EURObservational Research Programme

ROPAC
Registry Of Pregnancy And Cardiac disease

ROPAC co-chairs:

Roger Hall
ESC Valve Working Group

Jolien Roos-Hesselink
ESC Congenital Working Group

September 2015

EUROPEAN SOCIETY OF CARDIOLOGY®

Executive Committee
&
Project Coordination

Executive Committee

Co-Chairs
Professor Jolien Roos-Hesselink, the Netherlands
Professor Roger Hall, UK

Committee
Professor Mark Johnson, UK
Dr. Iris van Hagen, the Netherlands
Professor Jorg Stein, Austria
Professor Gary Webb, USA
Professor Uri Elkayam, USA
Professor Ariane Marelli, Canada
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Professor Werner Budts, Belgium
Professor Harald Kaemmerer, Germany
Professor Karen Sliwa, South Africa
Dr. William Parsonage, Australia
Professor Roberto Ferrari, ESC, Chair of the EORP Oversight Committee
Professor Luigi Tavazzi, ESC, Past-Chair of the EORP Oversight Committee
Dr. Aldo Maggioni, ESC, EORP Scientific Coordinator

EORP Department

Data Management Team, Project Coordination & Scientific Secretariat

Thierry Ferreira, Head of Department

Viviane Missiamenou, Data Monitor

Elin Folkesson Lefrancq, Project Officer

Cécile Laroche, Statistician

Charles Taylor, IT specialist

Emanuela Fiorucci, Project Officer

Gérard Gracia, Data Monitor

Marème Konte, Data Monitor

Maryna Andarala, Data Monitor

Myriam Glémot, Project Officer

Patti-Ann McNeill, Project Officer

Caroline Pommier, Assistant

Protocol

Introduction

- **Understand**
  - Impact of pregnancy on women with heart disease
  - Impact of maternal disease on the outcome of pregnancy
- **Information**
  - Incomplete
  - Fragmented
  - Heterogeneous nature
- **Develop management protocols**
- **Registry**
  - Large numbers of patients
  - Wide variety of possible situations

Objectives

- **Determining**
  - Variation between participating countries
- **Assessing**
  - Maternal and foetal mortality and morbidity
  - The use of medical resources

  Caesarean section, epidural anaesthesia etc.
  - Impact on outcome in different countries
- **Testing**
  - Value of the existing risk models
- **Comparing**
  - Different types of anticoagulant therapy
- **Support guidelines**

- **Provide better advice to mothers**

Methods

Inclusion:

All consecutive patients with structural heart disease becoming pregnant

- Patient consent if local IRB requires it

Exclusion:

Non structural heart disease (primary arrhythmic heart disease)

Period of Enrolment

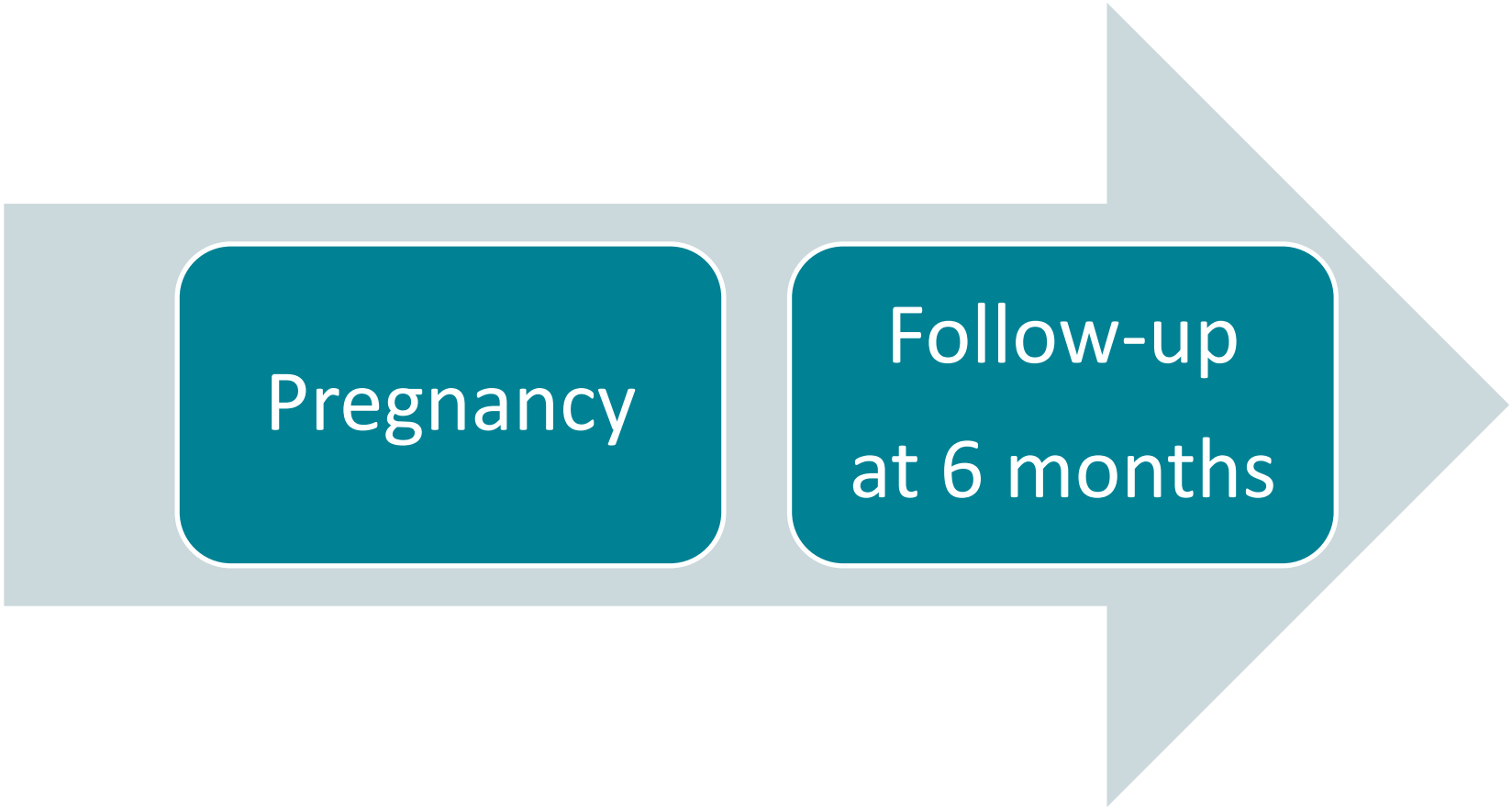
Enrolment type

This registry is

- **Prospective:**
  - **You can enrol every patient becoming pregnant who meet the inclusion criteria**

- **Retrospective:**
  - **Inclusion of patients that you consulted up to one year before enrolment.**

Structure of registry



Data collection & Case Report Form

Patient demography

- Age
- Information about the consultation or pregnancy
- Cardiac information

Diagnosis

- Cardiac medical history
- Other concomitant disease, Clinical conditions

Obstetric history

- Number of previous pregnancy (ies)
- Previous complications during the previous pregnancy (ies)

Home medication

- Cardiac treatments
- Anticoagulation treatments
- Complication due to anticoagulation

Events

- Events and complications during this present pregnancy

Delivery & Outcome

- Delivery
- Maternal outcome
- Neonatal outcome

Echocardiogram

- Details of examination

Follow-up (6 month)

- Maternal outcome
- Echocardiogram

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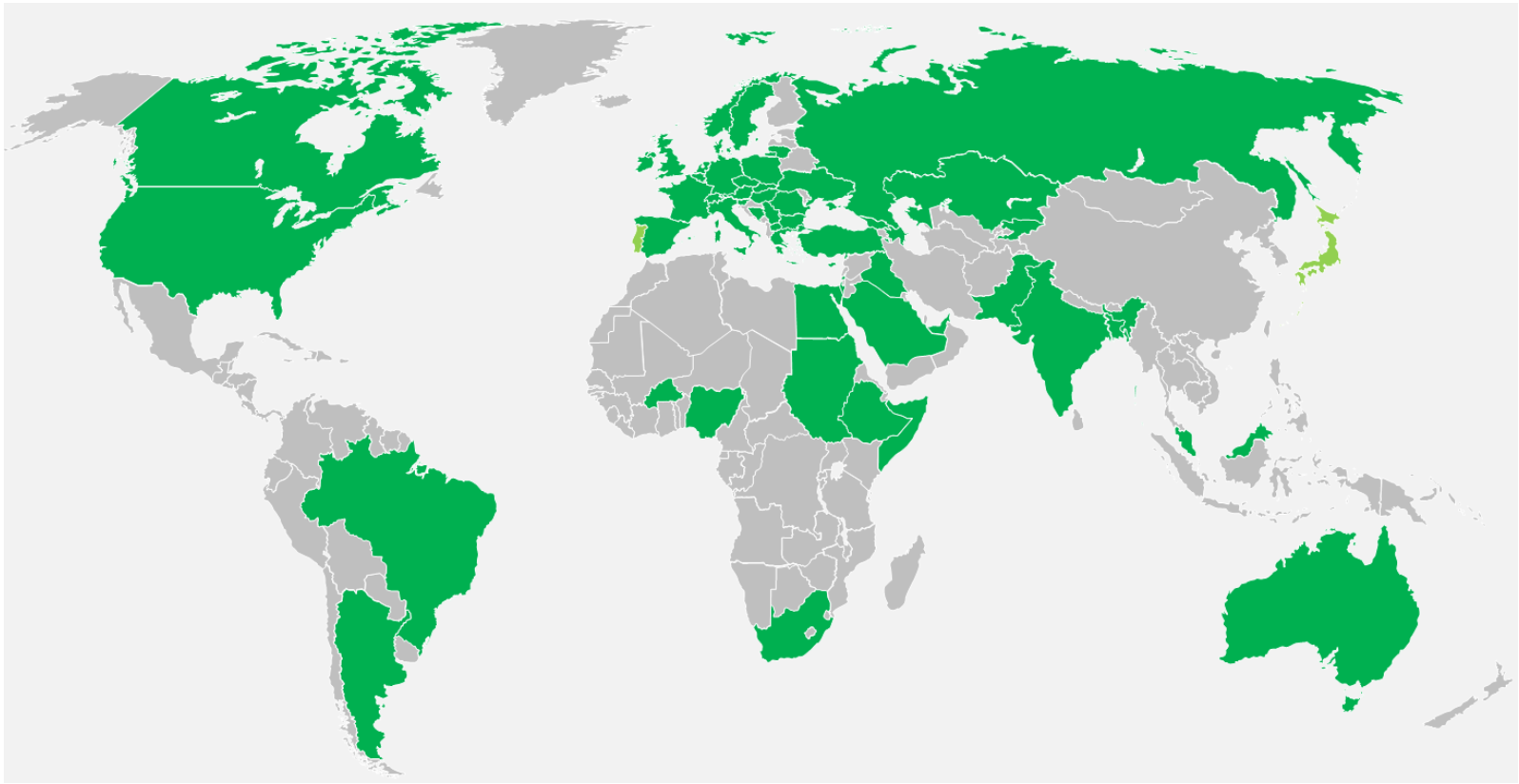
Participating Countries & Centres

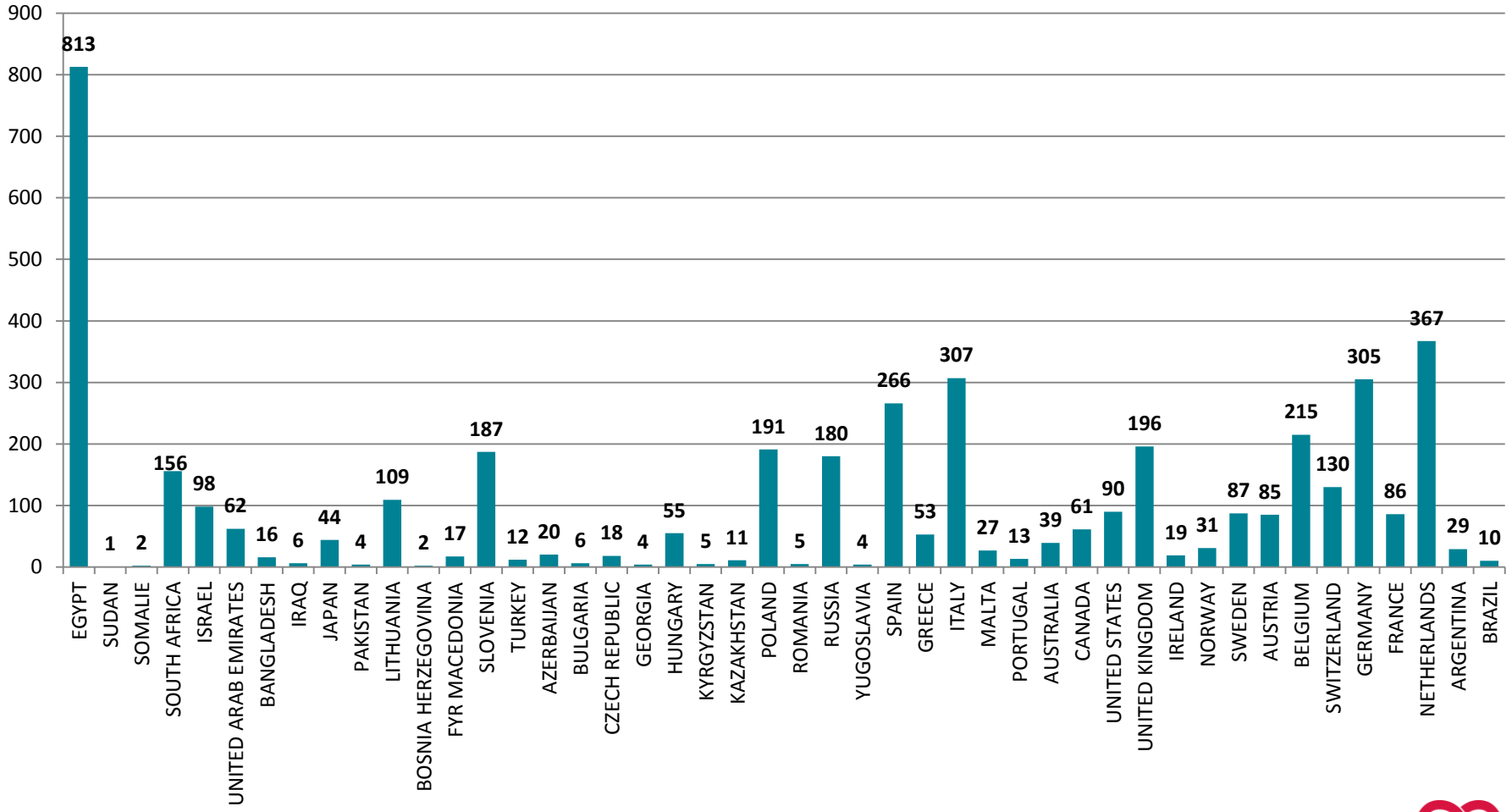
150 participating centres
57 countries so far…



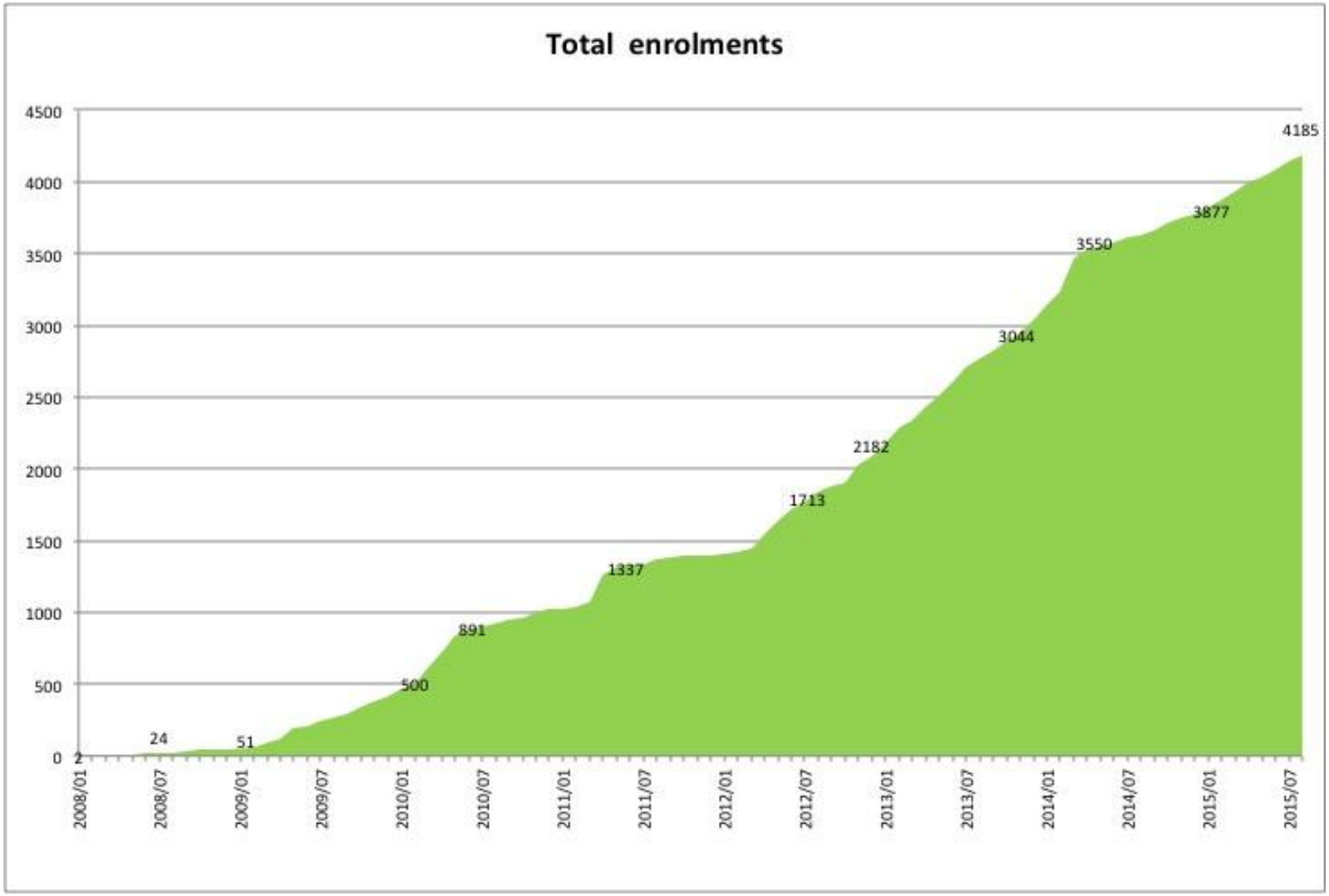
Analysis

- First analysis in June 2011
- Analysis in May 2014: 2966 ROPAC patients included up until April 2014
- Currently 4000 pregnancies
- Aim: at least 5000 pregnancies
- Acknowledge as ROPAC investigators

Participating countries and enrolment (end Aug.2015)



Enrolment: >4100 Aim: >5000



EUROBservational Research Programme

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Data presented

- **ESC** congress in Paris 2011
- **ACC** congress in Chicago 2012
- **Cardiac problems in pregnancy** (CPP) in Berlin 2012
- **ESC** congress in Munich 2012
- **AHA** congress in Dallas 2013
- **ESC** congress in Amsterdam 2013
- **Cardiac problems in pregnancy** (CPP) in Venice 2014
- **ESC** congress in Barcelona 2014
- **AHA** congress in Chicago 2014
- **ESC** congress in London 2015

- **National Congresses** in Japan, Australia, The Netherlands, UK...

PLANNED in 2016:

- **Cardiac problems in pregnancy** (CPP) in Las Vegas
- **ESC** congress in Rome

Previous publications

European Heart Journal (2013) **34**, 657–665
doi:10.1093/eurheartj/ehs270

CLINICAL RESEARCH
Coronary artery disease

Outcome of pregnancy in patients with structural or ischaemic heart disease: results of a registry of the European Society of Cardiology

Jolien W. Roos-Hesselink[1]*, Titia P.E. Ruys[1], Jörg I. Stein[2], Ulf Thilén[3], Gary D. Webb[4], Koichiro Niwa[5], Harald Kaemmerer[6], Helmut Baumgartner[7], Werner Budts[8], Aldo P. Maggioni[9], Luigi Tavazzi[10], Nasser Taha[11], Mark R. Johnson[12], and Roger Hall[13], on behalf of the ROPAC Investigators

ORIGINAL ARTICLE

Ruys TPE, *et al*. *Heart* 2014;**100**:231–238. doi:10.1136/heartjnl-2013-304888

Heart failure in pregnant women with cardiac disease: data from the ROPAC

Titia P E Ruys,[1] Jolien W Roos-Hesselink,[1] Roger Hall,[2] Maria T Subirana-Domènech,[3] Jennifer Grando-Ting,[4] Mette Estensen,[5] Roberto Crepaz,[6] Vlasta Fesslova,[7] Michelle Gurvitz.[8] Julie De Backer.[9] Mark R Johnson.[10] Petronella G Pieper[11]

International Journal of Cardiology 177 (2014) 124–128

Contents lists available at ScienceDirect

International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

Cardiac medication during pregnancy, data from the ROPAC☆,☆☆

Titia P.E. Ruys [a], Aldo Maggioni [b], Mark R. Johnson [c], Karen Sliwa [d], Luigi Tavazzi [e], Markus Schwerzmann [f], Petros Nihoyannopoulos [g], Mirta Kozelj [h], Ariane Marelli [i], Uri Elkayam [j], Roger Hall [k], Jolien W. Roos-Hesselink [a,*]

ORIGINAL ARTICLE

Ruys TPE, *et al*. *Heart* 2014;**0**:1–8. doi:10.1136/heartjnl-2014-306497

Is a planned caesarean section in women with cardiac disease beneficial?

Titia P E Ruys,[1] Jolien W Roos-Hesselink,[1] Antonia Pijuan-Domènech,[2] Elena Vasario,[3] Ilshat R Gaisin,[4] Bernard Iung,[5] Leisa J Freeman,[6] Elaine P Gordon,[7] Petronella G Pieper,[8] Roger Hall,[6] Eric Boersma,[1] Mark R Johnson,[9] on behalf of the ROPAC investigators

Circulation July 14, 2015

Valvular Heart Disease

Pregnancy in Women With a Mechanical Heart Valve

Data of the European Society of Cardiology Registry of Pregnancy and Cardiac Disease (ROPAC)

Iris M. van Hagen, MD; Jolien W. Roos-Hesselink, MD, PhD; Titia P.E. Ruys, MD, PhD; Waltraut M. Merz, MD, PhD; Sorel Goland, MD; Harald Gabriel, MD; Malgorzata Lelonek, MD, PhD; Olga Trojnarska, MD; Wael Abdulrahman Al Mahmeed, MD; Hajnalka Olga Balint, MD; Zeinab Ashour, MD; Helmut Baumgartner, MD, PhD; Eric Boersma, MD, PhD; Mark R. Johnson, MD, PhD; Roger Hall, MD, FRCP; on behalf of the ROPAC Investigators and the EURObservational Research Programme (EORP) Team*

JACC: CLINICAL ELECTROPHYSIOLOGY VOL. 1, NO. 4, 2015

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PUBLISHED BY ELSEVIER INC. http://dx.doi.org/10.1016/j.jacep.2015.04.013

Atrial Fibrillation or Flutter During Pregnancy in Patients With Structural Heart Disease

Data From the ROPAC (Registry on Pregnancy and Cardiac Disease)

Amar M. Salam, MBBS,* Ebru Ertekin, BSc,† Iris M. van Hagen, MD,† Jassim Al Suwaidi, MB, ChB,* Titia P.E. Ruys, MD, PhD,† Mark R. Johnson, MD, PhD,‡ Lina Gumbiene, MD, PhD,§ Alexandra A. Frogoudaki, MD, PhD,‖ Khaled A. Sorour, MD,¶ Laurence Iserin, MD,# Magalie Ladouceur, MD,# A. Carla C. van Oppen, MD, PhD,** Roger Hall, MD,†† Jolien W. Roos-Hesselink, MD, PhD†

EUROPEAN SOCIETY OF CARDIOLOGY®

Publications

Submitted:

- Ventricular arrhythmia's
- Prediction of maternal adverse outcome

In progress:

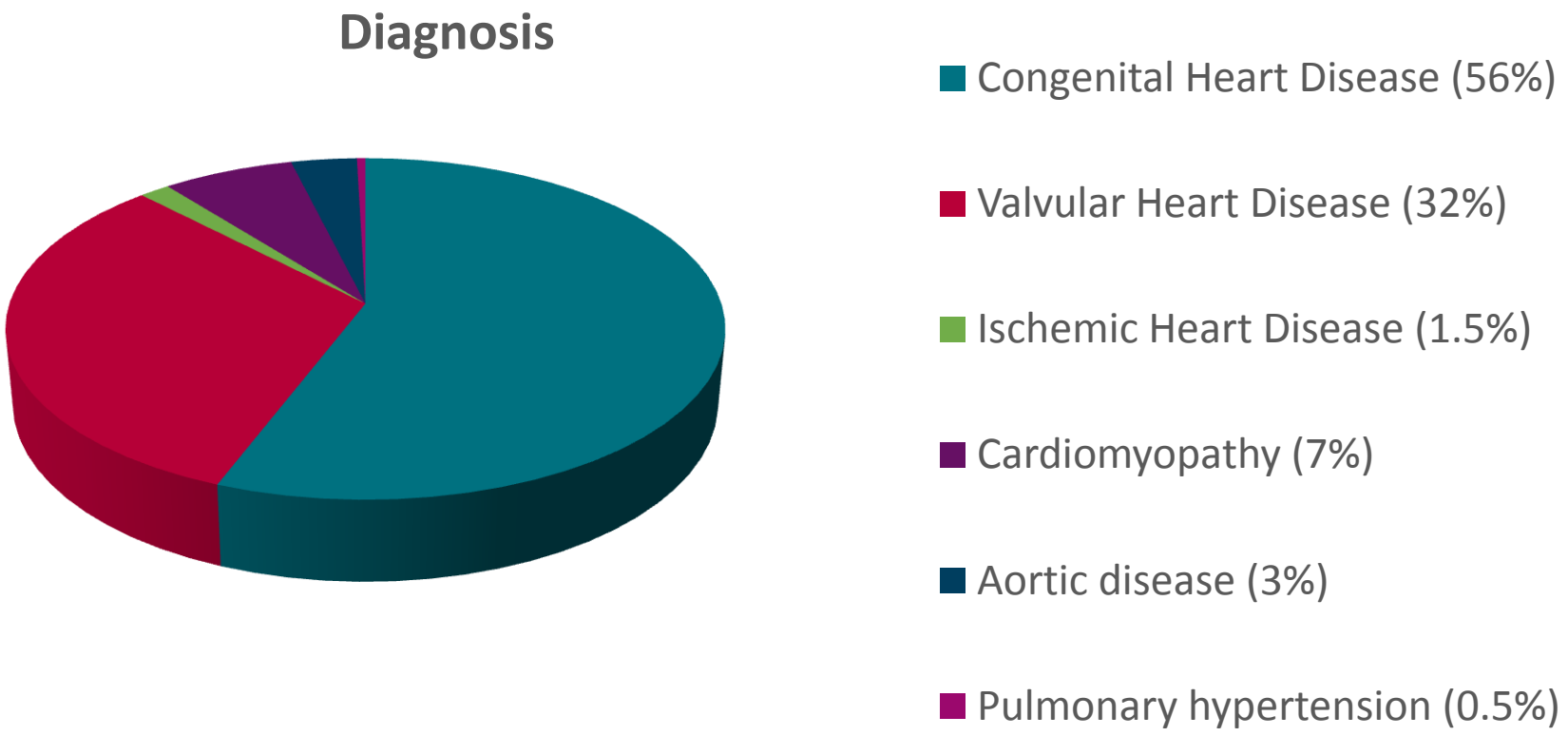
- Predictors of fetal adverse outcome
- Pulmonary hypertension
- Aortic stenosis

- Rheumatic valve disease
- Hypertrophic cardiomyopathy
- Interregional differences

New analysis performed in 2014

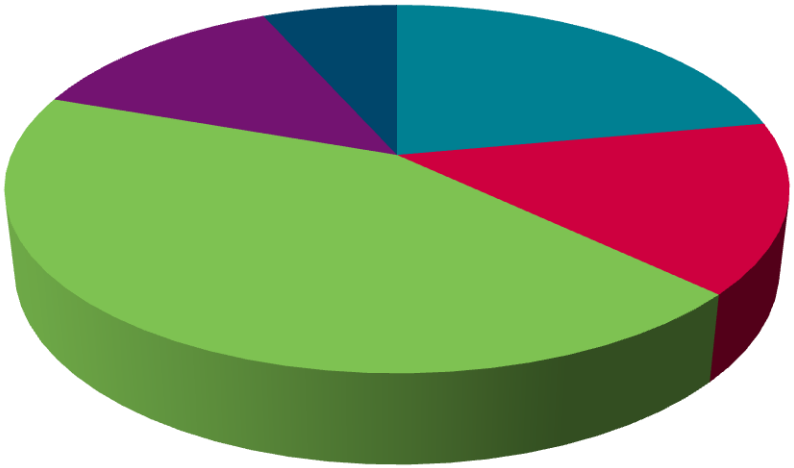
- **Patients included from January 2007 to April 2014**
  - **2966 pregnancies**
    - 99 centres
    - 40 countries
  - **Mean age 29.3 (15-52)**

Current status: baseline



Current status: baseline

WHO risk classification

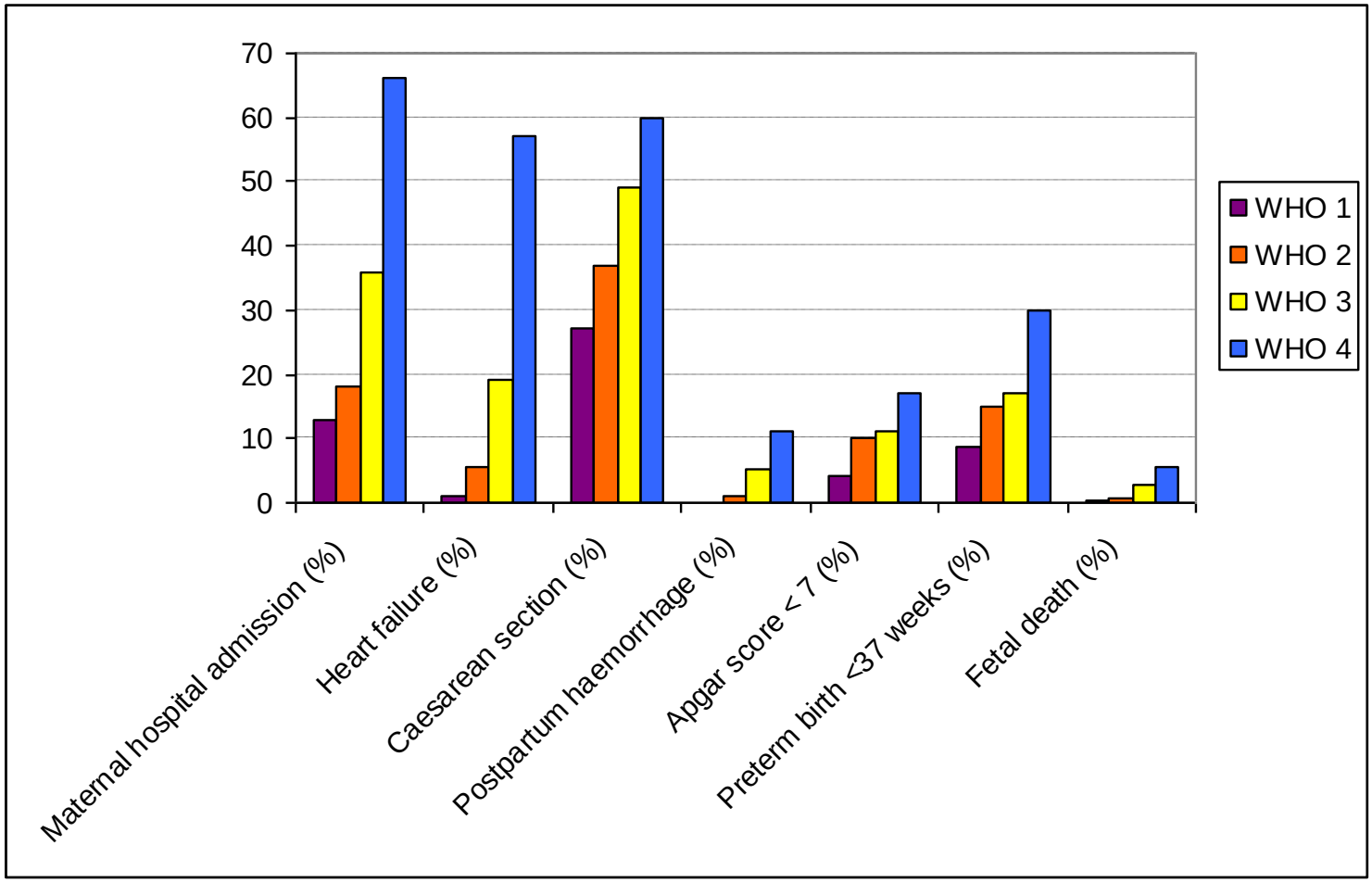


- WHO 1 (22%) no increased risks
- WHO 2 (15%) mildly increased risks
- WHO 2-3 (43%) moderatly increased risks
- WHO 3 (13%) significantly increased risks
- WHO 4 (7%) pregnancy contra-indicated

Current status: main outcome

Up to 1 wk after delivery	Percentage of pregnancies	n (2966)
Maternal mortality	0.4%	11
Hospital admission	24.8%	735
Cardiac reason	13.0%	387
Heart failure	12.5%	372
Ventricular arrhythmias	1.6%	47
Supraventricular arrhytmia	1.9%	57
Caesarean Section	45.8%	1385
Miscarriage <24 weeks	2.7%	80
Fetal mortality >24 weeks	0.7%	21

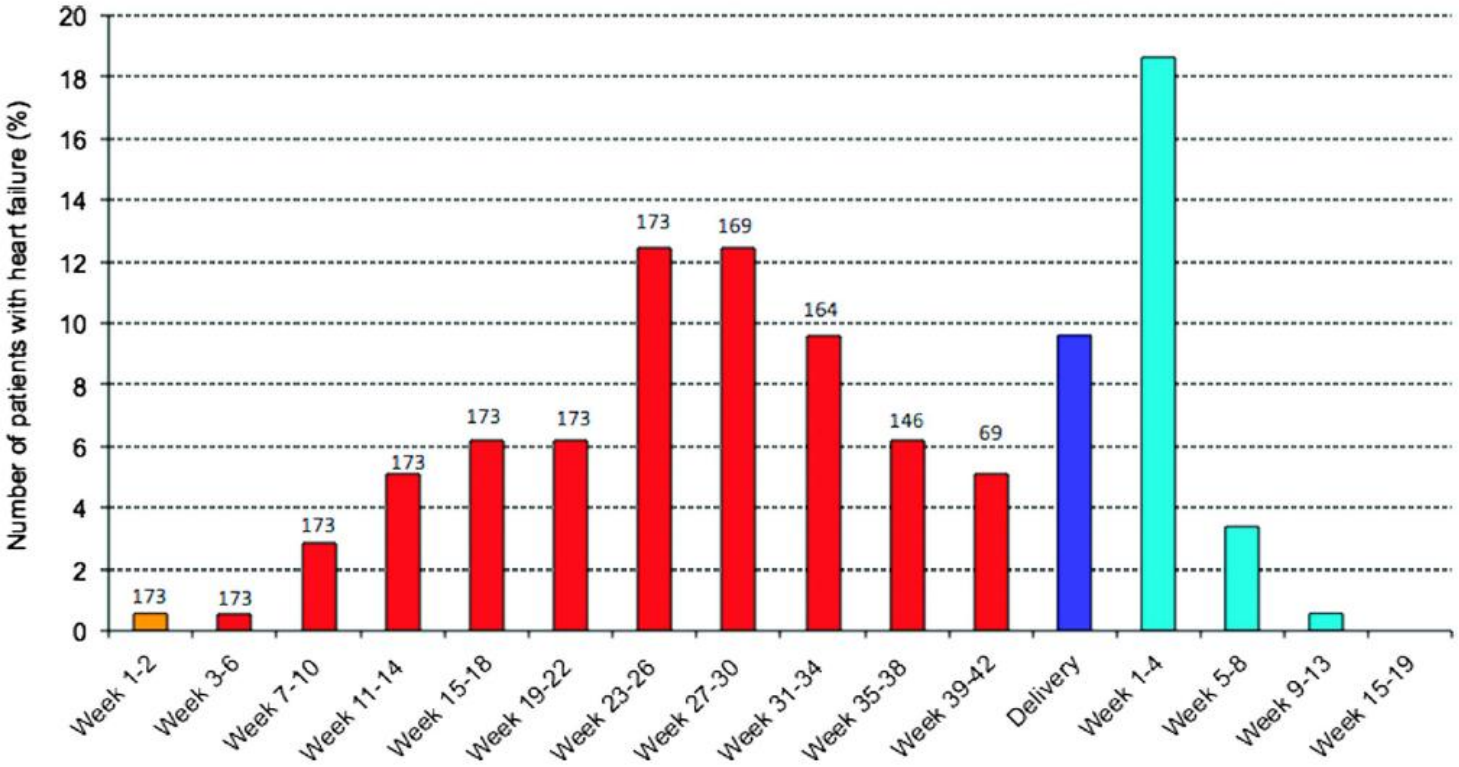
WHO risk stratification



Roos-Hesselink et al, *Eur Heart J* (2013);34:657-665

Heart Failure

4.8% mortality



Ruys et al, *Heart* (2014);100:231–238

Conclusions current status

- **Increased maternal and fetal mortality overall**
  - individual risks, e.g. cardiomyopathy, prosthetic valves, anticoagulants, aortic disease
- **More data needed to draw meaningful conclusions**
  - management
  - advising mothers about their individual risk of pregnancy

Future directions

- Ongoing data enrolment until at least 5000 patients
- New countries participating
- Publication of new analyses

Conclusions

- Large registry
- European based world wide inclusion
- Electronic patient inclusion
- Your help is needed!

Publication policy

- Ancillary analyses request (download form on EORP website)
- Proposal to executive committee via co-chairs
- After acceptance analysis will be performed based on an extensive and agreed studie outline

More data is needed

We need your help

Join us!

eorp@escardio.org

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