

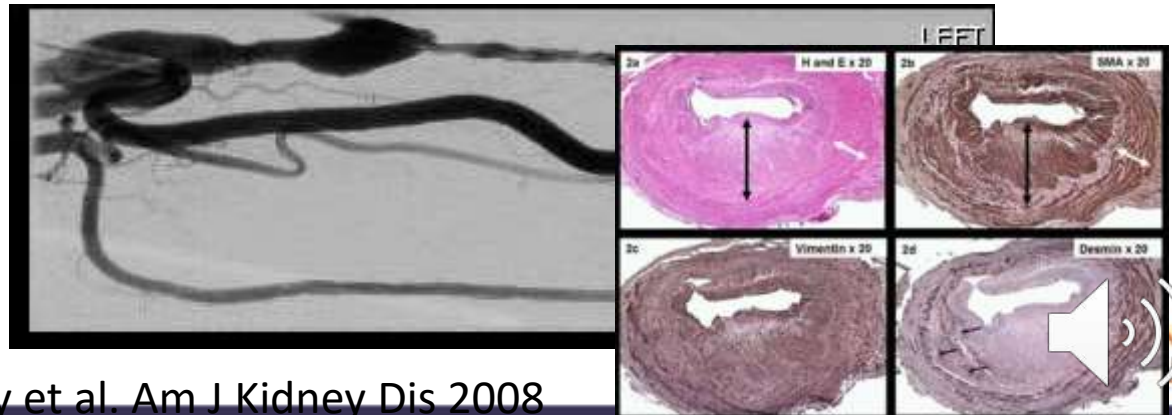
MagicTouch use at the graft-vein junction in thrombosed AVG

CS Tan, CW Tan, RY Tan, SC Pang, AP Gogna, KH Tay, TY Tang, TT Chong

A/Prof Tan Chieh Suai,
Head and Senior Consultant, Department of Renal Medicine, Singapore General Hospital
Clinical Associate Professor, Duke- NUS School of Medicine

Introduction

- A functioning dialysis access (AVF/AVG) is critical to the delivery of life saving hemodialysis therapy in patients with End Stage Renal Failure
- Neo-intimal hyperplasia occurs frequently within the dialysis access circuit
 - Poor flow
 - Obstruction
 - Thrombosis



Roy-Chaudhury et al. Am J Kidney Dis 2008

Background

- In arteriovenous graft (AVG), the primary cause of failure is venous stenosis of the graft-vein junction from neointimal hyperplasia
- Thrombosed AVG is known to have poor patency even after successful salvage intervention

Hypothesis

- Sirolimus-coated balloon (SCB) is effective in the inhibition of neo-intimal hyperplasia in the dialysis access circuit
 - Prolong the patency of access after successful intervention

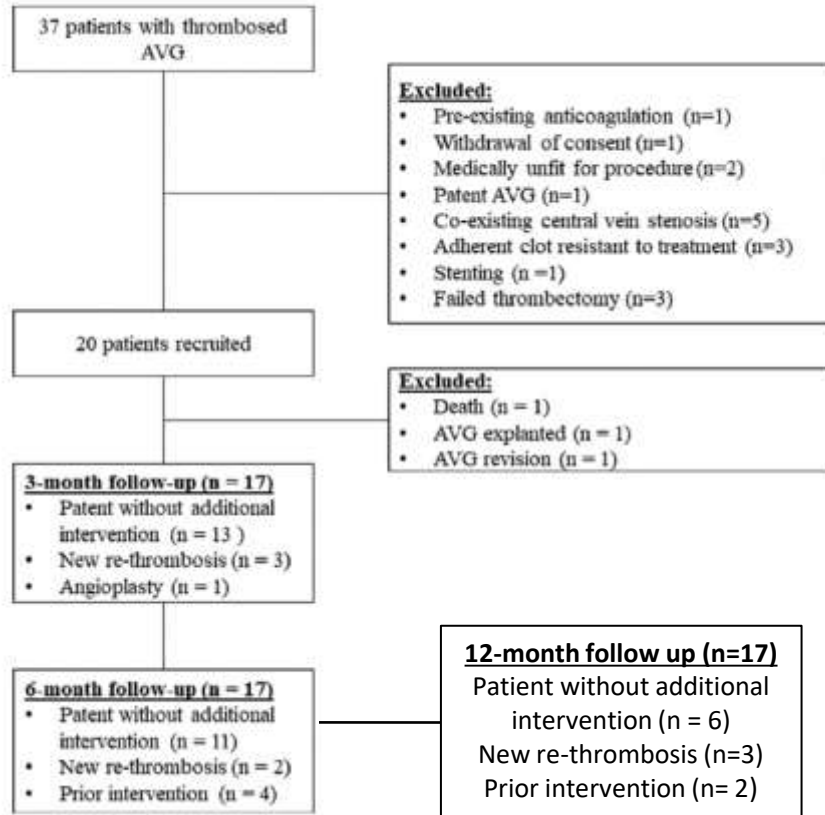
Aims and methods

- Single centre, prospective pilot study of patients (n = 20) presenting with thrombosed AVG
- Application of the sirolimus coated balloon at the graft vein junction following successful endovascular salvage of AVG
- **Primary endpoint:** Primary patency rate of the AVG at 3-month
- **Secondary endpoints:**
 - Primary patency rate of the AVG at 6-month and 12 month

Tan Ru Yu et al. CVIR Endovasc. 2020 Jul 5;3(1):34



Study Population



Tan CW at al. J Vasc Interv Radiol 2020

Baseline demographics

	n = 20
Median age, years (range)	68 (49, 80)
Male gender, n (%)	7 (35)
Etiology of ESRD, n (%)	
Diabetes Mellitus	8 (40)
Hypertension	7 (35)
Glomerulonephritis	4((20)
Polycystic Kidney Disease	1(5)
Median vintage of AVG, months (range)	14.5 (4.7, 102.4)
Types of AVG, n (%)	
Upper arm brachioaxillary	15 (75)
Upper arm brachiobasilic	3 (15)
Forearm brachiobasilic	2 (10)



Procedural characteristics

	n = 20
Thrombolytic agent, n (%)	
Tissue Plasminogen Activator	13 (65)
Urokinase	7 (35)
Size of high-pressure angioplasty balloon used, n (%)	
6mm	2 (10)
7mm	16 (80)
8mm	1 (5)
9mm	1(5)
Cutting balloon usage, n (%)	4 (20)
Size of Sirolimus balloon used, n (%)	
7mm	13 (65)
8mm	7(35)
Number of patients with residual stenosis, n (%)	0 (0)
Number of patients with residual clots, n (%)	0(0)

Results: 3-month patency rates

- Primary patency at 3 months : 13/17 (76%)*
 - Reasons:
 - Recurrent thrombosis: 3
 - Angioplasty for low flow: 1
- Primary assisted patency at 3 month: 14/17 (82%)

**One patient had surgical revision of A limb for pseudoaneurysm (day 8),*

**One died (day 40)*

**One had AVG explanted due to infection (day 88),*

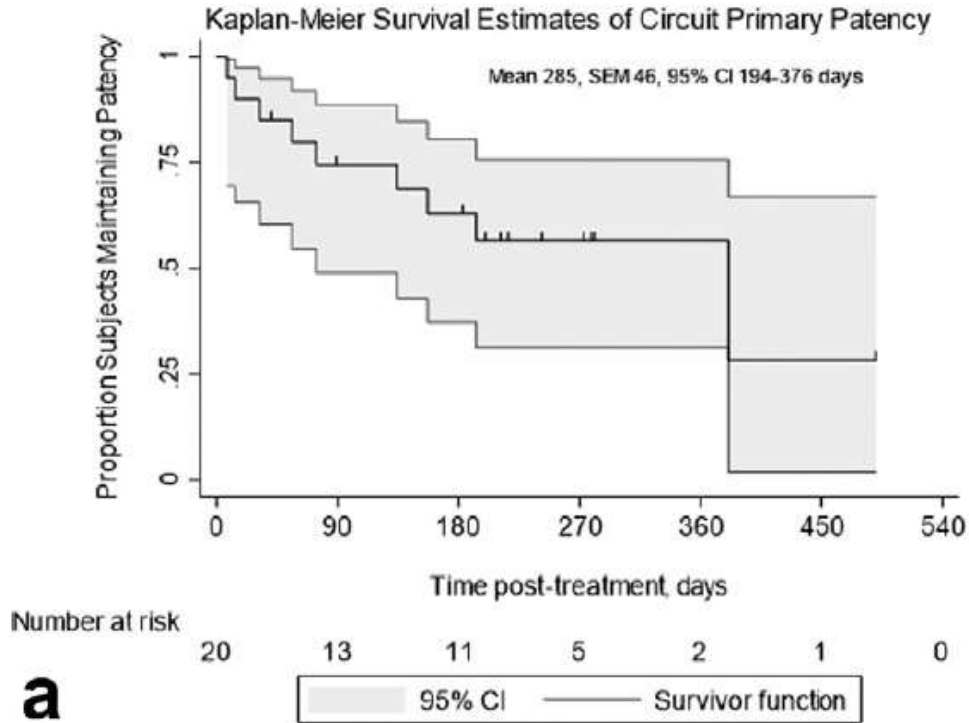
**All AVG were functioning at time of event*



Results: 6 month patency rates

- Primary patency at 6 month: 11/17 (65%)
 - 2 additional patients reached end point at 134 and 157 days post intervention respectively
- Primary assisted patency rate: 65%

Results: Kaplan-meier analysis



Tan CW at al. J Vasc Interv Radiol 2020



Results 12-month patency rates

N=17	3-month	6-month	12-month
Primary Patency, %	76	65	35
Primary Assisted Patency, %	82	65	47

Number of AVG abandoned at the end of 12 month = 5

Comparison with other studies for thrombosed AVG

	3-month	6-month
Average reported rates (%) ¹	49	38
Suggested threshold (%) ¹	44	31
Our reported rates (%) ²	55.5	35.8
Rates with Paclitaxel-coated balloon (%) ³	43.6	23.1
Sirolimus Pilot study (%) n= 17 [n=20]	76.4 [65]	64.7 [55]

1. *J Vasc Interv Radiol* 1999; 10: 491-498

2. *J Vasc Surg* 2019 pii: S0741-5214(19)31804-X

3. *Nephrology* 2019; 24(12): 1290-1295



Comparison with other studies for thrombosed AVG

	6-month Circuit patency	12 –month Circuit patency
Cutting balloon vs plain balloon(%)¹ (n = 145)	37.5 vs 29.3	Not reported
Stent graft vs plain balloon(%)² (n=129)	34.2 vs 21.8	Not reported
Sirolimus Pilot study (%) n= 17	65	35

1. *J Vasc Interv Radiol* 2005; 16: 1593-1603

2. *J Vasc Surg* 2016; 64:1400-1410

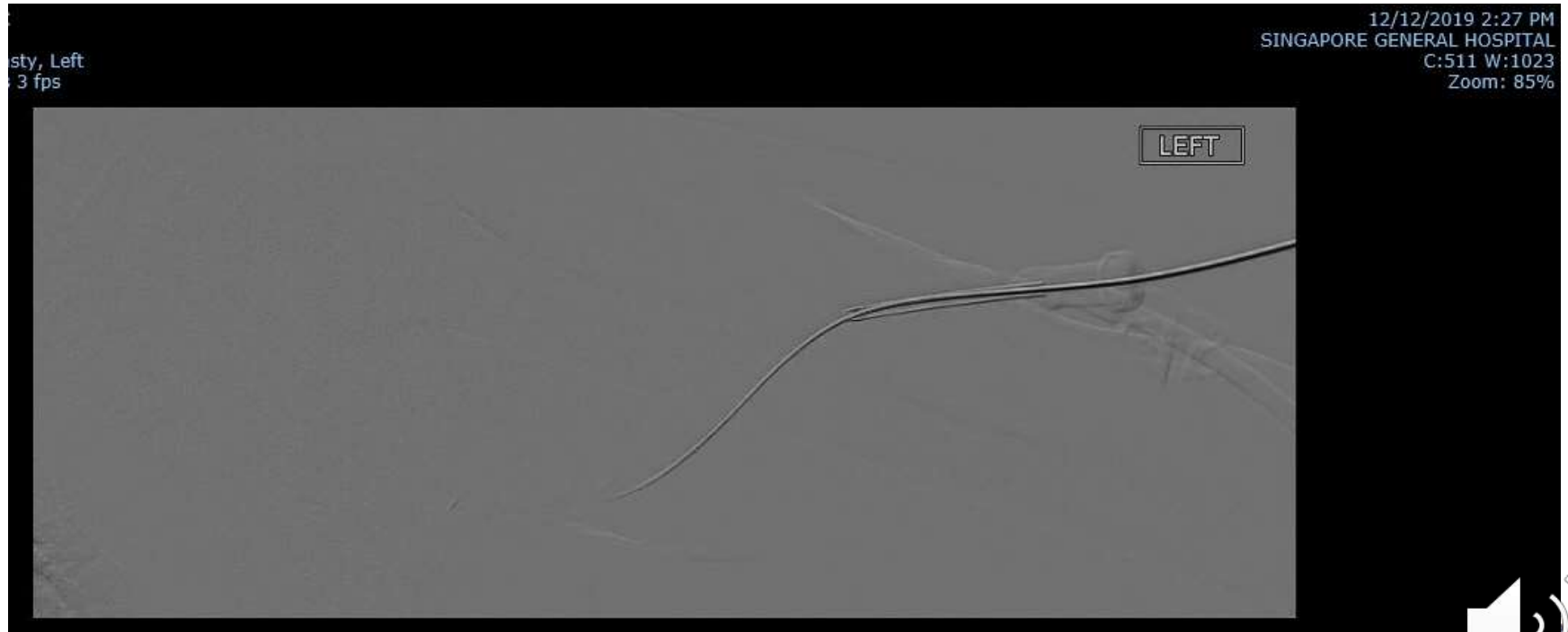
3. *J Vasc Interv Radiol* 2020 Dec 14



Case example



Case example



Hypothesis

- Sirolimus-coated balloon (SCB) is effective in the inhibition of neo-intimal hyperplasia in the dialysis access circuit
 - Prolong the patency of access after successful intervention



Hypothesis and Objective

- Hypothesis
 - Sirolimus coated balloon is superior to plain balloon angioplasty in maintaining access circuit patency
- Objective
 - Primary circuit patency rate 6-month post angioplasty
 - Freedom from clinically driven indication for re-intervention or
 - Access circuit thrombosis

Sirolimus coated balloon vs plain balloon in AVF

- Prospective
- Multi-center
- Double blinded RCT
- N = 170 patients with dysfunctional AVF
- Parallel assignment, 1:1 allocation into either group:
 - SCB – treatment arm
 - PB – control arm

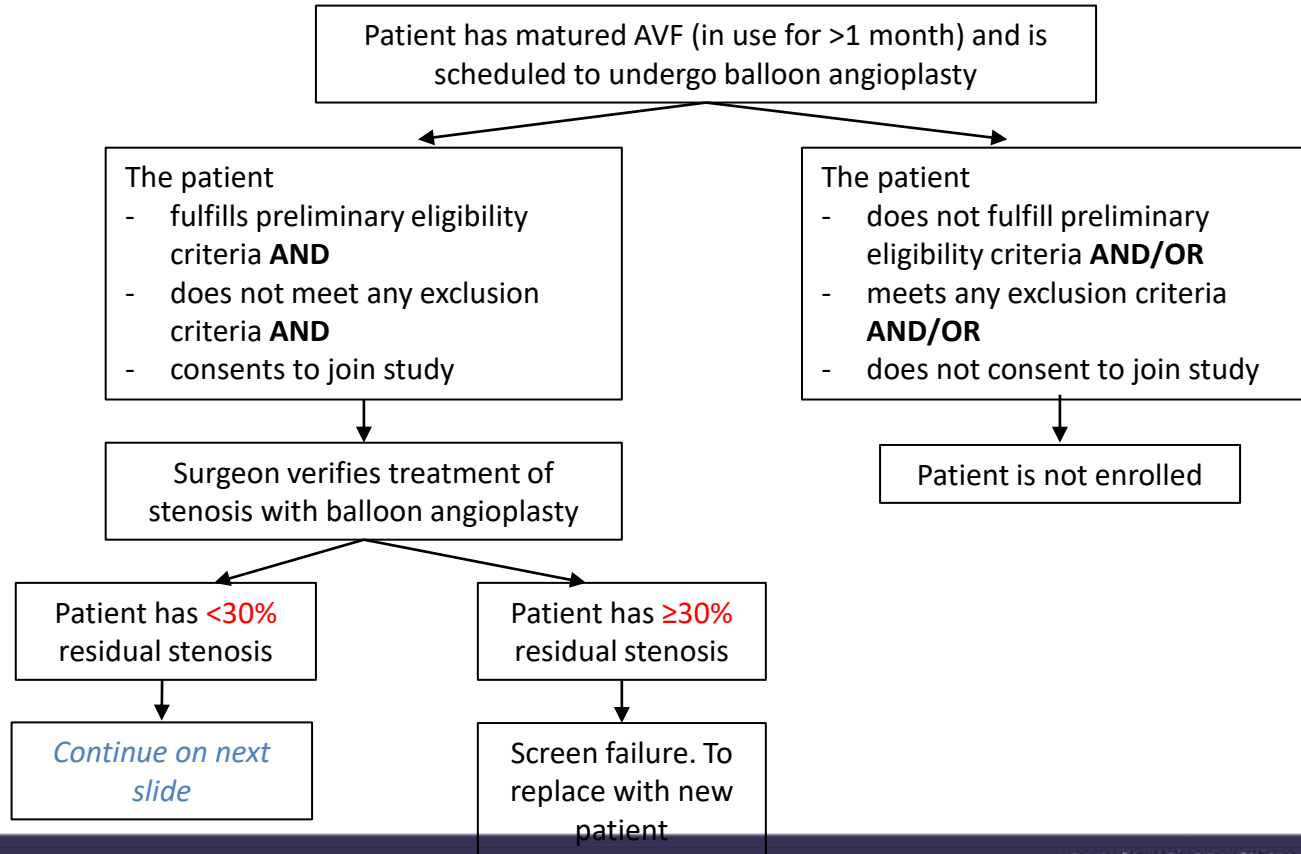
Inclusion criteria

1. Age 21-85 years
2. Patient who requires balloon angioplasty for dysfunction arteriovenous fistula
3. Matured AVF, defined as being in use for at least 1 month prior to angioplasty
4. Successful angioplasty of the underlying stenosis, defined as less than **30%** residual stenosis on Digital Subtraction Angiography (DSA) and restoration of thrill in the AVF on clinical examination

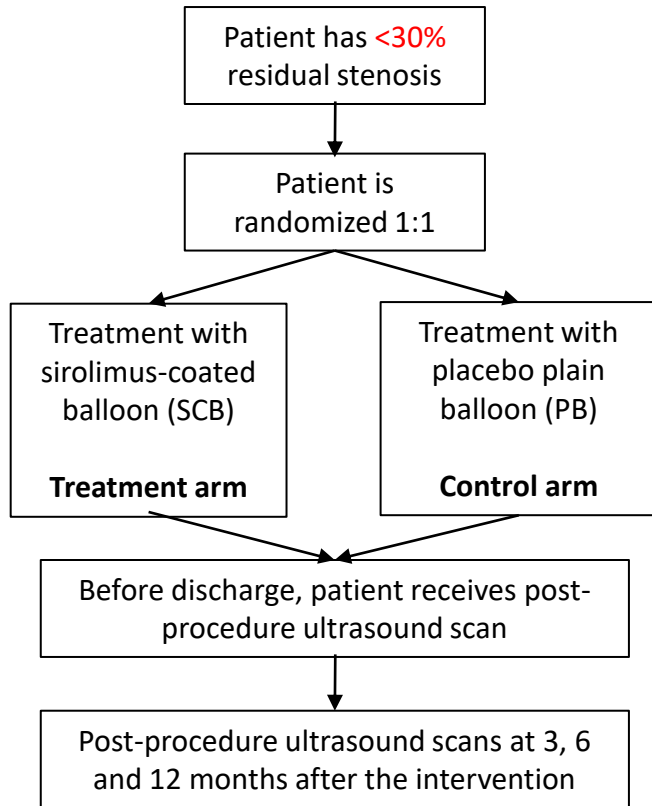
First 3 criteria
= preliminary eligibility
criteria

The last criteria can only
be determined during
procedure

Recruitment process



Recruitment process



Secure web-based randomization
Program developed by
Singapore Clinical Research Institute

Double-blinded: patients and the study
team will not know the treatment allocation

Only study coordinators remain un-blinded
throughout the study

Each site has received the emergency code
break envelopes. Only Site-PIs can break the blind.

Recruitment update

- First patient recruited 11 Jan 2021
- Total of 6 patients in 2 sites have been recruited as of 22 Jan 2021



Conclusions

- Application of sirolimus coated balloon in dialysis access circuit appears to be safe and effective
- Larger randomised controlled studies are on-going to verify our findings.

Thank You

Tan.chieh.suai@singhealth.com.sg