ACTIVE Study with CoCr Balloon Expandable Stent What advantages over Standard Self-Expandable Stent?

William A. Gray MD
Director of Endovascular Services
Associate Professor of Clinical Medicine
Columbia University Medical Center
The Cardiovascular Research Foundation

CARDIOVASCULAR RESEARCH FOUNDATION

COLUMBIA UNIVERSITY MEDICAL CENTER

Iliac Stent Clinical Evidence
Balloon expandable: MELODIE trial

- 151 patients/163 lesions treated with the EXPRESS LD stent
- Angiographic characteristics
  - TASC A/B: 84%
  - Lesion length: 3.2 cm
  - CIA 41%/EIA 52%
  - RVD: 7.9 mm
- 12 month TLR: 10.9%

Stockx L et al. J Endovasc Ther. 2010;17:633–641

Iliac Stent Clinical Evidence
Self expandable: CRISP-US trial

- 203 patients/lesion randomized to either the SMART stent or the Wallstent
- 12m primary patency:
  - 94.7% Smart vs. 91.1% Wallstent

Ponec D. J Vasc Interv Radiol. 2004 Sep;15(9):911-8.

COMPLETE SE Iliac Registry

Medtronic Complete SE Iliac Registry

Prospective, multi-center, non-randomized IDE Study to evaluate the safety and efficacy of the Complete SE Stent for Iliac indications

PI	William A. Gray (NY) Robert Molnar (MI)
# patients/ # sites	55 pts/10 US sites
Subject Population	Claudicants / rest pain
Primary EP	9m Primary Patency 30d and 9m MAE
Key Secondary EP	Acute Success (Device, lesion procedure); Clinical Success; ABI, Walking capacity

Key Inclusion criteria

- De novo or restenotic in the common or external Iliac
- Target lesion stenosis ≥50%
- Target vessel reference diameter ≥4.5mm and ≤9.5mm
- Lesion length ≤110mm

Key Exclusion criteria

- Presence of thrombus
- Heavily calcified or tortuous vessel
- Rutheford Class 5 or 6
- Previous stent in lesion or lesion within bypass graft
- Known allergy/contraindication to: Aspirin, Ticlopidine, Clopidogrel, Nickel titanium or sensitivity to contrast media

COMPLETE SE Iliac Registry

Baseline Characteristics

Patient (Baseline)	*N=55*
Age (mean ± SD)	66 ± 12 y
Male	60.0%
Diabetes mellitus	32.7%
Dyslipidemia	85.5%
Hypertension	90.9%
Smoking (past year)	85.5%
History of CAD	70.4%
Previous MI	42.4%
Previous PAD (other than iliac)	74.1%
Previous PTA/stent to target limb	16.4%

Lesions location	*N=61*
Right	57.4%
Common / External iliac	26.6% / 31.1%
Left	42.6%
Common / External iliac	14.8% / 27.9%

Lesions (Baseline)	*N=61*
RVD (mm)	7.0 ± 1.1
Mean lesion length (mm)	40.3 ± 23.5
% Stenosis (most severe)	72.4 ± 14.6
MLD (mm)	1.9 ± 1.0

CARDIOVASCULAR RESEARCH FOUNDATION

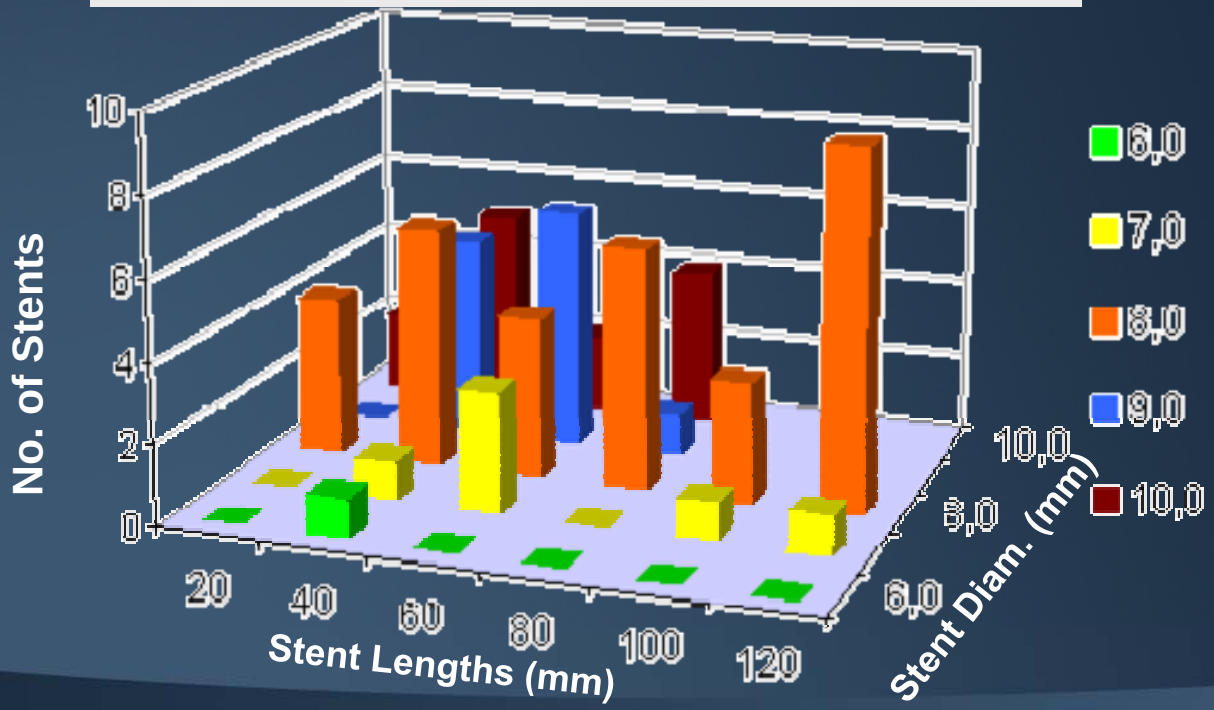
COLUMBIA UNIVERSITY MEDICAL CENTER

COMPLETE SE Iliac Registry

Procedural Characteristics

Lesions (Procedural) N=61	
Direct Stenting	31.1%
Post Proc. Diameter Stenosis (% ± SD)	17.9 ± 7.1
Post Procedure MLD (mm ± SD)	5.8 ± 1.1

Stent Mix



CARDIOVASCULAR RESEARCH FOUNDATION

COLUMBIA UNIVERSITY MEDICAL CENTER

COMPLETE SE Iliac Registry

Clinical Outcome to 9 months

Primary Endpoint

9-m MAE	**5.9%**
Device/procedure deaths	0.0%
Target limb loss	0.0%
TLR	3.9%
TVR	5.9%

Secondary Endpoints

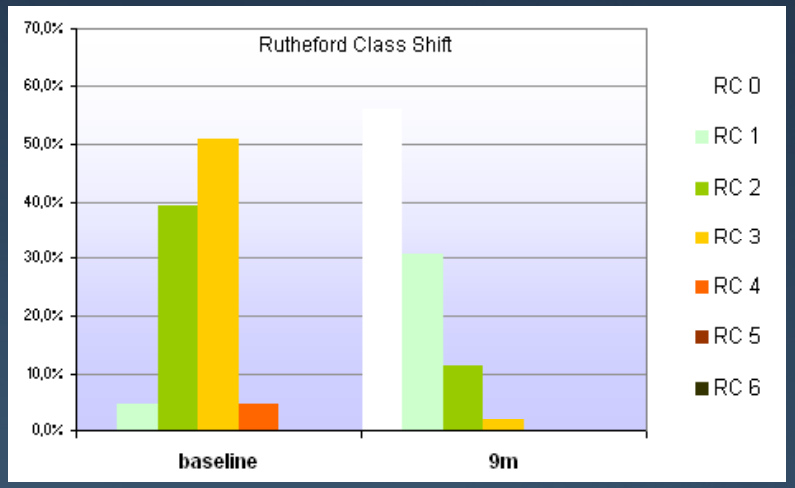
Primary patency rate [1]	100.0% (53/53)
Device success [2]	93.4% (57/61)
Lesion success [3]	96.7% (59/61)
Procedural success [4]	96.4% (53/55)
Clinical success [5]	88.5% (46/52)
All cause mortality [6]	3.64% (2/55)
Hemodynamic Success [7]	94.3% (50/53)

1. Primary patency is defined as Duplex ultrasound derived restenosis independent of any interval revascularization procedure
2. Device success defined as angiographic evidence of <30% final residual stenosis of the target lesion using only the assigned device
3. Lesion success defined as angiographic evidence of <30% final residual stenosis of the target lesion using any percutaneous method
4. Procedure success defined as angiographic evidence of <30% final residual stenosis of the target lesion after stent placement and no occurrence of a procedure-related MAE prior to hospital discharge (for subjects with more than one lesion stented the worse case is counted)
5. Clinical success is defined as an improvement on the Rutherford scale by ≥ 1 category between pre-procedure (Baseline) and the scheduled follow-up visits
6. one death on day 56 post-proc. for septic shock, one death on day 184 post-proc. from cancer. Both deaths unrelated to the procedure by CEC verdict
7. Hemodynamic success is defined as an improvement in Ankle-brachial Index (ABI) or Toe-brachial Index (TBI) >0.10 over pre-procedure level OR deterioration by ≤ 0.15 from first post-procedure exam OR pulse volume recording (PVR) distal to the target lesion treated maintained at ≥ 5 mm above pre-procedure tracing for those subjects with no pre-procedure ABI/TBI

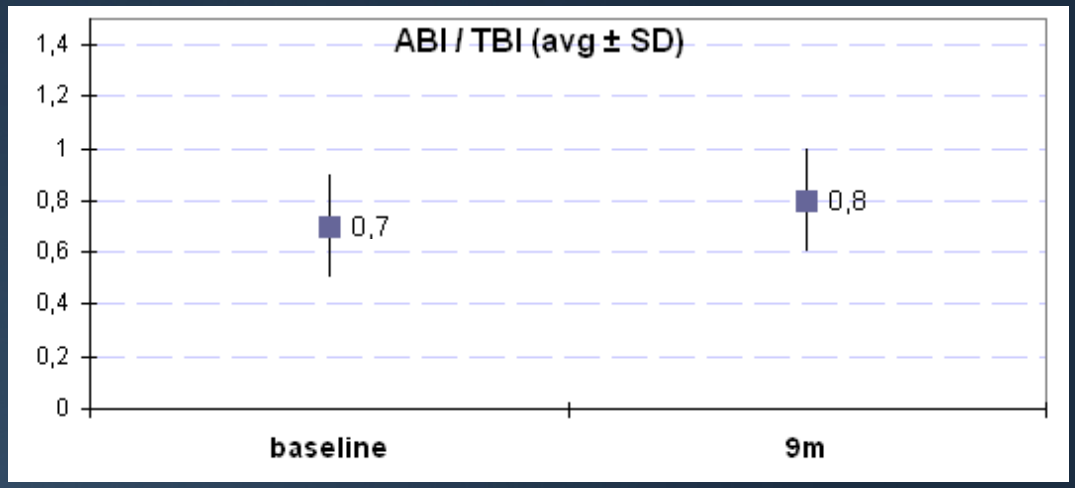
COMPLETE SE Iliac Registry

Clinical Outcome to 9 months

Rutherford Class



ABI / TBI



Walking Capacity

Walking assessment, (%)*	Baseline	9 months	P value (baseline vs 9-m)
Walking impairment	38.2 ± 34.0 (55)	77.0 ± 31.8 (49)	<0.0001
Walking distance	17.4 ± 23.5 (55)	49.3 ± 39.4 (49)	<0.0001
Walking speed	22.6 ± 26.7 (55)	42.4 ± 34.3 (49)	0.0013
Stair climbing	24.9 ± 26.9 (55)	49.5 ± 39.4 (49))	0.0003

*All values are mean ± SD (n)

The walking impairment questionnaire (WIQ) scores range from 0% (unable to perform due to severe claudication) to 100% (no impairment).

Complete SE Iliac registry: Summary

- Complete SE Iliac registry confirms the applicability, safety and efficacy of the Complete SE Stent for iliac indication
- High acute success was associated with low TLR rates at 9-month and durable improvements in clinical status, walking capacity and ABI

Iliac Stent Clinical Evidence
Balloon expandable: ACTIVE trial

Prospective, multi-center, non-randomized IDE Study to evaluate the safety and efficacy of the Assurant Cobalt Iliac BE Stent

PI	William A. Gray (NY) Robert Molnar (MI)
# patients / # sites	123 pts / 17 US sites
Subject Population	Claudicants / rest pain
Primary EP	9m MAE
Key Secondary EP	9m primary Patency; Acute Success (Device, lesion procedure); Clinical Success; ABI, Walking capacity

CARDIOVASCULAR RESEARCH FOUNDATION

Molnar R, Gray W. In review.

COLUMBIA UNIVERSITY MEDICAL CENTER

ACTIVE Trial

Baseline Chracteristics

Patient (Baseline)	*N=123*
Age (mean ± SD)	65.5±10.6 y
Male	56.1%
Diabetes mellitus	38.2%
Dyslipidemia	74.8%
Hypertension	82.9%
Smoking (past year)	50.4%
Smoking (currently)	42.3%
History of CAD	66.7%
Previous MI	26.5%
Previous PAD (other than iliac)	63.4%
Previous PTA/stent to target limb	8.1%

Lesions location	*N=159*
Right	52.8%
Common / External iliac	44.0% / 8.8%
Left	47.2%
Common / External iliac	36.5% / 10.7%

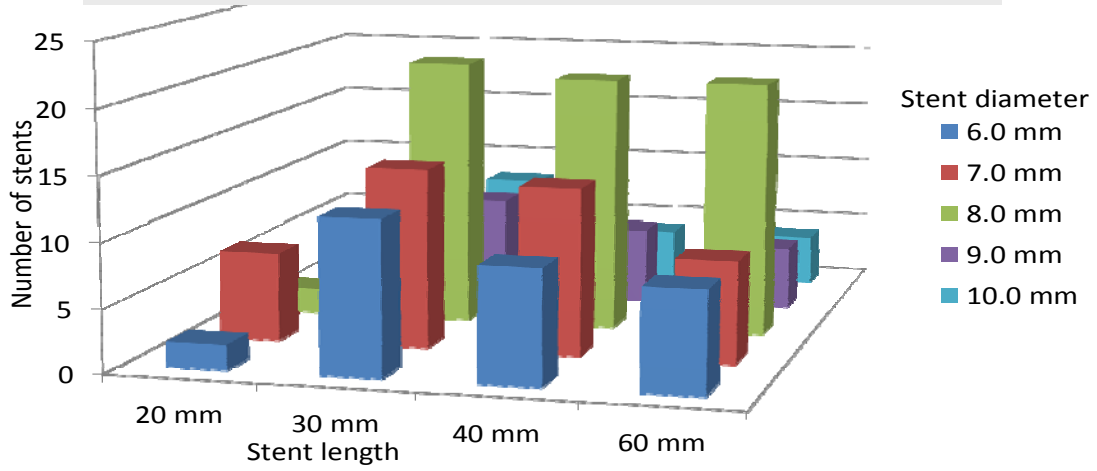
ACTIVE Trial

Procedural Characteristics

Lesions (Baseline) N=159	
RVD (mm)	7.62 ± 1.18
Mean lesion length (mm)	29.43 ± 14.66
% Stenosis (most severe)	68.74 ± 14.22
MLD (mm)	2.39 ± 1.17

Lesions (Procedural) N=159	
Direct Stenting	46.8%
Post Proc. Diameter Stenosis (% ± SD)	14.61 ± 6.99
Post Procedure MLD (mm ± SD)	6.58 ± 1.16

Stent Mix



CARDIOVASCULAR RESEARCH FOUNDATION

COLUMBIA UNIVERSITY MEDICAL CENTER

ACTIVE Trial

Clinical Outcome to 9 months

Primary Endpoint	
9-m MAE	**0.8%**
Death (device and proc. related)	0.0%
Target limb loss	0.0%
TLR	0.8%
TVR	0.8%

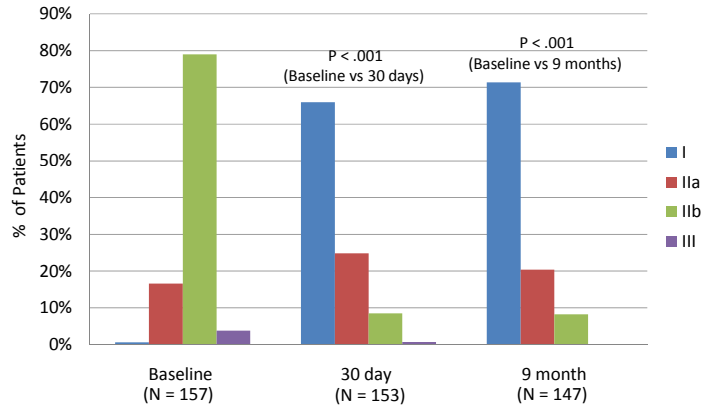
Secondary Endpoints	
Primary patency rate [1]	99.2% (140/141)
Device success [2]	97.5% (155/159)
Lesion success [3]	97.5% (155/159)
Procedural success [4]	96.7% (119/123)
Clinical success [5]	90.4% (132/146)
All cause mortality	0.0% (0/121)

1. Primary patency is defined as Duplex ultrasound derived restenosis independent of any interval revascularization procedure
2. Device success defined as angiographic evidence of <30% final residual stenosis of the target lesion using only the assigned device
3. Lesion success defined as angiographic evidence of <30% final residual stenosis of the target lesion using any percutaneous method
4. Procedure success defined as angiographic evidence of <30% final residual stenosis of the target lesion after stent placement and no occurrence of a procedure-related MAE prior to hospital discharge (for subjects with more than one lesion stented the worse case is counted)
5. Clinical success defined as the improvement of Fontaine classification by at least one stage above the pretreated (pre-procedure) clinical value

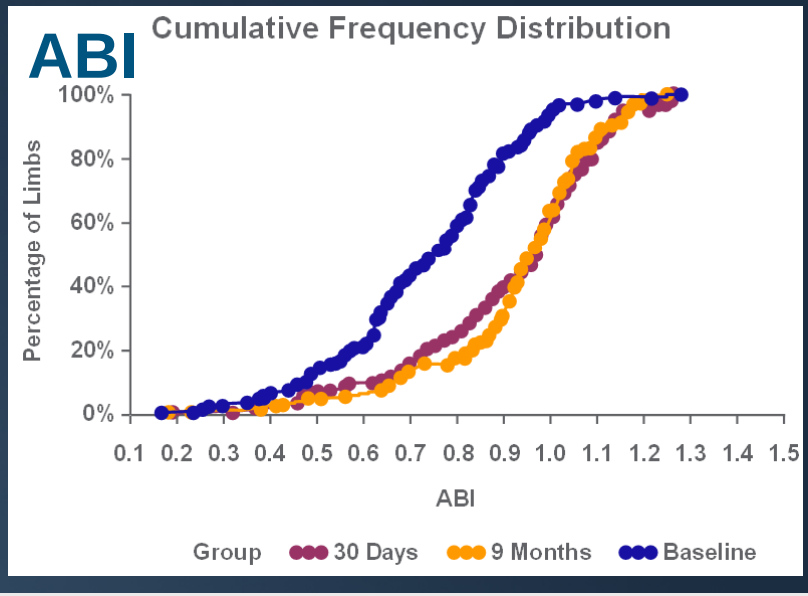
ACTIVE Trial

Clinical Outcome to 9 months

Fontaine Class



ABI



Walking Capacity

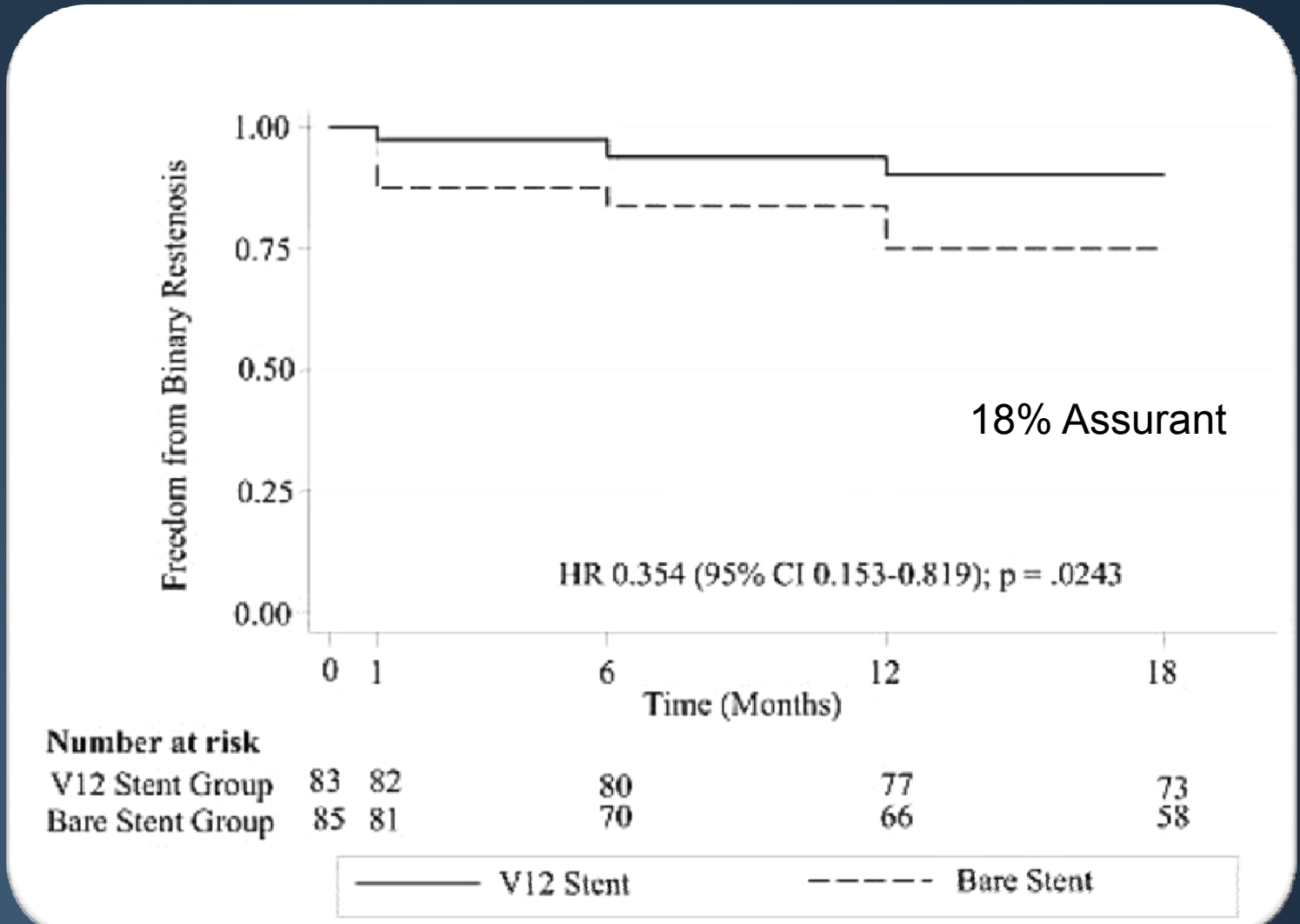
Walking assessment, (%)*	Baseline	30 days	P value (baseline vs 30-d)	9 months	P value (baseline vs 9-m)
Walking impairment	34.8 ± 28.6 (123)	76.0 ± 32.7 (121)	.001	75.5 ± 32.0 (111)	.001
Walking distance	22.9 ± 30.6 (123)	51.3 ± 40.1 (121)	.001	53.6 ± 39.8 (110)	.001
Walking speed	22.7 ± 29.2 (123)	42.2 ± 33.8 (119)	.001	45.6 ± 31.5 (109)	.001
Stair climbing	31.8 ± 33.9 (122)	56.2 ± 38.9 (120)	.001	61.7 ± 37.5 (111)	.001

*All values are mean ± SD (n)
The walking impairment questionnaire (WIQ) scores range from 0% (unable to perform due to severe claudication) to 100% (no impairment).

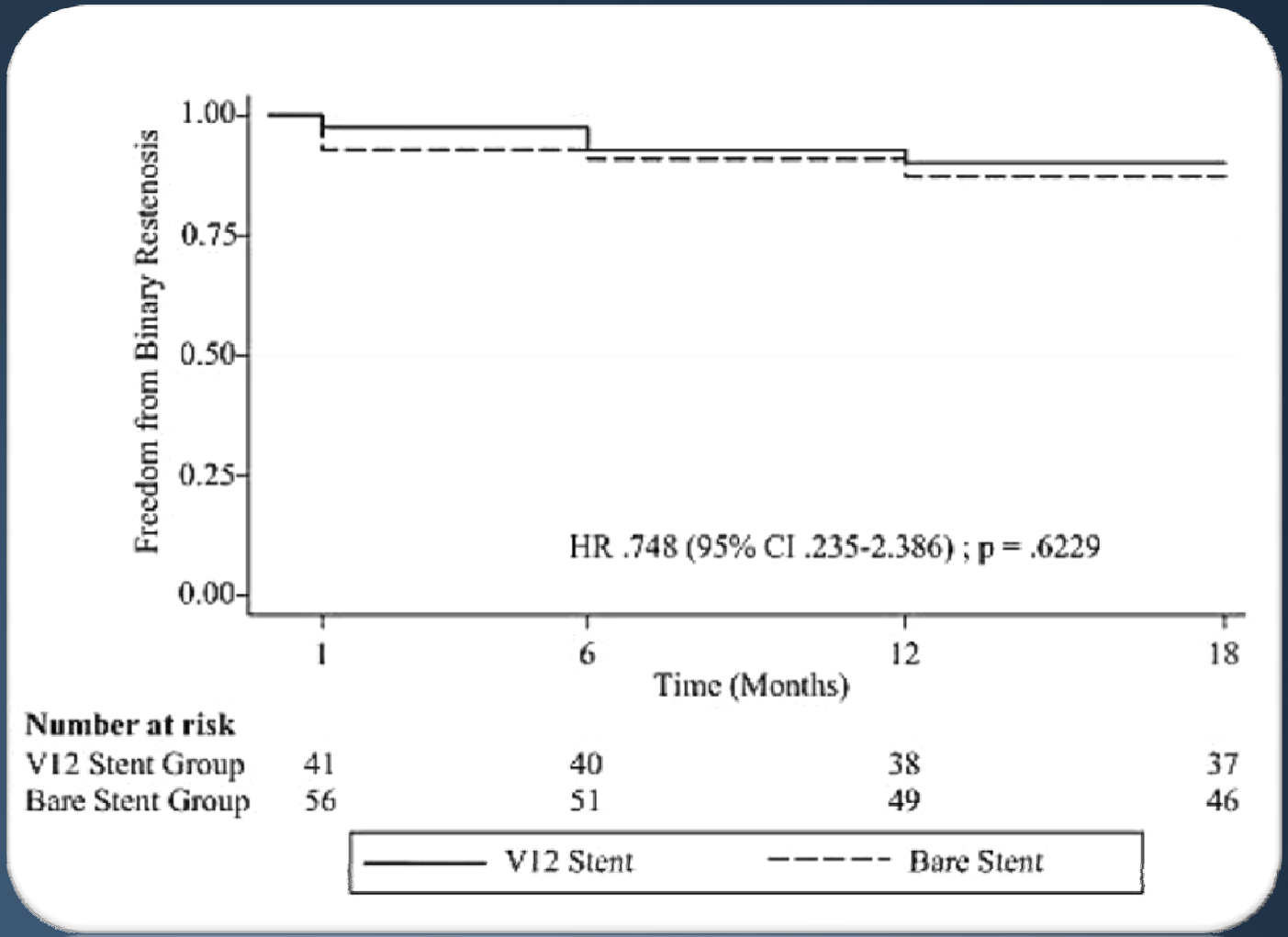
ACTIVE: Summary

- Assurant Iliac Stent demonstrated a remarkable safety profile associated with high technical, procedural, and clinical success and efficacy with >99.2 freedom from TLR at 9-months
- This translated into marked and durable improvements in clinical status, walking capacity and ABI
- ACTIVE results suggest a favorable outcome vs. historical benchmarks on iliac stenting

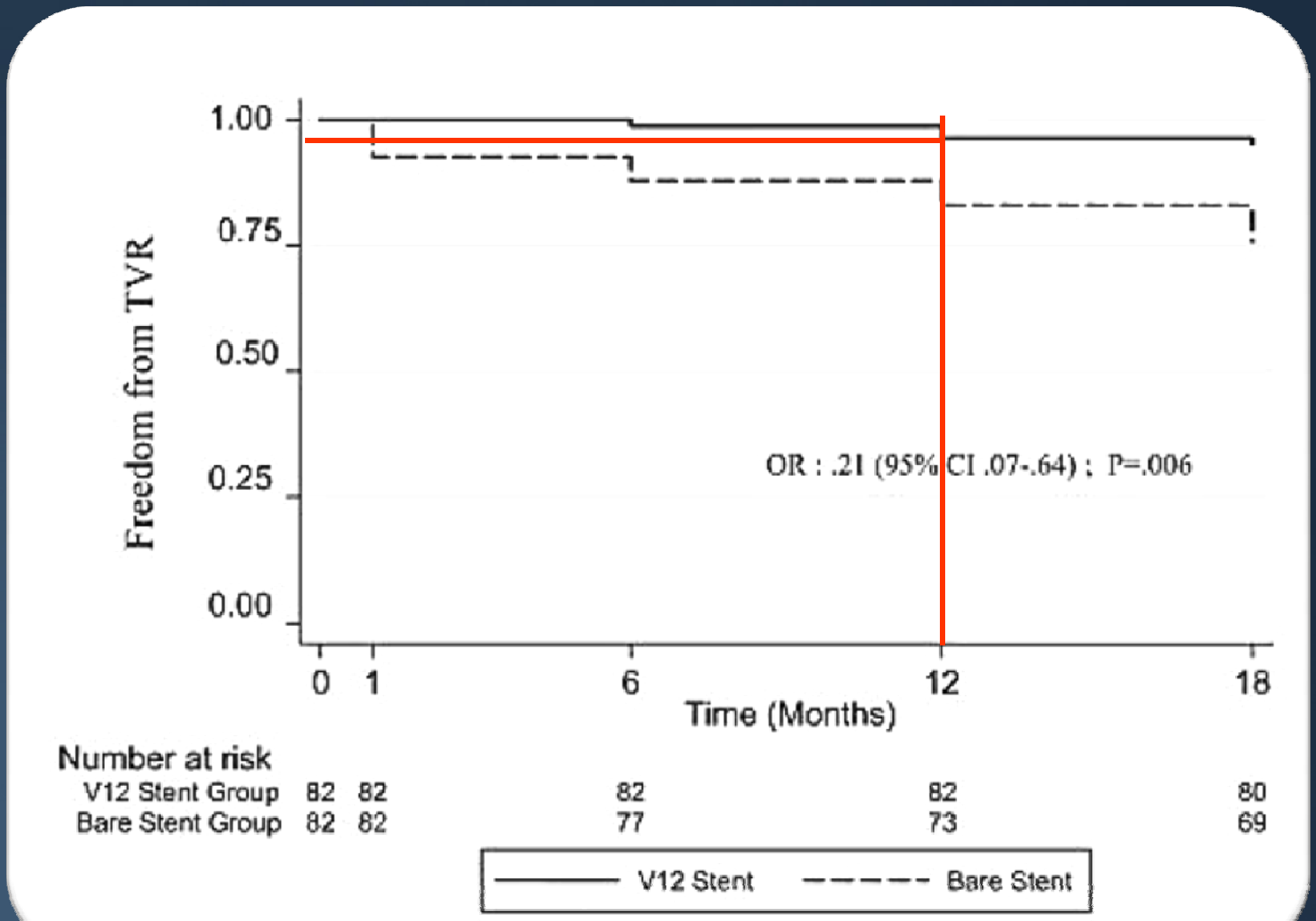
COBEST primary result



COBEST outcomes in TASC A/B lesions



COBEST TVR


1.00
0.75
0.50
0.25
0.00
Freedom from TVR
OR : .21 (95% CI .07-.64) ; P=.006
0
1
6
12
18
Time (Months)
Number at risk
V12 Stent Group 82 82 82 82 80
Bare Stent Group 82 82 77 73 69
V12 Stent
Bare Stent

Conclusion

- The Assurant Cobalt stent has demonstrated safety and durability profiles that extend the standards for iliac intervention outcomes
  - These results appear to compare favorably to the results of covered stent intervention
- Advantages of BE stent with robust clinical data include exact placement, radial force, deliverability and radio-opacity