IN.PACT DCB results from Real world experience of a Single vascular surgeon Prospective registry

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SFA/Pop Treatment Options

TASC A to D		
POBA	Initial success, restenosis up to 80% 12m	
BMS:	Absolute,Astron,Fast, Fact,Resilient, 4Ever	75% at 12m
	DURABILITY 200, VIASTAR	65% 12M
	SUPERB (SUPERA) Calcification	86% 12M
DCB	Thunder, Fempac, Levant 1, Pacifier,IN.PACT	78% at 12m
	Leipzig , Zeller Registry , IN.PACT	73-95% 12m
DES	Zilver PTX, Real Zilver Ptx,, Strides	85% at 12m
STENT grafts	Viabahn 25cm	67% 12m
	VIASTAR CS vs BMS	78 vs 53% 12m
Atherectomy alone and with DCB		

Clinical Trials

Critical to the Research process
Well-controlled, Rigorously conducted

Limited by sample size
Patient selection criteria
Closer level of oversight
Training of clinical personnel

May not tell the full story about function in “the real world.”

Prospective Cohort

One Surgeon
Multiple hospitals
Enrolment 2016, Continuing
Research Officer Assessment
Data Tool: Pre, Intra and Post Procedure
FUP Discharge, 1m, 3m ,6m, 12m, and 6mthly
Antiplatelet 3m dual then single for life

Clinical Assessment, Duplex scan, ABI
Angiogram: if Clinical indicated

Rutherford	2-6
Lesions	Fem POP
	TASC A to D
	Restenosis

No Clinical Events Committee
No Imaging Core Labs

Outcomes

Patient	Mortality Early and late, Major Amputation, Procedure related
Lesion	Symptomatic : Clinical reintervention(CD TLR) Non Symptomatic: Primary Patency

Major adverse event all-cause mortality, CD TVR, major target limb amputation, thrombosis at the target lesion site.

Primary safety composite endpoint was freedom from device- and procedure-related mortality through 30 days, and freedom from major target limb amputation and CD TVR within followup period

Patient Demographic/comorbidities

	(N=448)
Age (Y)	63.1 ± 12.3
Male Gender (%)	62%
Diabetes (%)	40%
Hypertension (%)	75%
Hyperlipidemia (%)	70%
Prior/ Current Smoker (%)	65%
Coronary Artery Hx/Interv	35%
Carotid Artery Hx/Interv.(%)	25%
Renal Insufficiency (%)(cr>110umol/l)	30%
Previous Peripheral Revasc. (%)	55%
Tissue loss (%)	15%
ABI	0.609± 0.195

Lesion Characteristic

Single	84%
Multiple	16%
<u>Lesion Type:</u>	
de novo	74%
restenotic (no ISR)	16%
ISR	10%
Lesion Length	13.97 ±12.57 cm
Total Occlusions	19.8%
Severe Calcification	20.1%
Diameter Stenosis (pre-treatment)	80.8% ± 15.5
No of balloon (1-8)	2 ± 1.04

Procedure Outcomes

Pre-dilatation	100%
Device Success	98%
Procedure Success	100%
Clinical Success	98.5%
Additional Stent	25%
Distal embolus	5.2%
Dissection	25%
Rupture	7%

Followup Outcomes

Median 21m (1-37)

Fup 45pts (10.1%) lost

Characteristic	Patient
Clinically-driven TLR	13.8%
Death (all-cause)(cardiac)	6.9%
Major Target Limb Amputation	1.1%
Thrombosis	2.9%
Primary Safety Endpoint	84%
Major Adverse Events	24.7%

Conclusions

Durable Safe and Effective IN.PACT Admiral in SFA/pop disease in the Australian poplulation in real world clinical practice

Problem single Arm Trial , no Independent monitor

Expensive treatment

Currently continuing to use DCB

Long term use depends on conclusion of current mortality controversy and PTX

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