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Title Assessment of a system for non-invasive hemoglobin monitoring

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Reference Link to the complete report on the CEDIT web site:
http://cedit.aphp.fr/surveillance-peroperatoire-invasive-en-continu-de-lhemoglobinemie-dispositif-masimo-radical-7/

Aim

To assess the value and the impact of the Radical-7™ system (Masimo company) for non-invasive continuous monitoring of hemoglobin, during and after surgery, at the Paris University Hospital (AP-HP).

Conclusions and results

Technical aspects: This device is composed of a sensor, a patient cable and a monitor. It enables the continuous monitoring of multiple physiological parameters, including hemoglobin, using finger plethysmography at 12 different wavelengths. The reference method is the CO-oxymetry performed in the laboratory. Two competitors begin trials. Portable monitors used at the bedside are able to provide measurements of hemoglobin and were used in operating rooms. The analysis of 34 series extracted from 21 articles shows that the measures of hemoglobin are not always technically feasible (mostly in case of perfusion index below 1.4), are assigned a low bias (0.20 ± 0.73 g / dl) but a substantial variability (standard deviation 1.27 g /dl).
A calibration from an initial measurement reference reduces the bias (-0.24 ± 0.85 g / dl) but diminishes only slightly the variability (standard deviation 1.01 g / dl). Thus, measurement errors might be related to hemoglobin itself and also to the perfusion index.

Clinical aspects: The hemoglobin transfusion threshold during a surgical intervention is between 6 and 10 g / dl, depending on the patient's condition. Hemoglobin is not the only parameter to be considered. The impact of measurement errors has rarely been analyzed in a formal way. Models suggest that the risk of decision error is around 14-15%, the initial calibration reducing this risk to 13-14% (but with a much greater uncertainty). Several authors propose a "neutral" area indicating the use of a reference measurement. Others suggest using the monitoring in order to analyze the trend of changes of hemoglobin. However the transfusion decision remains based on a reference (laboratory) measurement.
A randomized trial showed that continuous monitoring provides better control of hemoglobin and decrease the need for transfusions, but it was performed in conditions quite distant from the reference practices.

Economic aspects: The monitor is available at a cost of around € 7,000. A kit of single use components (e.g. sheath to the sensor) amounts to 35 € per patient. No economic evaluation is available.

Organizational aspects: the measurement of hemoglobin at the biology laboratory relies on fast connections between this laboratory and operating rooms, and the ability to respond to unplanned requests. The adoption of an autonomous analyzer in the operating room could relax these constraints but would give rise to a need for maintenance and quality assurance, as well as of the question of responsibility for these analyzes. Moreover, the impact of the presence of this analyzer on the functioning of the operating unit has not been evaluated.

Recommendations

The continuous measurement of hemoglobin could be a means for achieving better indications of intraoperative transfusions, and also to ease the functioning of both the operating room and the biology laboratory. However, the proposed monitoring system appears too imprecise to be able to replace the reference measurements and the initial calibration does not appear to solve this problem; Other suggested aims of this monitoring system (ex: monitoring trends) are not sufficiently documented to allow a judgment of their clinical impact. In the absence of a demonstrated clinical benefit, economic and organizational questions appear to be of secondary importance. The CEDIT does not currently recommend the use of this device at AP-HP.

Methods

The scientific secretariat of the CEDIT performed a systematic review of the literature pertaining to the technology and met with the manufacturer of the medical device.

Further research/reviews required

The continuous monitoring of hemoglobin during and after surgery should be trialed in high quality studies.

Written by

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