

## DOES DECREASED SCVO2 CORRESPOND TO INCREASED MORTALITY IN PATIENTS WITH SEPSIS? *Herbert Patrick MD*



Throughout the world, patients with severe sepsis have a mortality of approximately 40%. A landmark article by Dr. Emanuel Rivers in 2001, in the New England Journal of Medicine, proposed a 6 hour resuscitation scheme that significantly lowered mortality of patients with severe sepsis in the Emergency Room. One aspect of his resuscitation scheme was repeated measurements of each patient's central venous oxygen saturation, abbreviated ScvO2. Why are central venous oxygen measurements important to the reduction in mortality? First, the difference between arterial oxygen saturation and central venous saturation reflects the tissue uptake of oxygen. Second, tissue uptake of oxygen in patients with severe sepsis is greater than normal. Therefore, to lower the mortality of patients with severe sepsis requires knowledge of ScvO2 values which reflect tissue oxygen uptake.

At rest, the difference between arterial and central venous oxygen saturation is less than 30%. For example, if arterial saturation is 100% and central venous saturation is 55%, the tissues are taking up the difference of 100% - 55% = 45%. This difference is greater than the normal value of 30% and reflects an abnormally high tissue uptake of oxygen at rest. Dr. Rivers' team demonstrated that decreased mortality correlated with achieving a normal oxygen saturation difference less than 30%, translating to a central

venous oxygen sat. of 100% - 30% = 70%.

In order to measure central venous oxygen saturation in each patient, Dr. Rivers' team inserted a triple lumen central venous catheter equipped with two fiberoptic bundles (PreSep®, Edwards Lifesciences) into each patient's central vein using either the internal jugular or subclavian route. Light carried by one fiberoptic bundle illuminated the central venous blood and the reflectance of this light carried back by the second bundle correlated to central venous oxygen saturation.

Our project was to perform a validation study of Dr. River's work using patients with severe sepsis in the MICU instead of the Emergency Department. This project was sponsored by an unrestricted educational grant from Edwards Lifesciences.

The design for this research project was retrospective using a historic control group. Let's examine each of these terms for the research project design. Retrospective means looking back for data collection using the patient's medical records after all patients have been enrolled. A historic control means the data for newer patients who received care using ScvO2 will be compared with patients prior to the start of the use of ScvO2.

The first step between the principal investigator of the research project and the sponsor is to arrange a Confidentiality Agreement. This assures the sponsor that the principal investigator and other members of the investigative team will not disclose any project related information into the public domain unless first approved by the sponsor. Edwards Lifesciences provided their standard Confidentiality Agreement for this research project.

The second step is principal investigator submission of papers to the Institutional Review Board (IRB) describing details of the proposed project. These papers describe the project design and include a consent form for each subject to sign before enrolling and participating in the research project. IRB approval is necessary before initiating the research project by gathering data or enrolling subjects in the project. For a retrospective project, no consent form was required.

The third step for research projects funded by an outside agency is creating a funding account for handling salaries and supplies. A

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*Respiratory Research... Continued from page 16*

budget is needed for the total project, either tallied by subject enrolled or by calendar year. Now let's review the project.

The Background or Introduction of the research project explains interest in the topic and why the topic is significant. For this project, many MICU physicians were anxious for validation of the Emergency Department research published in 2001 before initiating ScvO<sub>2</sub> measurements to treat patients with severe sepsis.

The Question proposed is: Does decreased ScvO<sub>2</sub> correlate to increased mortality in MICU patients with severe sepsis? The preconceived answer by researchers to the Question is called the Hypothesis. For this project, the Hypothesis was: Yes, decreased ScvO<sub>2</sub> will correlate to increased mortality for MICU patients, analogous to the findings from the Emergency Department.

For the Methods, the Respiratory Care staff was involved in identifying patients with severe sepsis. A search of patients with severe sepsis was also performed using the medical records department. The goal for the project was 20 historic control patients treated without ScvO<sub>2</sub> measurements plus 60 patients treated with ScvO<sub>2</sub> measurements. None of the patients had to sign an Informed Consent form per the IRB. Each MICU patient's chart was reviewed and ScvO<sub>2</sub> recorded together with patient mortality at 38 days noted. ScvO<sub>2</sub> was separated into three groups: 1) measured with value equal to or greater than 70%, 2) measured with value below 70%, and, 3) unmeasured. The duration of the project was two years or until the required enrollment was achieved. The difference between mortality in the groups would be compared by t-tests with  $p < 0.05$  defined as significant.

To formulate the Results, the three groups of ScvO<sub>2</sub> data were analyzed as a bar graph with the groups plotted along the horizontal axis. The 28 day mortality was plotted as a % vertical bar. The 60 patients were subdivided into the three groups by ScvO<sub>2</sub> measurements: ScvO<sub>2</sub> equal to or greater than 70% = 25 patients, ScvO<sub>2</sub> below 70% = 35 patients, and ScvO<sub>2</sub> not measured = 20 patients. The mortality was 22%, 45% and 45% respectively. These mortalities were significantly different at  $p < 0.04$ .

The Conclusion was a decreased ScvO<sub>2</sub> below 70% correlates to increased mortality in MICU patients with severe sepsis. Therefore, in this project, the Hypothesis was supported, corresponding to a "yes" answer to the Question.

The Reflections offers an opportunity to critique the project, suggesting modifications that would improve the quality of the research. For example, patients needed a comparison of their severity of illness, such as an APACHE (Acute Physiologic And Chronic Health Evaluation) score. This score would help address whether the patients' demographic data were different. Reflections can also include a comparison with similar research.

Future Research is important because research should lead to more research. For example, this research project could lead to a larger, multi-site project based on the same experimental design.

References from similar research and the reference for non-parametric statistics are included in the Bibliography section.

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Conflicts of Interest are listed for all participating in authorship of the project. Conflicts include ownership of stock or receipt of services or gifts from companies related to the project.

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