



# Lutonix AV Global Registry

## 6 Month Results Singapore and Taiwan

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# Disclosure

Speaker name:

**Chong Tze Tec, MD**

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



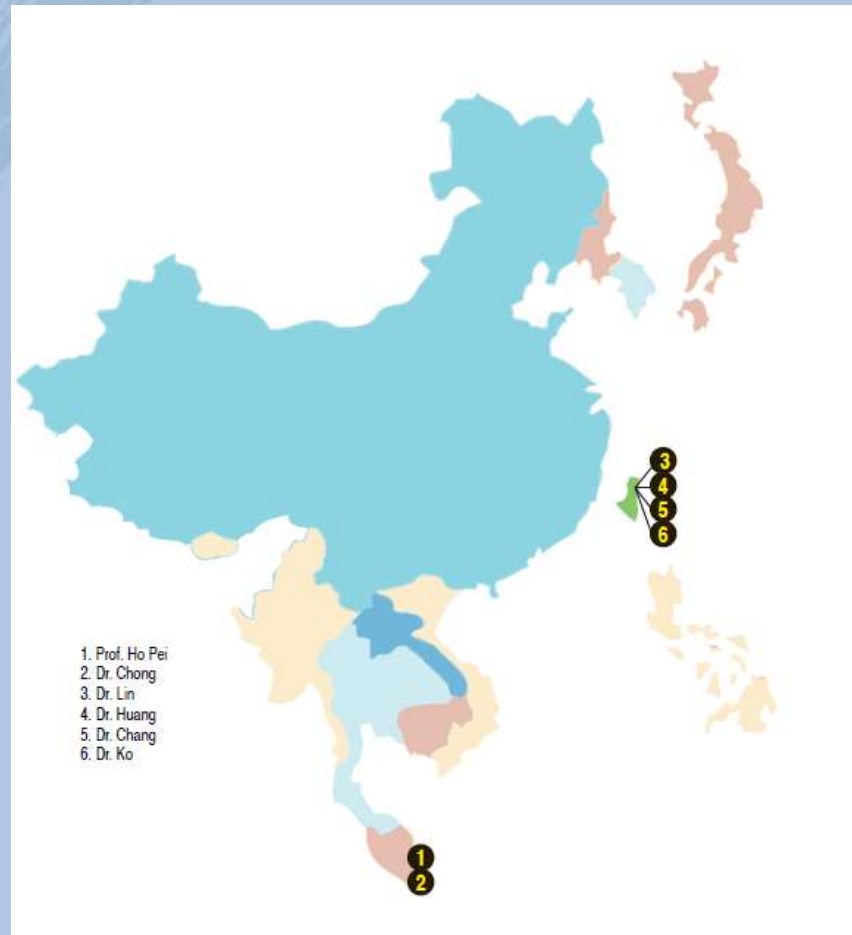
# Lutonix AV Global Registry

## Study Design

<b>Study Design</b>	A Prospective, Multicenter, Single Arm Real-World Registry Investigating the Clinical Use and Safety of the Lutonix <sup>®</sup> Drug Coated Balloon PTA Catheter for Treatment of Dysfunctional Native and Synthetic AV Fistulae
<b>Objective</b>	To demonstrate safety and assess the clinical use and outcomes of the Lutonix <sup>®</sup> DCB for treatment of dysfunctional AV fistulae located in the arm in a heterogeneous patient population in real world clinical practice
<b>Number of Subjects/Sites</b>	324 subjects enrolled at 25 international sites
<b>Primary Endpoints</b>	Efficacy: Target Lesion Primary Patency (TLPP) through 6 months. Safety: Freedom from any serious adverse event(s) involving the AV access circuit through 30 days
<b>Follow-up</b>	Clinical assessment at 6 months. Clinical or telephone assessment at 3 and 12 months
<b>Global PI</b>	Dimitrios Karnabatidis, MD- Patras, Greece

# Lutonix AV Global Registry

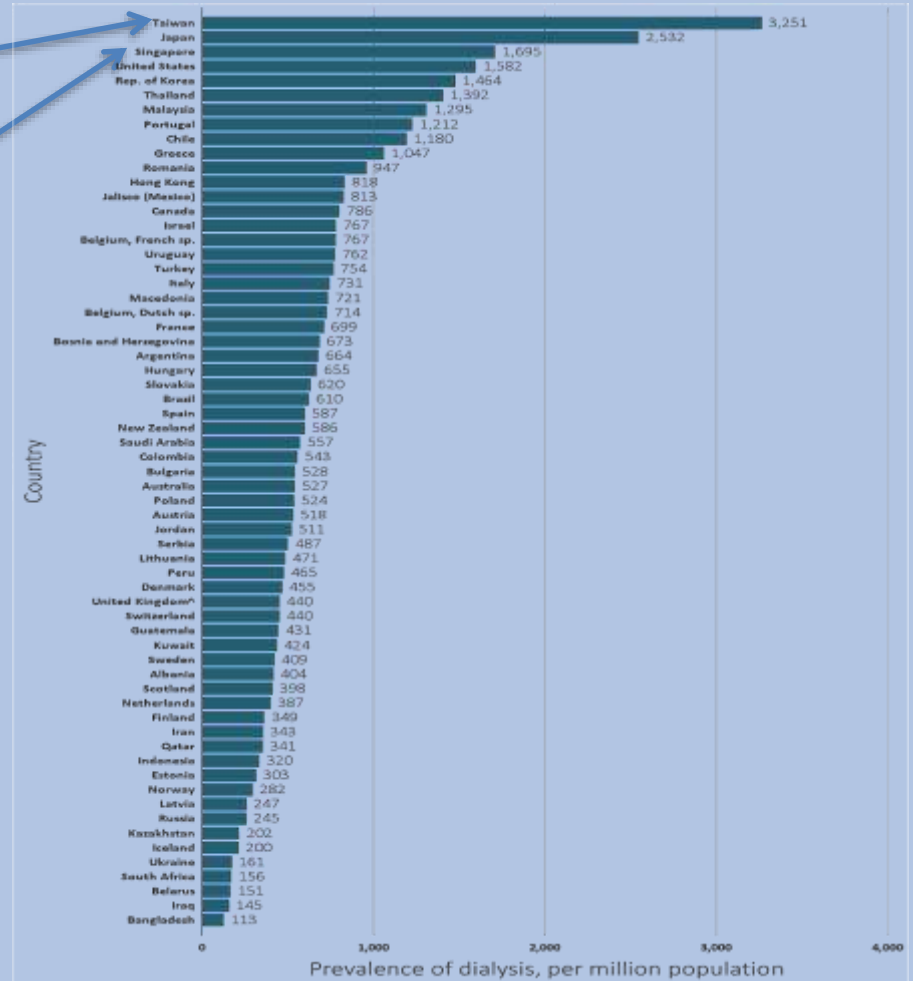
- 324 subjects enrolled in Global Registry
  - 99 subjects enrolled in Singapore and Taiwan



# Lutonix AV Global Registry

## Asian Population Differences

- Taiwan has highest prevalence of dialysis<sup>1</sup>
- Singapore has 3<sup>rd</sup> highest prevalence<sup>1</sup>
- Diabetes primary cause<sup>1</sup>
- Few transplants<sup>1</sup>
  - Taiwan 4 per 1000 patients
  - Singapore 11 per 1000 patients



1. USRDS Annual Data Report Chapter 11 2018 International Comparisons

# Lutonix AV Global Registry

## Similar Key Patient Demographics

	Diabetes	Hypertension	Dyslipidemia
Global Registry	41.9%	73.4%	26.9%
<b>Singapore &amp; Taiwan</b>	<b>42.4%</b>	<b>72.7%</b>	<b>25.3%</b>

# Lutonix AV Global Registry

## Similar AVF vs. AVG

### **Synthetic Graft/AVG**

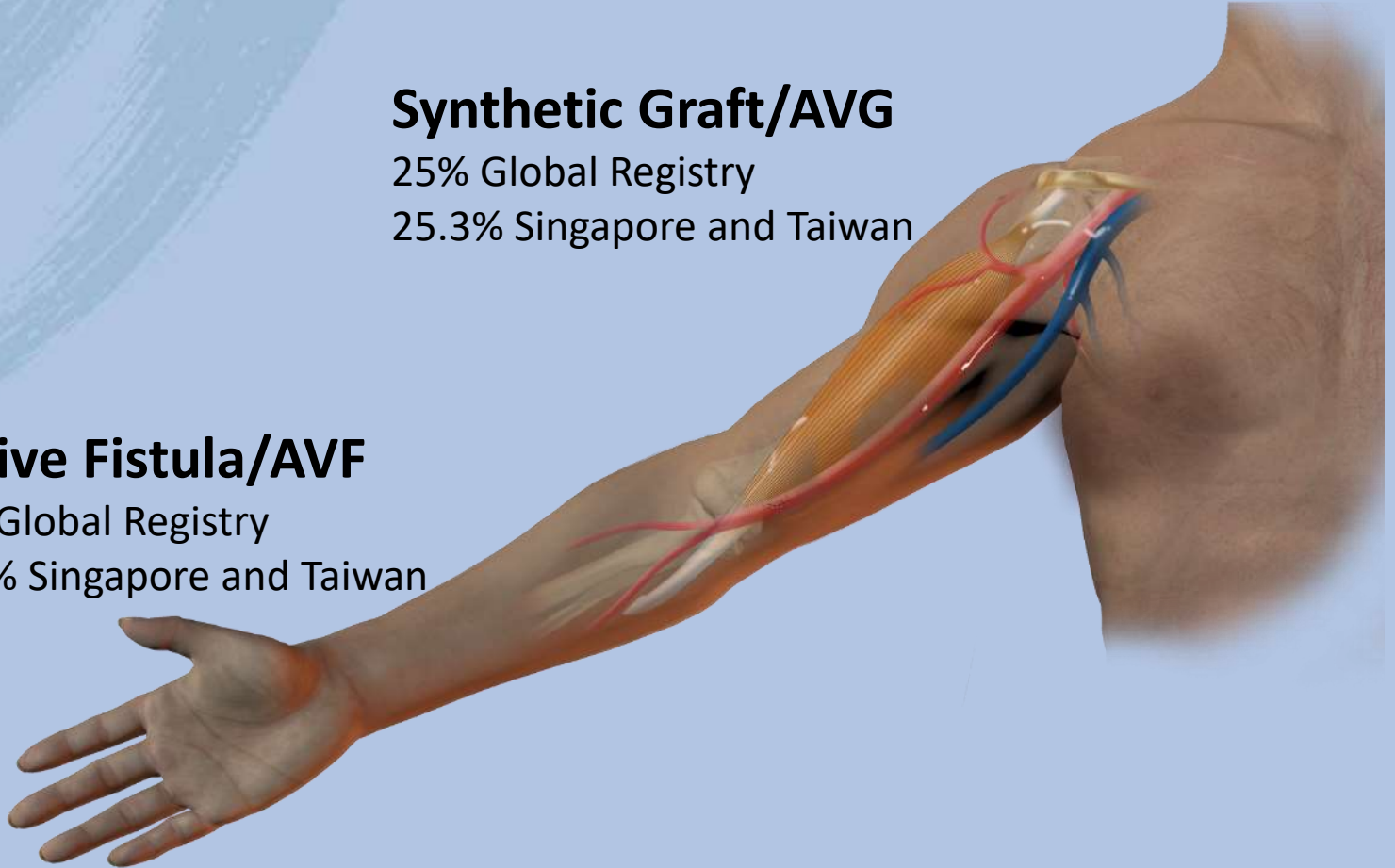
25% Global Registry

25.3% Singapore and Taiwan

### **Native Fistula/AVF**

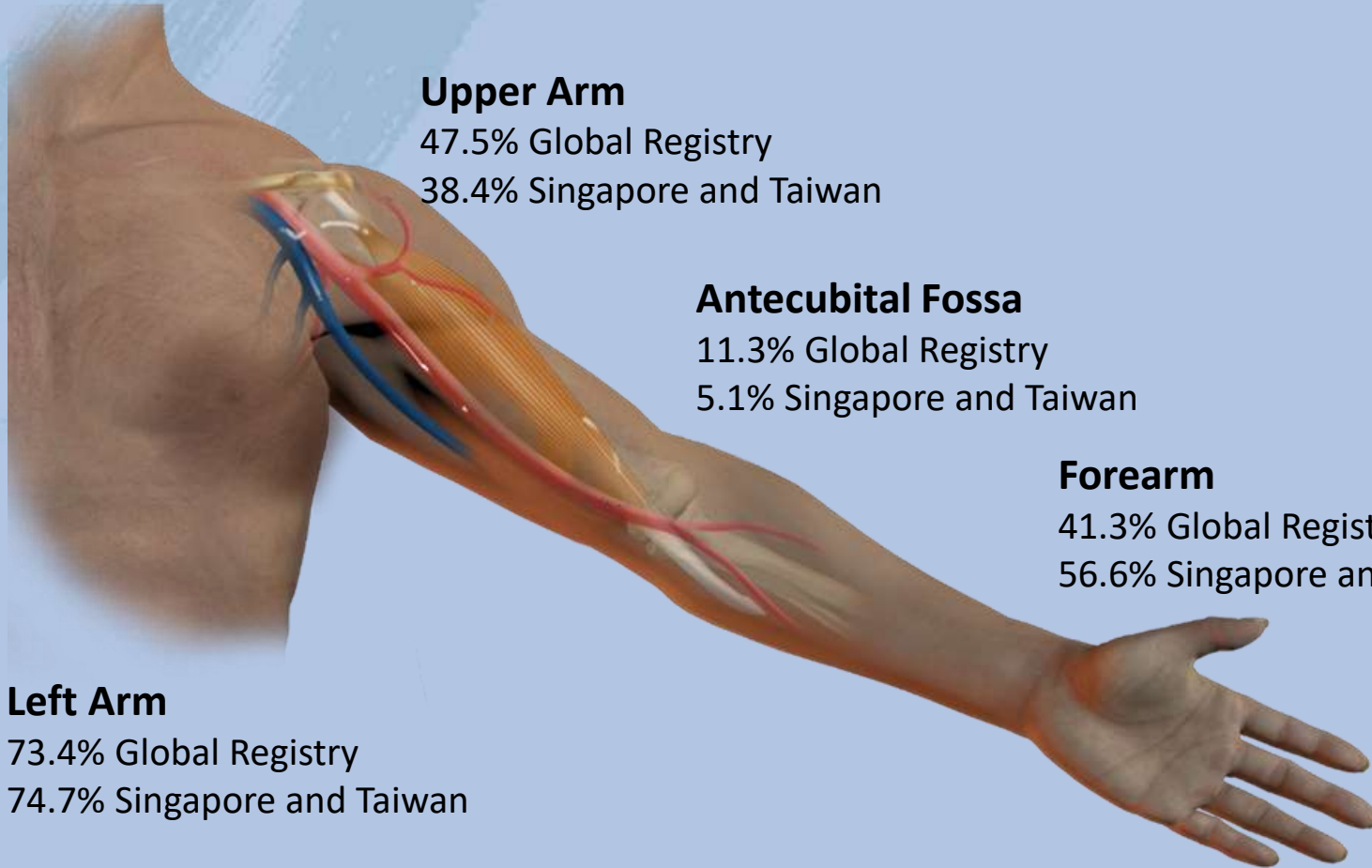
75% Global Registry

74.7% Singapore and Taiwan



# Lutonix AV Global Registry

## Access Location



### Upper Arm

47.5% Global Registry

38.4% Singapore and Taiwan

### Antecubital Fossa

11.3% Global Registry

5.1% Singapore and Taiwan

### Forearm

41.3% Global Registry

56.6% Singapore and Taiwan

### Left Arm

73.4% Global Registry

74.7% Singapore and Taiwan



# Lutonix AV Global Registry

## Similar Key Lesion Characteristics

	Mean Target Lesion Length
<b>Global Registry</b>	32.0 mm $\pm$ 20.86mm
<b>Singapore &amp; Taiwan</b>	35.4mm $\pm$ 24.24mm

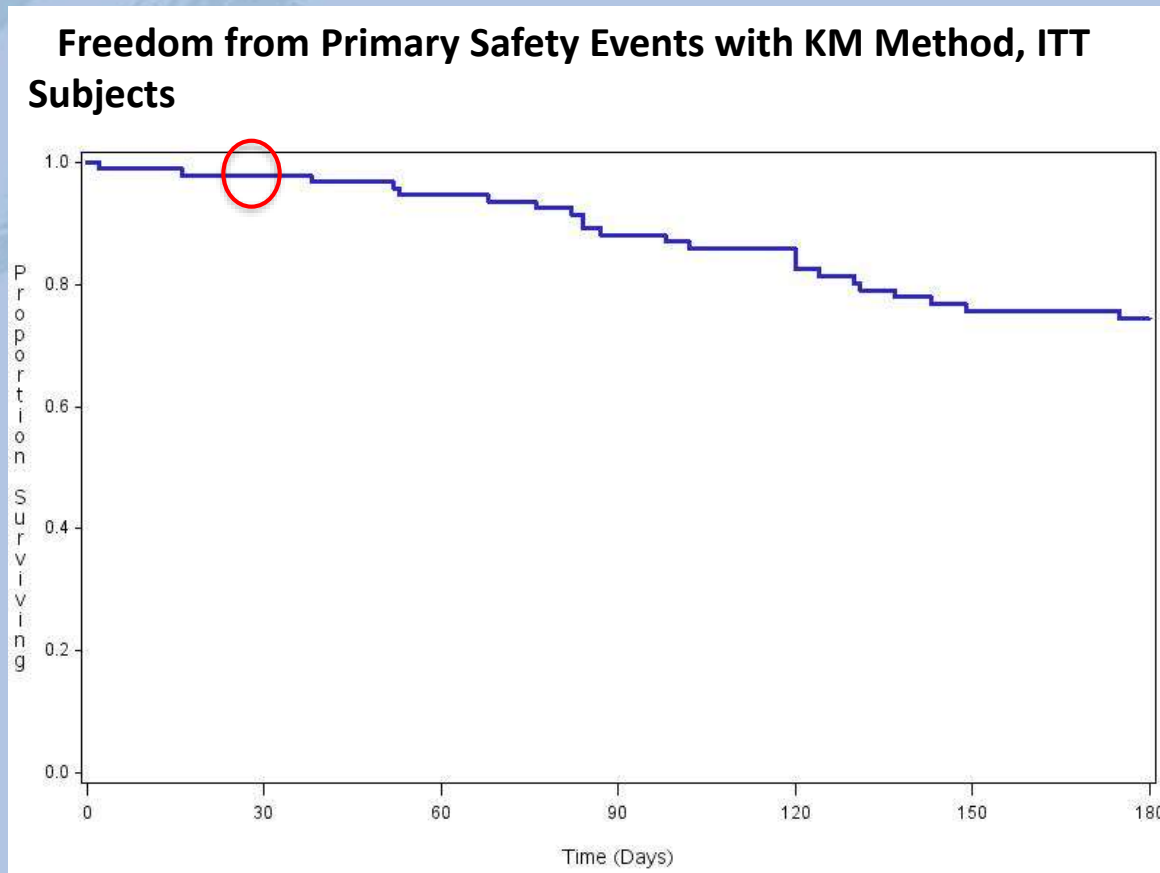
# Lutonix AV Global Registry

## Key Lesion Characteristics

	Restenotic	ISR	Central Vein
Global Registry	52.9%	11.1%	11.6%
<b>Singapore &amp; Taiwan</b>	<b>80.5%</b>	<b>10.5%</b>	<b>5.1%</b>

# Lutonix AV Global Registry

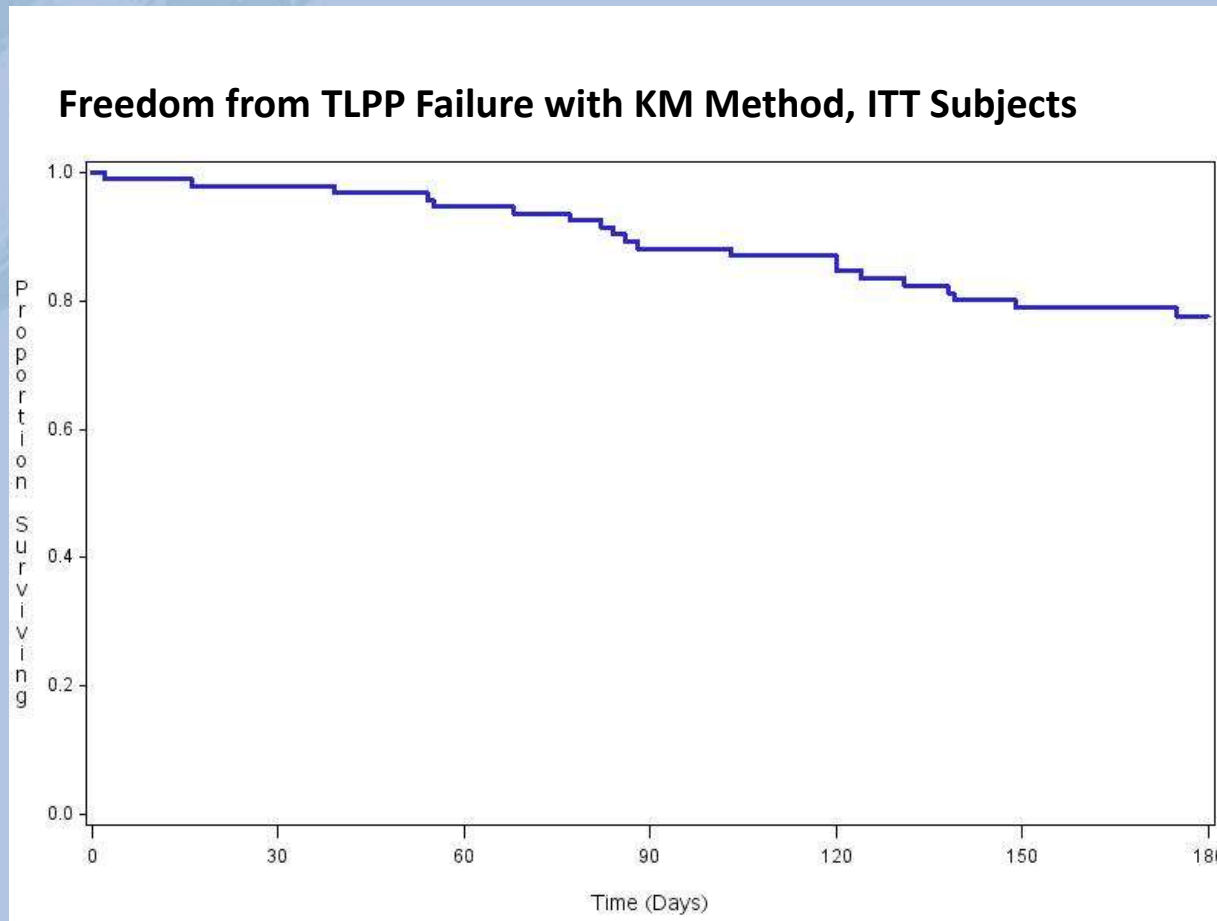
## 97.9% Freedom from Primary Safety Events- Singapore & Taiwan



Results shown are interim, site reported, and subject to change.

# Lutonix AV Global Registry

## 77.6% TLPP at 6 Months Singapore & Taiwan



Results shown are interim, site reported, and subject to change.

# Lutonix AV Global Registry

## 6 Month Similar TLPP

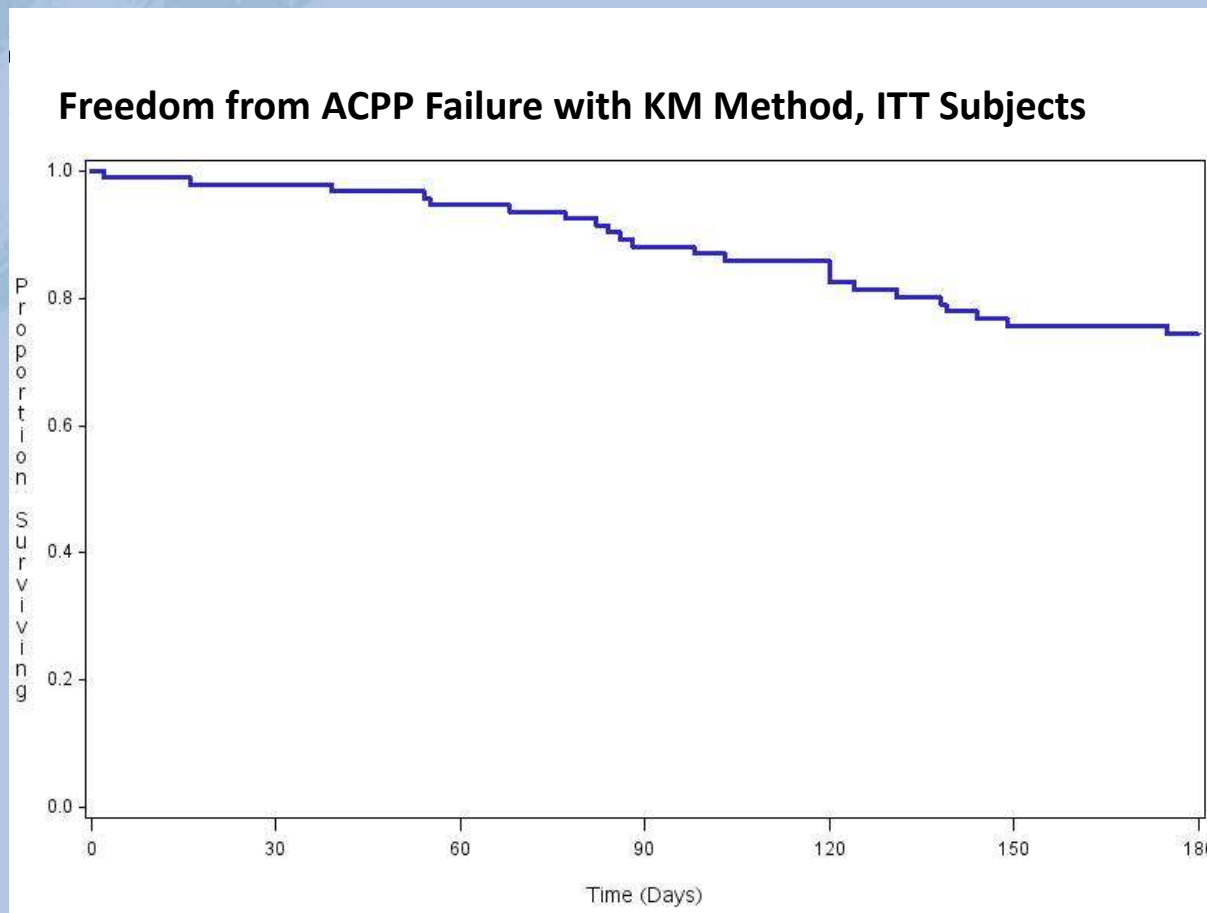
Lutonix AV Global Registry	Singapore & Taiwan	Trerotola et. al <sup>1</sup>	Kitrou et. al <sup>2</sup>
<b>73.5%</b>	<b>77.6%</b>	<b>71.4%</b>	<b>72.2%</b>

1. Trerotola et al. Drug Coated Balloon Angioplasty in Failing AV Fistulas: A Randomized Controlled Trial Clin J Am Nephrol 2018 Aug 7;13(8):1215-1224

2. Kitrou et al. Paclitaxel-Coated Balloons for the Treatment of Dysfunctional Dialysis Access. Results from a Single-Center, Retrospective Analysis Cardiovasc. Intervent Radiol DOI 10.1007/s00270-016-1479-y

# Lutonix AV Global Registry

## 63.6% ACPP at 6 Months Singapore & Taiwan



Results shown are interim, site reported, and subject to change.

# Lutonix AV Global Registry

## Singapore & Taiwan Summary

- **Despite differences in Asian dialysis population, results were similar**
  - Lutonix<sup>®</sup> DCB safety was similar in Asian patient population to Global Registry
  - 6 month TLPP in Asian patient population was similar to Global Registry



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