DETermination of the role of OXygen in suspected AMI

Robin Hofmann, MD
Karolinska Institute
Department of Clinical Science and Education
Division of Cardiology, Södersjukhuset
Stockholm, Sweden

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SWEDEHEART
OXYGEN in suspected acute myocardial infarction
$O_2 > 100$ years
Controversies in cardiovascular medicine

Oxygen therapy in acute coronary syndrome: are the benefits worth the risk?

Mony Shuvy\textsuperscript{1*}, Dan Atar\textsuperscript{2,3}, Philippe Gabriel Steg\textsuperscript{4}, Sigrun Halvorsen\textsuperscript{2}, Sanjit Jolly\textsuperscript{5}, Salim Yusuf\textsuperscript{5}, and Chaim Lotan\textsuperscript{1}

\textsuperscript{1}Heart Institute, Hadassah Hebrew University Medical Center, PO Box 12000, Jerusalem, Israel; \textsuperscript{2}Department of Cardiology, Oslo University Hospital Ullevål; \textsuperscript{3}Institute of Clinical Medicine, University of Oslo, Oslo, Norway; \textsuperscript{4}Université Paris-Diderot, INSERM U-698 and Hôpital Bichat, AP-HP, Paris, France; and \textsuperscript{5}McMaster University and the Population Health Research Institute, Hamilton Health Sciences, Hamilton, ON, Canada

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Potential harmful effects of oxygen

Shuvy, Atar et al.  
O₂ vs air
Oxygen therapy for acute myocardial infarction (Review)

Cabello JB, Burls A, Empananza JI, Bayliss S, Quinn T
COCHRANE Results

Rawles 1976
Wilson 1997
Ukholkina 2005
Ranchord 2012

430 patients total, 17 deaths
RR of death 2.05 (95% CI 0.75-5.58) on ITT
RR of death 2.11 (95% CI 0.78-5.68) on confirmed AMI
A definitive randomised controlled trial is urgently required!
“Dilemma” of RCTs

Eliminating the “expensive” adjective for clinical trials

Michael S. Lauer, MD, and Denise Bonds, MD Bethesda, MD

- Too limited in population (power), outcome and intervention
- results are not generalisable
- too expensive
- too difficult to perform without the trial infrastructure of the medical industry
DETermination of the role of OXygen in suspected Acute Myocardial Infarction

A Randomised, Registry based Clinical Trial (RRCT)

based on the nationwide SWEDISH HEART registry
SWEDEHEART: a nationwide registry

- RIKS-HIA: 90% < 80y, 66% > 80y
- SCAAR: > 95%
- SEPHIA: AMI < 75y > 80%
Eligible patient*: After informed consent

1:1 online randomisation in ambulance or ED

*Inclusion criteria:
- symptoms suggestive of AMI within 6h
- SpO2 ≥ 90%
- ≥ 30y
- ECG changes indicating ischemia and/or elevated troponin levels

Oxygen
6l/min for (6-)12h via Oxymask

Air

Primary Endpoint: 1-year total mortality

Additional secondary endpoint and sub studies

Data analysis through SWEDHEART registry and national mortality registry
Inclusion criteria

1. Chest pain or dyspnea suggestive of AMI
2. $\text{SpO}_2 \geq 90\%$
3. Age $\geq 30$ år
4. ECG changes and/or elevated troponin levels

For inclusion, all 4 criteria must be fulfilled!

- Treatment group receives 6L/min $O_2$ on Oxymask for 6-12 hours

Questions? Call DETO$_2$X personnel: 7462 or CCU on-call 3035
Exclusion criteria

- Unwillingness to participate
- Inability to understand given info
- Continuous O₂ treatment at home
- Cardiac arrest prior to inclusion

- Do NOT start O₂ therapy prior to inclusion assessment!
- Ongoing O₂ treatment prior to inclusion: contact doctor!

Questions? Call DETO₂X personnel: 7462 or CCU on-call 3035
Online randomisation in SWEDHEART

- personal identification number
- autocheck with national population registry
- dubbel inclusion not possible
### Inclusion Criteria

- Symptom (CBS/Dyspné) som vid AMI
- EKG-kriterier
- ST-höjning
- ST-sänkning
- LBBB
- T-negativitet
- Patologisk Q-våg
- Troponinförhöjning
- Syremättad

### Exclusion Criteria

- Ovilja att delaga
- Oförmåga att förstå information
- Pågående långtidsbeh. med syrgas
- Hjärtstopp innan randomiseringen

1. Inclusion criteria must be fulfilled (ECG and/or Troponins)
2. Exclusion criteria must not apply
3. Randomisation
Primary endpoint

1-year all-cause mortality

Intention-to-treat
Secondary endpoints

• **MACE**
  re-admission due to heart failure + 1-year mortality

• **Predefined sub group analysis:**

  Type 1 AMI vs other diagnosis
  NSTEMI vs STEMI
  Oxygen saturation levels  90-94% vs 95-100%
  Age groups
  Sex
  Sub groups with comorbidities (COPD, diabetes mellitus, renal failure)
Sub studies

- Assessment of myocardial damage and reperfusion injury with novel cardiac biomarkers assessing inflammation, apoptosis, oxidative stress, leukocyte and platelet activation (DETO2X-biomarkers)

- Assessment of myocardial function by advanced echo (Single Center)

- Assessment of coronary physiology and microvascular function during PCI (DETO2X-IMR)

- Assessment proposed analgetic effects of oxygen (OXYPAIN II)

- Health economy
Power calculations

Based on:
20% RR
1-total all-cause mortality estimated≈10%

6600
(2x3300)
patients with suspected AMI
Trial logistics

Information
Education
Co-operation

Prehospital EKG-tolkning

UPDATE !!
Pilot study
129 patients, 3m

Suspected AMI

Type I AMI

STEMI

NSTEMI

NoType I AMI

Type II AMI

Other cardiac diagnosis

Unspecified CP / other diagnosis

66%

33%

90%
At present: 

30 Hospitals active 
+ 12 starting

Study start date: 10/4-2013 

Total: 3038

Number of patients randomised 17/10-2014
Inclusion overview 20141017

Date range: 2013-04-01 to 2014-10-01

Included patients, total

- 0
- 1000
- 2000
- 3000

Inclusion rate currently >60/w
O₂ vs air
Thank you!

DETO2X steering board