Twelve-month results of an unrestricted use of bioresorbable vascular scaffolds in a real world coronary artery disease population: primary outcome of the prospective RAI registry

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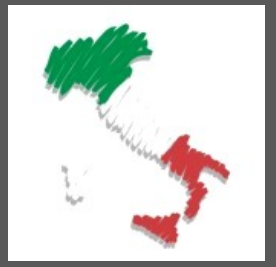
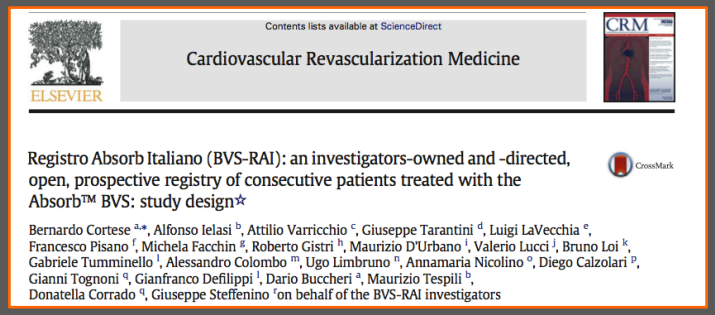
"Registro ABSORB Italiano"



- DESIGN: spontaneous, multicenter, prospective data collection on consecutive patients undergoing BVS implantation in Italy (June 2012-December 2015).

- OBJECTIVE: To evaluate the long-term safety and efficacy of Absorb BVS within an unrestricted cohort of patients undergoing PCI.



Contents lists available at ScienceDirect

Cardiovascular Revascularization Medicine

ELSEVIER

Registro Absorb Italiano (BVS-RAI): an investigators-owned and -directed, open, prospective registry of consecutive patients treated with the Absorb™ BVS: study design☆

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Cortese, Cardiovasc Revasc Med. 2015

RAI-centres

1. Cuneo Hospital: **G. Steffenino (PI)**
2. Fatebenefratelli Hospital, Milan: **B. Cortese**
3. Bolognini Hospital Seriate: **A. Ielasi**
4. Brotzu University Hospital Cagliari: **B. Loi**
5. Monaldi Hospital, Naples: **A. Varricchio**
6. Padua University Hospital: **G. Tarantini**
7. Parini Hospital, Aosta: **F. Pisano**
8. Asti Hospital: **G. Tumminello**
9. Second University Naples: **P. Calabrò**
10. Sacco Hospital, Milan: **A. Colombo**
11. Lodi Hospital: **P. Mazzarotto**
12. Este Hospital: **G.Pasquetto**
13. Grosseto Hospital: **U.Limbruno**
14. Riuniti Hospital Ancona: **G. Gabrielli**
15. Ascoli Hospital: **L. Moretti**
16. Palermo University Hospital: **D. Piraino**
17. Siena University Hospital: **M. Fineschi**
18. Valduce Hospital Como: **A. Durante**
19. Manzoni Hospital Lecco: **L.Piatti**
20. Pavia University Hospital: **M.Ferrario**
21. Belluno Hospital: **S.Coscarelli**
22. Treviso Hospital: **Z. Olivari**
23. S.Corona Hospital, Pietra Ligure: **A. Nicolino**
24. Ospedale S.Andrea Laspezia: **R. Gistri**
25. Ospedale di Avezzano: **V. Lucci**

study flow chart

Successful BVS implantation

Patient signs informed consent

Enrolment in the RAI Registry

6-month follow up through 5 years. Records of health status, clinical events and biochemistry

EuroPCR 2016

EuroPCR 2017

30dy | 6 m | 1 y | 2 y | 3 y | 4 y | 5 y

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Thirty-Day Outcomes After Unrestricted Implantation of Bioresorbable Vascular Scaffold (from the Prospective RAI Registry)

Bernardo Cortese, MD[a,b,*], Alfonso Ielasi, MD[c], Elisabetta Moscarella, MD[d], Bruno Loi, MD[e], Giuseppe Tarantini, MD, PhD[f], Francesco Pisano, MD[g], Alessandro Durante, MD[h], Giampaolo Pasquetto, MD[i], Alessandro Colombo, MD[j], Gabriele Tumminello, MD[k], Luciano Moretti, MD[l], Paolo Calabrò, MD, PhD[m], Pietro Mazzarotto, MD[n], Attilio Varricchio, MD, PhD[d], Maurizio Tespili, MD[c], Roberto A. Latini, MD[a], Gianfranco Defilippi, PhD[k], Donatella Corrado, PhD[c], and Giuseppe Steffenino, MD[p], on behalf of the RAI Investigators

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STUDY ENDPOINTS

Primary

- 12-month TLR
- SCAFFOLD THROMBOSIS (ARC definite, probable)

Secondary

- DOCE:
  - -cardiac death
  - -TLR
  - -TV nonfatal myocardial infarction

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STUDY ENDPOINTS

Exclusion criteria:

age >75 years

Enrolled patients: 1505

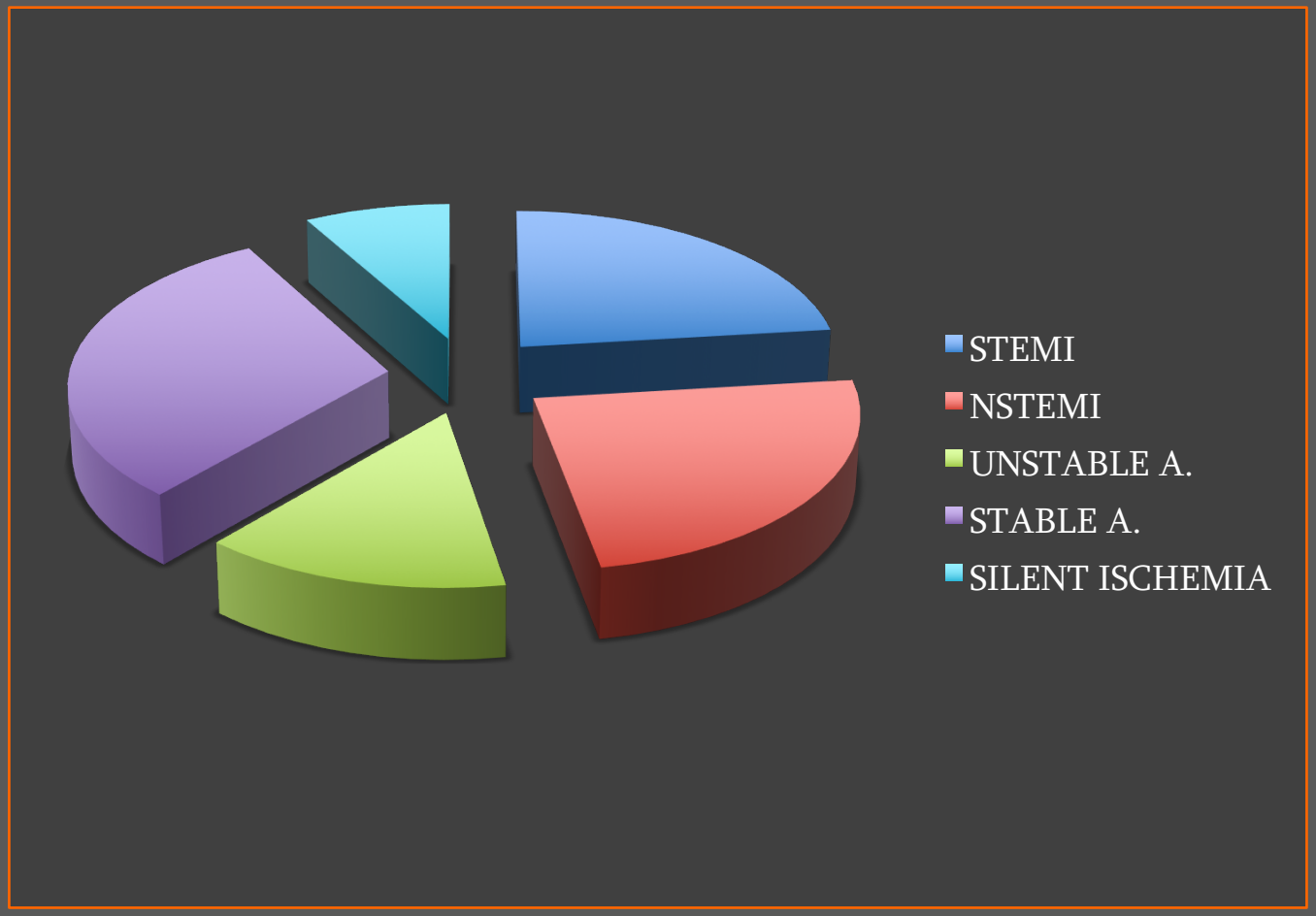
Available 12-mo data:

1445 (96%)

RAI STUDY-basal characteristics

Number of patients , n (%)	1505
Number of lesions, n (%)	1969
Age years, mean ± SD	59±10.4
Male gender, n (%)	1235 (82)
Arterial hypertension, n (%)	953 (63.3)
Diabetes mellitus, n (%)	337 (22.4)
Smoking history, n (%)	462 (30.7)
Previous MI, n (%)	423 (28.1)
Previous CABG, n (%)	46 (3.1)
LV Ejection Fraction, mean ± SD	54.2±8.9
eGFR (ml/min), mean ± SD	94.45±30.5
eGFR <60 ml/min, n (%)	142 (9.4)

RAI STUDY-clinical presentation



ACS = 61%

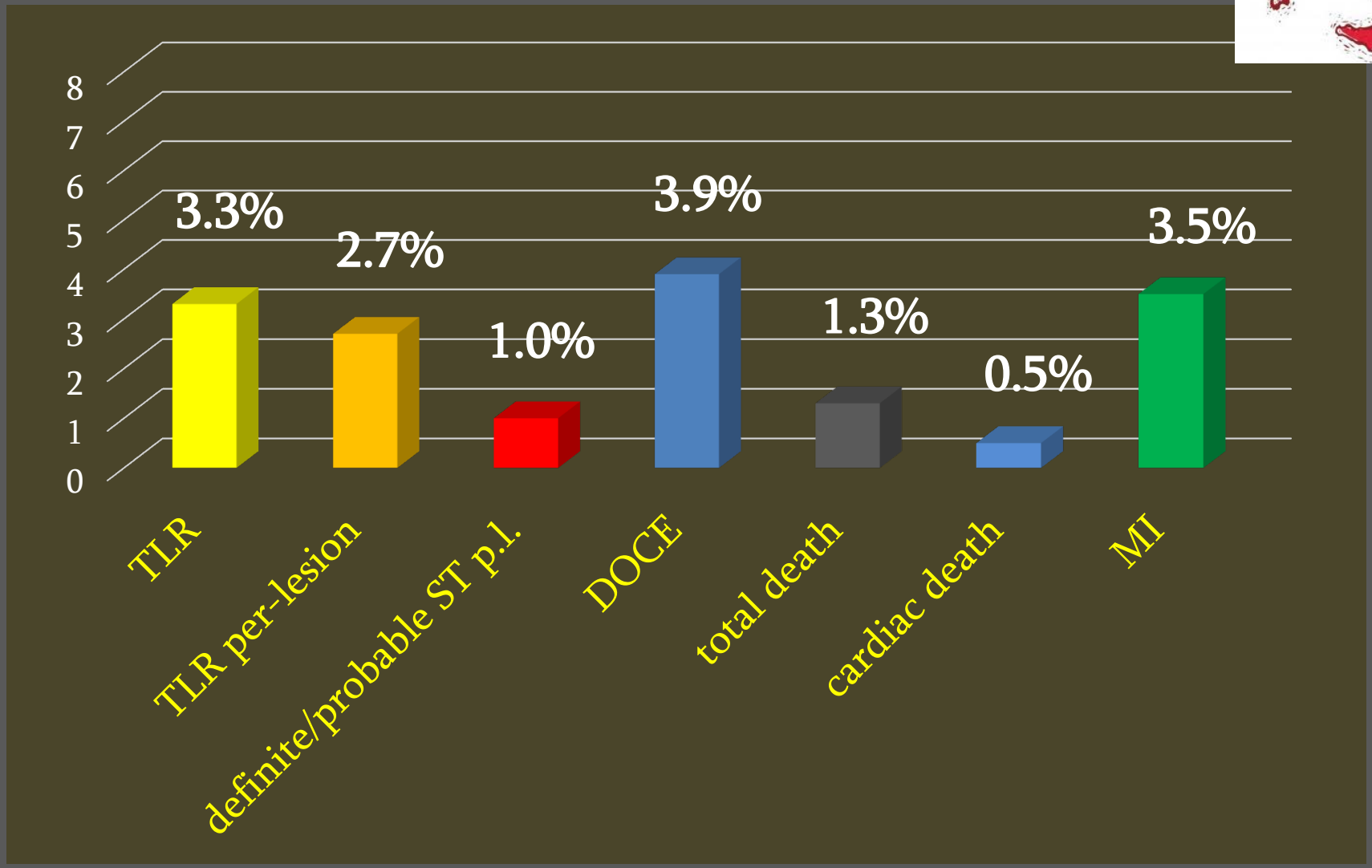
Angio & procedural data /1

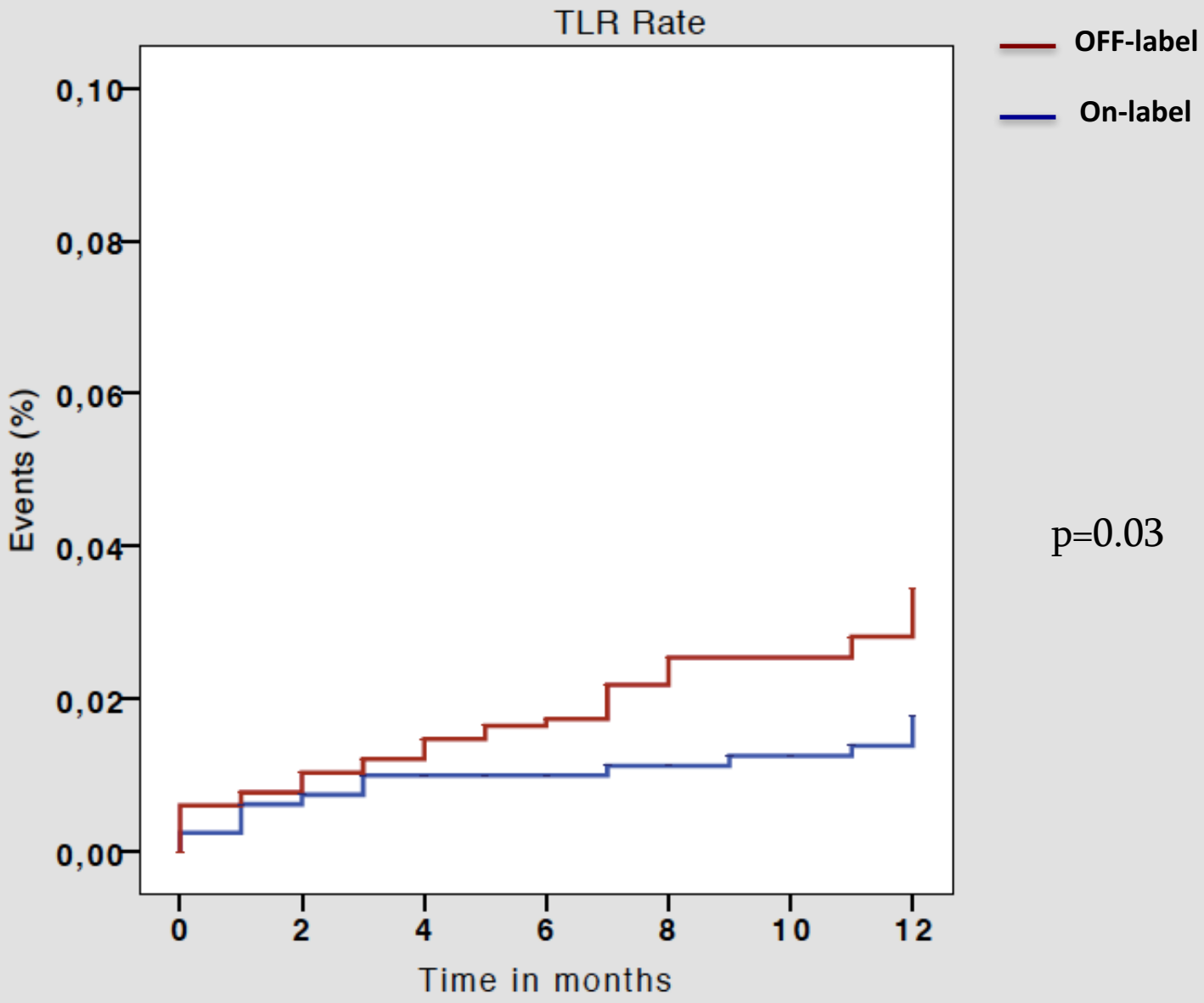
One-vessel, n (%)	**645 (42.9)**
Two-vessels, n (%)	470 (31.2)
Three-vessels, n (%)	376 (25.0)
In-stent Restenosis, n (%)	131 (6.7)
SCAD, n (%)	53 (2.7)
Bifurcation with SB >2mm, n (%)	233 (11.8)
Severe/moderate calcifications, n (%)	422 (21.4)
Overlapping BVS, n (%)	541 (27.5)
BVS-only PCI, n (%)	1378 (70.1)
OCT use, n (%)	118 (6.0)
IVUS use, n (%)	126 (6.4)
Syntax score, n ±SD	12.72±7.3

Angio & procedural data /2

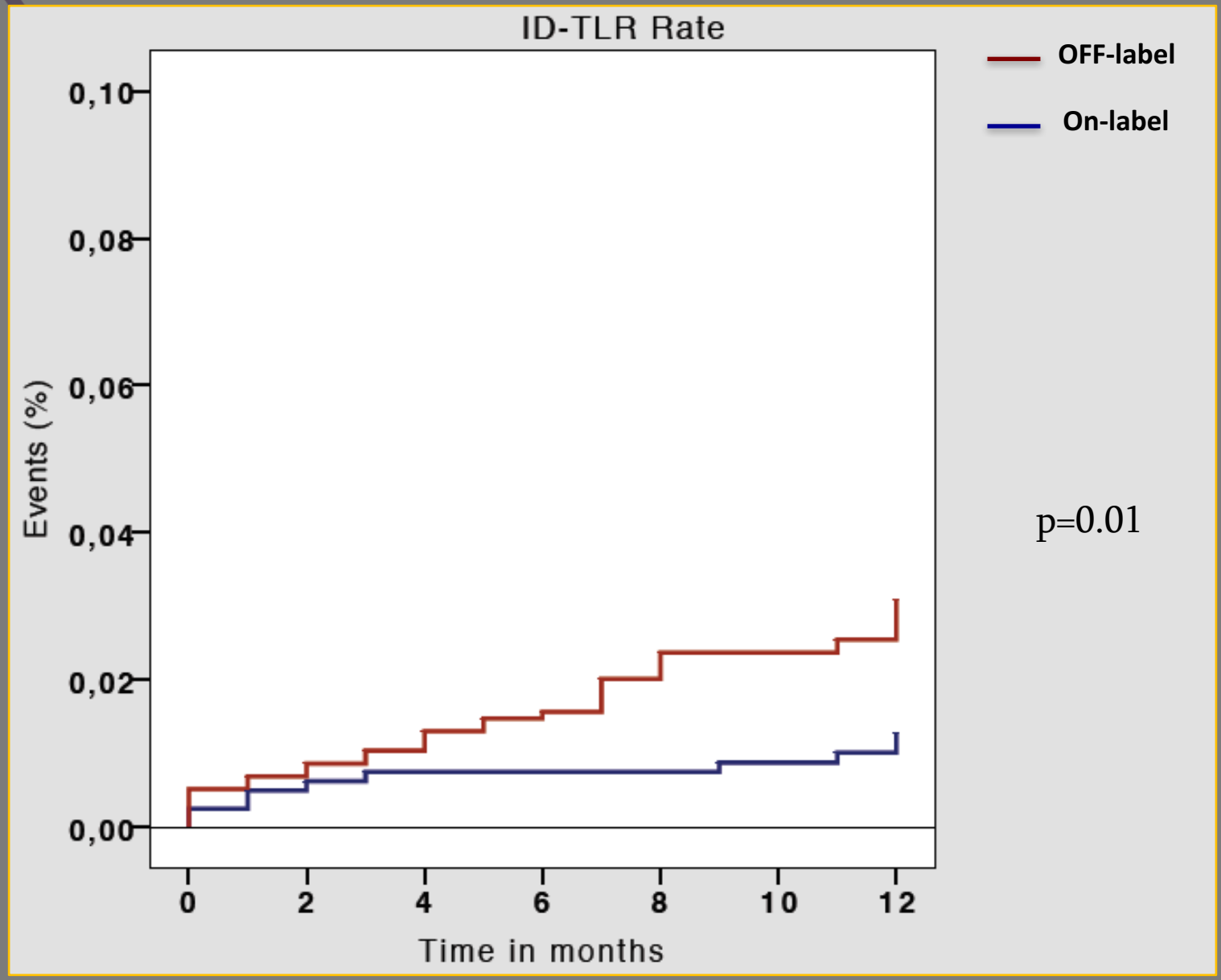
Lesion length, (mm)	21.51±11.2
RVD, (mm)	3.0±0.45
Number of BVS/lesion	1.2±0.4
BVS diameter, (mm)	3.0±0.4
BVS length , (mm)	22.10±5.7
Acute gain, (mm)	2.4±0.6
Diameter stenosis pre-procedure, (%)	81.2±13
Diameter stenosis post-procedure, (%)	2.4±0.44

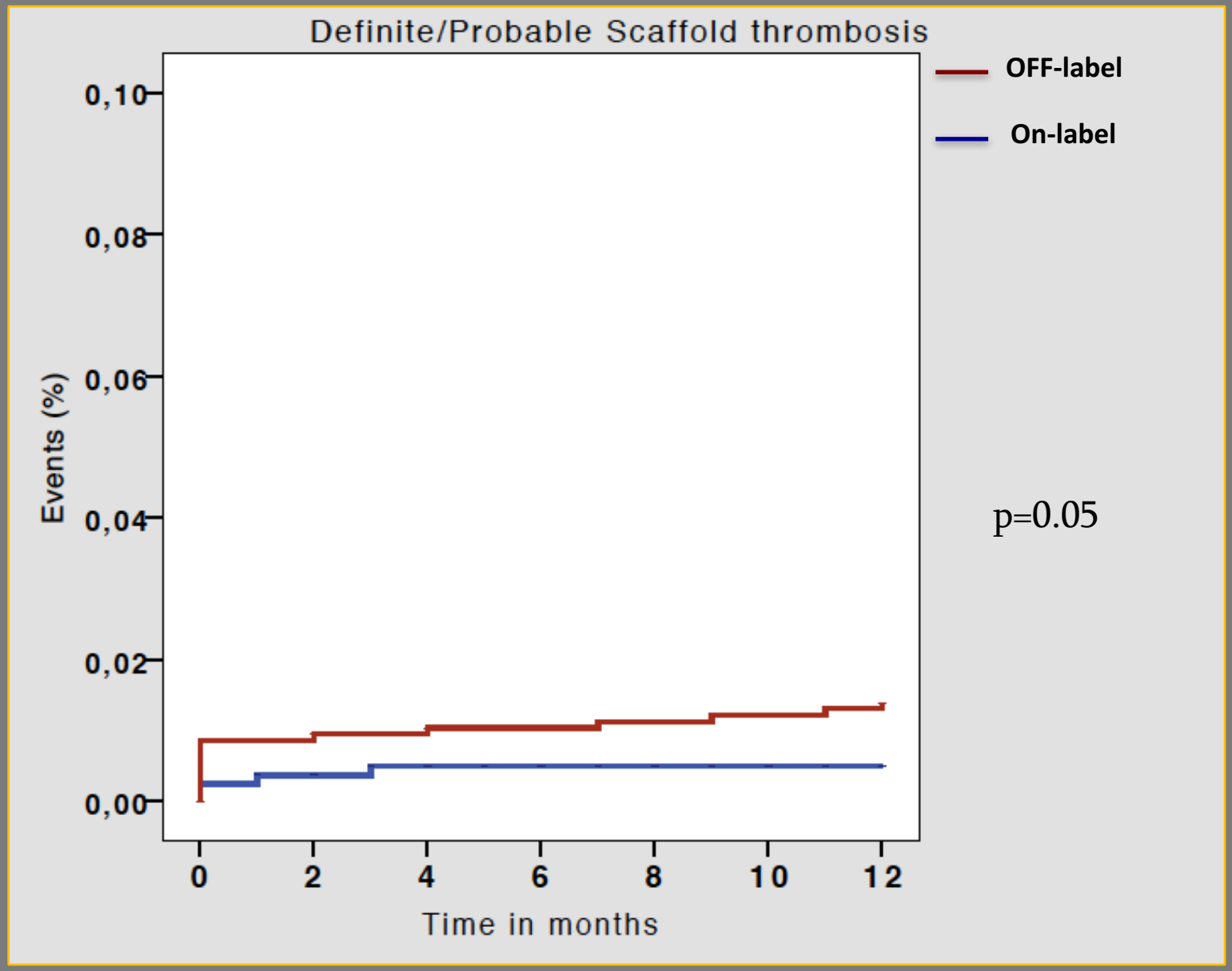
12-month clinical outcome




TLR Rate
OFF-label
On-label
0,10
0,08
0,06
0,04
0,02
0,00
Events (%)
0
2
4
6
8
10
12
Time in months

p=0.03


ID-TLR Rate
OFF-label
On-label
0,10
0,08
0,06
0,04
0,02
0,00
Events (%)
0
2
4
6
8
10
12
Time in months
p=0.01


Definite/Probable Scaffold thrombosis
OFF-label
On-label
0,10
0,08
0,06
0,04
0,02
0,00
Events (%)
0
2
4
6
8
10
12
Time in months
p=0.05

Predictors of TLR

	Hazard Ratio	P value	CI 95%	
			Inferior	Superior
Univariable model				
Previous CABG	0.31	0.057	0.111	0.876
ISR	2.80	0.010	1.367	5.755
Ostial lesions	11.11	0.085	1.525	80.97
CTO	3.60	0.013	1.511	8.611
BVS diameter 2.5 mm	0.32	0.007	0.135	0.770
Multivariable Model				
ISR	3.28	0.003	1.507	7.156
CTO	4.05	0.002	1.685	9.760

LIMITATIONS

- no head-to-head comparison to current standard of care
- device choice left to operators (selection bias)
- per protocol exclusion of “unsuccesfull implantations”

CONCLUSIONS

- The RAI registry represents a real world, contemporary BVS population, with very few exclusion criteria.
- The population enrolled is extremely well treated (predilatation, postdilatation).
- Current-era BVS use, according to specific and standardized techniques of implantation, show good clinical outcome in an unrestricted patient population at mid-term follow up.