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
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
Dr. Ulf Thilen, Sweden
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

2007  2012  2017
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

Pregnancy

Follow-up at 6 months
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
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)

**EUROObservational Research Programme**

www.escardio.org
Enrolment: >4100

Aim: >5000
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

PLANNED in 2016:
- Cardiac problems in pregnancy (CPP) in Las Vegas
- ESC congress in Rome

- National Congresses in Japan, Australia, The Netherlands, UK...
Previous publications

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

Heart failure in pregnant women with cardiac disease: data from the ROPAC
Cardiac medication during pregnancy, data from the ROPAC


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

Titia P E Ruys, Jolien W Roos-Hesselink, Antonia Pijuan-Domènech, Elena Vasario, Ilshat R Gaisin, Bernard Iung, Leisa J Freeman, Elaine P Gordon, Petronella G Pieper, Roger Hall, Eric Boersma, Mark R Johnson, on behalf of the ROPAC investigators.
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*
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

Diagnosis

- Congenital Heart Disease (56%)
- Valvular Heart Disease (32%)
- Ischemic Heart Disease (1.5%)
- Cardiomyopathy (7%)
- Aortic disease (3%)
- Pulmonary hypertension (0.5%)
Current status: baseline

WHO risk classification

- WHO 1 (22%) no increased risks
- WHO 2 (15%) mildly increased risks
- WHO 2-3 (43%) moderately increased risks
- WHO 3 (13%) significantly increased risks
- WHO 4 (7%) pregnancy contra-indicated
## Current status: main outcome

<table>
<thead>
<tr>
<th>Event</th>
<th>Percentage of pregnancies</th>
<th>n (2966)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Up to 1 wk after delivery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maternal mortality</td>
<td>0.4%</td>
<td>11</td>
</tr>
<tr>
<td>Hospital admission</td>
<td>24.8%</td>
<td>735</td>
</tr>
<tr>
<td><strong>Cardiac reason</strong></td>
<td><strong>13.0%</strong></td>
<td><strong>387</strong></td>
</tr>
<tr>
<td>Heart failure</td>
<td>12.5%</td>
<td>372</td>
</tr>
<tr>
<td>Ventricular arrhythmias</td>
<td>1.6%</td>
<td>47</td>
</tr>
<tr>
<td>Supraventricular arrhythmia</td>
<td>1.9%</td>
<td>57</td>
</tr>
<tr>
<td>Caesarean Section</td>
<td>45.8%</td>
<td>1385</td>
</tr>
<tr>
<td>Miscarriage &lt;24 weeks</td>
<td>2.7%</td>
<td>80</td>
</tr>
<tr>
<td>Fetal mortality &gt;24 weeks</td>
<td>0.7%</td>
<td>21</td>
</tr>
</tbody>
</table>
WHO risk stratification

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 study outline
More data is needed
We need your help

Join us!
eorp@escardio.org