# Registro Absorb Italiano (RAI)

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https://wwwcardio.marionegri.it/rai/

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Istituto di Ricerche Farmacologiche e Biomediche "Mario Negri", Milano

RAI maggio 2015

# A MULTICENTRE DYNAMIC REGISTRY TO STUDY THE USE AND LONG-TERM OUTCOMES OF A NEW BIORESORBABLE VASCULAR SCAFFOLDING IN A WIDE SPECTRUM OF PATIENTS WITH CORONARY ARTERY DISEASE (THE BVS-RAI REGISTRY)

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## INTRODUCTION

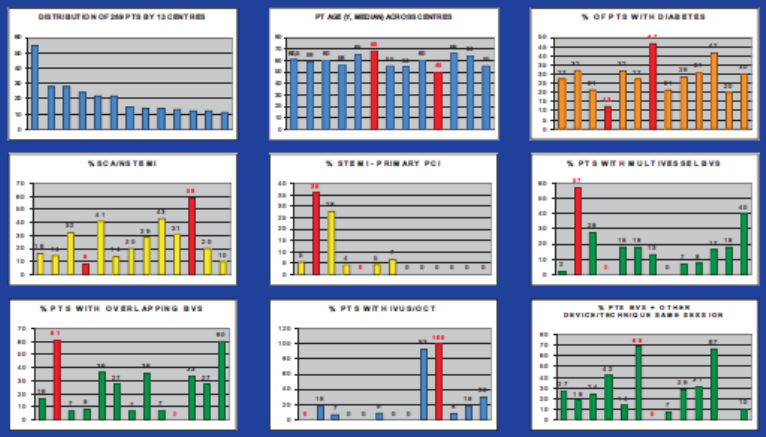
A bioresorbable, everolimus-eluting vascular scaffolding for the coronary arteries (BVS) has become available for use in Italy in Mar 2012. Data in limited numbers of patients with stable coronary disease and simple -mostly single - lesions treated with one BVS suggests that, despite thicker radiolucent struts, BVS may be as safe as 2nd generation everolimus-eluting metal stents in those conditions, as labelled. Complete BVS resorption by 3 years has been shown in man by endovascular imaging.

## AIMS AND METHODS

Although resorption can make BVS especially attractive in several patients and lesion subsets, superiority to bare or drug-eluting metal stents has so far been proven in none, and advice from Technology Assessment Bodies is missing as to indications for BVS use.
Aware of the urgent need for appraisal of BVS results in this setting, and of limitations inherent to manufacturer-driven or -rewarded data collections, a group of interventional cardiologists have devised their own unfunded registry.
This registry is intended for sharing data on use and long-term outcomes of all BVS patients, and attention can be re-focused on special lesion or patient subsets in the run.

## RESULTS

On-site data collection is ongoing in 23 centres, with consent by the Institutional Review Board to patient data transfer pending in some.
As of July 2013, 316 patients from 23 centres were considered. The present early report is limited to 269 patients from 13 centres with experience exceeding 10 cases and covers 411 of 496 BVS used.




## CONCLUSIONS

Our preliminary data shows that during the first year, across centres in this Registry, the BVS has been used in a wide spectrum of clinical and angiographic conditions, often off-label.
Although uneven economic and administrative conditions may have a role, this variability most likely reflects different attitudes among interventional cardiologists, supported by limited, slowly growing, evidence and poor consensus.
In this setting, information about the current use and the major outcomes of BVS in a number of different conditions can be captured by an adjustable registry, steered and operated by motivated professionals, like this one.

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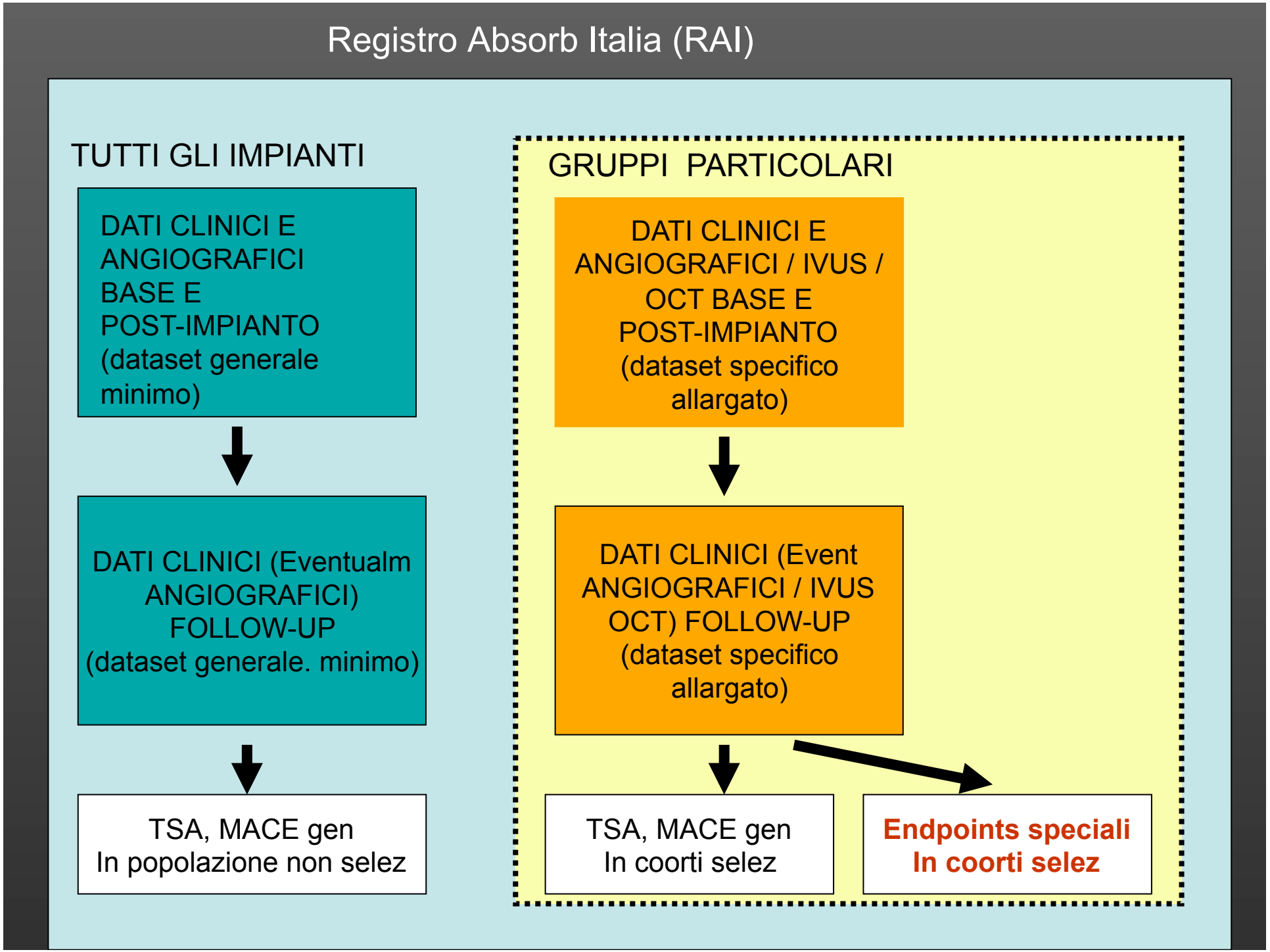
Registro Absorb Italia (RAI)
TUTTI GLI IMPIANTI
DATI CLINICI E ANGIOGRAFICI BASE E POST-IMPIANTO (dataset generale minimo)
DATI CLINICI (Eventualm ANGIOGRAFICI) FOLLOW-UP (dataset generale. minimo)
TSA, MACE gen In popolazione non selez
GRUPPI PARTICOLARI
DATI CLINICI E ANGIOGRAFICI / IVUS / OCT BASE E POST-IMPIANTO (dataset specifico allargato)
DATI CLINICI (Event ANGIOGRAFICI / IVUS OCT) FOLLOW-UP (dataset specifico allargato)
TSA, MACE gen In coorti selez
Endpoints speciali In coorti selez

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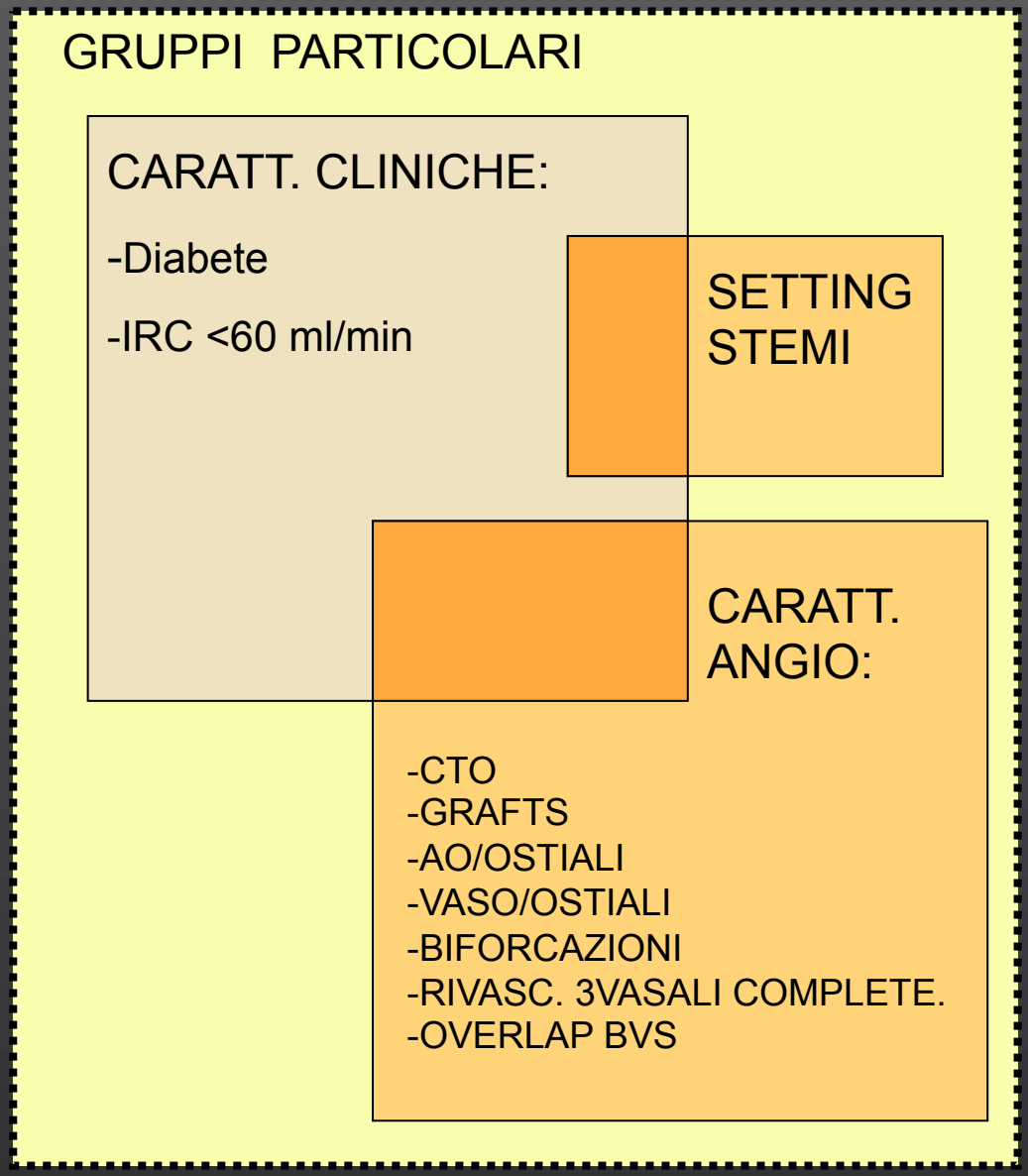

- Tutti i ricercatori registrati:
  - hanno accesso in visione a tutti i dati del CRF
  - Possono interrogare il CRF con apposite queries e seguire l'avanzamento e gli eventi
  - Condividono la proprietà dei dati e la responsabilità della loro correttezza
  - Possono proporre estrazioni ed analisi di dati di loro interesse per la pubblicazione
  - Possono individuare altri ricercatori con i quali condividere i dettagli della casistica di loro interesse

- Il RAI non riceve sovvenzioni dirette ne' indirette dal fabbricante o venditore del BVS
- L'arruolamento dei Pz non è indirizzato

  (la scelta di utilizzare il BVS è dell' operatore e del Centro, indipendentemente dal Registro)
- L'arruolamento dei Pz non è retribuito
- Viene proposto al Pz dopo l'impianto del BVS
- Unici criteri di sclusione: Pz >75 a o non consenzienti all' uso dei dati o al follow-up
- Il follow-up deve produrre le informazioni sugli eventi e lo stato clinico alle scadenze fissate, ma le modalità sono scelte da ogni Centro

- Ogni partecipante si è impegnato a
  - introdurre almeno 50 Pz, o tutti quelli trattati per un anno, comunque rigorosamente consecutivi,
  - riportare il follow-up clinico a 6 mesi, e annualmente fino a 5 aa
  - riportare i dati derivanti da eventuali angiografie o imaging intracoronarico al follow-up
  - produrre la documentazione per l'aggiudicazione degli eventi
  - accettare la RDSV

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Outcome measures are

- BVS target lesion failure within 1 year
- device-oriented major adverse cardiac events within 5 years.

- Raccolta dati prospettica
- Inizio della raccolta dati: variabile nei centri, dopo Ottobre 2012
- Chiusura arruolamenti: fine 2015
- Target arruolamenti: >1000 Pz

- **Int J Cardiol. 2014 Dec 15;177(2):497-9. Biovascular scaffolding of distal left main trunk: experience and follow up from the multicenter prospective RAI registry (Registro Italiano Absorb).**
  Cortese B, Orrego PS, Sebik R, Sesana M, Pisano F, Zavalloni D, Steffenino G, Seregni R; RAI registry investigators.

- **EuroIntervention.2014 Oct 30. Immediate and midterm outcomes following primary PCI with bioresorbable vascular scaffold implantation in patients with ST-segment myocardial infarction: insights from the multicentre "Registro ABSORB Italiano" (RAI registry).**
  Ielasi A, Cortese B Varricchio A, Tespili M, Sesana M, Pisano F, Loi B, Granata F, Moscarella E, Silva Orrego P, La Vecchia L, Steffenino G.

- **Int J Cardiol. 2015 Apr 3;189:132-133** Very late bioresorbable vascular scaffold thrombosis due to late device recoil.
  Cortese B, Piraino D, Ielasi A, Steffenino G, Orrego PS.