DISCLOSURE: Marco G Manzi, MD

Consultant for

- ABBOTT Vascular;
- AlviMedica/CID;
- Angiodroid;
- BDBard;
- Biotronik;
- Boston Scientific;
- Cook;
- Cordis;
- Ivascular;
- Medtronic;
- MicroMedical Solution;
- Terumo;

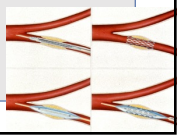
Brand names are included in this presentation for participant clarification purposes only. No product promotion should be inferred.

PTA vs Bare Metal Stents BTK

Cochrane 2018

PTA with stent placement is better than PTA alone for restoring vessel patency immediately

There is no clear difference in short-term patency at six months between the two groups.



Infrapopliteal use of DES

> J Endovasc Ther. 2020 Aug;27(4):547-564. doi: 10.1177/1526602820931488. Epub 2020 Jun 17.

Balloon Angioplasty of Infrapopliteal Arteries: A Systematic Review and Proposed Algorithm for Optimal Endovascular Therapy

JET 2020

Stefanos Giannopoulos [1], Ramon L. Varcoe [2], Michael Lichtenberg [3], John Rundback [4], Marianne Brodmann [5], Thomas Zeller [6], Peter A Schneider [7], Ehrin J Armstrong [1]

Affiliations + expand

> Cardiovasc Intervent Radiol. 2021 Sep;44(9):1309-1322. doi: 10.1007/s00270-021-02891-5. PMID: 32571125 DOI: 10.1177/152€ Epub 2021 Jun 25.

CIRSE Standards of Practice on Below-the-Knee Revascularisation

CVIR 2021

Stavros Spiliopoulos [1], Costantino Del Giudice [2], Marco Manzi [3], Lazaros Reppas [4], Thomas Rodt [5], Raman Uberoi [6]

Affiliations + expand

PMID: 34173044 DOI: 10.1007/s00270-021-02891-5

Infrapopliteal DES – Why?

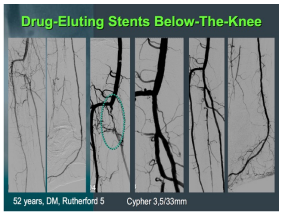
Background from those Papers

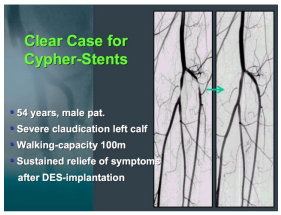
- "Infrapopliteal PTA is associated with 4 main failure mechanisms that lead to loss of vessel patency: dissection, residual stenosis, recoil, and restenosis. **Dissection** and **residual stenosis** occur acutely after balloon angioplasty, **recoil** occurs over 15 to 30 minutes after an
- gioplasty, and **restenosis** is a biologic response to inflammation that peaks in severity 3 to 6 months after angioplasty."[1]
- "Several multicenter, randomized controlled trials (**RCT**) designed to investigate the use of DES for infrapopliteal artery disease, have provided level as evidence to support the use DES for short-to-medium-length lesions. According to meta-analytical data, **DES** deployment in short–to–medium-length infrapopliteal lesions was **superior in terms of patency, target lesion revascularization, Rutherford improvement and wound healing at 1-year follow-up**, compared to bare metal stenting or plain balloon angioplasty."[2]

(1) J Endovasc Ther. 2020 Aug;27(4):547-564. doi: 10.1177/1526602820931488. Epub 2020 Jun 17. Balloon Angioplasty of Infrapopliteal Arteries: A Systematic Review and Proposed Algorithm for Optimal Endovascular Therapy. Stefanos Giannopoulos, Ramon L Varcoe, Michael Lichtenberg, John Rundback, Marianne Brodmann, Thomas Zeller, Peter A Schneider, Ehrin J Armstrong

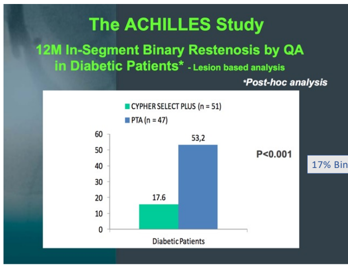
(2) Cardiovasc Intervent Radiol. 2021 Sep;44(9):1309-1322. doi: 10.1007/s00270-021-02891-5. Epub 2021 Jun 25. CIRSE Standards of Practice on Below-the-Knee Revascularisation. Stavros Spiliopoulos, Costantino Del Giudice, Marco Manzi, Lazaros Reppas, Thomas Rodt, Raman Uberoi

Milestones: Achilles 2012





Milestones: Achilles 2012



17% Binary Restenosis

Milestones: Varcoe 2019

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Online version at http://www.minervamedica.it
International Angiology 2019 April;38(2):121-35
DOI: 10.23736/S0392-9590.19.04049-5

REVIEW
PERIPHERAL ARTERIAL DISEASE

The use of drug-eluting stents in infrap
arteries: an updated systematic re
and meta-analysis of randomized t

Ramon L. VARCOE [1, 2, 3] *, Sharath C. PARAVASTU [1, 4], Shannon D. THOMAS [1, 2, 3], Michael H. BENNETT [2, 5]

[1]Department of Surgery, Prince of Wales Hospital, Sydney, Australia; [2]Faculty of Medicine, Wales, Sydney, Australia; [3]The Vascular Institute, Prince of Wales, Sydney, Australia; [4]Depart Gloucestershire Hospitals NHS Foundation Trust, Gloucester, UK; [5]Department of Anesthesia, Sydney, Australia

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E-mail: r.varcoe@unsw.edu.au

Conclusions

This meta-analysis has demonstrated that DES improve rates of primary patency, reintervention, sustained improvement in Rutherford category and major amputation compared with conventional therapy of angioplasty, DCB and BMS. These devices are known to both provide scaffolding and reduce the intimal hyperplasia response, which is the likely mechanism by which they limit restenosis after the percutaneous treatment of focal, infrapopliteal arterial stenoses. Further studies are needed which should include patients with longer patterns of tibial artery occlusive disease, longer-term follow-up, and consistent, relevant endpoints that include QOL and cost effectiveness.

Better patency, less hyperplasia and better QOL

Milestones: Varcoe 2024

Randomized Controlled Trial

N Engl J Med. 2024 Jan 4;390(1):9-19. doi: 10.1056/NEJMoa2305637.
Epub 2023 Oct 25.

Drug-Eluting Resorbable Scaffold versus Angioplasty for Infrapopliteal Artery Disease

Ramon L Varcoe [1], Brian G DeRubertis [1], Raghu Kolluri [1], Prakash Krishnan [1], David C Metzger [1], Marc P Bonaca [1], Mehdi H Shishehbor [1], Andrew H Holden [1], Danielle R Bajakian [1], Lawrence A Garcia [1], Steven W C Kum [1], John Rundback [1], Ehrin Armstrong [1], Jen-Kuang Lee [1], Yazan Khatib [1], Ido Weinberg [1], Hector M Garcia-Garcia [1], Karine Ruster [1], Nutte T Teraphongphom [1], Yan Zheng [1], Jin Wang [1], Jennifer M Jones-McMeans [1], Sahil A Parikh [1]; LIFE-BTK Investigators

Collaborators, Affiliations + expand

PMID: 37888915 DOI: 10.1056/NEJMoa2305637

Better Efficacy End Point (Freedom from CDTLR) 75% vs 44%

Our Study

The Cre8™ BTK Post Market Clinical Follow-up study - Retrospective Study

Final Clinical Study Report

	(Notified body 0373 of the Italian National Institute of Health (ISS)
Study Design	This is a retrospective, multicenter observational study, as defined in ISO 14155:2020

Study Rationale/Purpose	This study has the objective to collect retrospective data on the 1-year clinical outcomes of a sirolimus drug eluting stent in an unselected population. The product is CE marked
Study Objective	To systematically collect retrospective clinical data on the implantable medical device Cre8™ BTK in an unselected population, in the current clinical practice treated within the intended use. Data are collected via medical chart review in anonymous form to assess the safety and efficacy of Cre8™ BTK.
Study Primary endpoints:	SAFETY – Rate of Major Adverse Events (MAE), a composite endpoint of all causes of death, unplanned target limb major amputation through 12 months and/or clinically indicated target lesion revascularization (TLR) through 12 months. EFFICACY – Rate of clinically driven target lesion revascularization (TLR) at 12-month follow-up.
Secondary endpoints:	• Primary endpoints evaluated at 6 months • Primary patency at 6 and 12 months (if available, latest data available). Primary patency is defined as absence of clinically-driven target lesion revascularization or binary restenosis. Binary restenosis is defined as a peak systolic velocity ratio (PSVR) >2.4 (Duplex Ultrasound evaluation) • Limb-salvage rate (LSR) at 6 and 12 months defined as rate of patients free from major amputation. Major amputation is defined as at or above ankle, as opposed to minor amputation being at or below metatarsus preserving functionality of foot • Secondary patency (patency following successful target lesion revascularization (TLR) at 6 and 12 months or latest patency data available • Death within 30 days of the index procedure • Clinically driven Target Lesion Revascularization at 6 and 12 months

Study centers	1 site in Italy that has implanted the study devices between 2019 and 2021, in order to allow the collection of retrospective date at 1-year follow-up.

157 patients, Sample >30<50

Study Lesions

Diameter Stenosis (%)	N=31	Residual Stenosis (%)	N = 31
Mean ± SD	86.4 ± 11.7	Mean ± SD	0.3 ± 1.8
Median	90.0	Median	0.0
Min, Max	45.0, 99.0	Min, Max	0.0, 10.0
Q1, Q3	85.0, 90.0	Q1, Q3	0.0, 0.0
Re-established in-line flow to foot:		**N = 31**	
Yes		31 (100.0)	
No		0 (0.0)	
Technical success (stent implantation with residual DS <30%)		**N = 31**	
Yes		31 (100.0)	
No		0 (0.0)	

Majority of subocclusive and occlusive lesions

Study Results: TLR Primary Patency

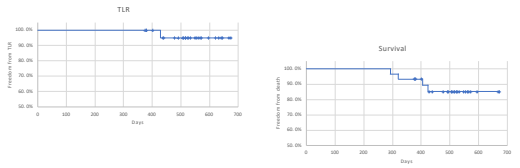
Clinically driven Target Lesion Revascularization (N = 0)	N (%)	N (%)
Surgical revascularization	0 (0.0)	0 (0.0)
Symptomatic Percutaneous Revascularization (Target lesion)	0 (0.0)	0 (0.0)

Primary Patency (N=31)	6-month rate N (%)	12-month rate N (%)
	31(100.0)	31(100.0)

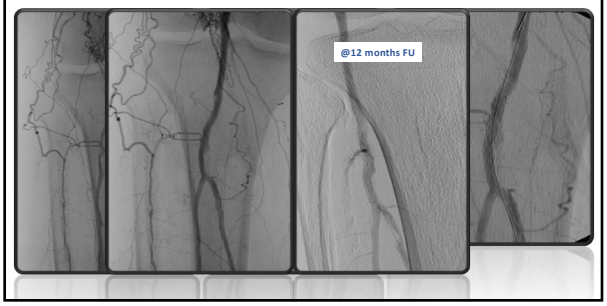
Table 19: Limb-salvage rate (LSR) at 6 and 12 months defined as rate of patients free from major amputation. Major amputation is defined as at or above ankle, as opposed to minor amputation being at or below metatarsus preserving functionality of foot.

Limb-salvage rate (LSR) (N=31)	6-months rate N (%)	12 months rate N (%)
	31(100.0)	31(100.0)

Study Results: TLR /. Surv

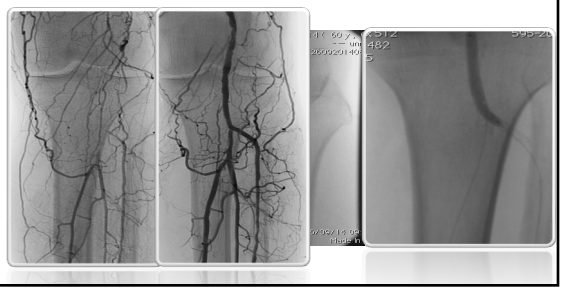


BTK Proximal: CALCIFIED PLAQUES = RE-COILING > SCAFFOLDING



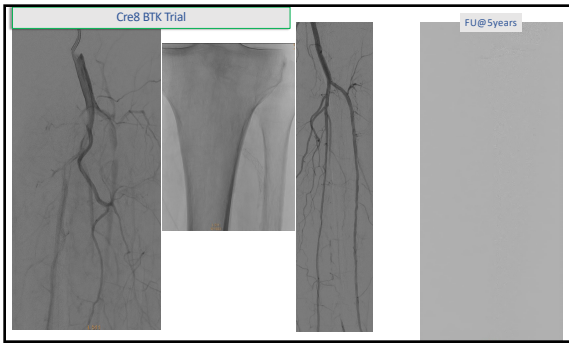
BIFURCATIONS RECONSTRUCTION

BIFURCATIONS RECONSTRUCTION



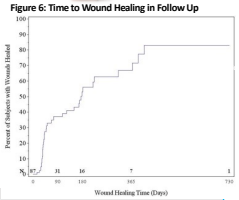
Dissections

Cre8 BTK Trial



BTK-BTA Longer /Distal lesions : SelfX Microstents (Heal Study ongoing)

Figure 6: Time to Wound Healing in Follow Up



HEAL Data:

- 115 active wounds in 87 patients prior to MicroStent procedure
- % of subjects with healed wounds ≤6M was 53% & ≤12M was 67% (by KM estimate)

Conclusions

- In our experience, DES in proximal BTK lesions ;
- Selfexpandible Interwoven more distally ;
- Vessel preparation is mandatory;
- Primary stenting is actually our first strategy;

Thanks