

急性MIにおける酸素補充の死亡率に対する有益性はない (LBCT Session, Abstract 3067)

DETOX2X-AMI: 心筋梗塞症状を有する患者において酸素療法は生存率を改善しない

DETOX2X-AMI: Oxygen therapy does not improve survival in patients with symptoms of myocardial infarction

心筋梗塞 (MI) 症状を有する患者に対する酸素療法は生存率を改善しない、と2017 ESC Congress で発表され、*NEJM* に掲載された。DETOX2X-AMI 試験には、MI 疑いの患者 6,229人が登録された。患者の半数はオープンフェイスマスクによる酸素療法群、残りの半数はルームエアーに割り付けられた。ランダム化1年後の死亡率は、2群間に統計的有意差はなかった ($p=0.80$)。同様に、新たなMIリスクまたはトロポニンT値で評価した心筋傷害などの副次的評価項目も、2群間で有意差はなかった。

Full Text

Oxygen therapy does not improve survival in patients with myocardial infarction (MI) symptoms, according to late-breaking research presented in a Hot Line LBCT Session at the 2017 ESC Congress and published in the *NEJM*.

"The DETOX2X-AMI study questions the current practice of routine oxygen therapy for all patients with suspected myocardial infarction said first author Dr. Robin Hofmann, a cardiologist from the Karolinska Institutet at Södersjukhuset, Stockholm, Sweden.

This prospective, randomized, open-label trial enrolled 6,229 patients with suspected MI from 35 hospitals across Sweden. Half of the patients were assigned to oxygen given through an open face mask and the other half to room air without a mask.

The primary outcome, the mortality rate one year after randomization, was not statistically different between the two groups (5.0% in the oxygen group versus 5.1% in the air group, $p=0.80$). Similarly, there was no significant difference between the two groups for secondary endpoints, including the risk of a new MI or myocardial injury assessed with troponin-T level.

Even in patients at high risk, such as smokers, older patients, patients with diabetes, or patients with previous heart disease, the results were similar concerning mortality within one year.

European Society of Cardiology (ESC) guidelines on treatment of patients with ST-segment elevation myocardial infarction (STEMI) recommend oxygen (by mask or nasal prongs) for patients who are breathless, hypoxic, or have heart failure. They add that the systematic use of oxygen in patients without heart failure or dyspnea "is at best uncertain".

"ESC guidelines have gradually shifted towards more restrictive use of oxygen," said author Prof Stefan James, a cardiologist at Uppsala University, Uppsala, Sweden. "While the current recommendations were based on expert opinion only, we can now add substantial new data from our large clinical trial."

"The study results will likely have an immediate impact on clinical practice and future guidelines," he added. "Our findings do not support the routine use of oxygen therapy in all patients with symptoms of a heart attack. The general use of oxygen in these cases is still widespread in the world but can now be adjusted."

A fear that oxygen therapy could be harmful arose after the AVOID trial found a larger infarct size in patients receiving oxygen therapy. "Routine oxygen therapy seems unnecessary in this patient group, but fortunately our data do not give any indication of increased risk for the patients on oxygen," said Prof James. "So, all of us who have generally used oxygen for decades can now rest assured."

The DETOX2X-AMI trial is the first large-scale randomized trial of oxygen therapy in patients with suspected myocardial infarction to be large enough to reveal meaningful findings on mortality and morbidity. The study enrolled six times more patients than all previous randomized trials of this therapy combined and included a much broader range of patients to make the results relevant to everyday clinical practice.

The study's registry-based randomized clinical trial protocol used national registries including SWEDEHEART for randomization, case record forms and follow-up. Dr. Hofmann said: "With this design we could enroll 6,629 patients with high quality data in less than three years and keep overall costs to a fraction of a conventional randomized trial."

The Swedish Heart-Lung Foundation, The Swedish Research Council and the Swedish Foundation for Strategic Research funded the study.

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