

**Title: The Italian Registry for Carotid Stenting (RISC):
Preliminary Results on 541 Patients From 14 Centres**

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The Italian Registry for Carotid Stenting (RISC: Registro Italiano per lo Stenting Carotideo) has been proposed by specialists of different disciplines interested and directly involved in Italy in the prevention of stroke from carotid bifurcation plaques through stenting of the carotid bifurcation. A national multi-centre, multi-disciplinary, non-randomised, prospective study was created for this purpose in May 2001, with the collaboration of Vascular Surgeons (VS), Interventional Radiologists (IR), Cardiologists (IC) and Neuro-radiologists (INR). The four disciplines are represented in the Executive Committee (EC) as well as in the Scientific Committee (SC) of the Registry. Corporates sponsoring the initiative are also represented in the EC. The SC convenes on a regular basis providing a thorough control of data, also with on-site visits and inspections.

Fondazione Villa Maria, a non-profit organisation with clinical and managerial experience in managing data base, was identified and hired to collect and analyse the RISC data in order to guarantee transparency and independency.

All data are collected and recorded on files.

The primary end-point of the Study is the identification of all neurological complications (TIAs, Minor & Major Strokes) and deaths following carotid stenting.

Second end-points are:

1. Other early non-neurological complications.
2. Rate of restenosis and late complications (at 6, 12 and 24 months follow-up).
3. Economical outcome and cost of the procedure compared to conventional procedures.

All Centres are left free to utilise or not a brain protection system during the procedure, different stents or access. Indications for the stenting procedure are those set forth by the guide-lines of the National Scientific Societies of the four disciplines involved in the Study. A minimum of 10 procedures per year are required for each single Centre to qualify to continue participating in the Study.

Each Centre utilises different informed consent forms for the stenting procedure, according to the standards adopted by each hospital. Another informed consent relative to the acceptance by the patient for the inclusion, has been devised and is adopted by all Centres participating in the Study.

It has been decided that for recruitment, patients must be entered by fax, possibly 24 hours prior to the start of the procedure. Within 24/48 hours, data with the description of the procedure, clinical and neurological (assessed by a neurologist) conditions of the patients, etc. must be collected and sent to the FVM. The follow-up of the patients is at 7 days, 1, 6, 12 and 24 months from the procedure.

Protocol violations were detected by the SC in 114 cases and the corresponding patients were consequently excluded from the Study. The most frequent causes of exclusion of the patients for protocol violation were:

- - Discordance between duplex and angiographic assessment of carotid stenosis.
- - Refusal from the patient to undergo the procedure.
- - Delay in the transmission of the data to the FVM with reference to the time the procedure was started.

The first point was mostly related to the attitude in some Centres to pose indication to carotid stenting, on the basis of the rate of carotid stenosis at duplex scan examination, which may not be subsequently confirmed by angiography. The differences in the approaching process to the patient presented by various Centres, such as performing angiography immediately before the stenting procedure is started, also raised two series of problems: one related to violation of the protocol requirements and the other to the temporal distribution of the neurological complications.

Recruitment started in October 2001 and will be concluded in October 2003. The expected volume of entered patients in the Study will be 1,500. Patients will be subsequently followed-up until October 2005.

From October 2001 to 31 October 2002, 541 patients were considered suitable for inclusion and were entered in the Study from 23 Centres. There were 374 male (69%) and 167 female (31%) patients.

The mean age was 72 years (min: 42 ys, max 100 ys). Two hundred and twenty four patients were entered from 4 IC units (41%), 171 (32%) from 9 IR & INR units and 146 (27%) from 10 VS units. There were 446 (82.4%) primary lesions and 95 (17.6%) restenoses. One hundred and ninety four (35.8%) patients presented with neurological symptoms at the time of the procedure, whilst 347 (64.2%) were asymptomatic. Out of the 194 symptomatic patients, 56.7% had a pre-procedural TIA, 17.8% presented with amaurosis fugax and 25.5% with a stroke. A brain CT scan was performed on all patients and appeared to be positive in 256 cases (47.3%), and negative in 285 cases (52.7%). A positive CT scan correlated with the carotid side, was present in sixty-two (11.5%) asymptomatic patients.

For what is concerning the procedure, a pre-stenting dilatation was performed in 30% of the cases and a post-stenting dilatation in 94.4%.

Ninety per cent (487) of the cases were performed under brain protection with the following distribution: 96.5% with a distal filter, 2.2% with a distal balloon occlusion and 1.3% with a flow reversal.

The overall non neurological carotid complications were 7 (1.29%) represented by carotid dissection in 3 cases and carotid occlusion in 4 cases. In 3 cases (0.6%) the procedure could not be carried out for difficult access (intention to treat).

There were 4 (0.7) on table conversions to open procedure.

The overall neurological complications were 18 (3.1%) divided in TIAs (1.4), Stroke (1.6%) and Death (0.1%).

In conclusion, the good early results presented, seem to confirm that carotid stenting is a fairly safe procedure in the prevention of brain embolisation from carotid bifurcation plaques and to demonstrate that the continuation of the Study is ethical.

Appendix:

The following Centres participated in the Study:

Istituto Policlinico San Donato, U.O. di Chirurgia Vascolare 1^a – San Donato Milanese - D. Tealdi, MD; Istituto Policlinico San Donato, Servizio di Emodinamica e Radiologia Interventistica – San Donato Milanese – L. Inglese, MD; Azienda Ospedaliera G. Salvini, U.O. di Chirurgia Vascolare – Garbagnate Milanese – R. Mattassi, MD; Ospedale Maggiore C.A. Pizzardi, Servizio di Radiologia 2^a – Bologna, A. Ziosi, MD; Centro Nazionale per il Salvataggio d’Arto – Milano – E. Calabrese, MD; EMO Centro Cuore Columbus – Milano – A. Colombo, MD; Policlinico Le Scotte, U.O. di Chirurgia Vascolare – Siena – A. Cappelli, MD; Azienda Ospedaliera Cà Granda Niguarda, U.O. di Chirurgia Vascolare – Milano – M. Puttini, MD; Casa Sollievo della Sofferenza, Servizio di Radiologia Interventistica – San Giovanni Rotondo – W. Lauriola, MD; Cliniche Gavazzeni, U.O. di Neuroradiologia – Bergamo – P. Sganzerla, MD; Ospedale Maggiore San Giovanni Battista Molinette, Servizio di Angioradiologia Interventistica – Torino – C. Rabbia, MD; Ospedale Mauriziano Umberto I, Servizio di Radiologia --Torino – P. Carbonatto, MD; Azienda Ospedaliera San Gerardo Ospedale Bassini, U.O. di Chirurgia Vascolare – Cinisello Balsamo – G. Deleo, MD; Ospedale Civile Sant’Agostino, U.O. di Chirurgia Vascolare – Modena – G. Coppi, MD; Policlinico Tor Vergata, Servizio di Radiologia – Roma – G. Simonetti, MD; Policlinico Umberto I, U.O. di Chirurgia Vascolare – Roma – F. Benedetti Valentini, MD; Policlinico Sant’Orsola, U.O. di Chirurgia Vascolare – Bologna – M. D’Addato, MD; Villa Maria Cecilia Hospital, Servizio di Emodinamica - Cotignola – A. Cremonesi, MD; Azienda Ospedaliera Santissima Annunziata, Servizio di Radiologia – Taranto – M. Resta, MD; Policlinico Le Scotte, U.O. di Neuroradiologia – Siena – C. Venturi, MD; Azienda Ospedaliera Sant’Anna, Servizio di Emodinamica – Como – R. Galli, MD; Ospedale di Careggi, U.O. Cardiologia 2^a – Firenze – M. Santoro, MD; Azienda Ospedaliera Manzoni, U.O. di Chirurgia Vascolare – Lecco – G. Lorenzi, MD.

Acknowledgment:

The cooperation and contribution of Fondazione Villa Maria in the setting of the data base and then, in the collection, management and analysis of data, is gratefully acknowledged.