2013 TCTAP

Wrap-Up Interview

Femoropopliteal Lesions

Moderator
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Interviewees
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Issues Briefs

Atherectomy Controversy

- Clinical studies: DEFINITE LE...
- Discussion: for whom, which device

Drug-eluting Balloon

- Clinical studies: THUNDER, FemPac, LEVANT I, PACIFIER, DEBATE-SFA
- Discussion: TASC C or D, Future perspective (ISR lesions..)

Drug-eluting Stent

- Clinical studies: ZILVER-PTX trial and registry
- Discussion: TASC C or D, Future perspective (ISR lesions..)

STOP ISR

- Clinical studies: STOP-IC trial
- Discussion: How long, To whom ?

Periprocedural Outcomes

Outcomes	Claudication (RCC 1-3)	CLI (RCC 4-6)	All subjects (RCC 1-6)
Device success (≤ 30% stenosis after plaque excision)	76%	72%	75%
Procedural success (≤ 30% stenosis at the end of procedure)	91%	83%	89%

Key Etudy Endpoints

Claudicants	Primary endpopint: Primary patency at 12 months (PSVR≤ 3.5)		Secondary endpoint: secondary patency at 12 months (PSVR≤ 2.4)	
	Patency	LL (cm)	Patency	LL (cm)
All (n=743)	82%	7.4	78%	7.4
Diabetic (n=345)	80%	7.6	77%	7.6
Non-diabetic (n=398)	83%	7.4	78%	7.4

CLI	Primary endpoint: freedom from major unplanned amputation of the target limb at 12 months
All (n=201)	95%

Primary Patency in subgroup

Subgroup	Claudicants (n=743)		CLC (n=279)	
	Patency (PSVR≤2.4)	Lesion length (cm)	Patency (PSVR≤2.4)	Lesion length (cm)
All (n=1022)	78%	7.5	71%	7.2
Lesion type				
Stenosis (n=806)	81%	6.7	73%	5.8
Occlusion (n=211)	64%	11.1	66%	10.3
Lesion location				
SFA (n=671)	75%	8.1	68%	8.6
Popliteal (n=162)	77%	6.0	68%	5.4
Infrapopliteal (n=189)	90%	5.5	78%	6.0

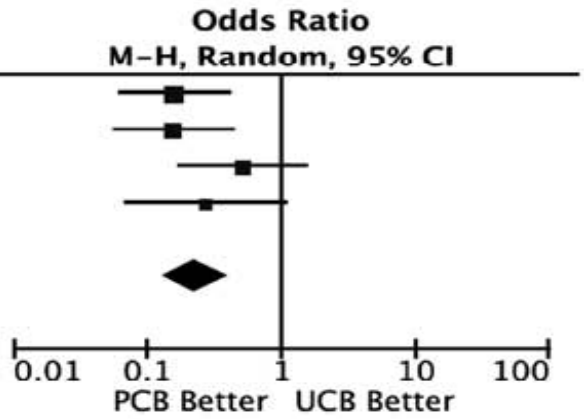
DEB for de novo lesion

Meta-analysis

A Target lesion revascularization

Study or Subgroup	PCB Events	PCB Total	UCB Events	UCB Total	Weight	Odds Ratio M-H, Random, 95% CI	Year
THUNDER	7	48	28	54	32.1%	0.16 [0.06, 0.42]	2008
FemPac	6	45	21	42	27.3%	0.15 [0.05, 0.44]	2008
LEVANT I	6	47	10	45	24.7%	0.51 [0.17, 1.55]	2010
PACIFIER	3	40	9	39	16.0%	0.27 [0.07, 1.09]	2011
Total (95% CI)		**180**		**180**	**100.0%**	**0.23 [0.13, 0.40]**	
Total events	22		68				

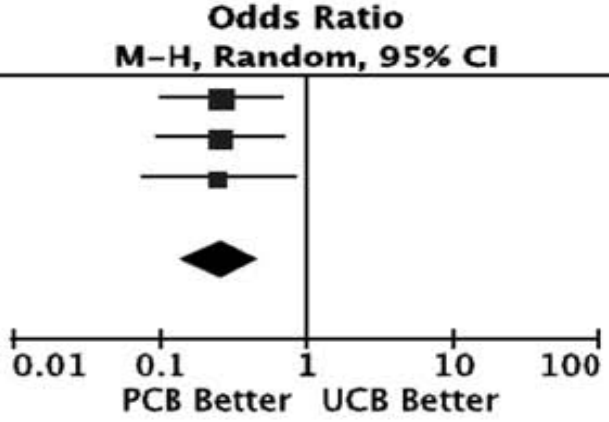
Heterogeneity: $Tau^2 = 0.02$; $Chi^2 = 3.19$, df = 3 (P = 0.36); $I^2 = 6\%$
Test for overall effect: Z = 5.09 (P < 0.00001)
$Heterogeneity_{(exact)}$: $Chi^2 = 3.26$, df = 3 (P = 0.35)
$Test\ for\ overall\ effect_{(exact)}$: P < 0.00001



A Binary restenosis

Study or Subgroup	PCB Events	PCB Total	UCB Events	UCB Total	Weight	Odds Ratio M-H, Random, 95% CI
THUNDER	7	41	21	48	38.8%	0.26 [0.10, 0.71]
FemPac	10	31	22	34	36.1%	0.26 [0.09, 0.73]
PACIFIER	4	40	12	39	25.1%	0.25 [0.07, 0.86]
Total (95% CI)		**112**		**121**	**100.0%**	**0.26 [0.14, 0.48]**
Total events	21		55			

Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 0.01$, df = 2 (P = 1.00); $I^2 = 0\%$
Test for overall effect: Z = 4.27 (P < 0.0001)
$Heterogeneity_{(exact)}$: $Chi^2 = 0.004$, df = 2 (P = 0.99)
$Test\ for\ overall\ effect_{(exact)}$: P < 0.00001



Circ Cardiovasc Interv. 2012;5:582-589

DEB for de novo lesion

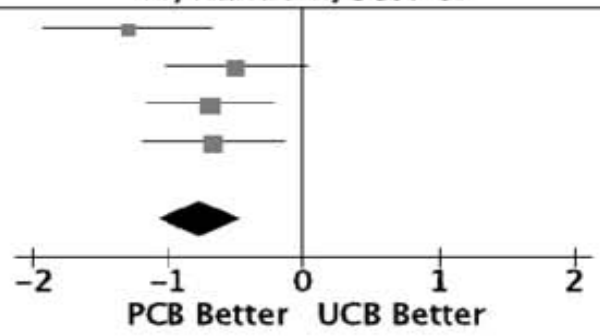
Meta-analysis

B Late lumen loss

Study or Subgroup	PCB Mean	PCB SD	PCB Total	UCB Mean	UCB SD	UCB Total	Weight	Mean Difference IV, Random, 95% CI
THUNDER	0.4	1.2	41	1.7	1.8	48	19.6%	−1.30 [−1.93, −0.67]
FemPac	0.5	1.1	31	1	1.1	34	25.2%	−0.50 [−1.04, 0.04]
LEVANT I	0.4	1.1	39	1.09	1	35	29.7%	−0.69 [−1.17, −0.21]
PACIFIER	−0.05	1.1	40	0.61	1.3	39	25.5%	−0.66 [−1.19, −0.13]
Total (95% CI)			**151**			**156**	**100.0%**	**−0.75 [−1.06, −0.45]**

Heterogeneity: $Tau^2 = 0.02$; $Chi^2 = 3.95$, df = 3 (P = 0.27); $I^2 = 24\%$

Test for overall effect: Z = 4.78 (P < 0.00001)



C Death

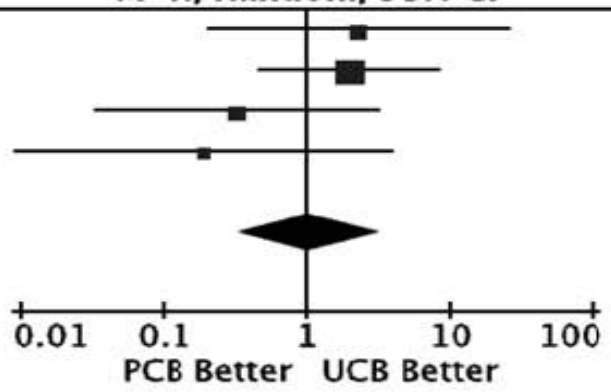
Study or Subgroup	PCB Events	PCB Total	UCB Events	UCB Total	Weight	Odds Ratio M-H, Random, 95% CI
THUNDER	2	48	1	54	19.4%	2.30 [0.20, 26.25]
FemPac	6	45	3	42	46.6%	2.00 [0.47, 8.57]
LEVANT I	1	48	3	49	21.5%	0.33 [0.03, 3.25]
PACIFIER	0	41	2	41	12.6%	0.19 [0.01, 4.09]
Total (95% CI)		**182**		**186**	**100.0%**	**1.04 [0.34, 3.18]**
Total events	9		9			

Heterogeneity: $Tau^2 = 0.15$; $Chi^2 = 3.37$, df = 3 (P = 0.34); $I^2 = 11\%$

Test for overall effect: Z = 0.06 (P = 0.95)

Heterogeneity$_{(exact)}$: $Chi^2 = 4.37$, df = 3 (P = 0.22)

Test for overall effect$_{(exact)}$: P = 0.98



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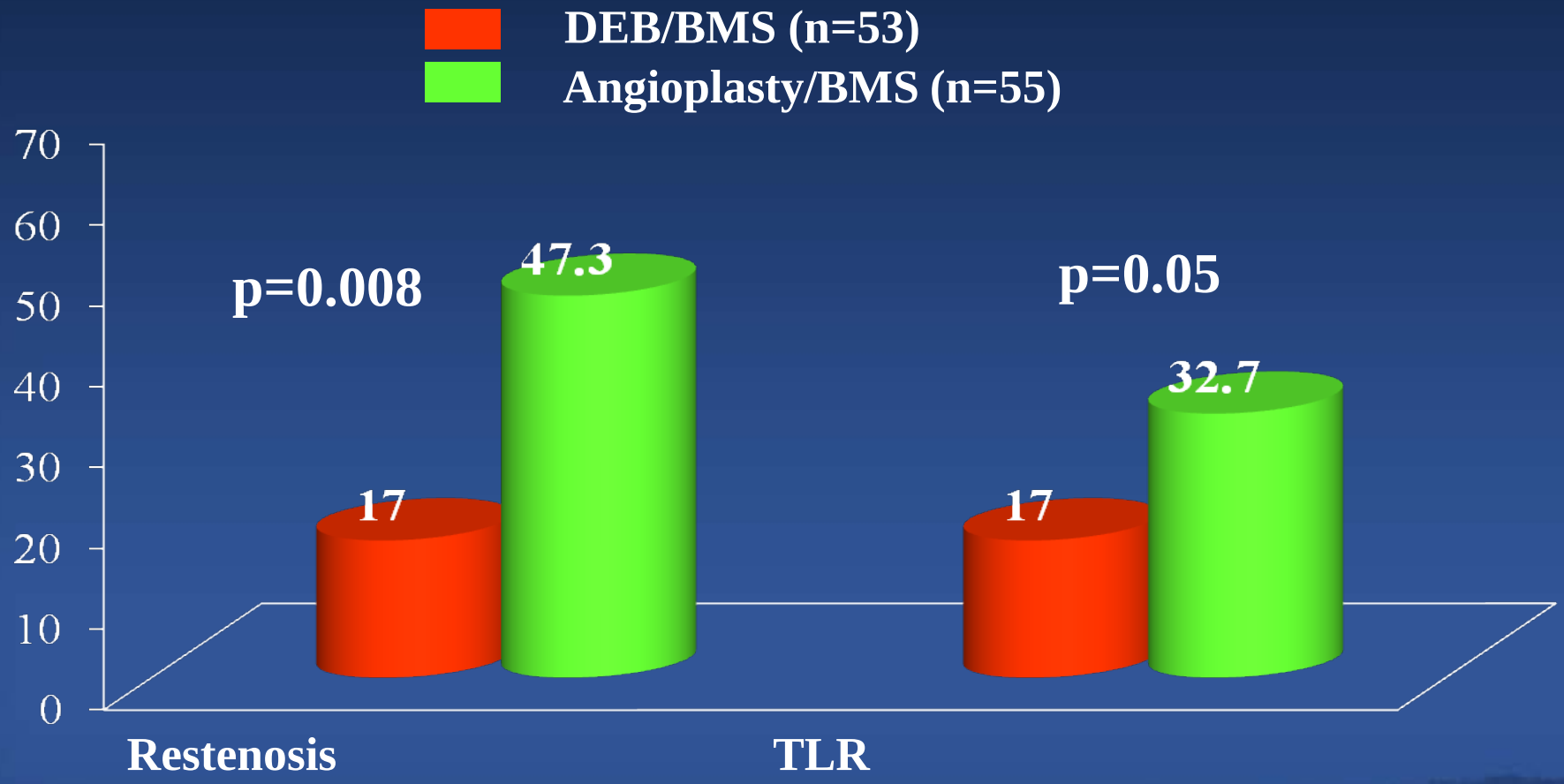
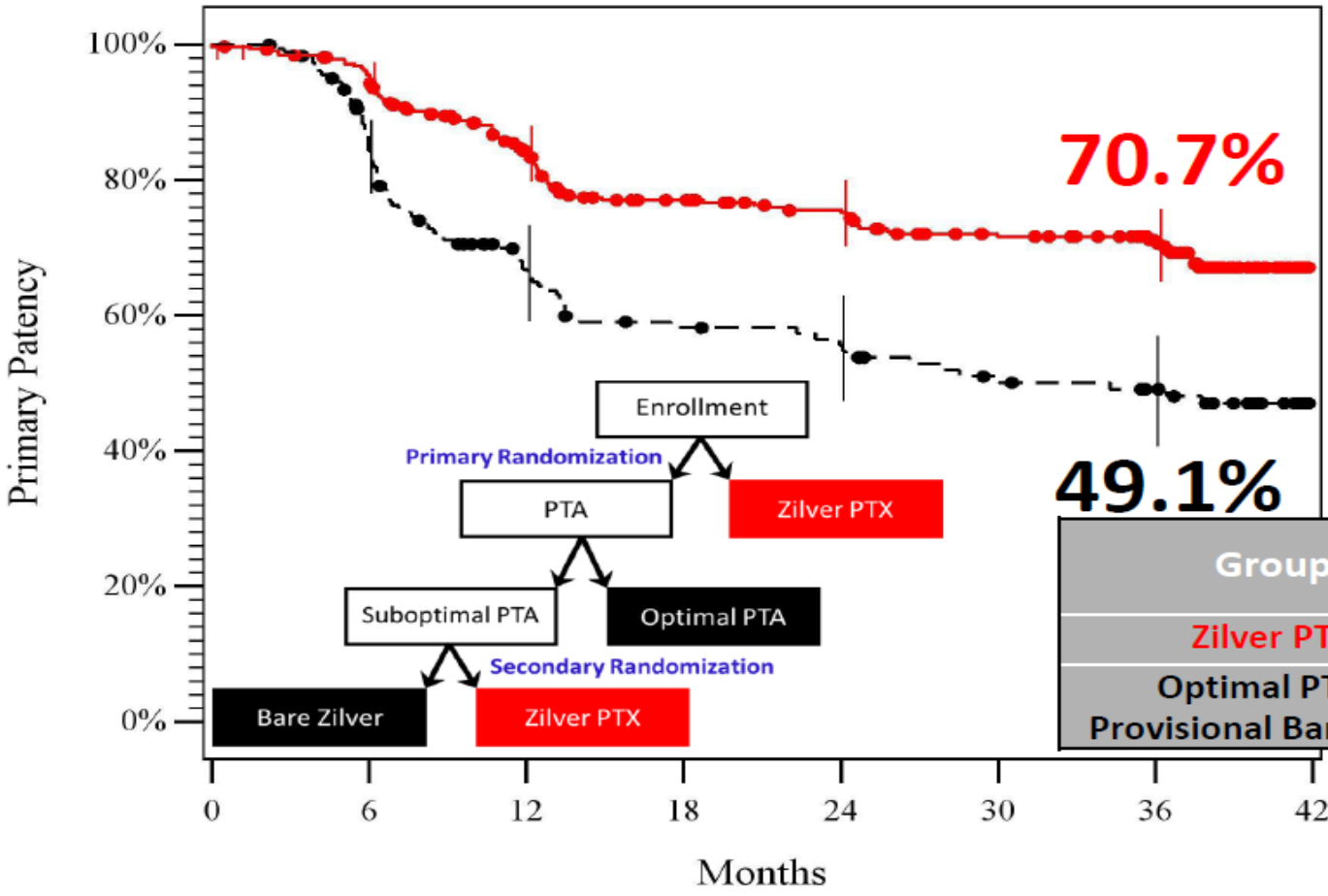
DEBATE SFA trial

1-YEAR OUTCOMES



3-Year Primary Patency (PSVR < 2.0)
Zilver PTX vs. Standard Care



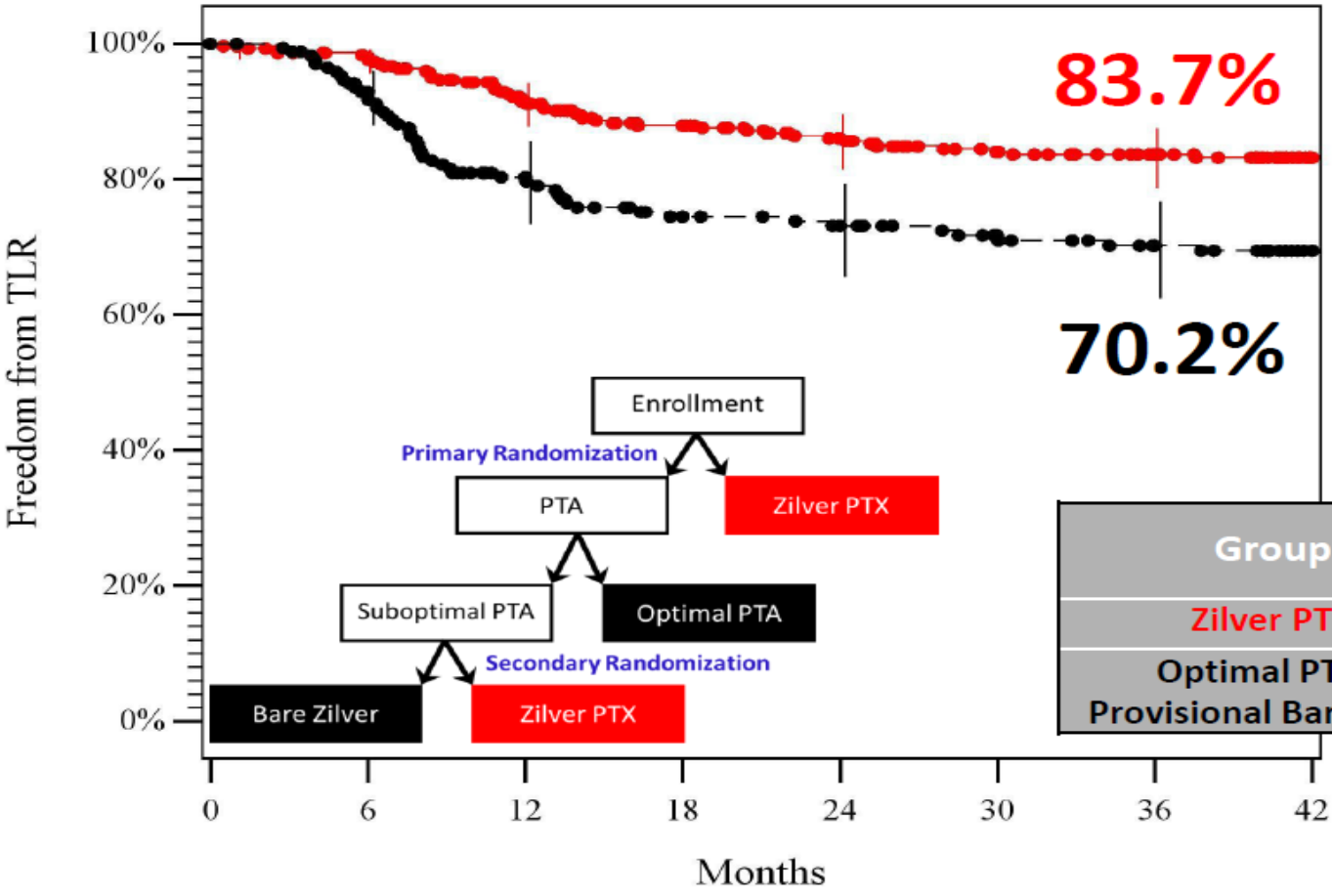
Zilver PTX
234 lesions

Optimal PTA
+ Bare Zilver
130 lesions

$p < 0.01$
log-rank

Group	3-year Restenosis	
	Rate	Reduction
Zilver PTX	29.3%	42%
Optimal PTA + Provisional Bare Zilver	50.9%	

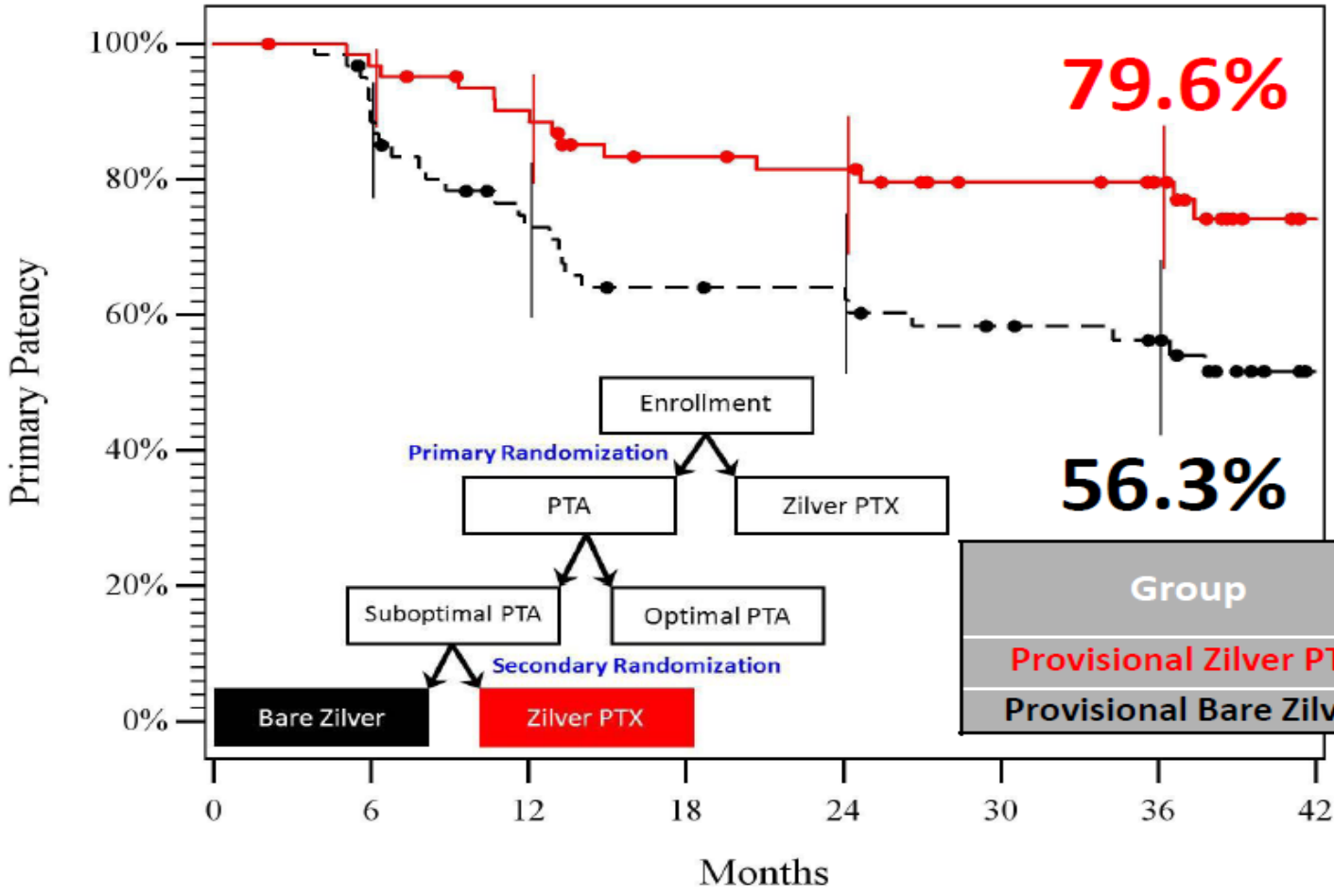
3-Year Freedom from TLR
Zilver PTX vs. Standard Care



Group	3-year TLR	
	Rate	Reduction
Zilver PTX	16.3%	45%
Optimal PTA + Provisional Bare Zilver	29.8%	

3-Year Paclitaxel Effect

Patency (PSVR < 2.0): **Provisional Zilver PTX vs. BMS**

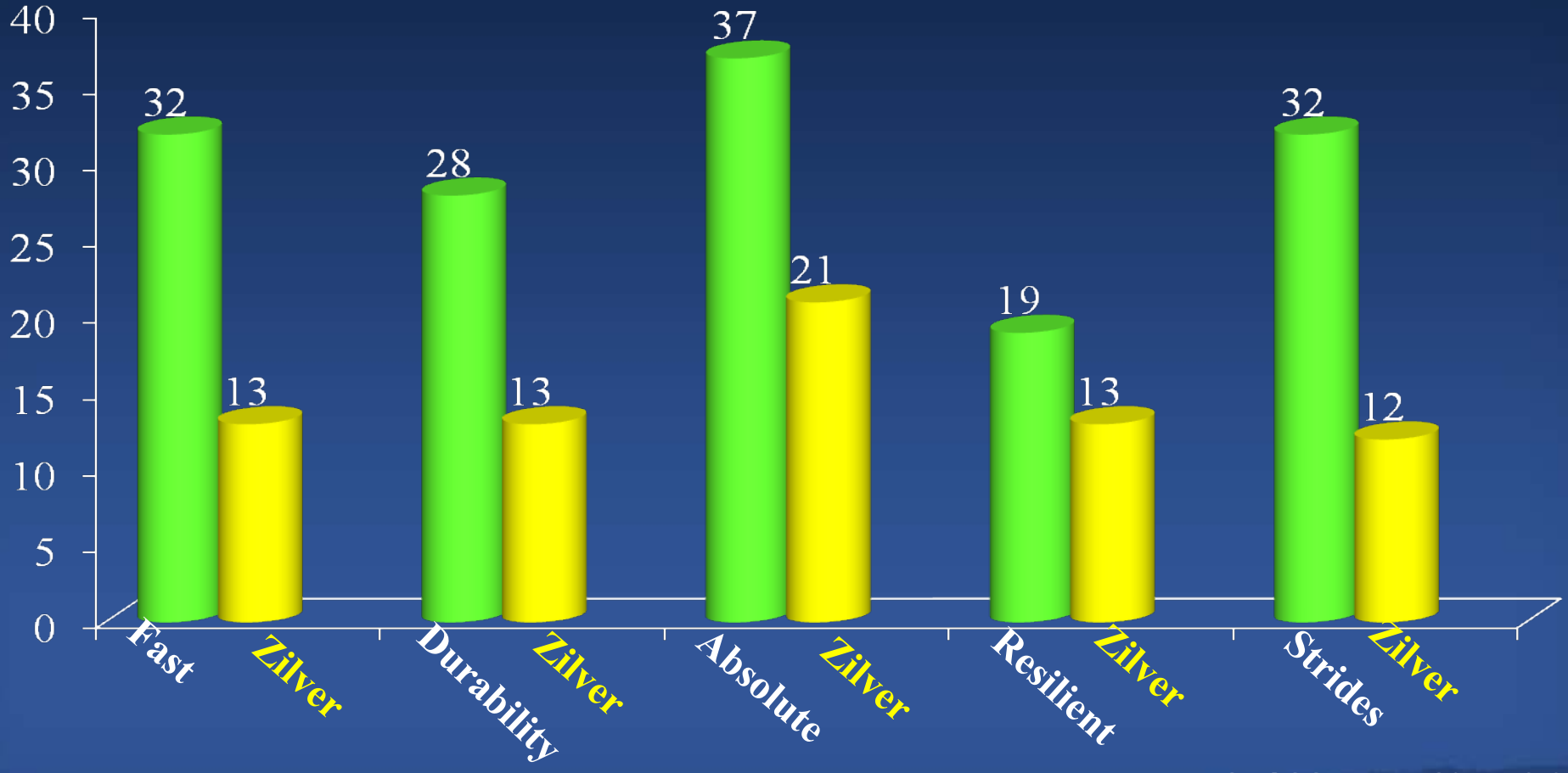


Group	3-year Restenosis	
	Rate	Reduction
Provisional Zilver PTX	20.4%	53%
Provisional Bare Zilver	43.7%	

Zilver PTX for de novo lesion

Matching comparison with other stent trials

12 months restenosis



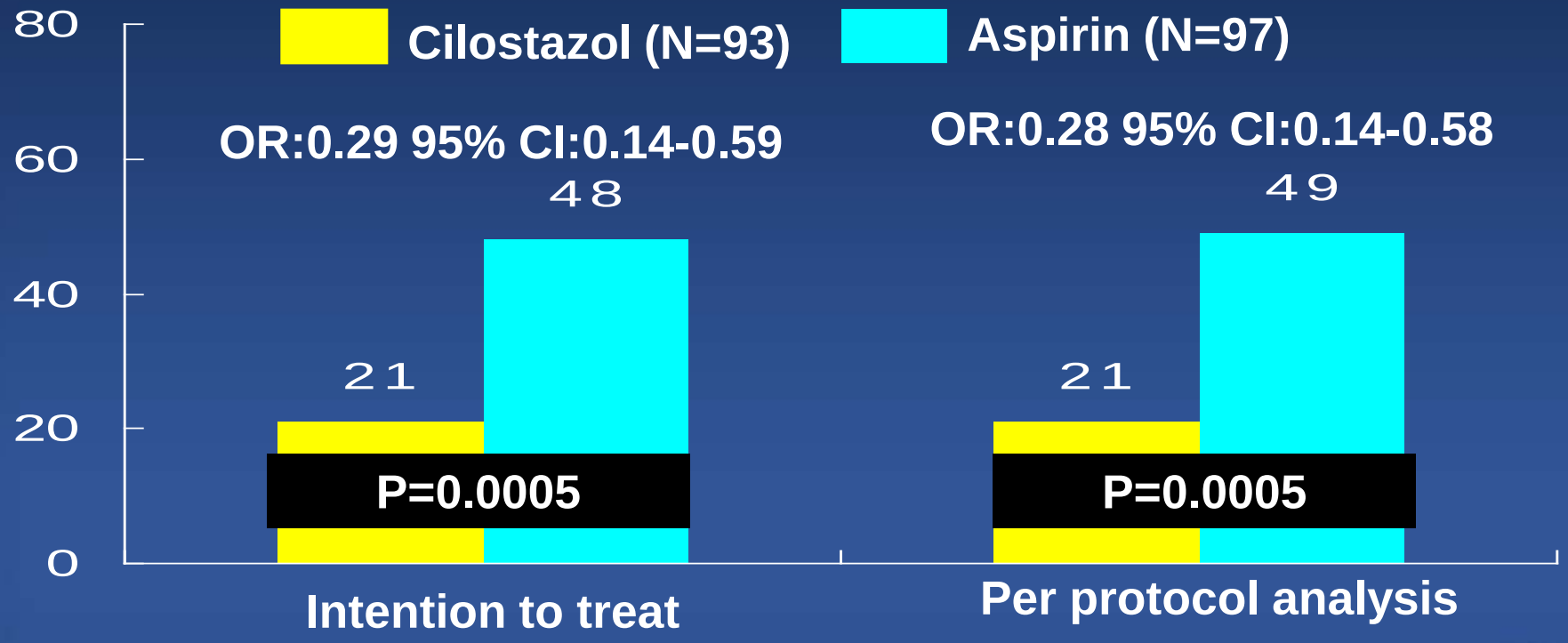
J ENDOVASC THER 2011;18:613–623

STOP-IC

Aspirin vs. Aspirin/Cilostazol for 1 year after stenting

- 190 patients randomization
- All patients received aspirin ticlopidine for 1 month

12 Months angiographic restenosis



TCT 2012

Discussion

- **Most Optimal Strategy for SFA**
  - Atherectomy, DEB, DES, or DEB with BMS
- **Post-stenting Maintenance**
  - Cilostazol
  - Others?