Updates on FUTURE-SFA and FUTURE-BTK Randomised Controlled Trials

A/Prof Jackie P Ho

On behalf of FUTURE-SFA, FUTURE-BTK investigators

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Disclosure

Speaker name:

Jackie Pei Ho

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

Sirolimus coated balloon (MagicTouch) Vs Conventional plain balloon

FUTURE SFA
N = 153

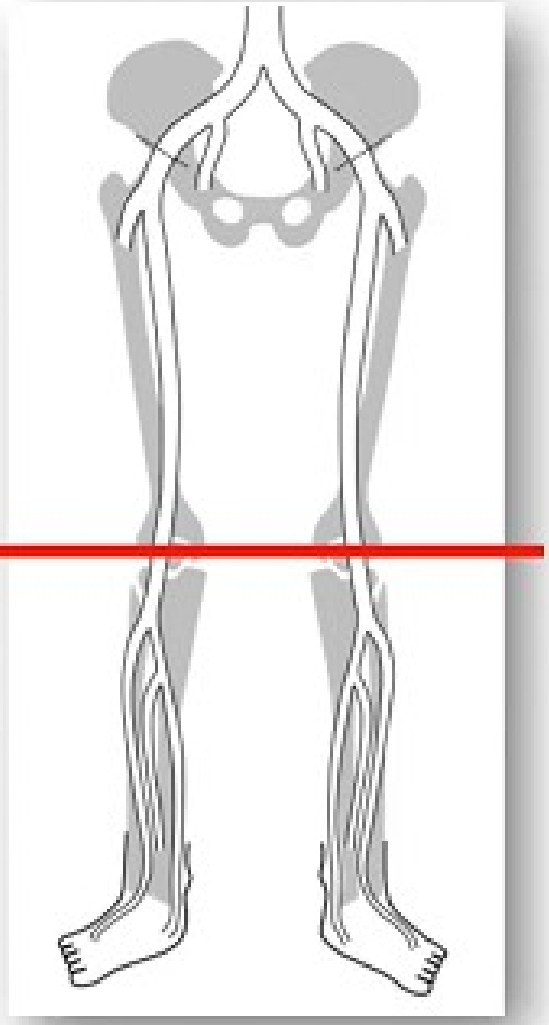
Rutherford 3 to 6

NCT04511234

FUTURE BTK
N = 210

Rutherford 4 to 6

NCT04511247



Randomized Controlled Trial of **F**irst Sirolim**U**s Coa**T**ed Balloon Vers**U**s Standa**R**d Balloon Angioplasty in The Tr**E**atment of Superficial Femoral + Popliteal Artery Disease & Below-the-knee Disease

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FUTURE-SFA

- Subject target: 279
- Rutherford class 3-6
- SFA, P1, P2
- Single or sequential lesion, 2-20cm
- De novo or re-stenosis lesion
- No significant inflow dis
- At least 1 patent crural artery run-off to foot

- Determine effectiveness (primary patency)
- Quadruple blinded (Participants, care provider, investigator, outcome assessor)
- 2:1 enrolment
- CRO controlled
- Core Lab adjudicated
- Follow-up 6, 12, 24 months

FUTURE-BTK

- Subject target: 219
- Rutherford class 4-6
- Proximal 20cm of BTK arteries
- Single or sequential lesion, 2-20cm
- De novo or re-stenosis lesion
- No significant inflow dis
- Target vessel has run-off to foot after Rx

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Exclusion criteria

- Post PTA residual stenosis >/= 30%
- Life expectancy < 1 year
- Heel gangrene
- Planned for major amputation
- Prior bypass surgery or prior stenting of target vessel
- Highly calcified lesion
- Participating other drug eluting technology trial
- Contraindicated to antiplatelet agents, allergy to heparin/sirolimus/contrast reagent
- Pregnancy or vulnerable individuals

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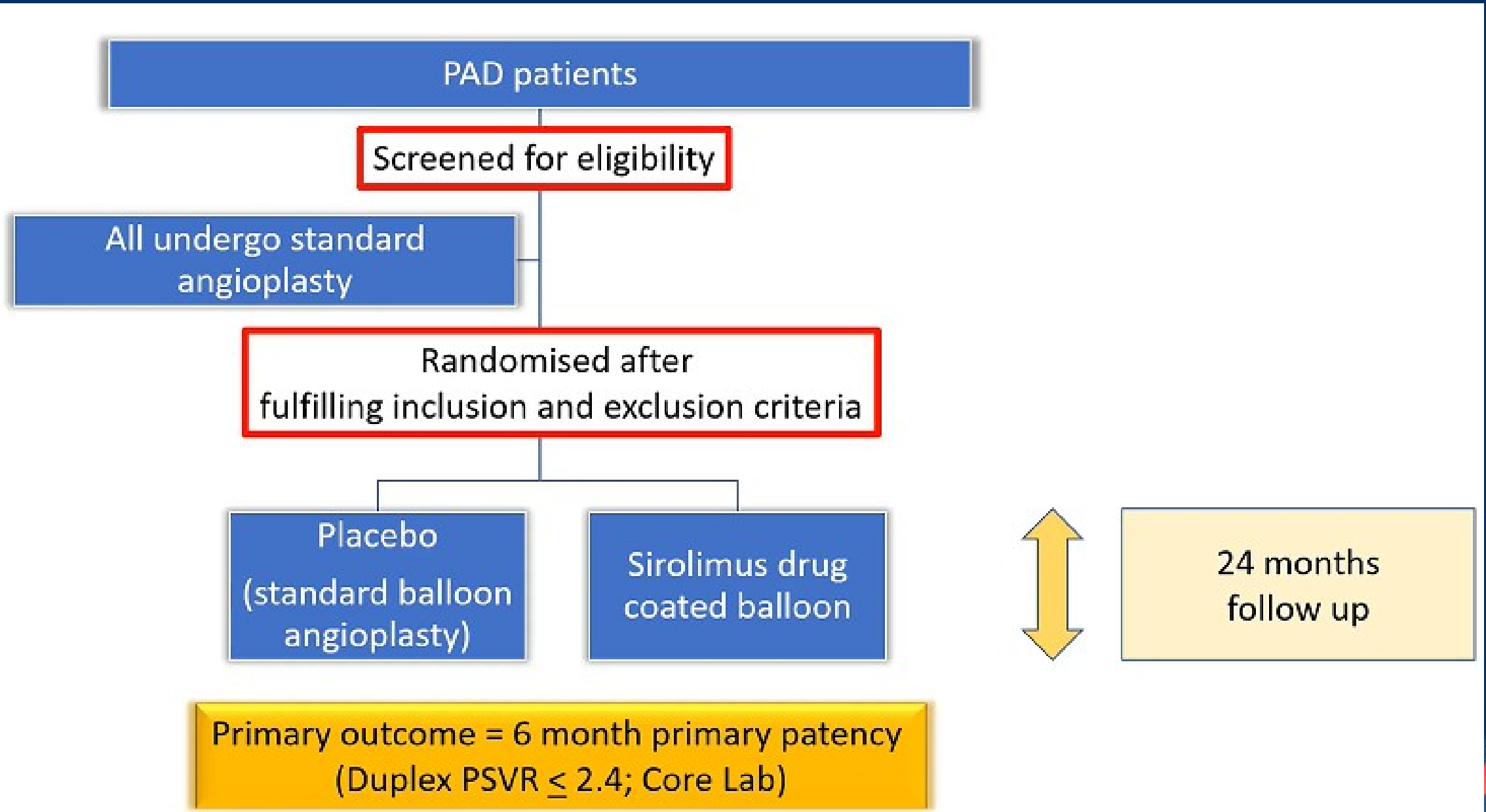
Study end-points

Primary end-point

- 6-month primary patency determined by Duplex PSV ratio <= 2.4

Secondary end-points (safety, effectiveness, functional)

- Technical/Procedural success
- 30-day device/procedure related death
- All-cuase death/major amputation/target vessel thrombosis
- 6, 12, 24-month Freedom from clinical driven TLR and TVR
- 12, 24-month primary patency
- Freedom from MAE
- Amputation-free survival/ wound size if any
- Change of Rutherford classification
- EQ-5D/ walking impairment questionnaire


PAD patients
Screened for eligibility
All undergo standard angioplasty
Randomised after fulfilling inclusion and exclusion criteria
Placebo (standard balloon angioplasty)
Sirolimus drug coated balloon
24 months follow up
Primary outcome = 6 month primary patency (Duplex PSVR ≤ 2.4; Core Lab)

Participating Centers

Singapore	PI
Sengkang General Hospital	Edward Choke
National University Hospital	Jackie Ho
Ng Teng Fong General Hospital	Vikram Vijayan
Singapore General Hospital	Tang Tjun Yip
Khoo Teck Phuat Hospital	Leong Chuo Ren
Tan Tock Seng Hospital	Pua Uei

Korea	PI
Asan Medical Centre	Dr Lee Seung Hwan
St. Mary Hospital	Dr Kim Jang Yong

Taiwan	PI
National Taiwan University Hospital	李任光 (lǐ rèn guāng)
Shin Kong Wu Ho-Su Memorial Hospital	林佳勳 (lín jiā xūn)
Taipei Mackay Memorial Hospital	蔡政廷 (cài zhèng tíng)
Taipei Tzu Chi Hospital	黃玄禮 (huáng xuán lǐ)
Far Eastern Memorial Hospital	陳哲伸 (chén zhé shēn)
Linkou Chang Gung Memorial Hospital	陳俊吉 (chén jùn jí)

Thailand	PI
Ramathibodi	Dr. Suthas & Dr. Nutsiri
Siriraj	Dr. Nattawut, Dr. Chumpol
Vajira	Dr. Wuttichai
Songklanakarind	Dr. Keerati
Thammasart	Dr. Boonying
Koraj	Dr. Veera

4 countries, 20 centers

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Progress

- Enrolment commenced Aug 2020
- 8 patients enroled (5 SFA, 3 BTK)
- 6-month results ready by July 2022

Thank you