2019 IHVI Cardiovascular Symposium

Lower Extremity Revascularization

Endovascular Should Be First

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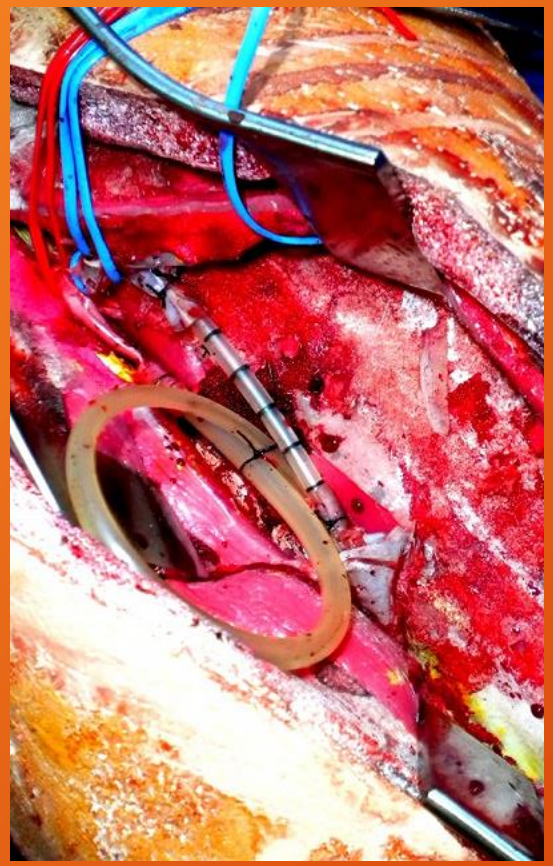
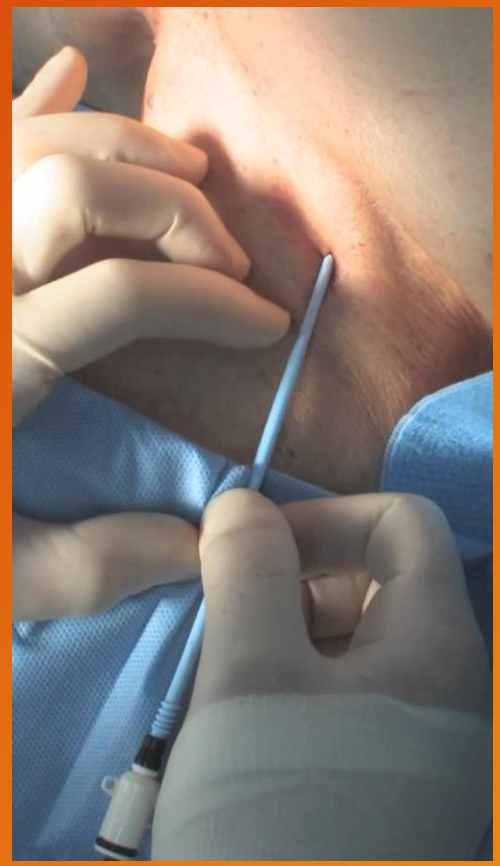
Conflicts of Interest

- None to declare relevant to PAD.

Starting Point



- By advocating for “endo-first”, I am not saying there is no role for open surgery in PAD.
- I am suggesting, that for the average patient, with the average clinical scenario, the least invasive, least morbid, safe and effective option should be chosen first.
- For the average PAD patient, that is endo-first.



Revascularization Conditions

- Chronic Limb Ischemia: Functional improvement.
  - Failed medical and exercise therapy.
  - Risk of limb loss very low.
  - Emphasis on long-term patency.
- Critical Limb Ishemia: Tissue loss, mortality high.
  - Urgent revascularization.
  - Establish straight-line flow to foot.
  - Institute optimal medical therapy.

Current State of the Art

- Femoral popliteal lesions: DCB > DES > BMS.
  - There are no comparative trials of Fem-Pop DCB vs DES.
  - DCB is preferred to leave no metal behind.
- Below-knee lesions: DES > BMS > PTA.
  - No role at this time for DCB.
  - DES (coronary) for ≤ 40 mm lesions.

Drug-Coated Devices and Mortality

NEWS • INTERVENTIONAL

Two Trials Halted in Wake of Study Linking Paclitaxel-Coated Devices to Deaths in PAD

A special meeting will be held in the coming months to review the issue. The lead author says he's pleased endovascular specialists are taking it seriously.

By L.A. McKeown | December 17, 2018

Treatment of Peripheral Arterial Disease with Paclitaxel-Coated Balloons and Paclitaxel-Eluting Stents Potentially Associated with Increased Mortality - Letter to Health Care Providers

SHARE | TWEET | LINKEDIN | PIN IT | EMAIL | PRINT

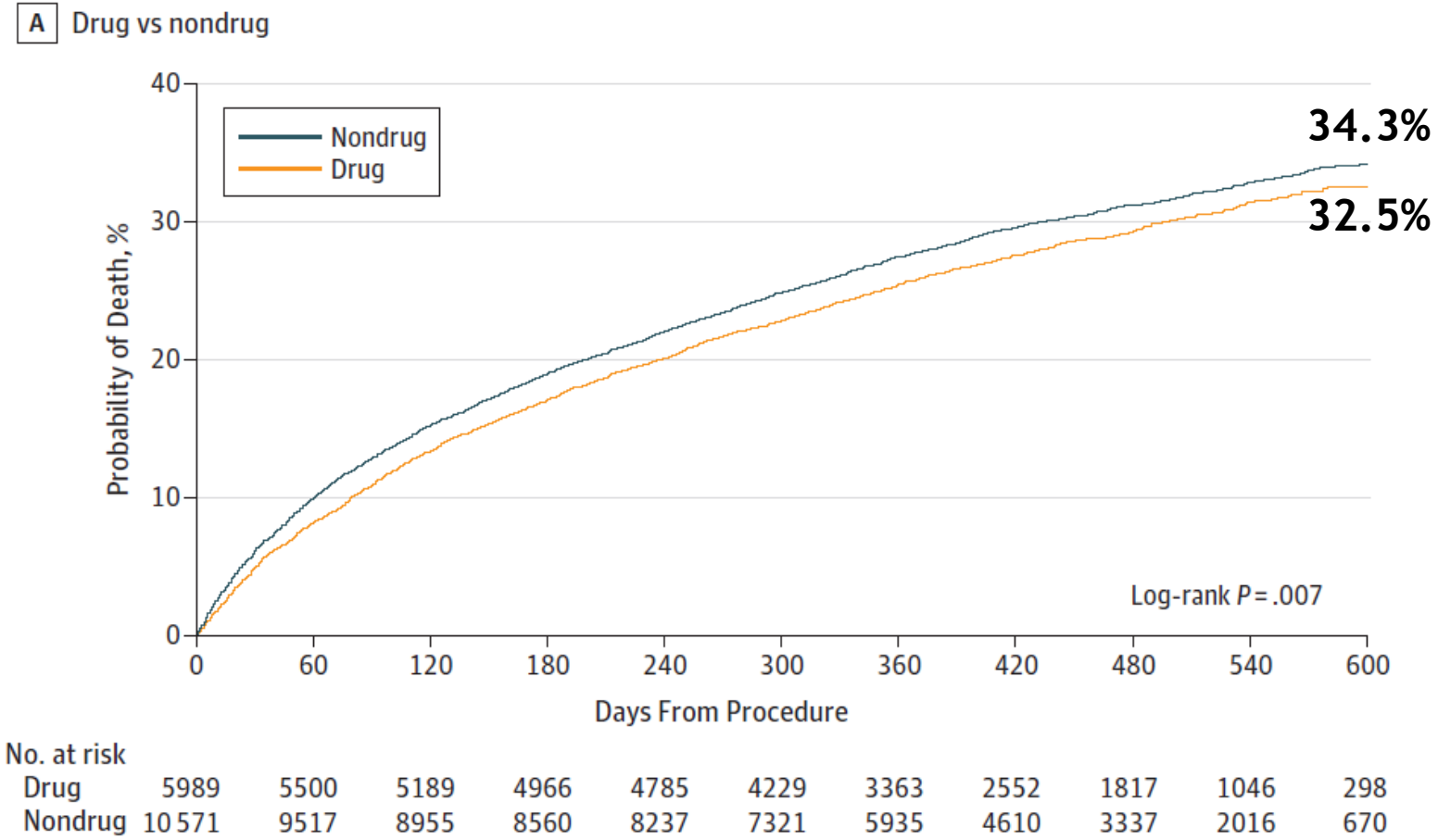
January 17, 2019

Dear Peripheral Interventionalists and Vascular Medicine Physicians:

We are writing to inform you that the FDA is evaluating recent information regarding the potential for increased long-term mortality after use of paclitaxel-coated balloons and paclitaxel-eluting stents to treat peripheral arterial disease (PAD) in the femoropopliteal artery.

A recent meta-analysis of randomized trials published in the Journal of the American Heart Association (JAHA) suggests a possible increased mortality rate after two years in PAD patients treated with paclitaxel-coated balloons and paclitaxel-eluting stents compared to patients treated with control devices (non-coated balloons or bare metal stents). The specific cause for this observation is yet to be determined.

All Patients, All Devices (DCB & DES)

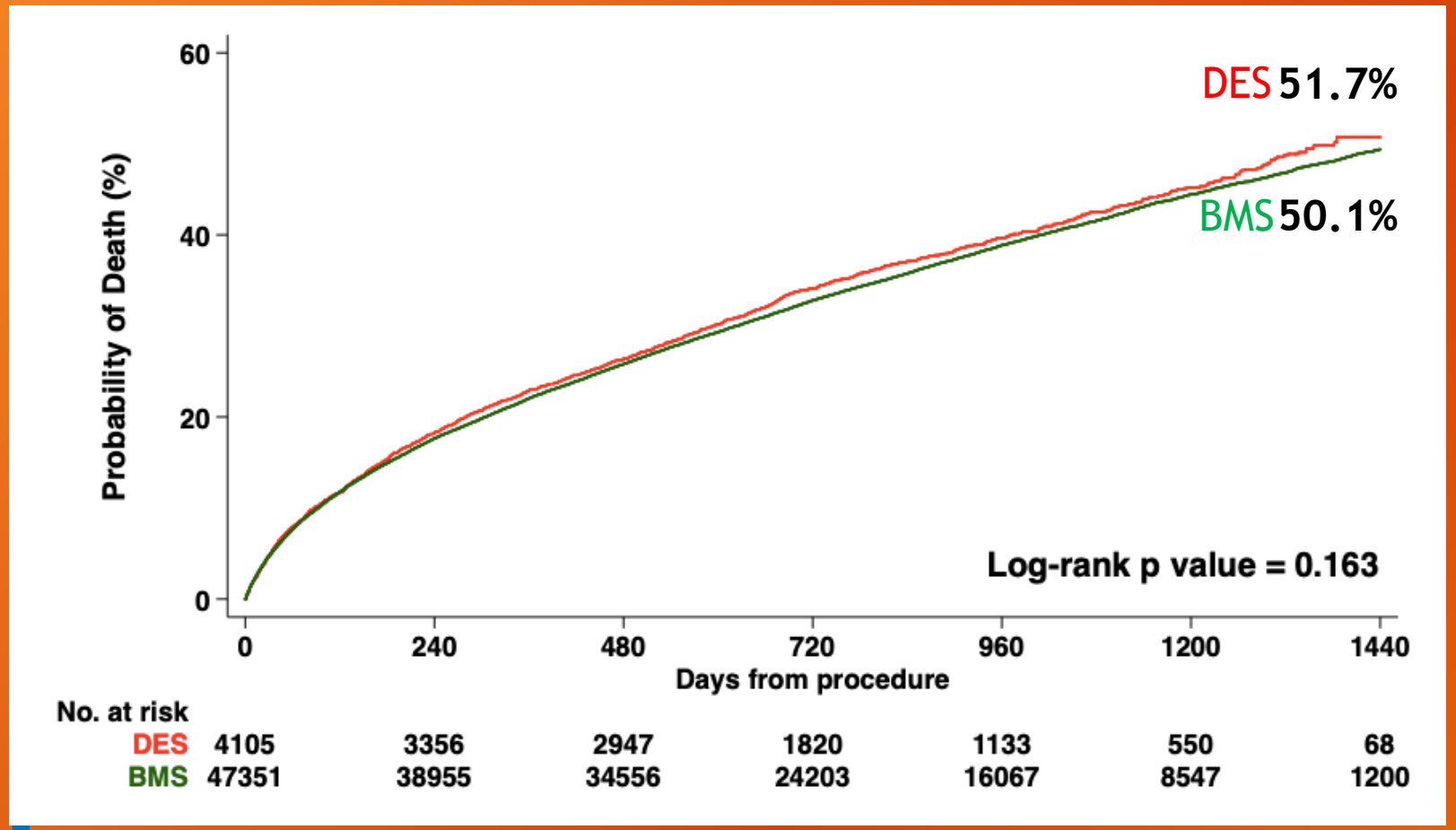


No difference in survival in adjusted analysis

Adjusted HR 0.97; 95% CI, 0.91-1.04; P = .43

Secemsky EA, et al. JAMA Cardiol. 2019;4(4):332-340. doi:10.1001/jamacardio.2019.0325

Long-Term Survival after Peripheral DES



No difference in survival in adjusted analysis

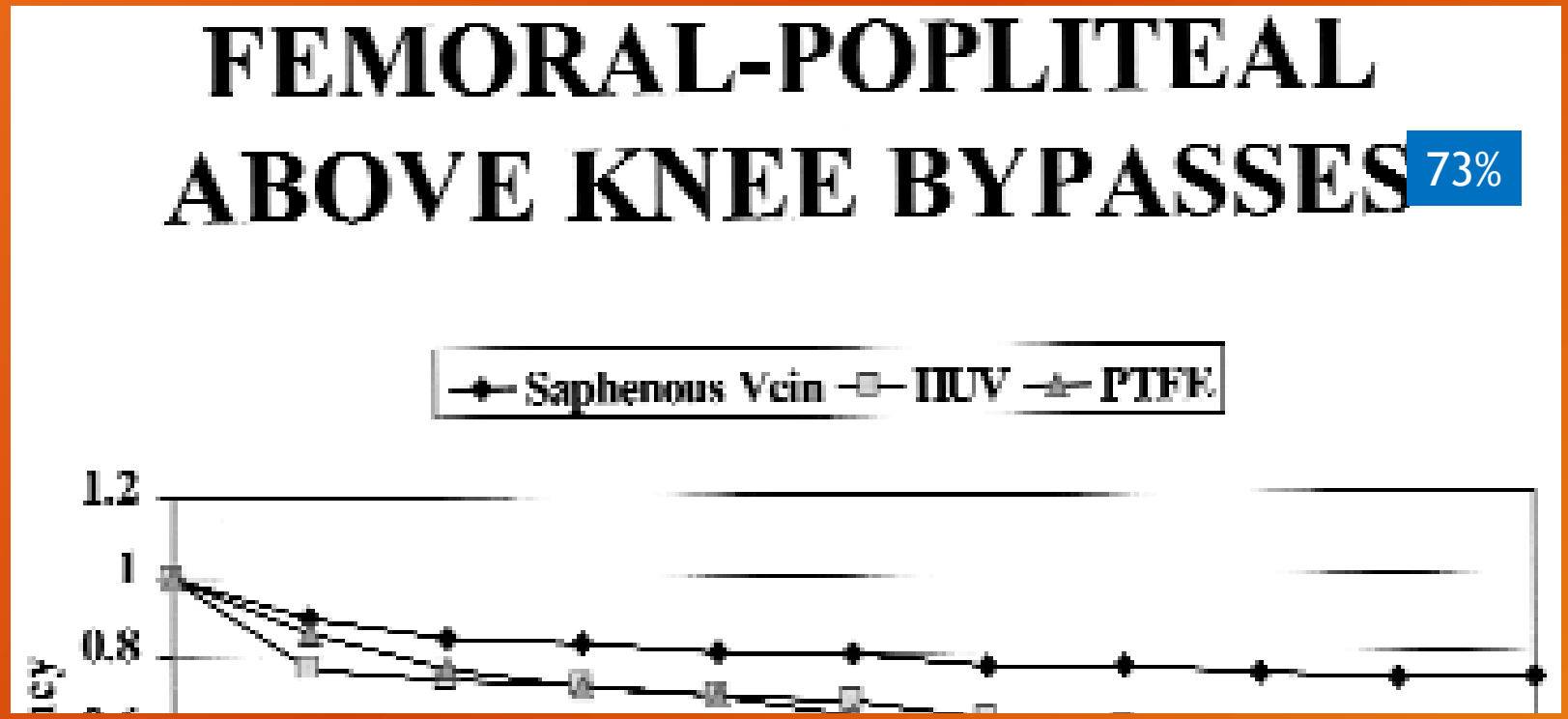
Adjusted HR 0.98; 95%CI, 0.93-1.03; P = .53

Secemsky EA, et.al. JACC 2019:https://doi.org/10.1016/j.jacc.2019.02.020

Evidence: Fem-Pop Revascularization

- Gold standard: Autogenous vein graft.

768 patients, VA hospitals, 3 armed prospective trial



Saphenous vein

Umbilical vein

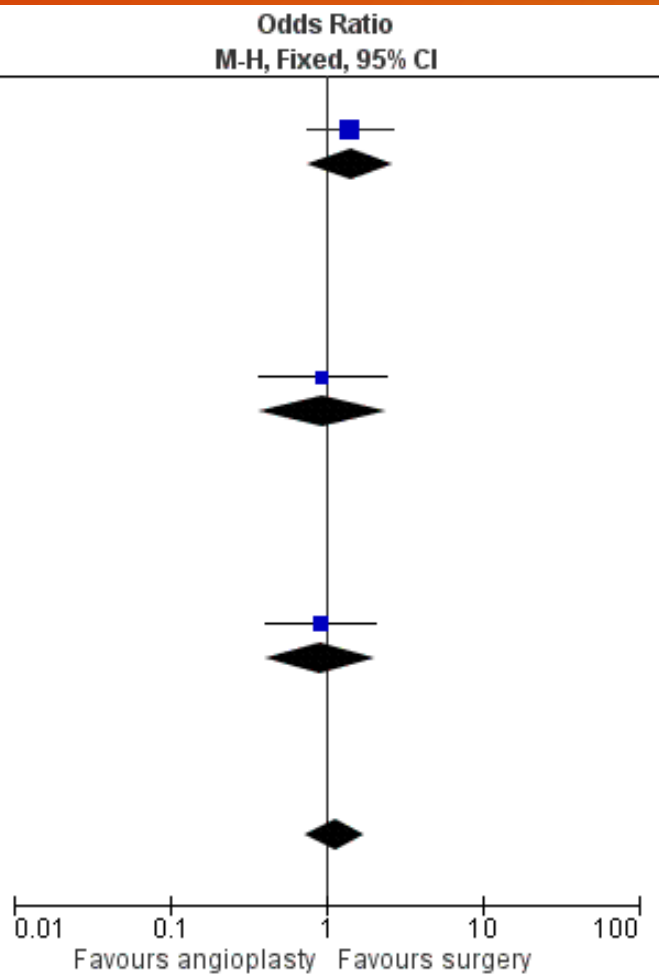
PTFE

Johnson et al. J Vasc Surg 2000;32:268

Endo vs Bypass: Primary Patency 4 yrs

- Randomised controlled trials of bypass surgery versus PTA.
- NO DCB/DES trials.

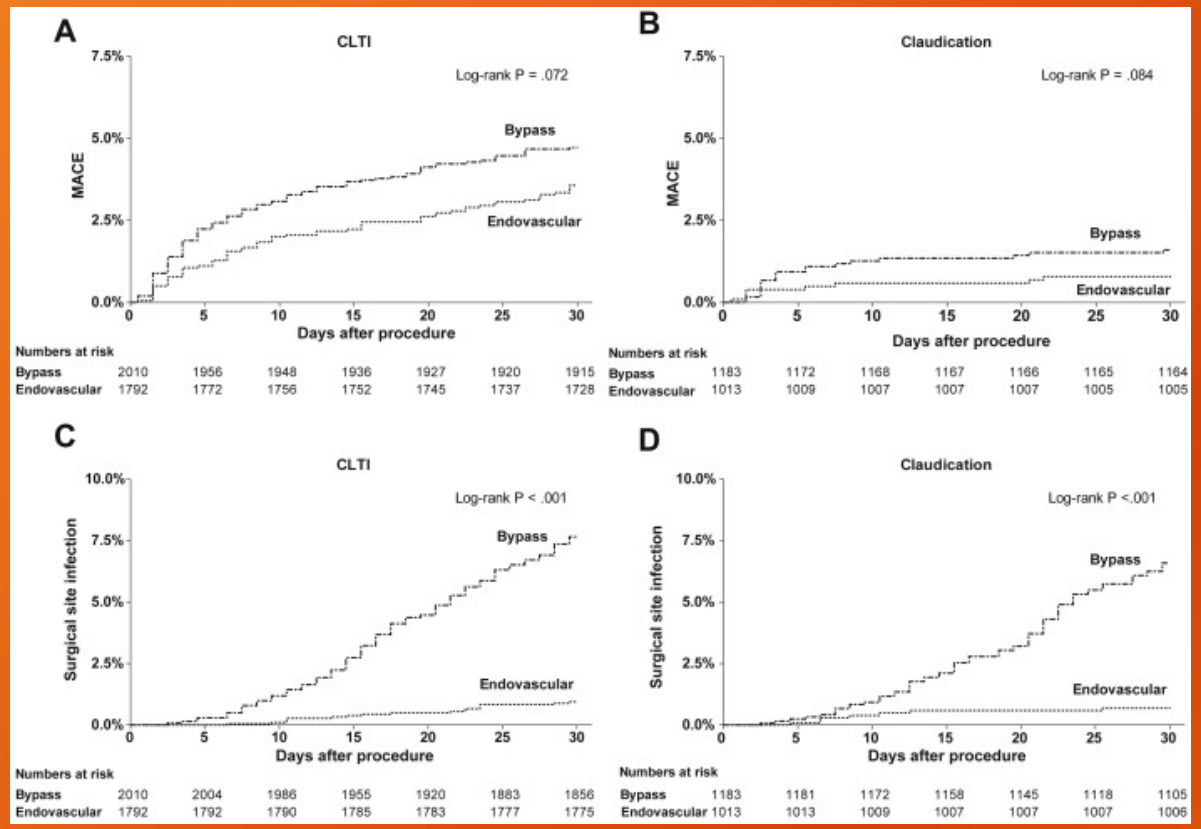
Study or Subgroup	Surgery Events	Surgery Total	Angioplasty Events	Angioplasty Total	Weight	Odds Ratio M-H, Fixed, 95% CI	Year
1.7.1 Intermittent claudication							
Veterans Study	70	94	65	97	43.1%	1.44 [0.77, 2.69]	1993
Subtotal (95% CI)		**94**		**97**	**43.1%**	**1.44 [0.77, 2.69]**	
Total events	70		65				
Heterogeneity: Not applicable							
Test for overall effect: Z = 1.13 (P = 0.26)							
1.7.2 Critical limb ischaemia							
Veterans Study	22	39	19	33	23.7%	0.95 [0.37, 2.43]	1993
Subtotal (95% CI)		**39**		**33**	**23.7%**	**0.95 [0.37, 2.43]**	
Total events	22		19				
Heterogeneity: Not applicable							
Test for overall effect: Z = 0.10 (P = 0.92)							
1.7.3 Combined intermittent claudication and critical limb ischaemia							
McQuade 2010	29	50	30	50	33.2%	0.92 [0.41, 2.04]	2009
Subtotal (95% CI)		**50**		**50**	**33.2%**	**0.92 [0.41, 2.04]**	
Total events	29		30				
Heterogeneity: Not applicable							
Test for overall effect: Z = 0.20 (P = 0.84)							
Total (95% CI)		**183**		**180**	**100.0%**	**1.15 [0.74, 1.78]**	
Total events	121		114				
Heterogeneity: Chi² = 0.93, df = 2 (P = 0.63); I² = 0%							
Test for overall effect: Z = 0.63 (P = 0.53)							
Test for subgroup differences: Chi² = 0.93, df = 2 (P = 0.63), I² = 0%							



Antoniou GA, et. al. Cochrane Reviews. 17:2017; DOI: 10.1002/14651858.CD002000.pub3.

Endo vs Surgery: 30 Day Complications

NSQIP Data Set 2011 - 2014



- A total of 5998 patients underwent first-time infrainguinal revascularization and were included in this study.
- In the CLTI cohort of 3802 patients, 2010 (53%) were treated with a bypass-first approach (19% of these were tibial procedures) and 1792 (47%) with an endovascular-first approach (31% were tibial procedures).
- Among 2196 patients with claudication, 1183 (54%) underwent first-time bypass (5% were tibial procedures) and 1013 (46%) first-time endovascular intervention (9% were tibial procedures).

Bodewes TCF, J Vasc Surg 2018:67:206-16

Femoral-Popliteal Revascularization

Table IV. Outcomes/complications

	Bypass	*Primary angioplasty/ stent*	P *value*
Length of stay (mean days)	3.9 (2-11)	1.2 (1-3)	<.01
Acute myocardial infarction	1%	0	NS
Pseudoaneurysm	0	4%	NS
Wound infection	16%	0%	<.01
Renal failure >20% increase in creatinine	3%	3%	NS
Return to operating room	3%	0	NS
Bleeding complication	2%	1%	NS
Hematoma	0	2%	NS
Postoperative occlusion	2%	0	NS

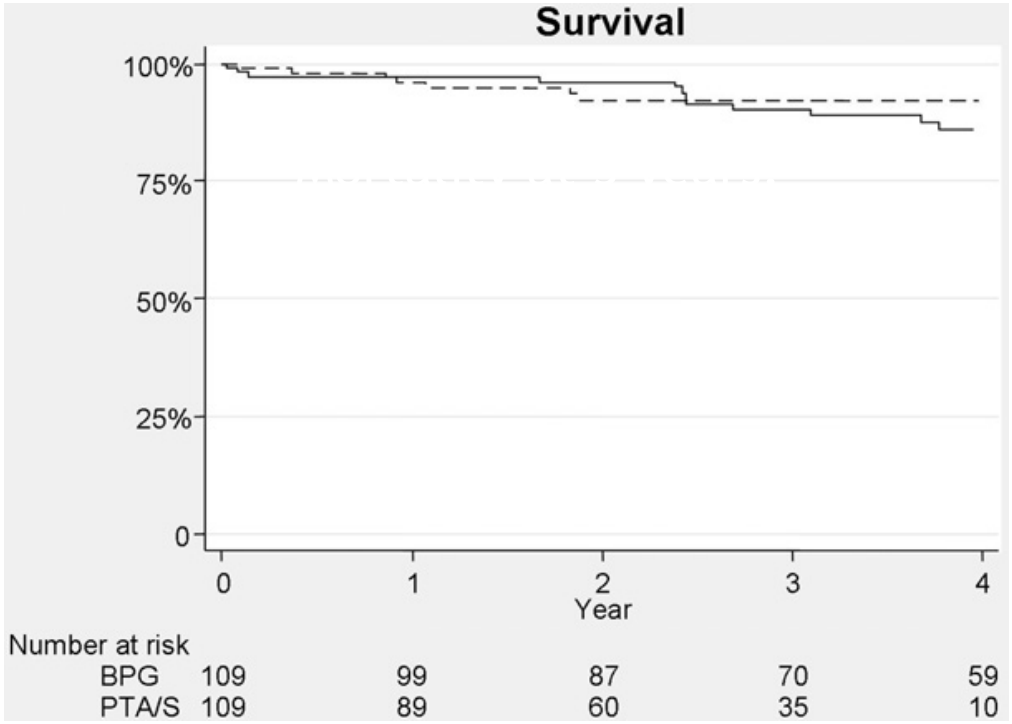


Fig 6. There is no difference in mortality between bypass (*BPG*) and percutaneous transluminal angioplasty ± stent (*PTA/S*) at 3 years.

Siracuse et al. J Vasc Surg 2012;55:1001

Bypass: Surgical Site Infections

Table V. Comparison of 30-day morbidity and mortality for patients with and without surgical site infection (*SSI*)

Variable	No SSI (n = 2713), No. (%)	SSI (n = 320), No. (%)	*P* value[a]
Transfusion	768 (28.4)	151 (47.3)	<.01
Amputation	222 (8.2)	51 (16.3)	.02
Major amputation	62 (2.3)	28 (9.0)	<.01
Readmission			
Lymph leak	26 (1.0)	15 (4.8)	<.01
Thrombectomy/lysis	37 (1.4)	4 (1.3)	1.00
Open bypass revision			
Surgical	19 (0.7)	11 (3.9)	<.01
Percutaneous	8 (0.3)	2 (0.7)	.98
Myocardial infarction	59 (2.2)	8 (2.6)	1.00
TIA/stroke	15 (0.6)	10 (3.2)	0.19
Dialysis	3 (0.1)	4 (1.3)	0.30
Death	26 (1.0)	11 (3.5)	1.00

- Michigan statewide database
- 3,033 bypasses
- Surgical site infection: 10.6%

Davis et al. J Vasc Surg 2017;65:1769

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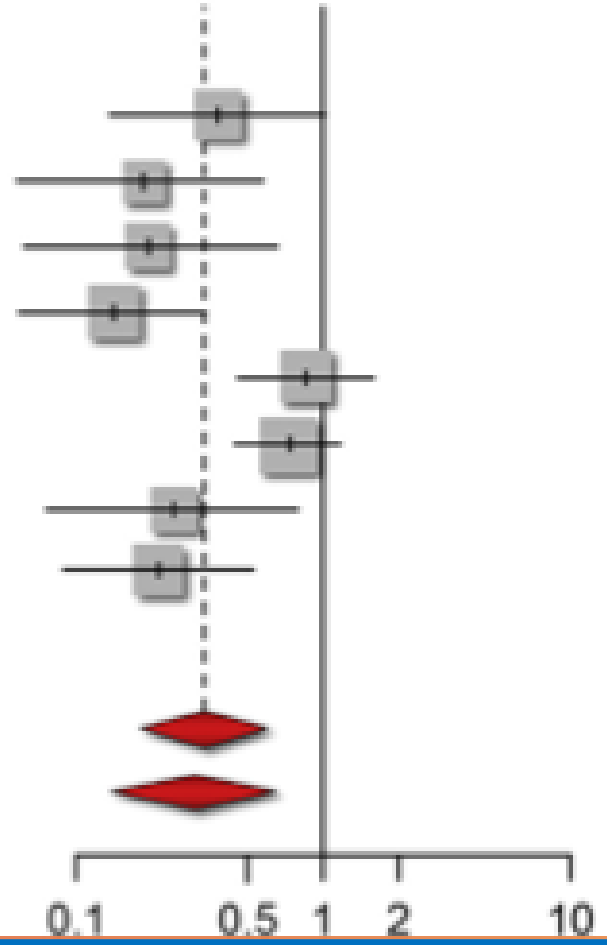
DCB >> PTA: Meta-Analysis Fem-Pop

	DCB Events	DCB Total	PB Events	PB Total	RR [95% CI]	Weight	Z Value	p Value
Biolux P-I	4	25	10	24	0.38 [0.14, 1.06]	11.6%	-1.848	0.065
FAIR	3	47	16	44	0.18 [0.06, 0.59]	10.3%	-2.864	0.004
FemPac	3	45	14	42	0.20 [0.06, 0.65]	10.2%	-2.687	0.007
IN.PACT SFA	6	207	22	107	0.14 [0.06, 0.34]	12.9%	-4.404	<0.001
LEVANT I	13	45	14	42	0.87 [0.46, 1.62]	15.3%	-0.447	0.655
LEVANT 2	35	285	24	143	0.73 [0.45, 1.18]	16.8%	-1.278	0.201
PACIFIER	3	42	12	43	0.26 [0.08, 0.84]	10.1%	-2.242	0.025
THUNDER	5	48	26	54	0.22 [0.09, 0.52]	12.9%	-3.341	0.001
Frequentist	**72**	**744**	**138**	**499**	**0.33 [0.19, 0.57]**	**100%**	**-3.997**	**<0.001**
Bayesian					**0.30 [0.14, 0.58]***			

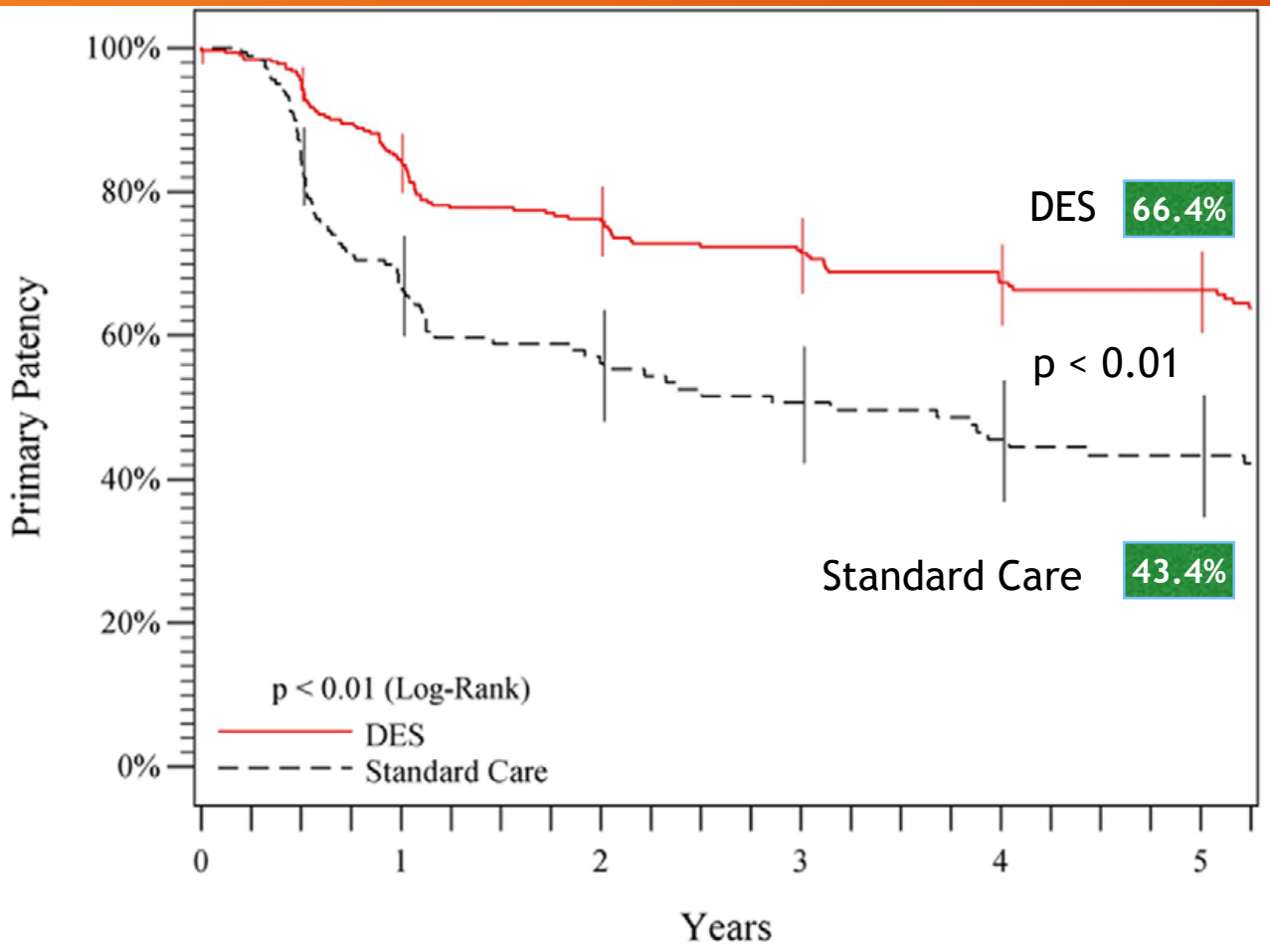
Q=22.85, p=0.002, τ^2=0.405, I^2=69.4%



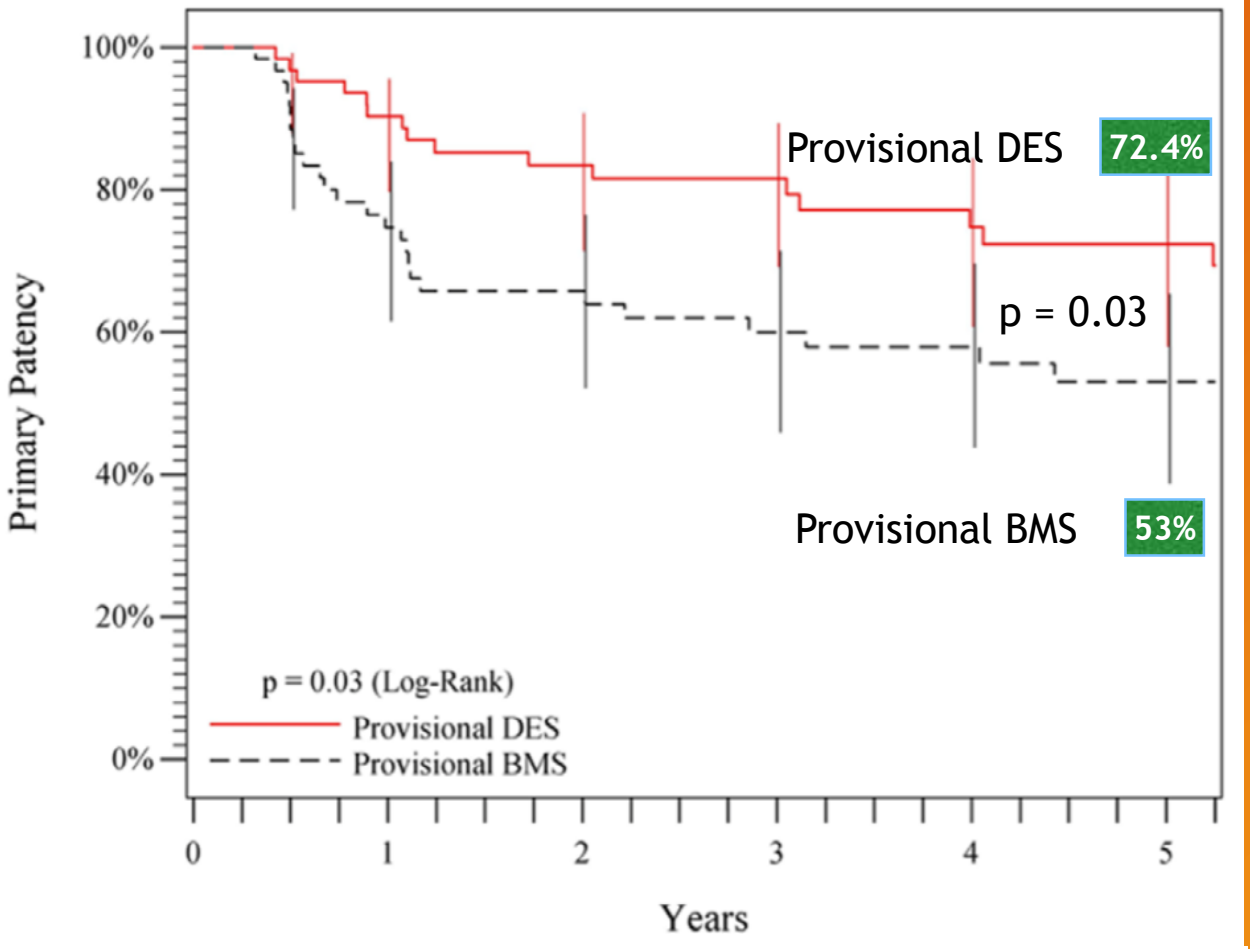
Giacoppo D. JACC: CARDIOVASCULAR INTERVENTIONS, 9;2016:1731-42.

FEMORAL: DES vs. PTA at 5 Years

DES = 1° DES + Provisional DES
Standard Care = Optimal PTA + Provisional BMS



PTA + Provisional DES
PTA + Provisional BMS



Dake, M.D. et. al. Circulation. 2016;133:1472-1483.

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Angioplasty of Femoral-Popliteal Arteries With Drug-Coated Balloons

5-Year Follow-Up of the THUNDER Trial

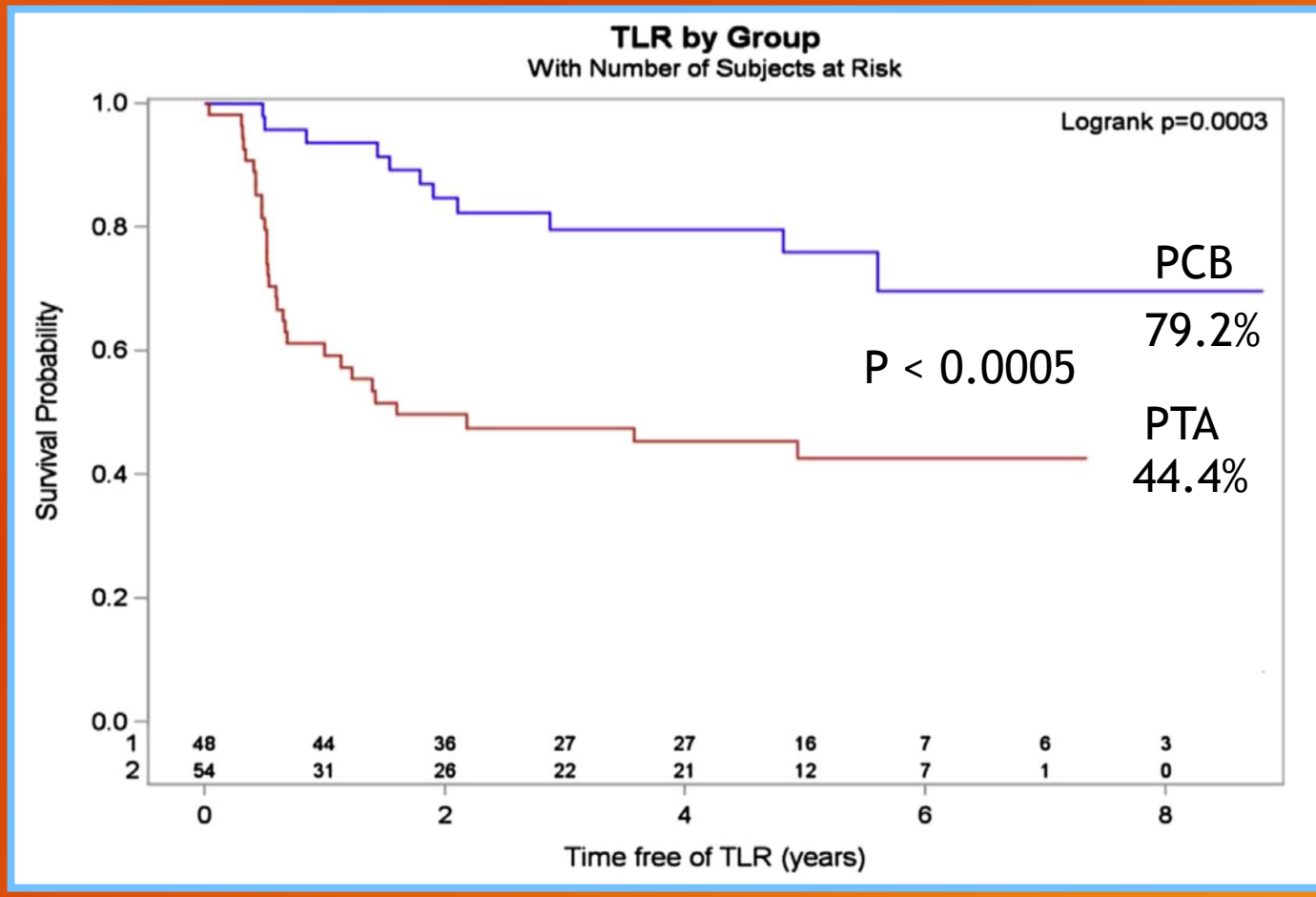
Gunnar Tepe, MD,* Beatrix Schnorr, DVM,† Thomas Albrecht, MD,‡ Klaus Brechtel, MD,§ Claus D. Claussen, MD,§ Bruno Scheller, MD,‖ Ulrich Speck, PhD,† Thomas Zeller, MD¶

TABLE 2 LLL, Binary Restenosis, and Cumulative TLR Over the Study Period

	Control Group (n = 54)		PCB Group (n = 48)		
LLL (mm)	Mean ± SD	Patients With Data, n	Mean ± SD	Patients With Data, n	p Value
6-month FU	1.7 ± 1.8	48	0.4 ± 1.2	41	0.0007
12-month FU	1.9 ± 1.9	36 14 with previous TLR	0.7 ± 1.5	33 2 with previous TLR	0.01
5-year FU	1.5 ± 1.3	11 4 with previous TLR	0.7 ± 1.9	13 1 with previous TLR	0.54

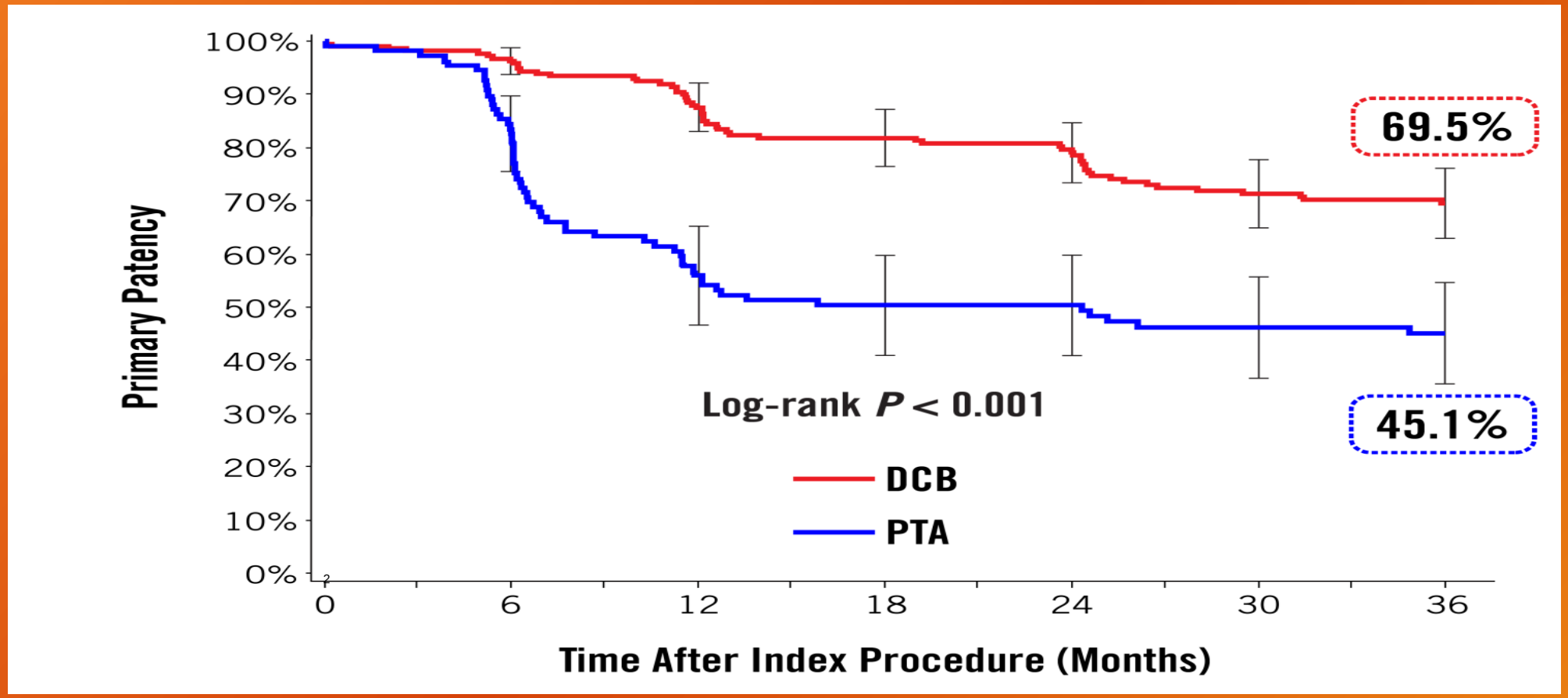
Binary Restenosis (%)	n	% Related to Patients With Data	n	% Related to Patients With Data	p Value
6-month FU	21	43.8	7	17.1	0.01
12-month FU	17	60.0	8	24.2	<0.05
5-year FU	7	54	3	17	0.04

First TLR (cumulative)	n	Treated Patients, % (n = 54)	n	Treated Patients, % (n = 48)	p-value
6-month FU	20	37.0	2	4.2	<0.0001
12-month FU	26	48.1	5	10.4	<0.0001
24-month FU	28	51.9	8	16.7	0.0003
5-year FU	30	55.6	10	20.8	0.0005



Tepe G, et al. J Am Coll Cardiol Intv 2015;8:102–8

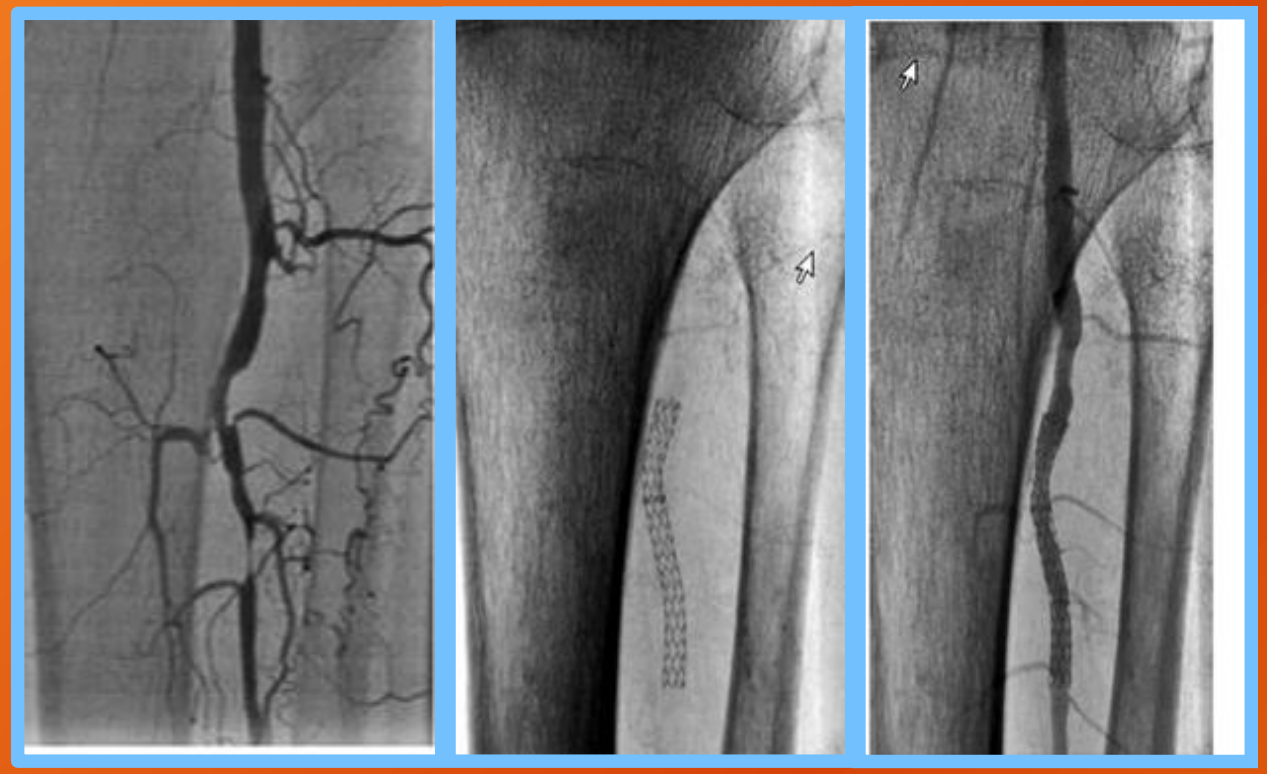
DCB Primary Patency at 3 Years



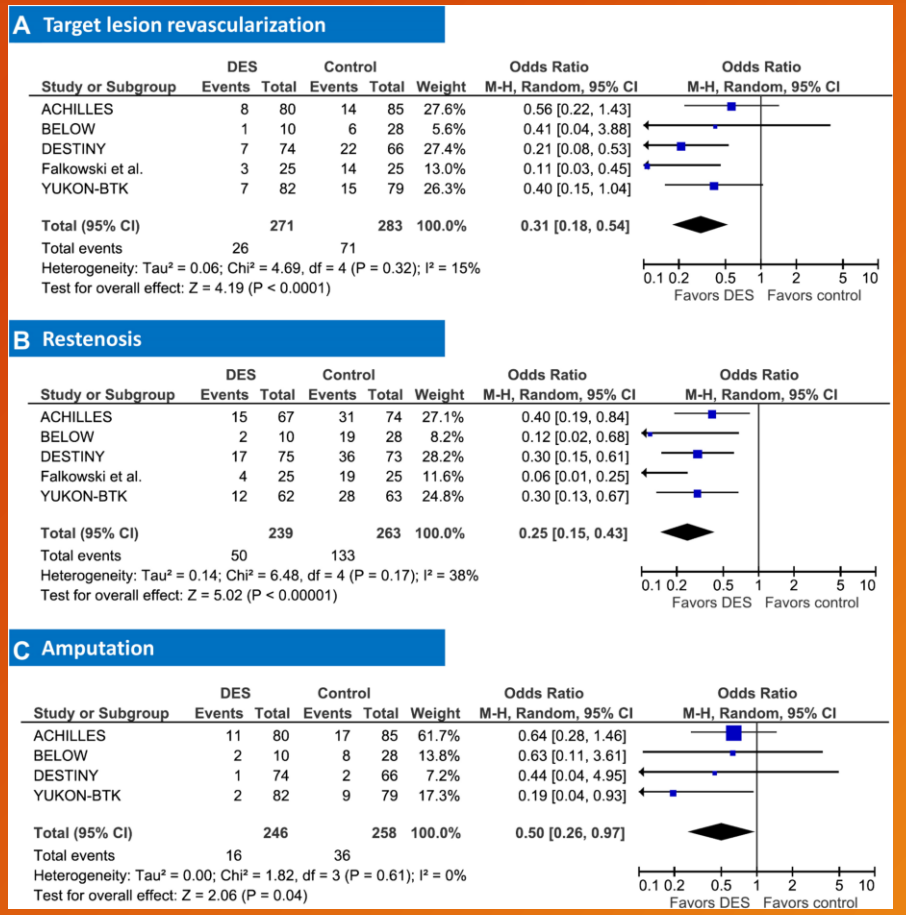
Schneider et al. Circulation: Cardiovasc Interv 2018;11:e005891

Below-Knee: Drug Eluting Stents

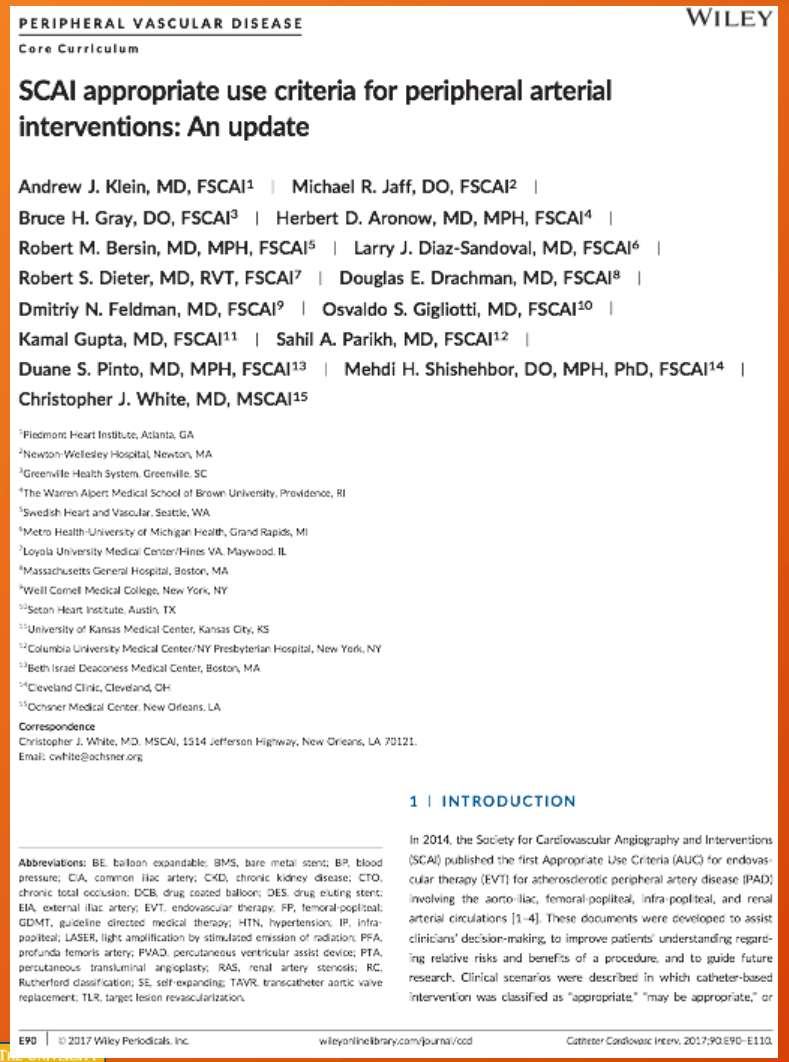
Drug-Eluting Stents for Revascularization of Infrapopliteal Arteries: Updated Meta-Analysis of Randomized Trials



Feiring, AJ, Wesolowski, AA. CCI 2007,69:665-670



PAD APPROPRIATE USE CRITERIA



PERIPHERAL VASCULAR DISEASE

WILEY

Core Curriculum

SCAI appropriate use criteria for peripheral arterial interventions: An update

Andrew J. Klein, MD, FSCAI[1] | Michael R. Jaff, DO, FSCAI[2] | Bruce H. Gray, DO, FSCAI[3] | Herbert D. Aronow, MD, MPH, FSCAI[4] | Robert M. Bersin, MD, MPH, FSCAI[5] | Larry J. Diaz-Sandoval, MD, FSCAI[6] | Robert S. Dieter, MD, RVT, FSCAI[7] | Douglas E. Drachman, MD, FSCAI[8] | Dmitriy N. Feldman, MD, FSCAI[9] | Osvaldo S. Gigliotti, MD, FSCAI[10] | Kamal Gupta, MD, FSCAI[11] | Sahil A. Parikh, MD, FSCAI[12] | Duane S. Pinto, MD, MPH, FSCAI[13] | Mehdi H. Shishehbor, DO, MPH, PhD, FSCAI[14] | Christopher J. White, MD, MSCAI[15]

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1 | INTRODUCTION

In 2014, the Society for Cardiovascular Angiography and Interventions (SCAI) published the first Appropriate Use Criteria (AUC) for endovascular therapy (EVT) for atherosclerotic peripheral artery disease (PAD) involving the aorto-iliac, femoral-popliteal, infra-popliteal, and renal arterial circulations [1–4]. These documents were developed to assist clinicians' decision-making, to improve patients' understanding regarding relative risks and benefits of a procedure, and to guide future research. Clinical scenarios were described in which catheter-based intervention was classified as "appropriate," "may be appropriate," or

Abbreviations: BE, balloon expandable; BMS, bare metal stent; BP, blood pressure; CIA, common iliac artery; CKD, chronic kidney disease; CTO, chronic total occlusion; DCB, drug coated balloon; DES, drug eluting stent; EIA, external iliac artery; EVT, endovascular therapy; FP, femoral-popliteal; GDMT, guideline directed medical therapy; HTN, hypertension; IP, infra-popliteal; LASER, light amplification by stimulated emission of radiation; PFA, profunda femoris artery; PVAD, percutaneous ventricular assist device; PTA, percutaneous transluminal angioplasty; RAS, renal artery stenosis; RC, Rutherford classification; SE, self-expanding; TAVR, transcatheter aortic valve replacement; TLR, target lesion revascularization.

- The AUC for PAD have the potential to impact physician decision making, healthcare delivery, and reimbursement policy.
- Recognition of 'uncertain' clinical scenarios facilitates identification of areas that would benefit from future research.
- The objective of AUC is to improve health outcomes in a cost-effective manner, but are not intended to ignore ambiguity and nuance intrinsic to patient-centered clinical decision making.
- AUC should not be considered a substitute for sound clinical judgment based on experience.

Catheter Cardiovasc Interv. 2017:90:E90-E110

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TABLE 2.1 Intermittent Claudication; No Prior Guideline-Directed Medical Therapy

Indications	AUC Score: Initiate Medical Therapy	Endovascular Treatment	Surgical Treatment
14. ■ Any lower extremity disease	A (9)	R (2)	R (1)

A = Appropriate; AUC = Appropriate Use Criteria; R = Rarely Appropriate.

TABLE 2.2 Intermittent Claudication Despite Guideline-Directed Medical Therapy—Stenotic Lesions

Indications	AUC Score: Continue or Intensify Medical Therapy	Endovascular Treatment	Surgical Treatment
15. ■ Aortoiliac	A (9)	A (8)	M (4)
16. ■ SFA and popliteal artery	A (9)	A (7)	M (6)
17. ■ Below the knee	A (9)	M (5)	R (3)

A = Appropriate; AUC = Appropriate Use Criteria; M = May Be Appropriate; R = Rarely Appropriate; SFA = superficial femoral artery.

TABLE 2.3 Intermittent Claudication Despite Guideline-Directed Medical Therapy—Chronic Total Occlusion

Indications	AUC Score: Continue or Intensify Medical Therapy	Endovascular Treatment	Surgical Treatment
18. ■ Aortoiliac	A (9)	A (7)	M (6)
19. ■ SFA and popliteal artery	A (9)	M (6)	M (6)
20. ■ Below the knee	A (9)	M (4)	R (3)

A = Appropriate; AUC = Appropriate Use Criteria; M = May Be Appropriate; R = Rarely Appropriate; SFA = superficial femoral artery.

Appropriate Use Criteria

- Intermittent Claudication
  - Ao-Iliac
  - Fem-Pop Stenosis
  - Fem-Pop Occlusion
- Favor Endo-first over Surgery

Bailey SR, et.al. J Am Coll Cardiol 2019;73:214-37.

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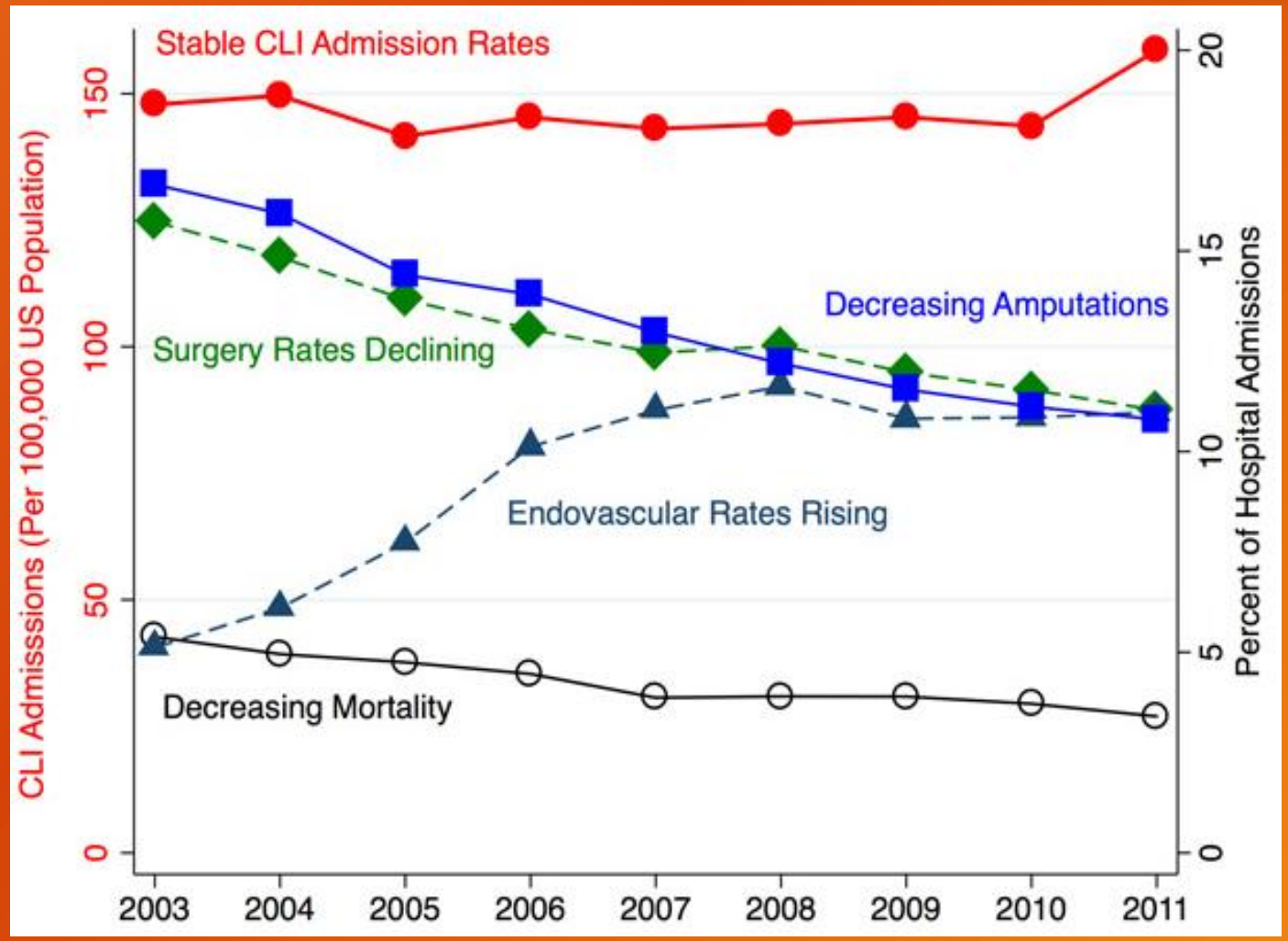
CLI: US Trends



Agarwal S, et.al. J Am Coll Cardiol 2016;68:2002-15 .

- In 2019, an Endo-First strategy for PAD revascularization is safe and effective when compared to Open Surgery.

Thank You

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