

MITRA SWISS newsletter

N. 3 - January 2017

Dear MitraSwiss participants,

We are pleased to send you the fourth SWISS MitraClip Registry Newsletter, which encloses an update (December 2016) of the first 800 patients included in the registry until September 2016 by the ten centres currently performing MitraClip in Switzerland (Universitätsspital Zürich, Kantonsspital Luzern, Cardiocentro Ticino, Universitätsspital Basel, Inselspital Bern, HerzKlinik Hirslanden Zürich, Klinik Im Park Zürich, Kantonsspital Aarau, HUG Genève, CHUV Lausanne). Current recruitment status and yearly inclusion rate are listed in Table 1 and 2.

As you all know, the inclusion in the national registry – supported by an unrestricted grant of Abbott and by an additional support from the Working Group PCI – still remains one of the main conditions for the reimbursement, a goal which cannot be achieved without your convinced motivation in providing us your data. We remember that the MitraClip is on the DRG list with the code F98C and the cost weight for 2017 as been adapted to 5.407 (+0.232).

Within the coordination team we recently addressed the question concerning the final number of patients to be officially included into the registry: the initial (predefined) number of 500 has been largely overcome and we are now approaching 1000 patients. Our current proposal, which also takes into account the increasingly financial requirements, is to stop the “scientific” inclusion, once reached the number of 1000, maintaining a sort of fast inclusion based on a low number of variables, and, of course, according to the protocol, the follow programme at 5 years.

Among the good news we “adjusted” the data base in order to make it available for other form of percutaneous repair, first of all the Cardioband, and we dispose since December of a website (<http://mitra-swiss.org>) with updated information on the registry's status.

Concerning the scientific activity we have many projects running (comparison functional vs degenerative MR, outcome good responders, outcome subgroup CRT patients, role of biological predictors,...) which should lead within short time to relevant publication. We are currently working on the “main paper” (D. Sürder et al.) with highly interesting results with regard to the 2 years outcome stratified according to the MR aetiology (functional vs degenerative). The baseline characteristic and periprocedural results of the entire cohort divided per MR aetiology are depicted in table 3 and 4.

We would now take the opportunity to officially thank for their excellent work our two study monitoring, Manuela Mombelli and Simona Maspoli, who concluded their cooperation with the registry

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and warmly welcome Mr Giuseppe Prosperini who is going to take over this important task. We are confident that he will replace in the best manner Manuela and Simona.

Last but not least a big thank to Catherine Klersy and Moreno Curti for their constant and extremely competent support to our registry and to all our scientific projects.

Thanking you all for the excellent collaboration we wish you all a 2017 plenty of satisfaction and happiness.

Yours

Daniel Sürder and Giovanni Pedrazzini

Ongoing analysis

- Comparison functional vs degenerative MR (within the main article); D. Sürder
- Outcome of the initially good responders; S. Toggweiler
- Outcome subgroup CRT patients; A. Auricchio
- Role of biological predictors; R. Jeger

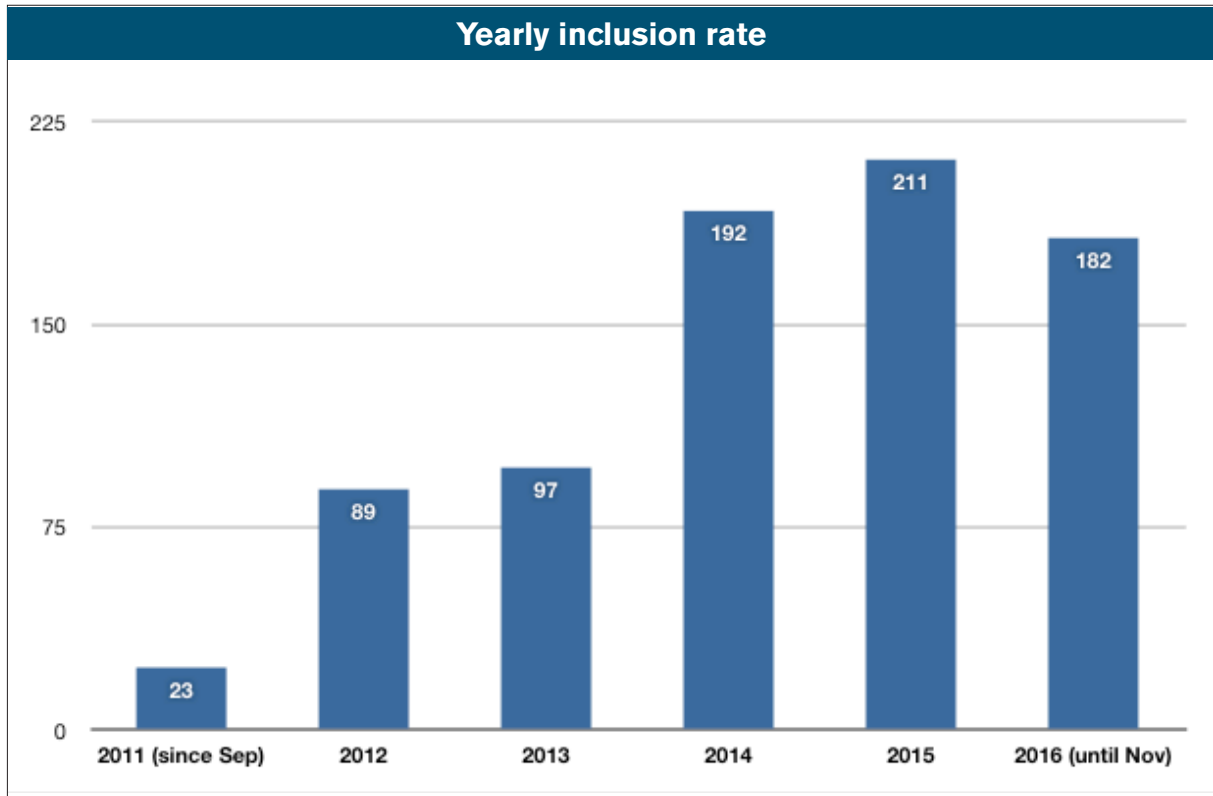
PRELIMINARY RESULTS

The chart below shows a summary of the current recruitment status of each centre as well as the monthly enrolment.

Site	Status	1 st patient	Recruited	Monthly average
Basel	Recruiting	02/2012	66	1.14
Bern	Recruiting	12/2012	78	1.62
Cardiocentro Lugano	Recruiting	09/2011	74	1.17
Lucerne	Recruiting	11/2011	63	1.03
Klinik im Park Zürich	Recruiting	11/2012	127	2.59
University Hospital Zürich	Recruiting	09/2011	232	3.68
Heart Clinic Hirslanden	Recruiting	11/2012	94	1.92
Aarau KS	Recruiting	05/2014	35	1.13
HUG	Recruiting	10/2014	17	0.65
CHUV	Recruiting	08/2014	15	0.54
Total patients		09/2011	801	12.71

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I - Baseline characteristics of the treated patients (n = 722)

	All	DMR	FMR	p
Age – years; median (range)	79 (71-84)	81 (76-85)	76 (69-81)	0.000
BMI - kg/m ² ; median (range)	25.0 (22.2-27.9)	24.5 (21.9-27.3)	25.6 (22.5-28.7)	0.000
Gender (male) - %	62.3	57.2	67.5	0.005
Hypertension - %	75.7	74.6	76.8	0.531
Hyperlipidemia - %	49.3	42.4	55.9	0.001
Diabetes - %	21.4	13.2	29.3	0.000
CAD - %	55.9	43.4	67.8	0.000
Previous MI - %	29.1	13.4	44.1	0.000
Previous PCI - %	37.0	25.3	48.4	0.000
Previous CABG - %	20.4	11.7	28.7	0.000
Previous valve surg - %	10.3	12.1	8.7	0.165
Previous TAVR	3.7	4.3	3.2	0.543
Prev. episode of HF - %	31.2	28.3	34.0	0.130

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II - Baseline characteristics of the treated patients (n = 722)

	All	DMR	FMR	p
NYHA class				
I / II	26.3	30.5	22.2	0.044
III	58.1	54.5	61.7	
IV	15.6	15.0	16.2	
Co-morbidities				
GFR	43 (32-59)	45 (34-60)	42 (30-55)	0.037
Logistic EuroScore (%)	8.0 (4.4-21.0)	7.0 (4.3-16.6)	10.7 (4.8-23.7)	0.023
Euro Score II	4.8 (2.9-11.1)	3.8 (2.2-6.9)	6.0 (3.4-12.4)	0.000
STS Score	5.1 (2.6-15.1)	5.0 (2.8-10.4)	5.6 (2.4-15.8)	0.598
Chronic / par. AF - %	54.1	54.1	54.2	1.000
HR	73 (63-82)	72 (62-82)	73 (64-82)	0.844
Previous PM or ICD implantation - %	24.9	14.4	35.2	0.000
CRT - %	13.8	4.6	22.7	0.000
Mitral valve - grade of mitral regurgitation at baseline - %				
Moderate	1.0	0.6	1.4	0.000
Moderate to severe	15.6	10.7	20.5	
Severe	83.3	88.8	77.8	
MR etiology - %				
Functional	46.4	-	-	-
Degenerative	46.6	-	-	-
Mixed	6.8	-	-	-
LVEF	48 (31-60)	60 (50-65)	35 (26-48)	0.000
LVEDV	142 (104-193)	123 (95-156)	170 (121-224)	0.000
LVESV	83 (43-134)	47 (35-77)	118 (80-165)	0.000

BMI: body mass index; PCI: Percutaneous coronary intervention; CABG: coronary artery bypass graft; PM: pacemaker; ICD: implantable cardioverter defibrillator; CRT: cardiac resynchronization therapy; LVEF: left ventricular ejection fraction; COPD: chronic obstructive lung disease

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Periprocedural results and safety (n = 722)

No implanted clips (%)	All	DMR	FMR	p
Clip implantation not done / possible	1.7	2.5	0.8	0.405
1 clip	39.1	39.7	39.8	
2 clips	48.6	46.7	50.6	
3 clips	9.1	9.8	8.4	
4 clips	1.5	1.4	1.7	
Post-proced. transmitral mean gradient (mmHg)				
after 1 clip – median (range)	2.0 (2.0-3.0)	2.9 (2.0-4.0)	2.0 (2.0-3.0)	0.015
after 2 clips – median (range)	3.0 (2.0-4.0)	3.0 (2.0-4.0)	3.0 (2.0-4.0)	0.447
after 3 clips – median (range)	3.0 (2.0-4.0)	3.0 (2.0-4.0)	3.0 (2.0-4.0)	0.761
after 4 clips – median (range)	3.0 (2.0-4.5)	3.0 (2.0-5.0)	3.0 (2.0-3.0)	0.505
Overall at discharge – median (range)	3.9 (2.5-5.0)	4.0 (3.0-5.0)	3.5 (2.0-5.0)	0.026
APS (%)				
Overall	90.9	89.7	92.0	0.355
30 d mortality (%)				
Periprocedural mortality	0.6 (0.15-1.4)	0.6	0.6	1.000
Mortality at 30 days	2.9 (1.7-4.1)	1.9	3.9	0.127
Cardiac surgery / Redo PMVR at 30 days	0.8	1.1	0.6	0.686
Hospitalization for HF	2.1	1.9	2.2	0.801
Cumulative event rate (hosp any case)	7.3	7.0	7.5	
Periprocedural complications (%)				
Artificial respiration > 48h	0.6	0.9	0.3	0.364
LVAD	0.9	1.2	0.6	0.442
Bleeding requiring transfusion	1.6	1.5	1.8	1.000
Complication due to transeptal puncture	1.9	2.8	1.2	0.167
Cerebrovascular infarction	0.3	0.6	0	0.239
Hospital stay – days				
ICU/CCU stay – median (IQR)	2.0 (1.3)	2 (1-2)	2 (1-3)	0.0040
Total hospital stay	6 (5.0-8.0)	6.0 (4.0-8.0)	6.0 (5.0-9.0)	0.082

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Prof. Dr. Francesco Maisano, Mrs. Ulrike Sängler

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Hopital Univ. de Genève: PD Dr. Stephane Noble; Mrs. Armelle Delort

Next Meeting:

During SGK Meeting 2017

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