XTOSI First in man study on the clinical use and safety of the Magic Touch PTA Sirolimus coated balloon for SFA and BTK lesions: Interim Analyses

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Associate Professor, DUKE-NUS Medical School

Singapore

Disclosure

Speaker name:

Edward Choke

I have the following potential conflicts of interest to report:

- ☐ Consulting
- ☐ Employment in industry
- ☐ Stockholder of a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

- ☐ I do not have any potential conflict of interest

XTOSI First in man clinical trial:
Clinical efficacy and safety of the Magic Touch PTA Sirolimus coated balloon for SFA and BTK lesions

Design: Prospective, premarket, non-randomized, all comers single-arm trial

XTOSI

Sirolimus Coated Balloon

Target
N=50

PRIMARY ENDPOINT

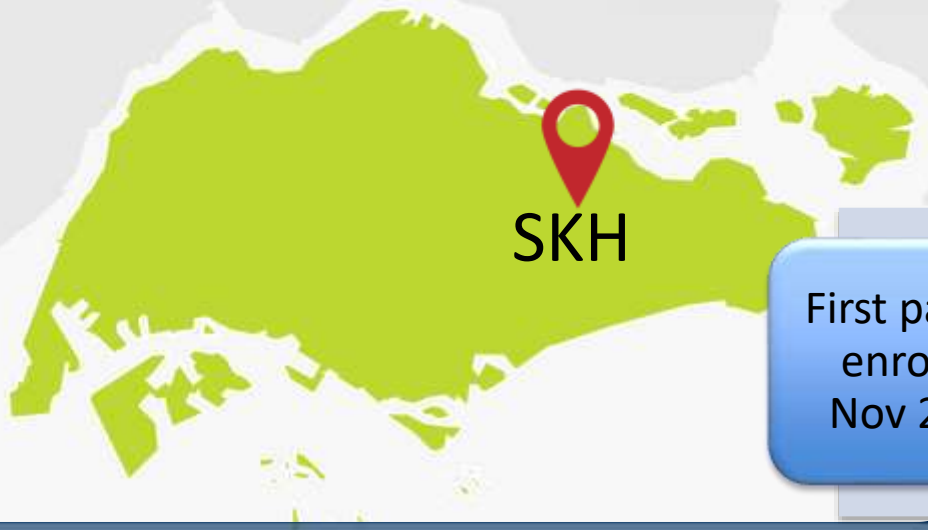
Primary patency at 6 months

Duplex PSVR <2.4

Blinded assessment

PI: Edward Choke

Single centre study
4 investigators
Singapore
Sengkang General Hospital



First patient enrolled Nov 2018

Final patient enrolled Nov 2019

Full 6 month data in April 2020

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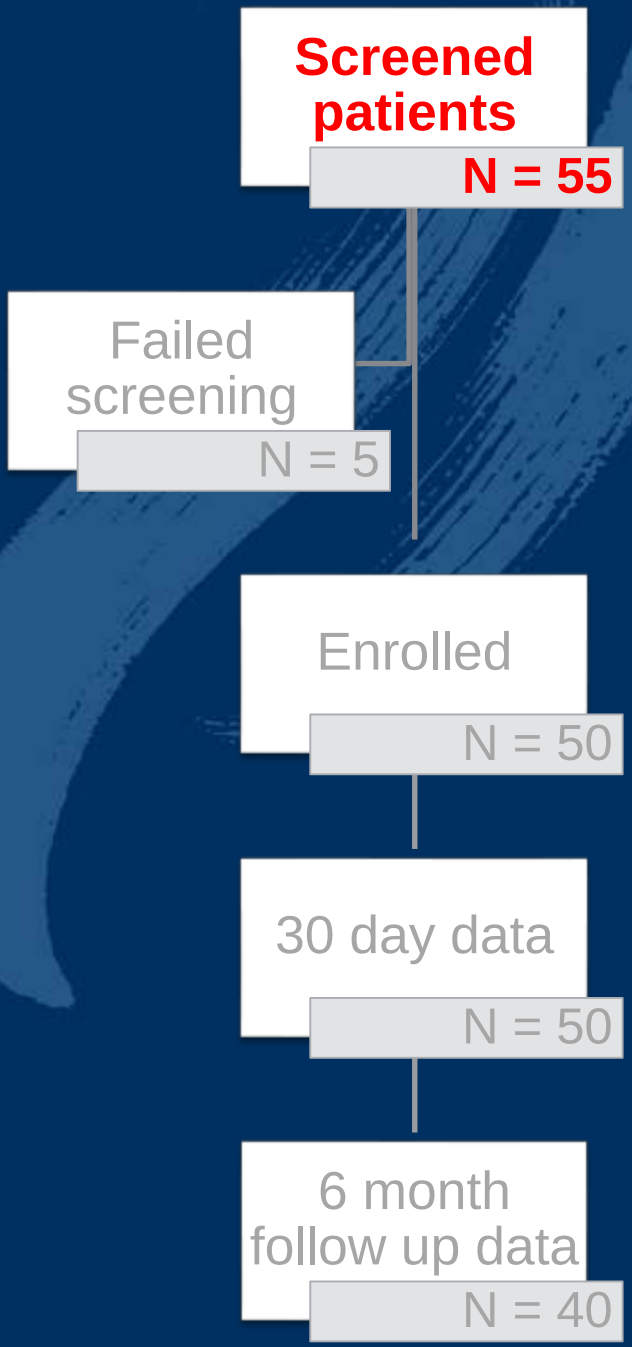
Key inclusion criteria

- Age ≥ 21 years
- Rutherford 0 to 6
- Any lesion(s) in the SFA or popliteal artery and proximal 200mm of tibial arteries
- Inflow free from lesions
- Good outflow

Key exclusion criteria

- Life expectancy ≤ 1 year
- Failure to successfully cross the target lesion
- Unsuccessful treatment with conventional balloon



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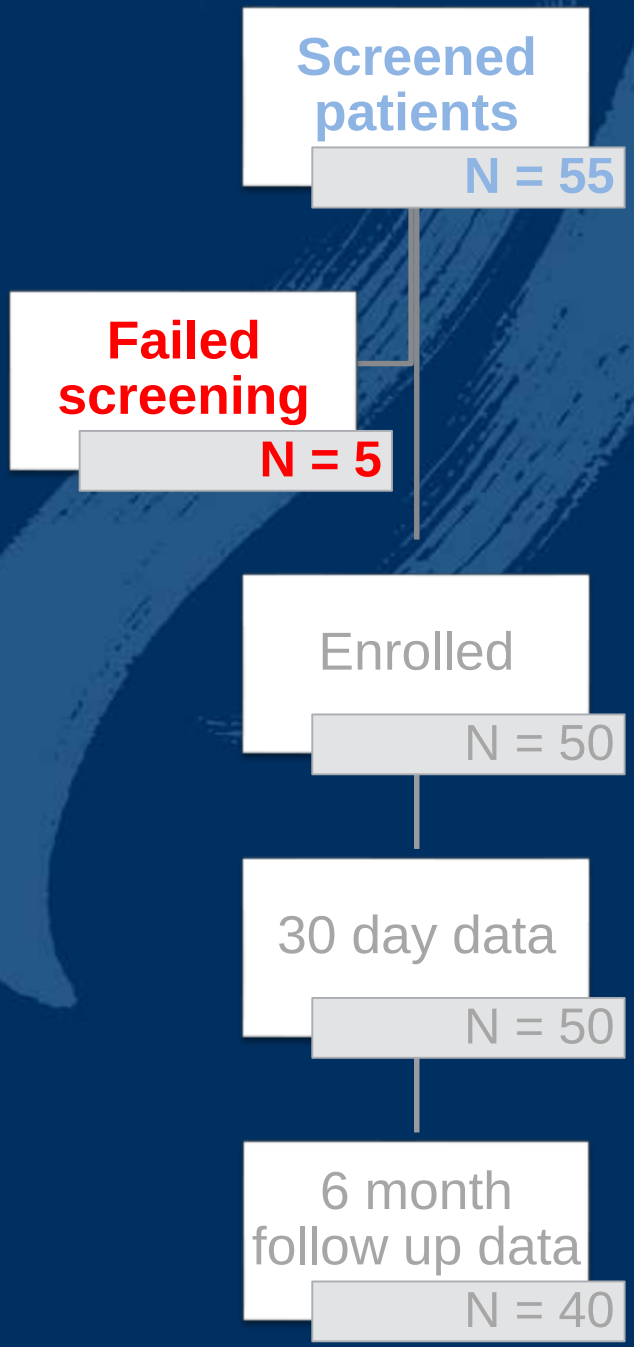

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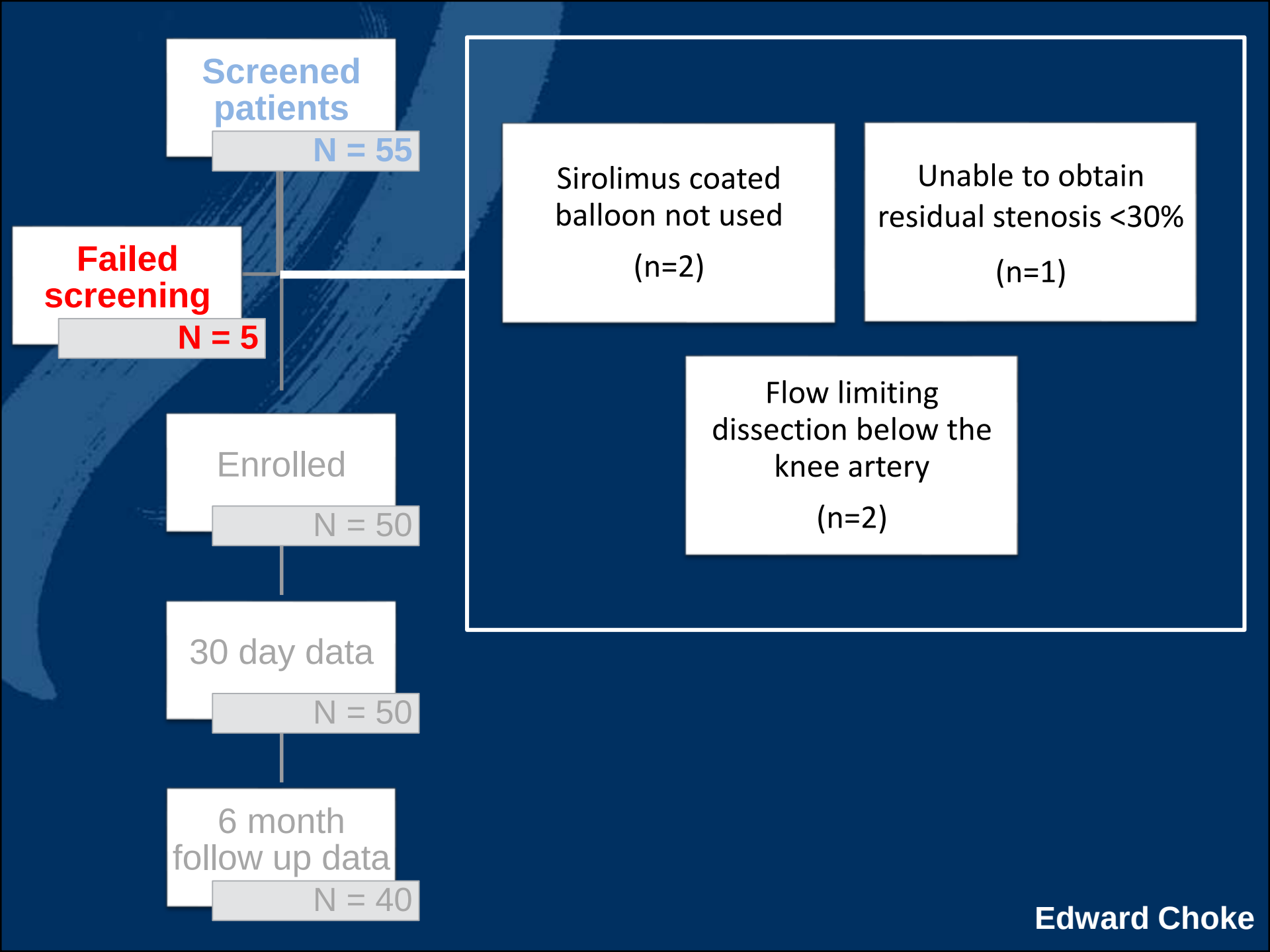
Screened patients
N = 55
Failed screening
N = 5
Sirolimus coated balloon not used
(n=2)
Unable to obtain residual stenosis <30%
(n=1)
Flow limiting dissection below the knee artery
(n=2)
Enrolled
N = 50
30 day data
N = 50
6 month follow up data
N = 40
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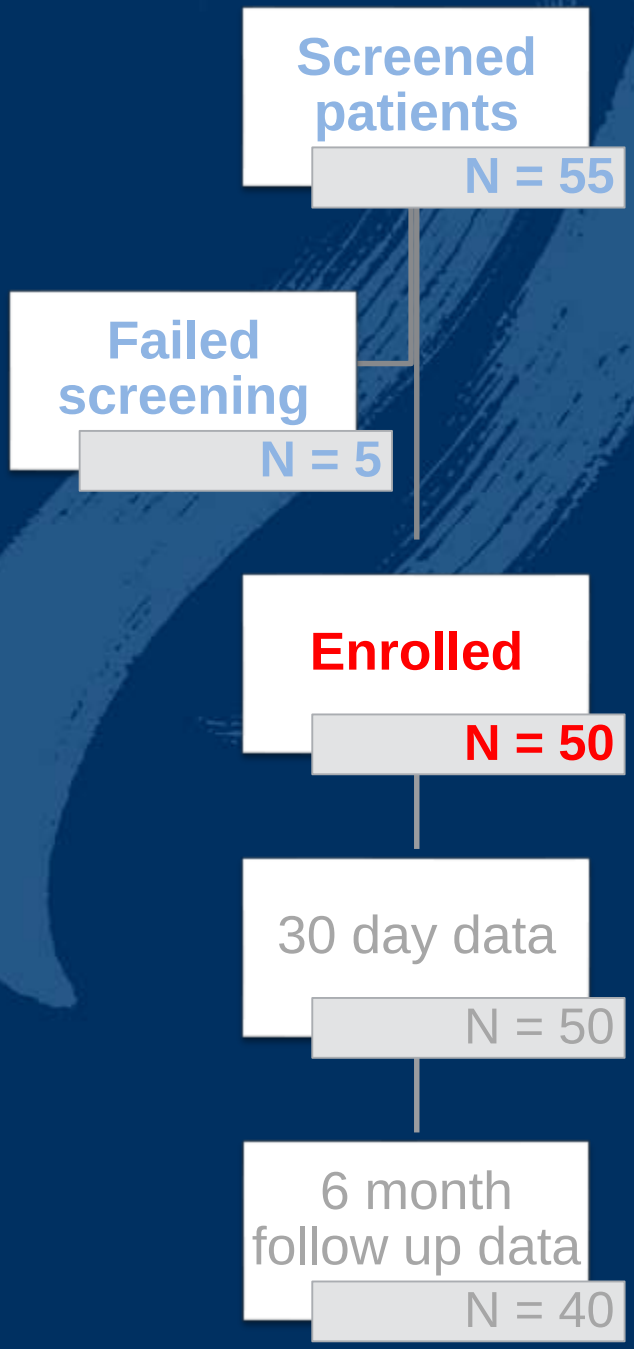

Demographics	N=50
Age	67 (41-89)
Male	31 (62%)
Diabetes	45 (90%)
Hypertension	41 (82%)
High cholesterol	43 (86%)
Dialysis	11 (22%)
Coronary artery disease	18 (36%)
Previous Myocardial Infarct	13 (26%)
ASA	
2	10 (20%)
3	39 (78%)
4	1 (2%)

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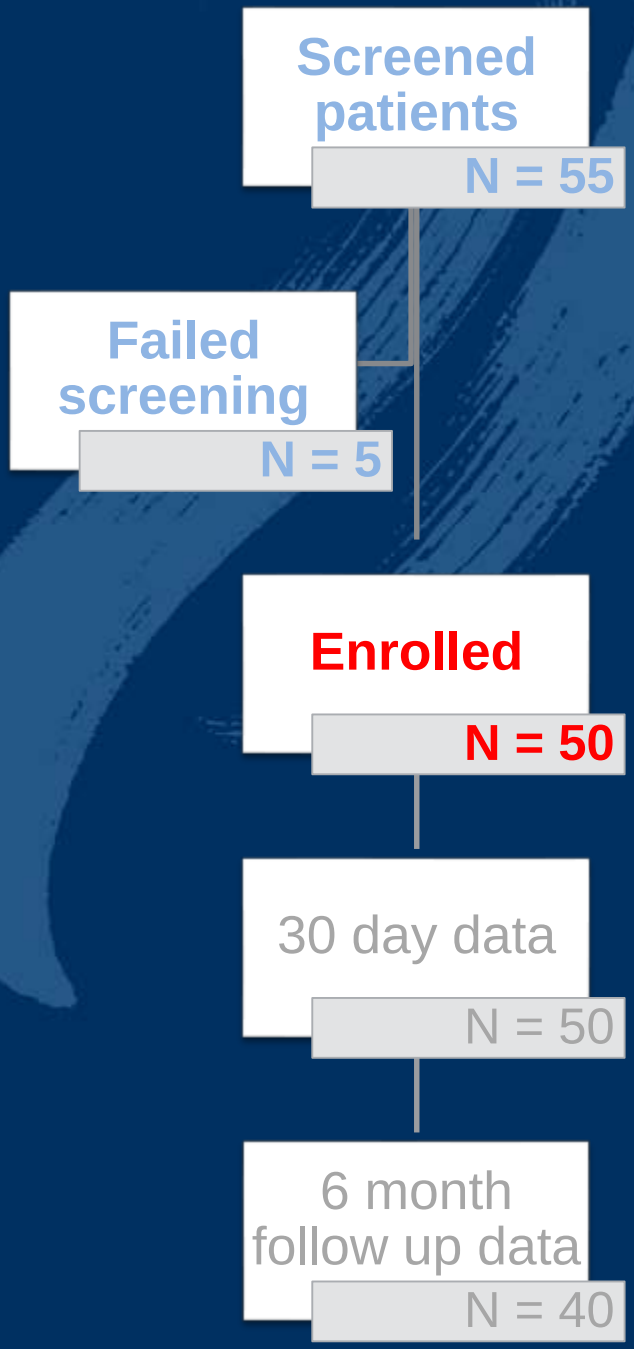

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High risk cohort

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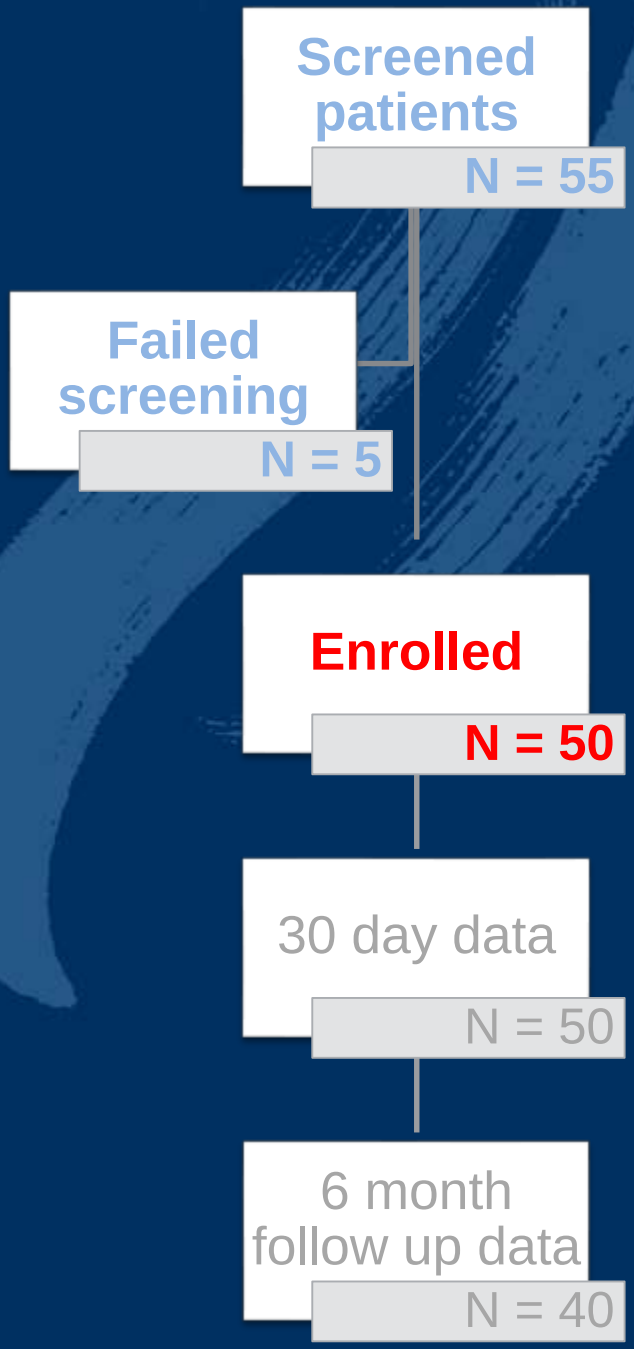

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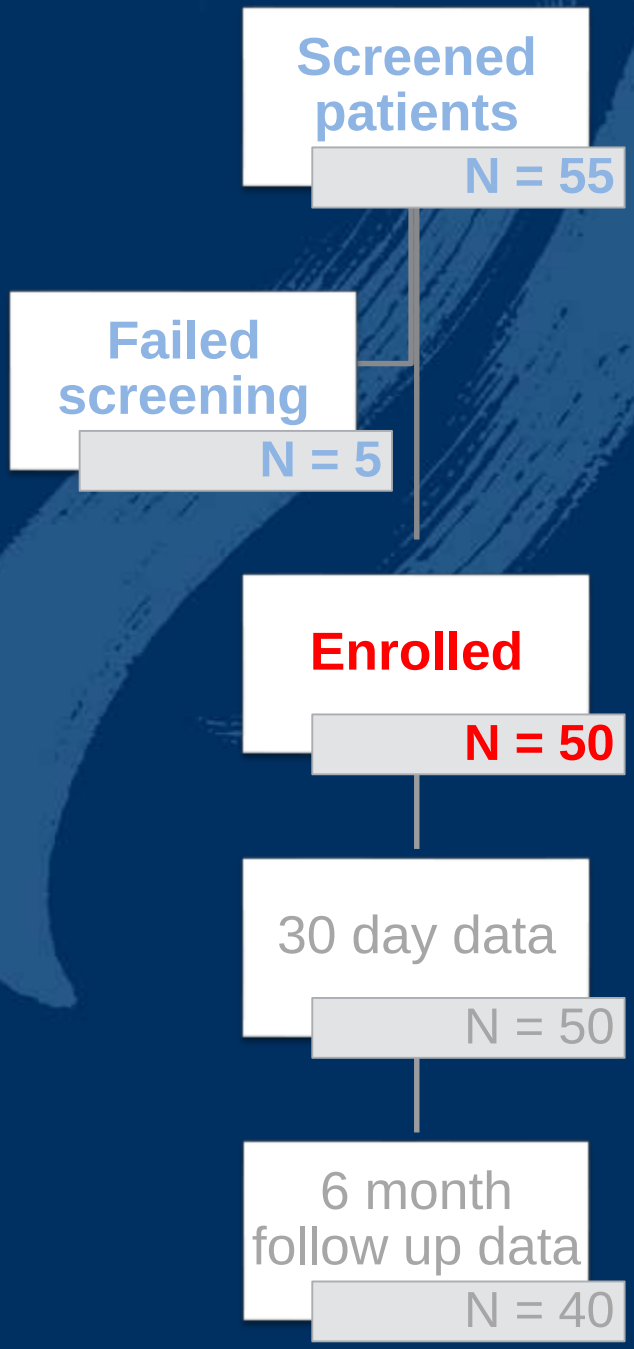
High risk cohort

High ASA score



Demographics	N=50
Rutherford scores	
0	1 (2%)
3	2 (4%)
4	1 (2%)
5	38 (76%)
6	8 (16%)
Patients with ulcers/gangrene	N=46
WIFI	
1 to 3	22 (48%)
4 to 8	24 (52%)

Vast majority performed for limb salvage

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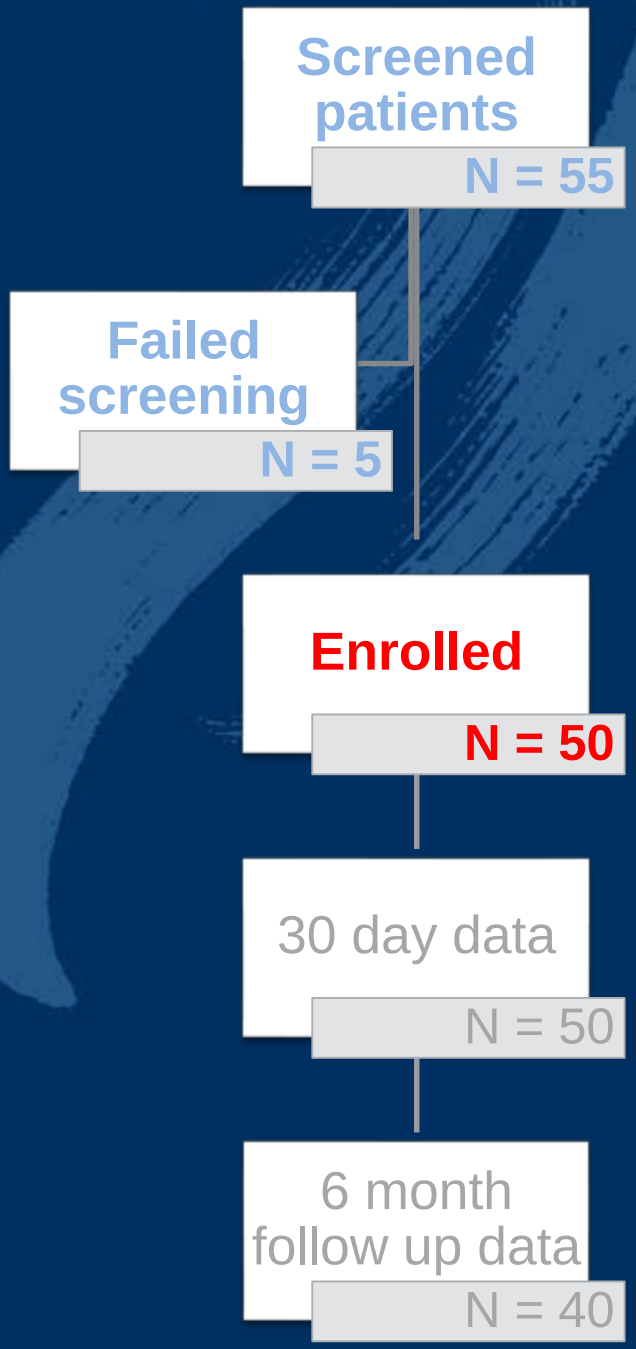

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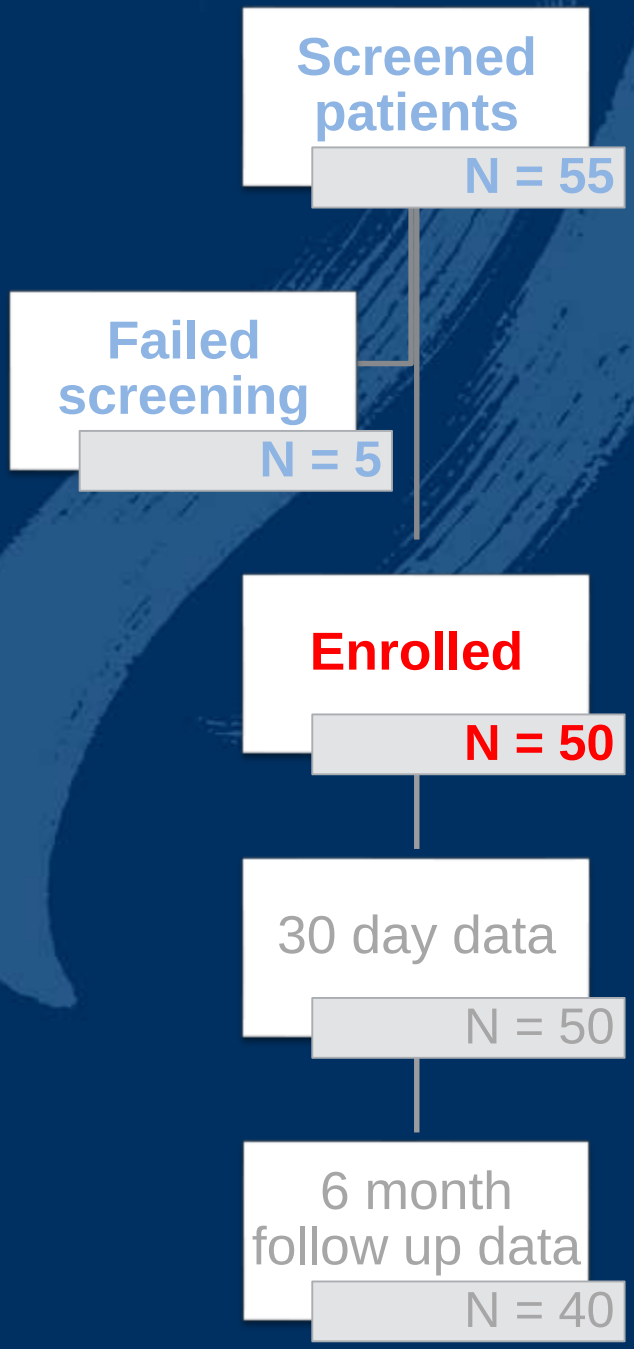
Majority had poor prognosis for limb salvage according to WIFI scores



Lesion characteristics	N=50
Target lesion location	
Femoropopliteal (SFA)	19 (38%)
Tibial arteries (BTK)	31 (62%)
Total length Sirolimus coated balloon used	
Femoropopliteal (SFA)	276.3mm
Tibial arteries (BTK)	193.5mm
Stenosis	33 (66%)
In stent restenosis	1 (2%)
Stented	5 (10%)
Retrograde access required	18 (36%)

Majority had long BTK revascularisation

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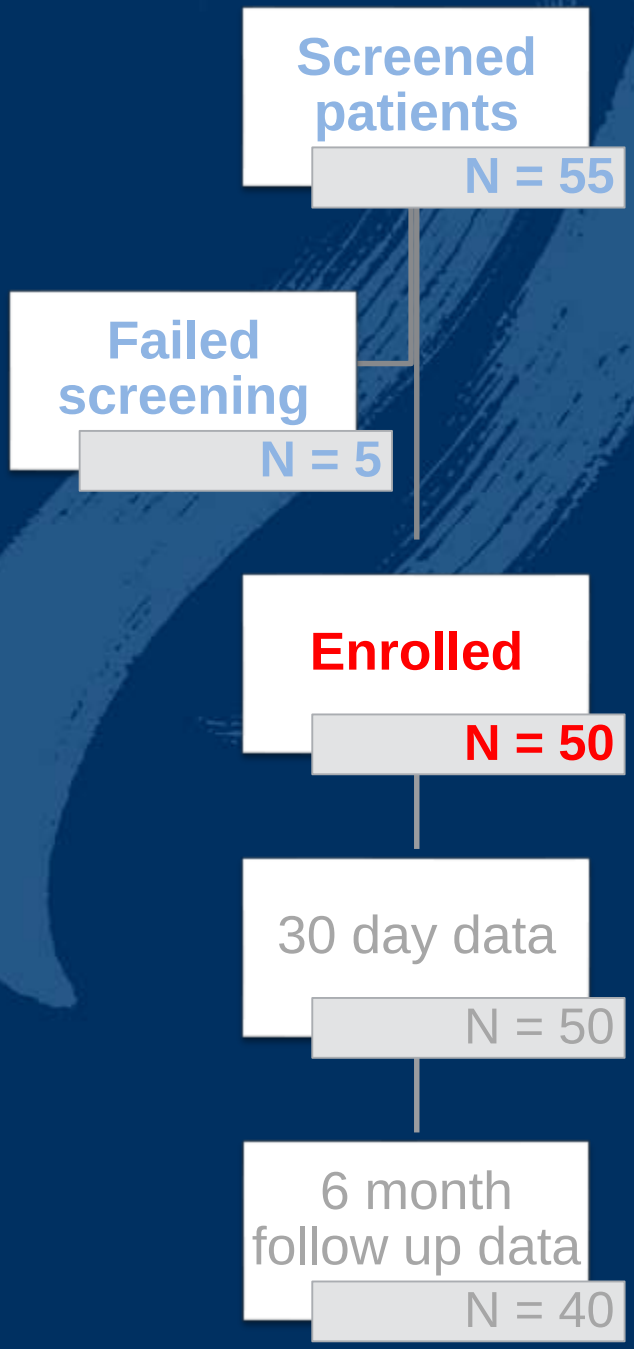

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Target lesion location	
Femoropopliteal	19 (38%)

Significant had occlusions which required retrograde approach

Total length Sirolimus coated balloon used	
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Tibial arteries (BTK)	193.5mm
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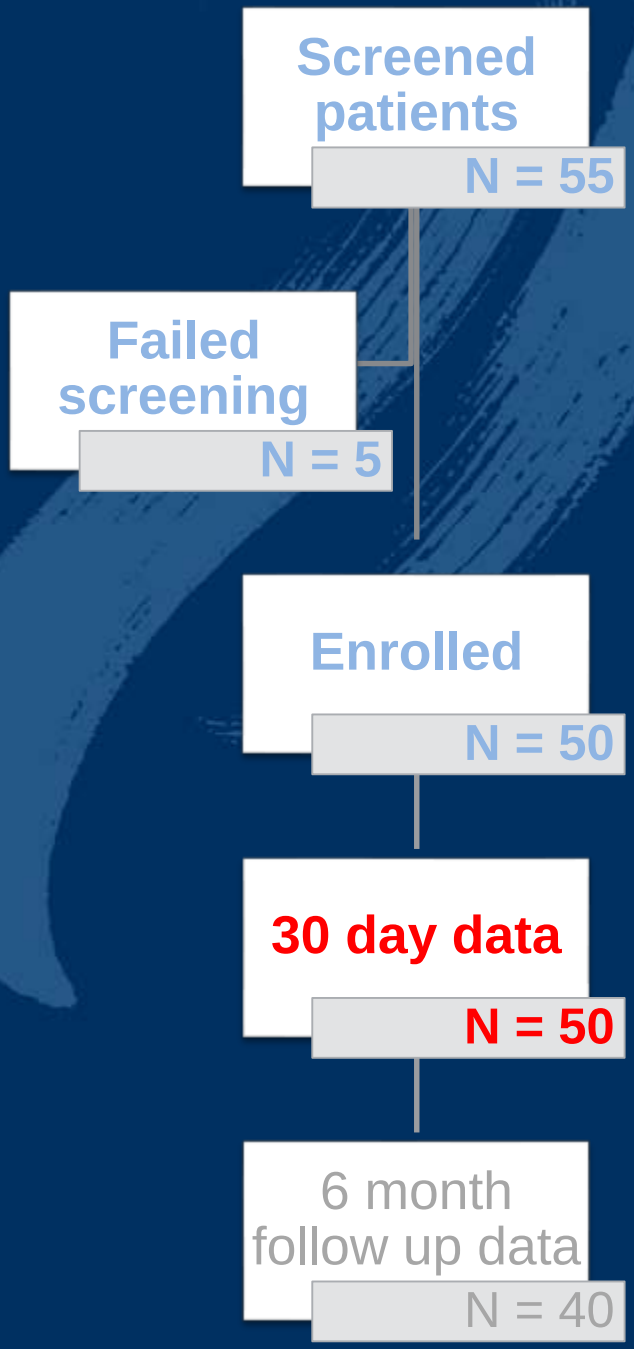

30 day outcomes	N=50
30 day Death	1 (2%)
30 day Major limb amputation	1 (2%)
Device success	100%
Technical success	100%

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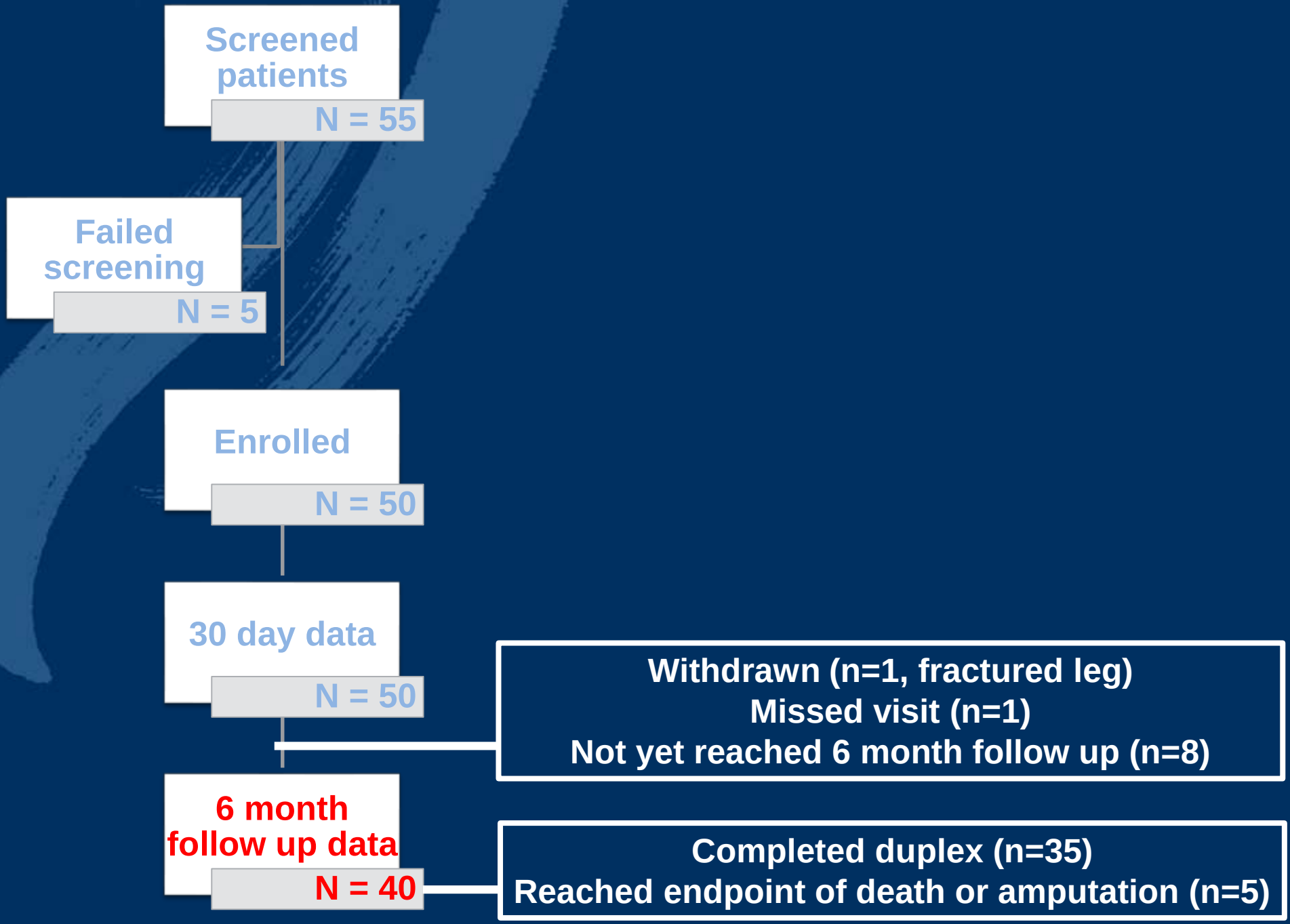
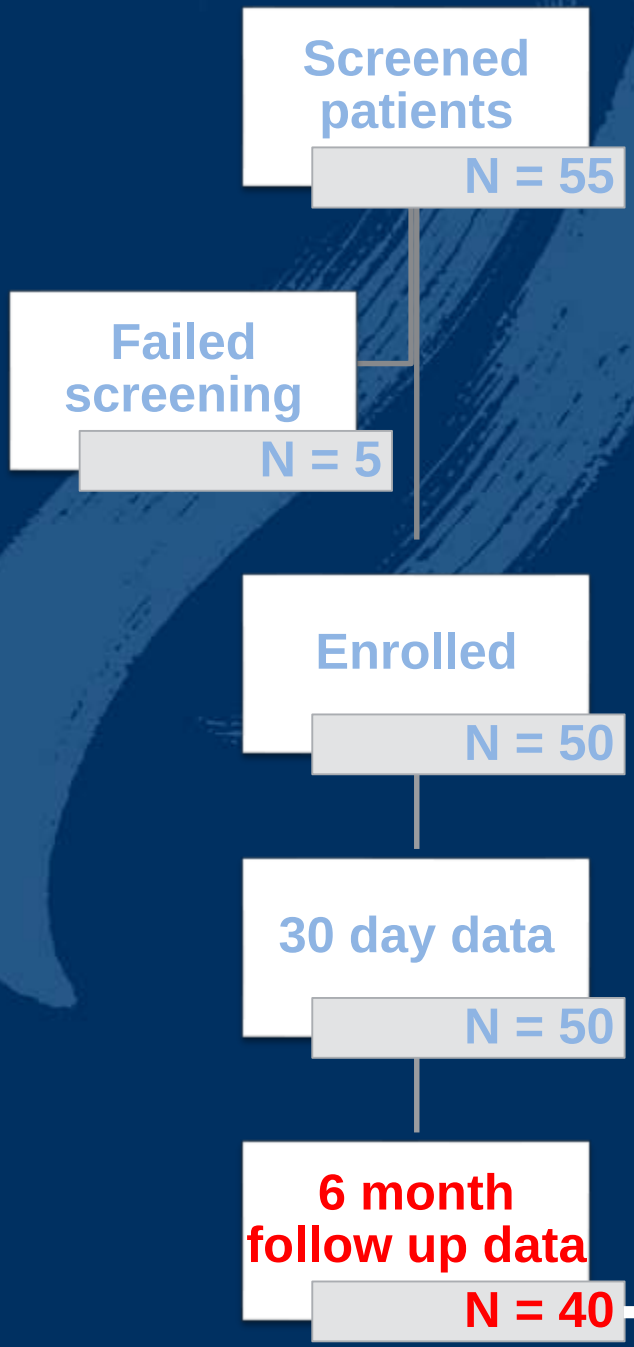

Screened patients
N = 55
Failed screening
N = 5
Enrolled
N = 50
30 day data
N = 50
Withdrawn (n=1, fractured leg)
Missed visit (n=1)
Not yet reached 6 month follow up (n=8)
6 month follow up data
N = 40
Completed duplex (n=35)
Reached endpoint of death or amputation (n=5)



6 month outcomes	N=35
Primary patency	
All (N=35)	28 (80.0%)
SFA (N=16)	14 (87.5%)
BTK (N=19)	14 (73.7%)
Freedom from Target Lesion Revascularisation	
All (N=35)	31 (88.5%)
SFA (N=16)	1 (93.8%)
BTK (N=19)	3 (84.2%)

Completed duplex (n=35)
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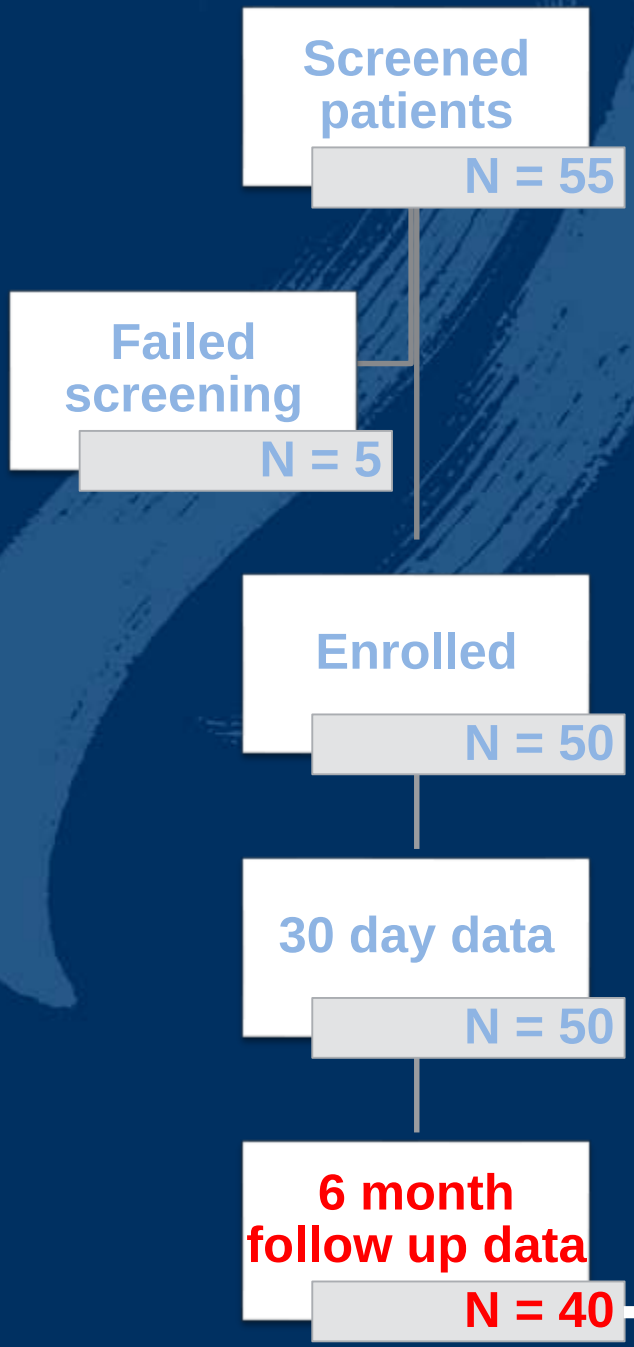

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*Singapacli BTK RCT Paclitaxel	40%

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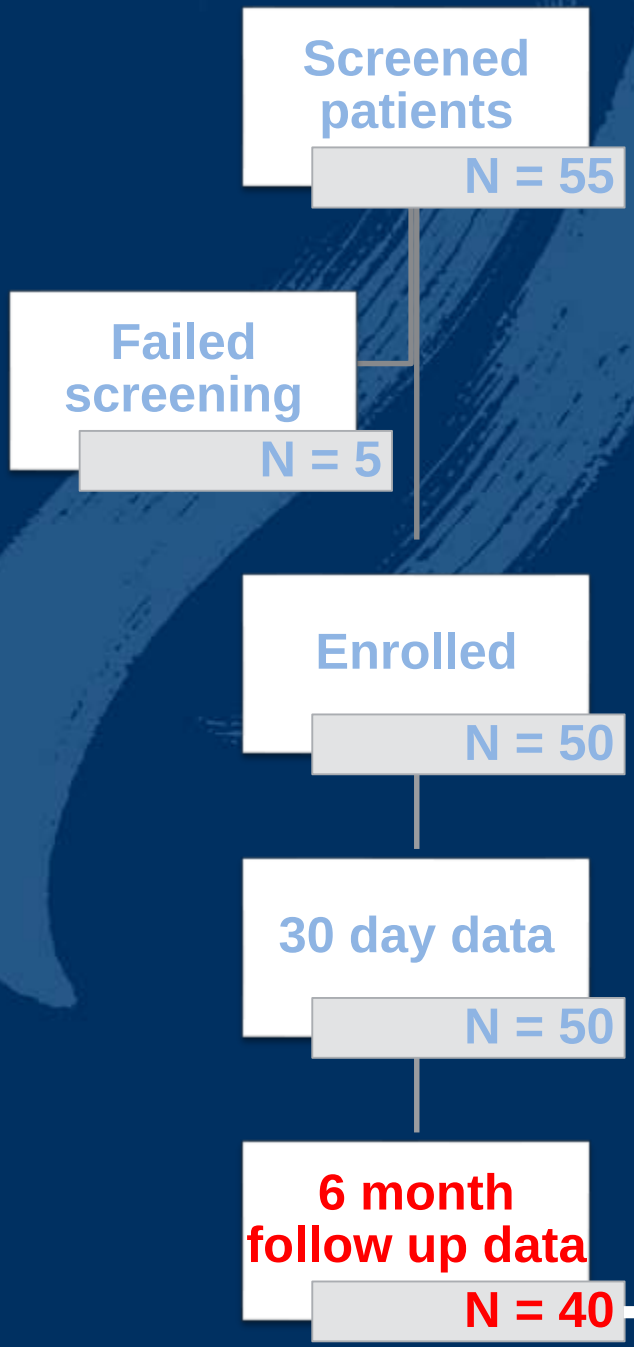

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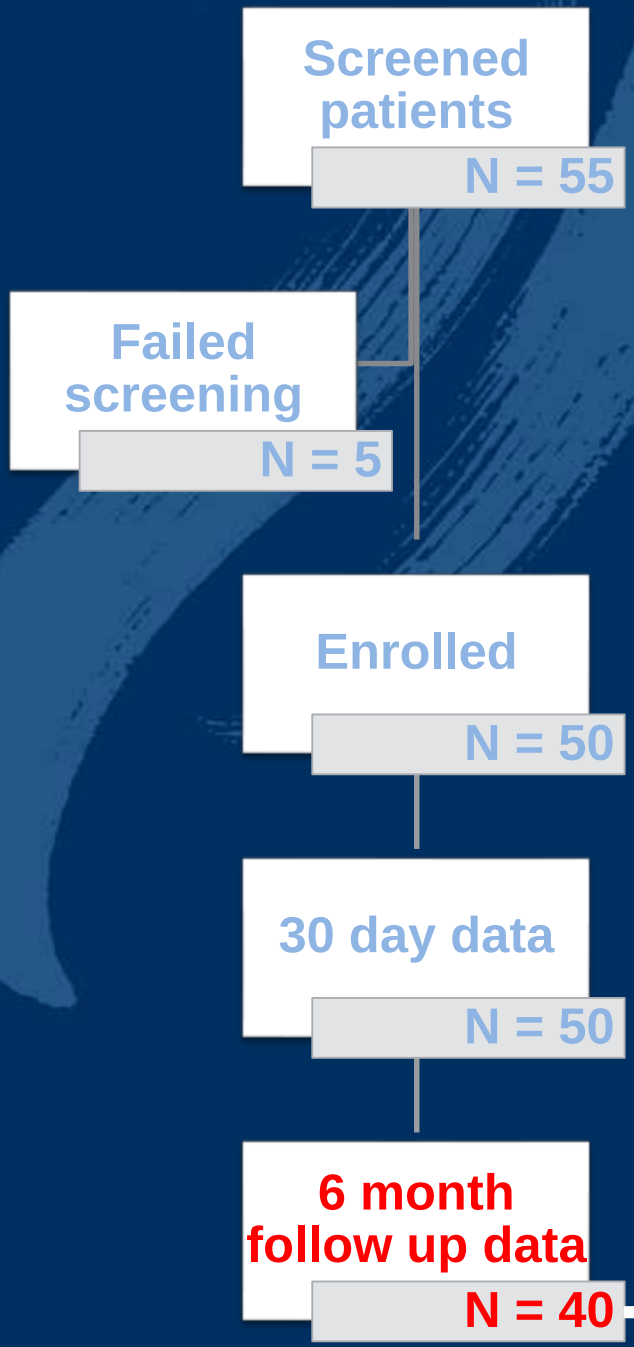

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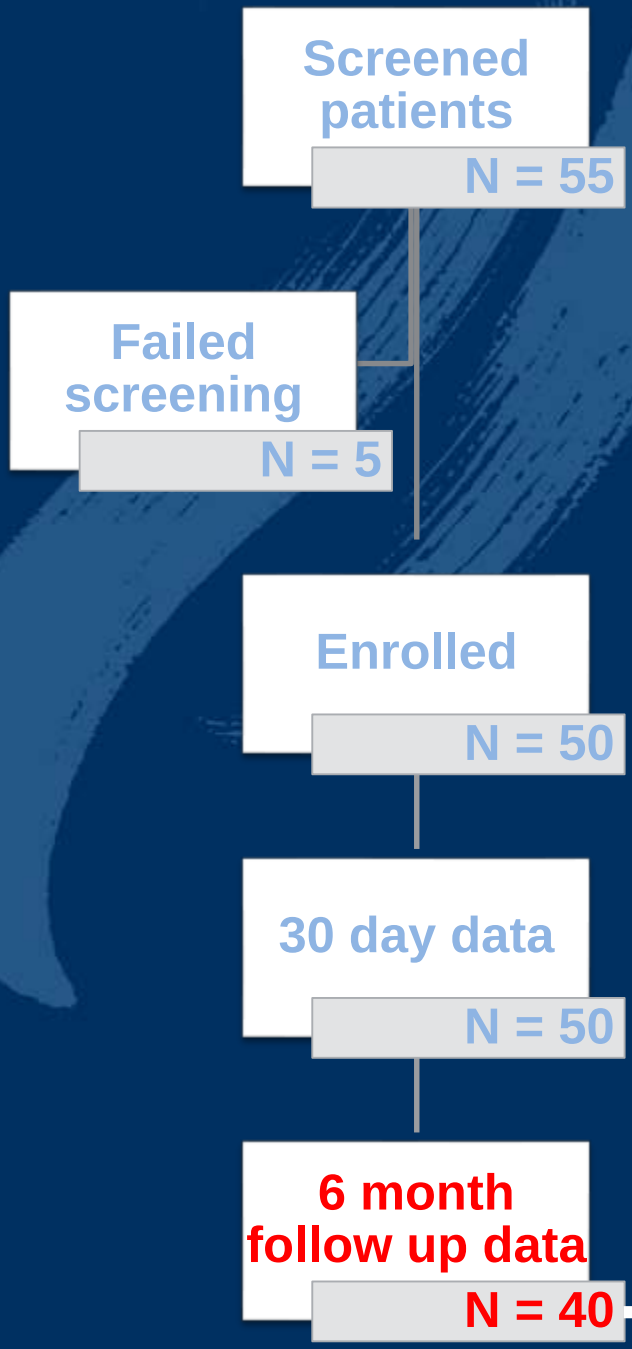
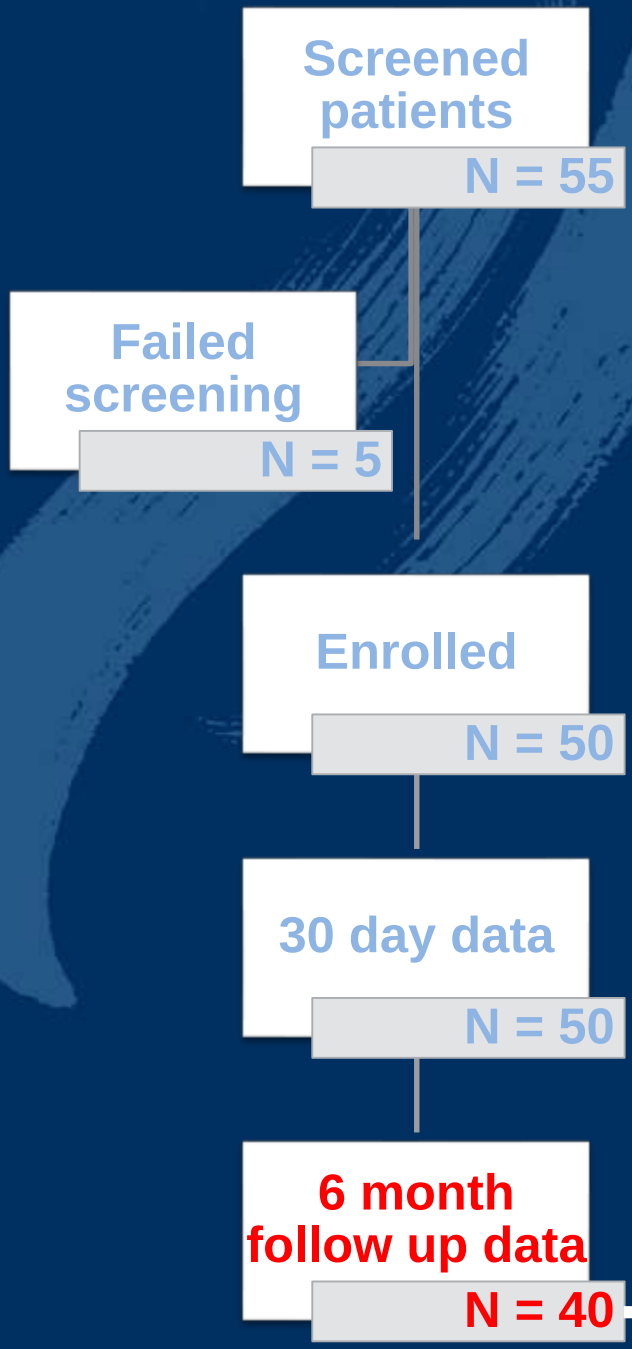


6 month outcomes	N=40
Safety endpoint achieved	85.0%
Absence of:	
30 day mortality	N=1
30 day limb amputation	N=1
6 month target lesion revascularisation	N=4
Death	4 (10.0%)
Ischemic heart disease	3
Not known	1
Amputation Free Survival	35 (87.5%)
Limb salvage	97.5%

Completed duplex (n=35)
Reached endpoint of death or amputation (n=5)



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	30 day limb amputation	N=1
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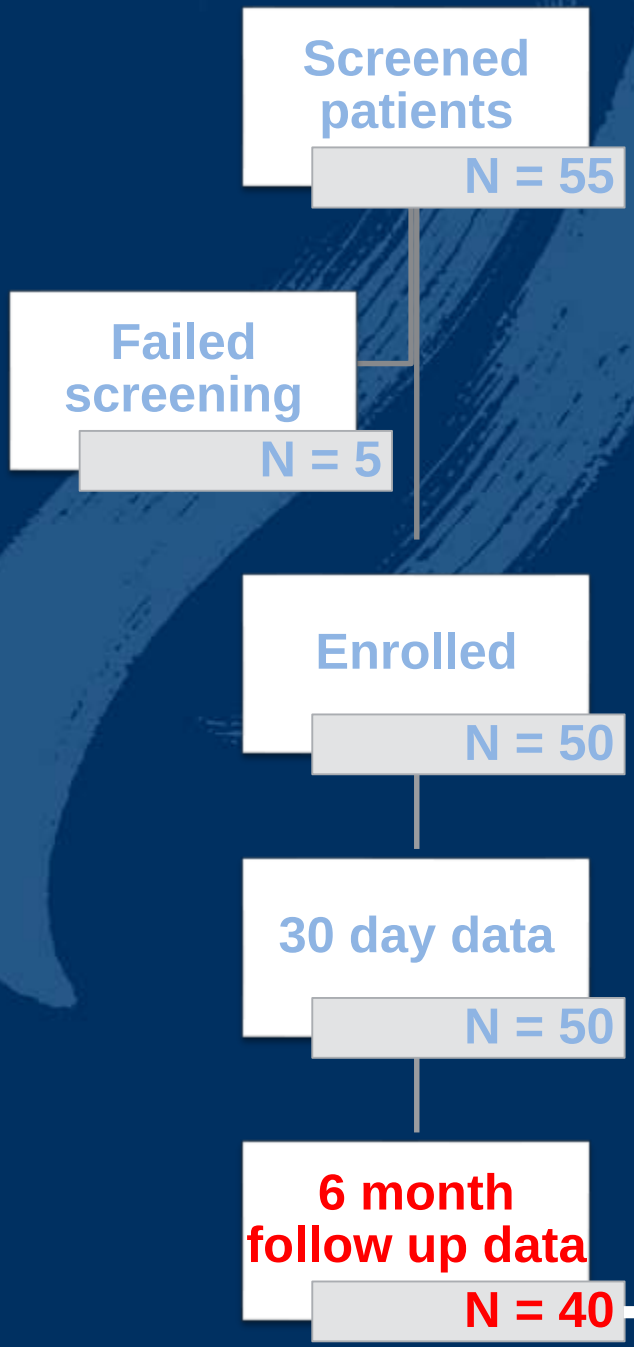

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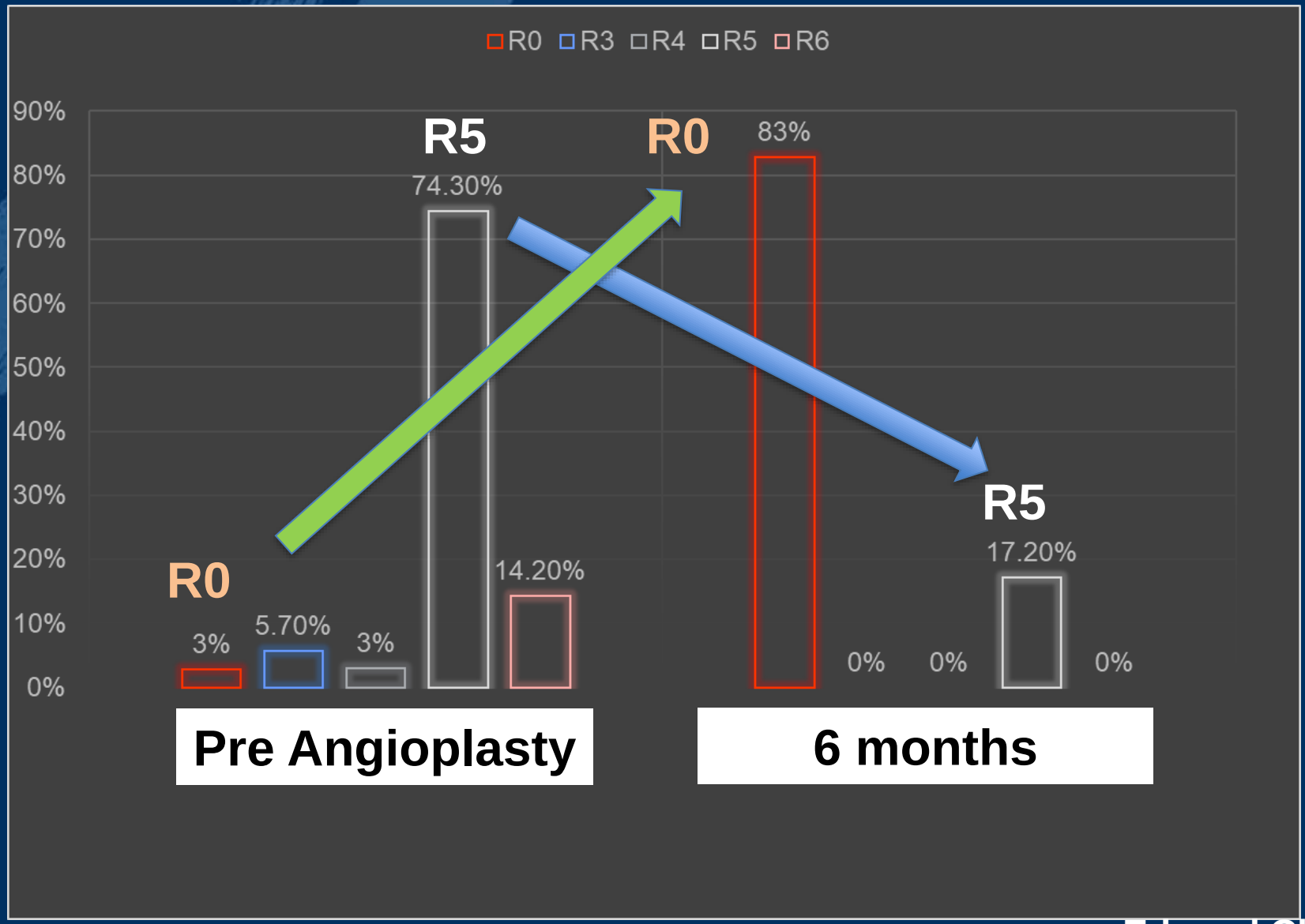
6 month Clinical improvement in Rutherford scores



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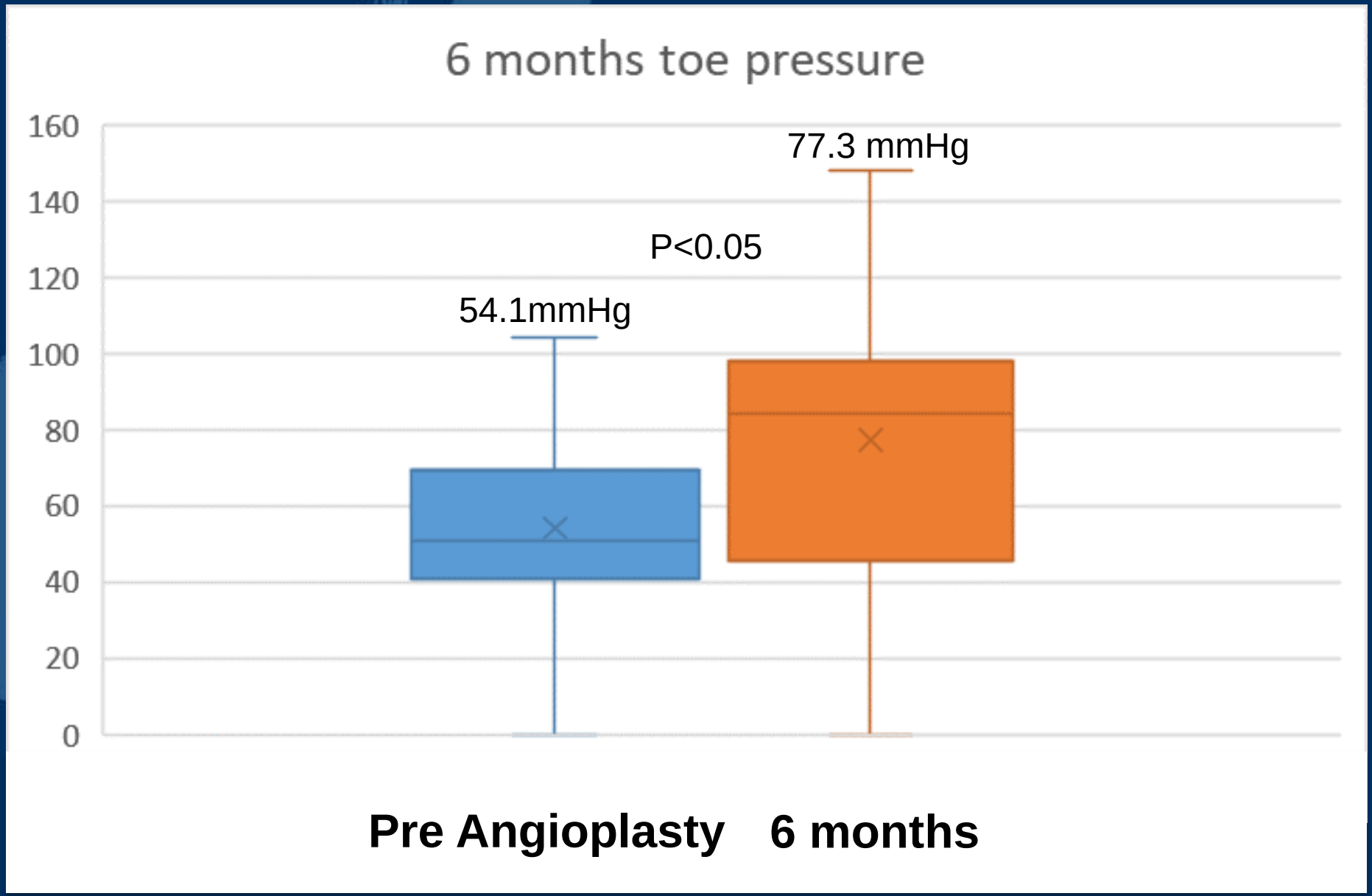
6 months toe pressure
160
140
120
100
80
60
40
20
0
77.3 mmHg
P<0.05
54.1mmHg
Pre Angioplasty
6 months

XTOSI

Sirolimus Coated Balloon

Summary

XTOSI interim analyses showed Magic Touch sirolimus coated balloon to have promising efficacy for both SFA and BTK

First demonstration of efficacy for BTK lesions

29624

Short term safety is also promising

Multicentre double blinded randomised controlled trials (SFA and BTK) of sirolimus DCB versus standard PTA

- FUTURE SFA
- FUTURE BTK

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