BK bypass 857



**1152 HePTFE bypasses**

# ITALIAN REGISTRY

AVEZZANO, CATANIA, FIRENZE,  
MESTRE, REGGIO EMILIA, TERNI, VARESE



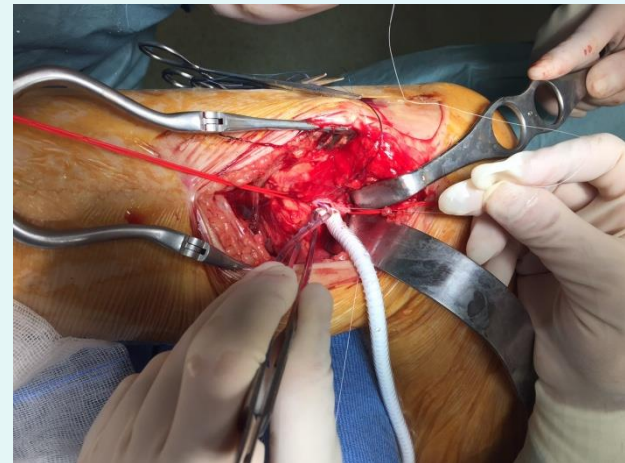
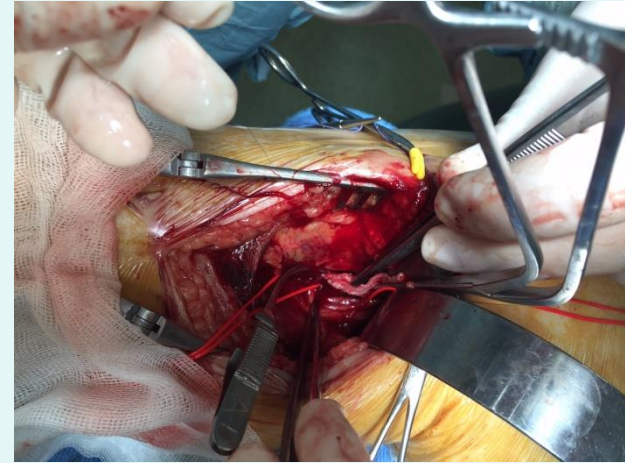
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➤ **Results in BTK  
bypass in 683  
patients with CLI**

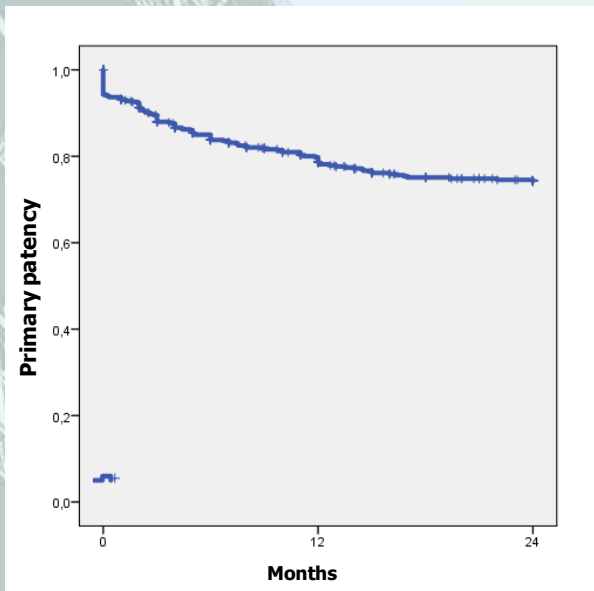
➤ **Propaten Score**



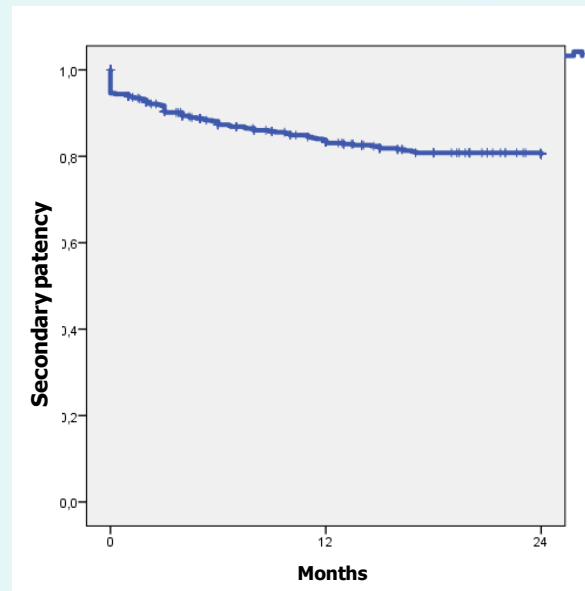
# Two-year analysis



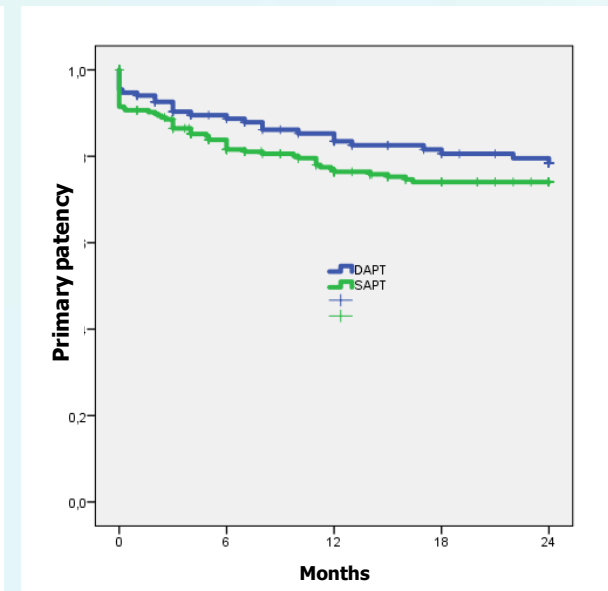
To have a group of patient with a complete 2-year follow-up (follow-up index equal to 1) we excluded from the analysis all the patients who had a follow-up time shorter than 24 months and did not have any event during those two years. The analysis of follow-up events in the remaining **633** patients was stopped at 24 months



**75%, SE 0.02**



**80%, SE 0.02**



*Primary patency on the basis of postoperative SAPT or DAPT*

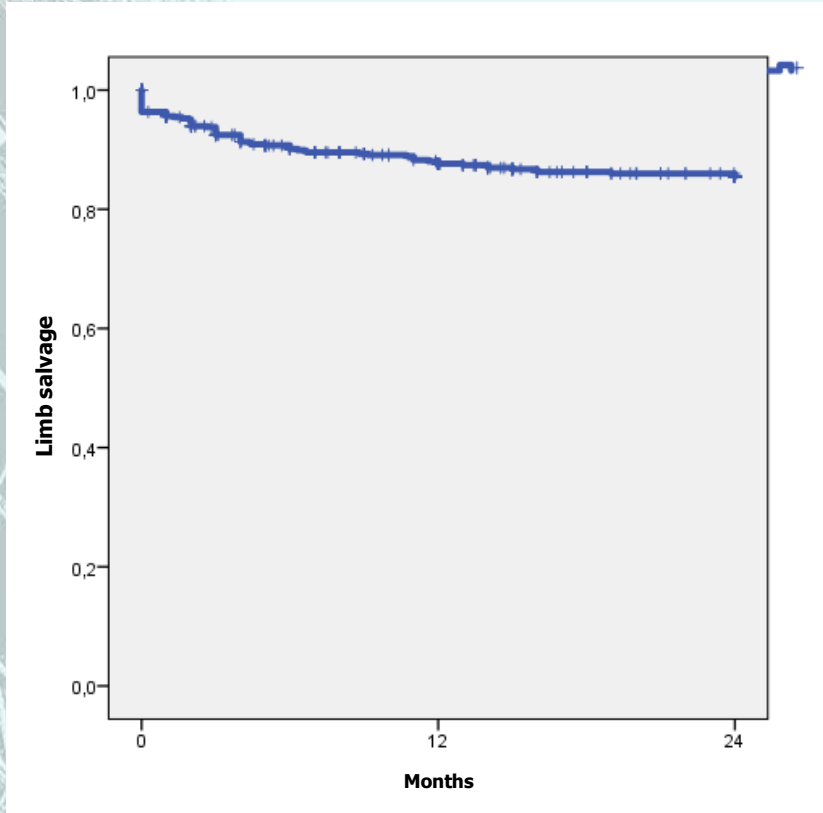
# Two-year analysis

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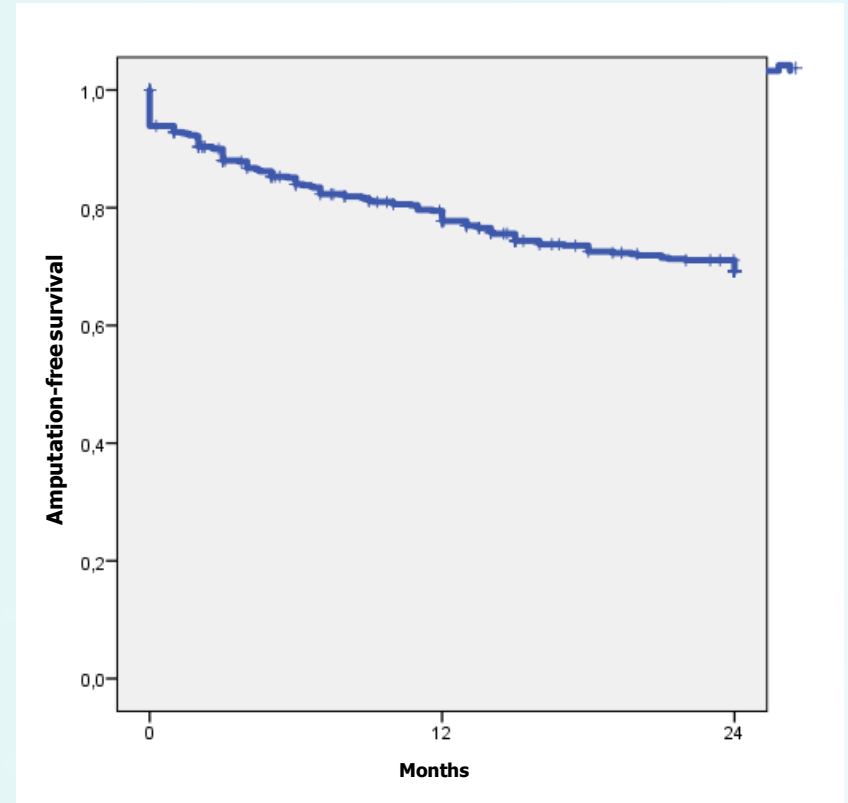


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**85.5%, SE 0.016**



**70%, SE 0.02**

# ITALIAN REGISTRY

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MESTRE, REGGIO EMILIA, TERNI, VARESE



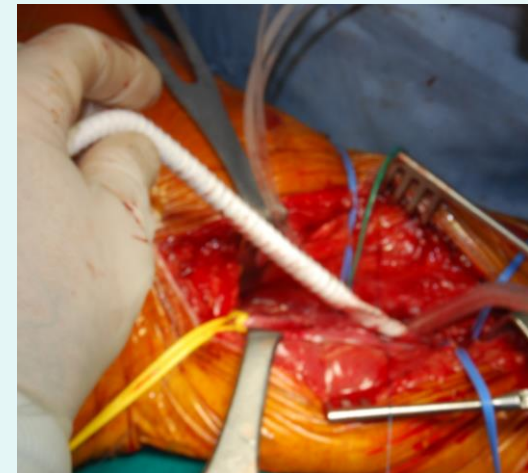
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➤ Results in BTK bypass in 683 patients with CLI

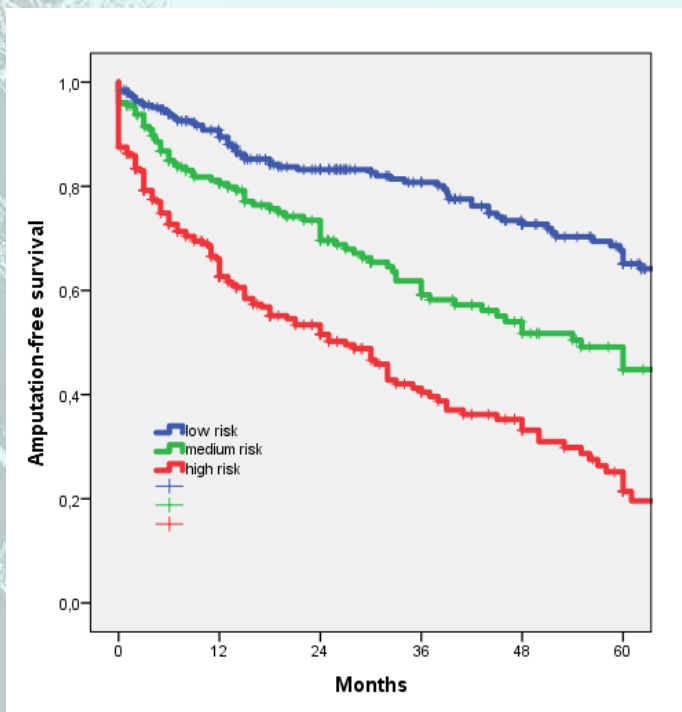
➤ Propaten Score







# A Multicenter Predictive Score for Amputation-Free Survival for Patients Operated on with an Heparin-Bonded ePTFE Graft for Critical Limb Ischemia



Months	0	12	24	60
<b>Low risk</b>				
N. at risk	247	199	156	77
SE	0.008	0.02	0.02	0.04
<b>Medium-risk</b>				
N. at risk	171	125	94	33
SE	0.015	0.03	0.03	0.05
<b>High-risk</b>				
N. at risk	217	134	86	19
SE	0.02	0.03	0.03	0.04

Risk groups	5-year AFS	HR (95% CI)	p
<b>Low-risk</b>	<b>67.7%</b>	<b>-</b>	<b>-</b>
<b>Medium-risk</b>	<b>49.2%</b>	<b>1.8 (1.2-2.7)</b>	<b>&lt;0.001</b>
<b>High-risk</b>	<b>25.2% %</b>	<b>2 (1.5-2.6)</b>	<b>&lt;0.001</b>

# Univariate analysis for PP in HePTFE group



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		Log-rank	<i>p</i>
Age (years)			
≥75	40	1	0.3
<75	43		
<b>Gender</b>			
<b>Female</b>	<b>30.5</b>	<b>9.3</b>	<b>0.002</b>
<b>Male</b>	<b>45</b>		
<b>Hyperlipemia</b>			
<b>Yes</b>	<b>41</b>	<b>2.5</b>	<b>0.1</b>
<b>No</b>	<b>44</b>		
Hypertension			
Yes	43	0.1	0.7
No	48		
<b>Coronary artery disease</b>			
<b>Yes</b>	<b>46</b>	<b>3.2</b>	<b>0.007</b>
<b>No</b>	<b>38</b>		
Diabetes			
Yes	42	1.1	0.3
No	41		
Dialysis			
Yes	31	0.2	0.7
No	43		
<b>Reintervention</b>			
<b>Yes</b>	<b>32</b>	<b>19.7</b>	<b>&lt;0.001</b>
<b>No</b>	<b>47</b>		
Clinical status			
Rest pain	45	0.4	0.4
Tissue loss	37.5		
<b>Level of anastomosis</b>			
<b>Popliteal</b>	<b>45</b>	<b>16.2</b>	<b>&lt; 0.001</b>
<b>Tibial</b>	<b>28</b>		
<b>Distal procedures</b>			
<b>Yes</b>	<b>47</b>	<b>5.1</b>	<b>0.02</b>
<b>No</b>	<b>30</b>		
<b>Run-off (vessel)</b>			
>1	49	11.2	0.001
0-1	34		



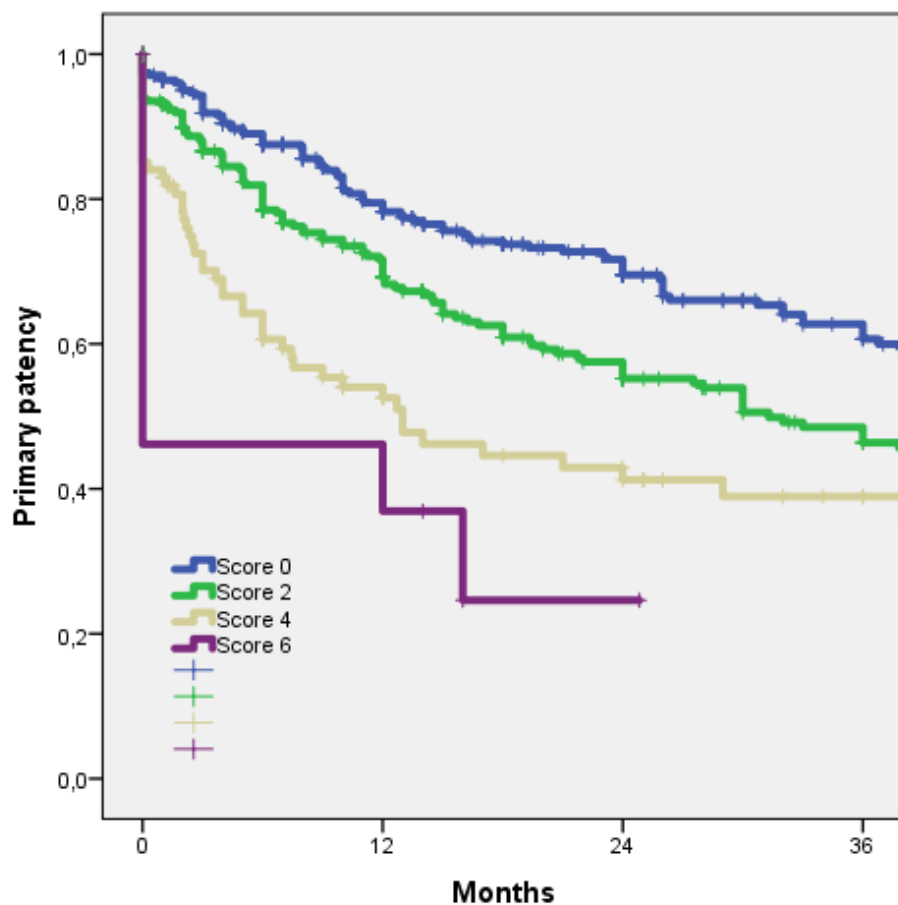
# Multivariate analysis for PP in HePTFE group and Propaten score

	<i>95% CI</i>	<i>HR</i>	<i>p</i>	<i>B-coefficient</i>	<i>Integer score</i>
<b>Female gender</b>	<b>1.1-2</b>	<b>1.5</b>	<b>0.001</b>	<b>0.43</b>	<b>2</b>
<b>Reintervention</b>	<b>1.1-2.1</b>	<b>1.6</b>	<b>&lt;0.001</b>	<b>0,55</b>	<b>2</b>
<b>Tibial anastomosis</b>	<b>1.1-2.1</b>	<b>1.6</b>	<b>&lt;0.001</b>	<b>0,46</b>	<b>2</b>

	Yes	No
Female gender	2 pts.	0 pt.
Reintervention	2 pts.	0 pt.
Tibial anastomosis	2 pts.	0 pt.

# Propaten® Score

## PP score



Scores (n. of patients)	3-year PP
0 (307 patients)	63%
2 (262 patients)	46%
4 (94 patients)	39%
6 (13 patients)	25%



# Conclusions

## HB PTFE graft:

- ✓ Propaten score analysis demonstrated very satisfying results **in patients with a good score** not only in terms of amputation free survival, but also of primary patency
- ✓ Cost-effectiveness?



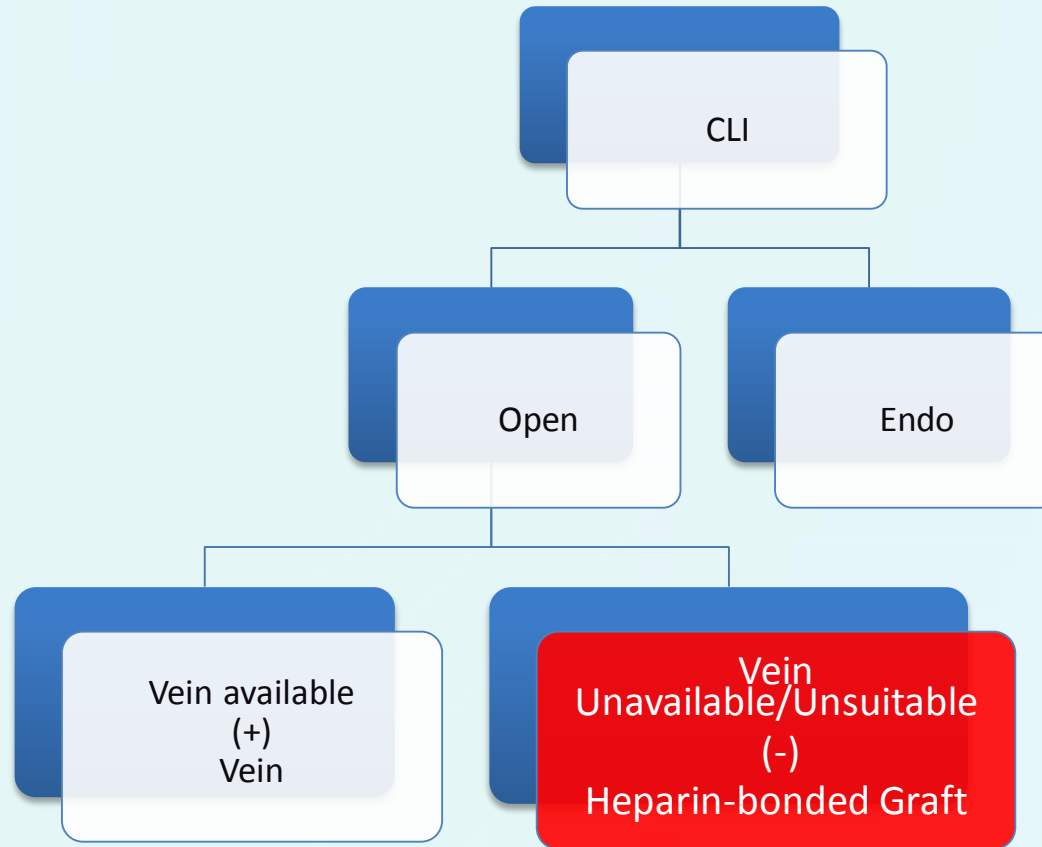
# Gouëffic Y.

Heparin Bonded PTFE Grafts (Propaten from Gore)  
for BTK bypasses in CLI: advantages, patency results and cost issues.

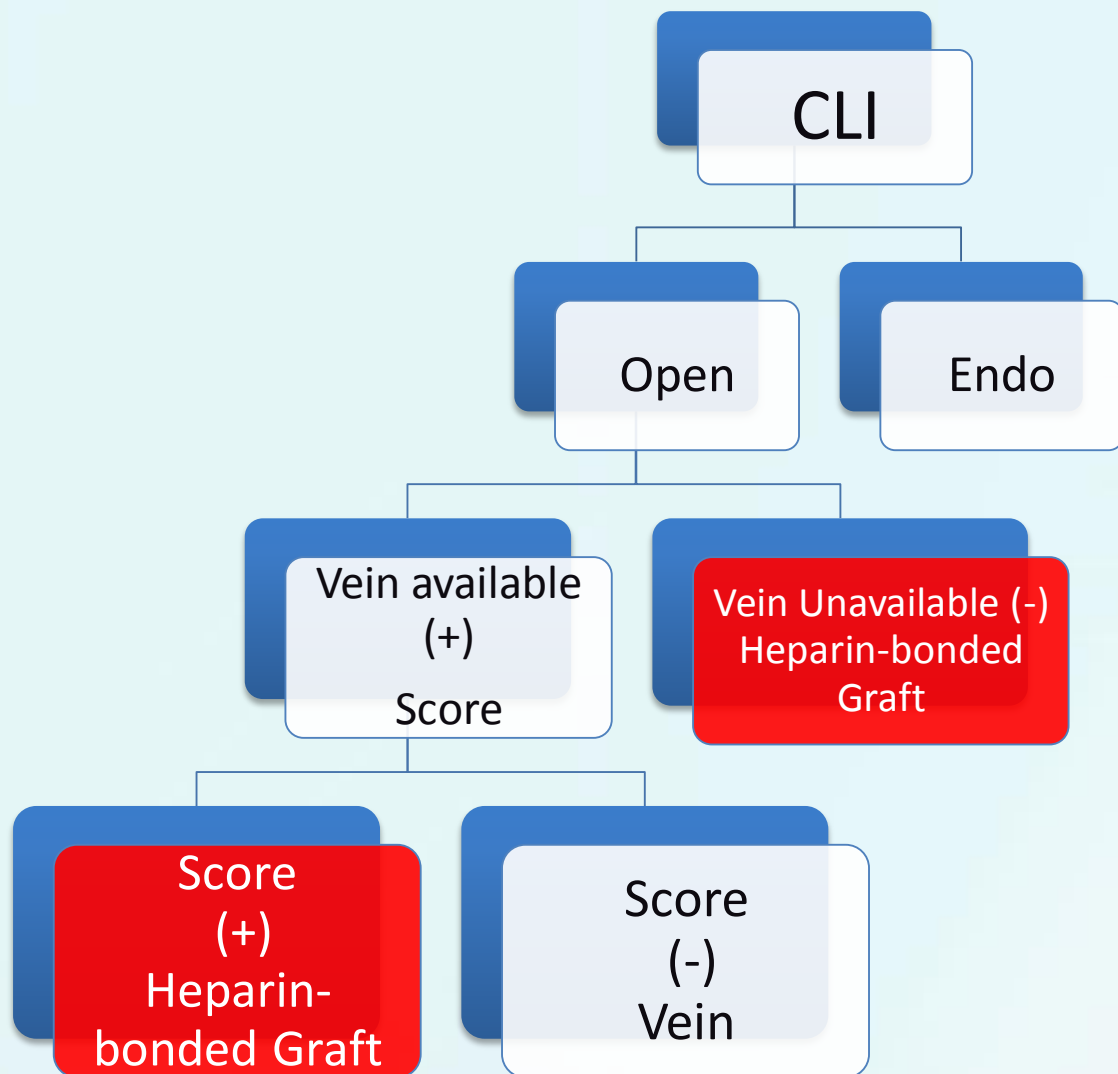
## Take home messages

- Registries for BTK 2-year primary patency for Propaten<sup>®</sup> grafts showed a high patency rate.
- Our model-based analysis showed a strong economic incentive in favor of the widespread use and reimbursement for Propaten<sup>®</sup>.
- However, type I level clinical evidence is still lacking for BTK Propaten<sup>®</sup> bypasses in CLI patients.

# Our Actual paradigm:



# Can we change the paradigm on the basis of the suggested score ?





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Thanks for your attention