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

A/Prof Jackie P Ho

On behalf of FUTURE-SFA, FUTURE-BTK investigators

National University Health System

National University of Singapore
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

Randomized Controlled Trial of First Sirolimus Coated Balloon Versus Conventional Balloon Angioplasty in the Treatment of Superficial Femoral + Popliteal Artery Disease & Below-the-knee Disease
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
Exclusion criteria

- Post PTA residual stenosis \( \geq 30\% \)
- 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
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-cause 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

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<tr>
<th>Singapore</th>
<th>PI</th>
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<tr>
<td>Sengkang General Hospital</td>
<td>Edward Choke</td>
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<tr>
<td>National University Hospital</td>
<td>Jackie Ho</td>
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<tr>
<td>Ng Teng Fong General Hospital</td>
<td>Vikram Vijayan</td>
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<td>Singapore General Hospital</td>
<td>Tang Tjun Yip</td>
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<td>Khoo Teck Phuat Hospital</td>
<td>Leong Chuo Ren</td>
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<td>Pua Uei</td>
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<tr>
<td>Asan Medical Centre</td>
<td>Dr Lee Seung Hwan</td>
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<td>St. Mary Hospital</td>
<td>Dr Kim Jang Yong</td>
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<td>李任光（lǐ rèn guāng）</td>
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<tr>
<td>Shin Kong Wu Ho-Su Memorial Hospital</td>
<td>林佳勳（lín jiā xūn）</td>
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<td>Taipei Mackay Memorial Hospital</td>
<td>蔡政廷（cài zhèng tīng）</td>
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<td>Taipei Tzu Chi Hospital</td>
<td>黃玄禮（huáng xuán lǐ ）</td>
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<td>Far Eastern Memorial Hospital</td>
<td>陳哲伸（chén zhé shēn）</td>
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<td>Linkou Chang Gung Memorial Hospital</td>
<td>陳俊吉（chén jùn jí ）</td>
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<tr>
<td>Ramathibodi</td>
<td>Dr. Suthas &amp; Dr. Nutsiri</td>
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<tr>
<td>Siriraj</td>
<td>Dr. Nattawut, Dr. Chumpol</td>
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<td>Vajira</td>
<td>Dr. Wuttichai</td>
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<td>Songklanakarind</td>
<td>Dr. Keerati</td>
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<td>Thammasart</td>
<td>Dr. Boonying</td>
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<td>Koraj</td>
<td>Dr. Veera</td>
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4 countries, 20 centers
Progress

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

Thank you