Reviewer’s report

Title: Assessment of a Continuous Blood Gas Monitoring System in Animals during Circulatory stress.

Version: 2 Date: 21 June 2010

Reviewer: James Baumgardner

Reviewer’s report:

Major Compulsory Revisions

Overall:

1) This is a limited but solid animal study comparing an interesting variation of a commercial device for continuous blood gas measurements, to conventional, discretely sampled blood gas analysis. The emphasis is on covering the adequacy of agreement over a wide range of hemodynamic conditions. The basic idea for modifying the commercial device, is to place this external device in an arterial-venous loop so that arterial blood continuously flows past the optodes of the device. The basic device (CDI 500 sold by Terumo Cardiovascular Systems) is sold as an external device to accept continuous flow in association with cardiopulmonary bypass. Since the device was never intended for use as a patient monitor off bypass by use of an AV loop, the authors describe their modification of the device as an “off-label” use. The study of 12 pigs does cover a broad range of hemodynamic conditions, and accompanying this range of hemodynamic states is a broad range of PaCO2 and pH. The range of PaO2 covered is more narrow, but still relevant to many critically ill patients. The comparison of results from this new continuous ABG approach to conventional ABG, by Bland-Altman analysis, is quite favorable, as summarized in figure 1.

2) I think the authors have done a good job at showing the feasibility of this interesting approach in their animal study, and this is certainly a necessary first step. My main concern, at the global view, is that the discussion could easily leave a reader, only superficially familiar with this area, with an overly rosy view of the prospects of continuous blood gas analysis by this approach. To apply this approach, “off-label”, with the current device as it is sold, in ICU patients, without more extensive safety testing, would be hazardous to say the least. Although the tubing of the device is heparinized, I could not find any data on the manufacturer’s website concerning use in non-heparinized patients, for hours at a time (a time course relevant to ICU care). In terms of the prospects for further development and commercialization of this approach, the authors rightly point out in their discussion that a larger trial, in patients, in a clinical study, would be required. But I believe the issue goes beyond demonstration of reliability, ie how the new device compares to conventional ABG. The crucial issue is more along the lines of cost/benefit, ie does the additional information change clinical care in a way that is meaningful enough to justify the added costs. The commercial demise of several prior attempts at continuous ABG, most notably the Paratrend,
suggests that this cost/benefit ratio is a steep road to climb. And the environment since that time has become, if anything, even more cost-conscious. I would like to see a discussion of these issues in the manuscript.

Specific Points:

Methods, the Experimental Prep

3) 3rd Paragraph- How was the flow in AV loop controlled? How was it guaranteed to be more than 35 ml/min? How was this measured and confirmed?

4) 3rd Paragraph- Did you mean to say “data were collected by a single investigator (FL)”? How often was the data collected and recorded? I presume from the description that data acquisition to the computer was not continuous and automated?

5) Experimental Protocol, at the end- the description of the cannula in the carotid, for conventional ABG, should be moved to the experimental prep section.

Methods, the Experimental Protocol

6) The times spent at each of the hemorrhage states, and after volume resuscitation, are not listed. Also the total time of the experiment should be listed, since it is no doubt a much shorter time interval that the tens of hours that might be more typical of ICU monitoring.

7) The total number of blood gases is stated to be 120, but in tables 1 and 2 it appears there was data collection at 13 timepoints x 10 animals or 130 total ABG.

Results

8) Table 1- is there any way to join a,b, and c together to make one table, perhaps by using opposing pages?

9) Table 1- labels indicate PAC and TEE, but as the methods are written all the CO, SV, SR were obtained from the PRAM device, and there is no mention of PAC or TEE in the methods. Also CO and SV are subscripted as ThD but no thermodilution method was described.

Discussion

I think 4 additional points should be discussed:

a) As far as I know, the Most-Care has never been validated under conditions of pressor and inotrope infusions, which could impact aortic elastance. This is not a major concern since the broad directions of changes in hemodynamics sought here do not require a high degree of accuracy, but I think the reader should be aware that the numbers are approximate.

b) Calibration of the device after use for “long times” could become an issue when the device is in fact used for long times.

c) Optode devices intrinsically have lower signal to noise ratio at higher PO2; the nice agreement shown here for a lower range of PO2 may not hold up as well in a high range, and it seems unfair to compare to correlations from prior studies that did investigate a full range of PaO2.
d) I think more should be said about the amount of further work that will be required to make this into a viable clinical approach (see above).

Minor Essential Revisions
References: refs 2 and 10 are the same ref.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests.