An In Vitro Comparison of Micro Air Passage in the Venous Reservoir Bag

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Abstract

The increasing use of membrane oxygenators and collapsible venous reservoir bags (VRB) imposes a concern which is not normally associated with bubble oxygenators: Venous line air. Controversy exists concerning the superiority of membrane or bubble oxygenators. In membrane oxygenators there is no direct blood-gas interface as there is with the bubble oxygenator. This offers the advantage of not creating bubbles in the blood which then have to be removed before the blood is returned to the patient. Since there are persistent questions about the efficiency of defoaming sponges used in bubblers, and indeed their tendency to embolize silicone anti-foam material, it can be argued that membrane oxygenators are inherently less likely to transmit microemboli. This, of course, assumes that no air is present in the blood that enters the membrane. For this condition to exist in the absence of a defoaming sponge, the venous reservoir must be able to remove any air which enters through the venous line.

The purpose of this study is to determine the air removal efficiency of seven commercially available VRBs. By comparing them in an experimental setting, we were able to establish their relative efficiency in removing air from the venous return.

Materials and Methods

Seven commercially available VRBs: Bentley 1400 cc (BMR1400)\(^a\), Bentley 1900 cc (BMR1900)\(^b\), Terumo 1000 cc\(^c\), J & J 1000 cc\(^d\), SciMed 1300 cc (SM1300)\(^e\), SciMed 1500 cc (SM1500)\(^f\), and Shiley 1500 cc\(^g\); were examined to determine their ability to separate air from the venous return. A simple circuit consisting of a VRB, six feet of 3/8" perfusion tubing through a roller pump\(^1\), a hollow fiber membrane oxygenator\(^b\) (HFMO), and six feet of 1/2" perfusion tubing returning to the venous line. There were significant differences (p<.001) between the bags in all three microbubble size ranges. Although the two best VRBs, BMR1900 and Shiley1500 had similar counts, their design is remarkably dissimilar. The BMR1900 contains a 200µ heparin coated screen and is the only VRB utilizing a barrier in the blood path.

<table>
<thead>
<tr>
<th>VRB</th>
<th>10–50µ</th>
<th>50–100µ</th>
<th>&gt;100µ</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMR1400</td>
<td>208.00 ± 50.29</td>
<td>307.00 ± 82.8</td>
<td>48.83 ± 18.2</td>
</tr>
<tr>
<td>BMR1900</td>
<td>165.83 ± 62.39</td>
<td>1.83 ± 0.09</td>
<td>0.00 ± 0</td>
</tr>
<tr>
<td>J&amp;J1000</td>
<td>147.33 ± 40.75</td>
<td>46.16 ± 19.98</td>
<td>4.33 ± 3.44</td>
</tr>
<tr>
<td>SM1300</td>
<td>226.16 ± 55.07</td>
<td>56.00 ± 22.91</td>
<td>11.66 ± 12.64</td>
</tr>
<tr>
<td>SM1500</td>
<td>332.33 ± 66.41</td>
<td>116.00 ± 24.30</td>
<td>13.33 ± 10.58</td>
</tr>
<tr>
<td>SHILEY1500</td>
<td>110 ± 18.54</td>
<td>7.33 ± 3.61</td>
<td>0.00 ± 0</td>
</tr>
<tr>
<td>TERUMO1000</td>
<td>206.00 ± 49.68</td>
<td>49.80 ± 15.66</td>
<td>4.00 ± 5.51</td>
</tr>
</tbody>
</table>

The purpose of this study is to determine the air removal efficiency of seven commercially available VRBs. By comparing them in an experimental setting, we were able to establish their relative efficiency in removing air from the venous return.

Introduction

The rapidly increasing use of membrane oxygenators and collapsible venous reservoir bags (VRB)

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\(^a\) American Bentley, Irvine, CA 92714
\(^b\) Terumo, Piscataway, NJ 08854
\(^c\) J & J Cardiovascular, King of Prussia, PA
\(^d\) SciMed Life Systems, Minneapolis, MN 55441
\(^e\) Shiley, Irvine, CA 92714
\(^f\) Cobe Laboratories, Lakewood, CO 80215
ous inlet of the VRB, was used in each trial. A Hatteland BD100 ultrasonic bubble detector sensor was placed at the outlet of the VRB. The circuit was primed to maximum capacity with normal saline. Once primed, recirculation at 5 LPM was begun. The microbubble counter was calibrated by passing gas through a 40μ screen filter and allowing these sized bubbles to pass the sensor of the counter. The circuit was completely degassed by applying vacuum to the gas phase of the HFM0₂. When zero bubble counts were obtained, 50cc of air was injected over three seconds through a stopcock in the venous return line. Microbubble counts were recorded for thirty seconds in six trials of all seven VRBs. Microbubble size ranges were set at 10–50μ, 50–100, and >100μ. Between each injection of air, the entire circuit was debubbled and verified to be completely degassed with the bubble detector.

Statistical Analysis
All data were subjected to statistical analysis. This included one way analysis of Variance (ANOVA) of the mean bubble counts in each of the bubble size ranges. Further analysis included Students t-tests for each combination of VRB pairs in each bubble range. To decrease the chance of a Type I or alpha error as a result of multiple comparisons, we made p<.01 our point for statistical significance. All statistical analysis was performed by a 512K Macintosh computer using the Stat Works™ statistical package.

Results

Figure 1 compares graphically the means of each of the VRBs in the 10–50μ range. Analysis of variance revealed significant differences between the mean bubble counts of the VRBs in this range (p<.001). In order to determine differences between individual VRBs, a Students t-test was performed for each combination of bag pairs. This produced three groups of bags with similar bubble counts: low, medium, and high. The low group included: Shiley 1500—110.00 ± 18.54; J & J 1000—147.33 ± 40.75; BMR1900—165.83 ± 62.39. The medium group included: Terumo 1000—206.00 ± 49.68; BMR1400—208.00 ± 50.29; SM1300—226.16 ± 55.07. The high group included: SM1500—332.33 ± 55.07.

Figure 2 shows the means of each of the VRBs in the 50–100μ range. Analysis of variance showed highly significant differences within the bags in this range (p<.001). Again Students t-tests were used to illuminate these differences. There were five significantly different groups with similar bubble counts. Although the best two VRBs were statistically different (p<.005), there is questionable clinical significance; therefore, these two were included in the same class. This produced four groups: low, medium, medium-high, and high. The low group included: BMR1900—1.83 ± .09; Shiley1500—7.33 ± 3.61. The medium group included: J & J 1000—46.16 ± 19.98; Terumo1000—49.80 ± 15.66; SM1300—56.00 ± 22.91. The medium high group included: SM1500—116.00 ± 24.30. The high group included BMR1400—307.00 ± 82.80.

Figure 3 displays the means of perhaps the most clinically significant range: >100μ. One way analysis of variance again showed a highly significant degree of difference between the VRBs (p<.001). There were three significantly different groups as determined by Students t-tests: low, medium, and high. The low group included: BMR1900—0.00 ± 0; Shiley1500—0.00 ± 0. The medium group included: Terumo1000—4.00 ± 5.51; J & J 1000—4.33 ± 3.44; SM1300—11.66 ± 12.64; SM1500—13.33 ± 10.58. The high group included: BMR1400—48.83 ± 18.20.

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g Apple Computer, Cupertino, CA 95014
h Cricket Software, Philadelphia, PA 19104
Bubble oxygenators, by definition, create bubbles in the blood, and therefore must have some way of removing them. All current bubblers have a defoaming sponge treated with a silicone agent such as Anti-fom-A which removes the air from the blood as it passes through. Not only does this allow the safe bubbling of blood, but also removes the risks of venous line air.

Membrane oxygenators have little use for a defoaming sponge since no direct blood-gas interface exists within them. While this offers the distinct advantage of no gaseous micro emboli production, it imposes the need for an alternative method of air removal. Traditionally, collapsable VRBs have been used with membrane oxygenators, and many people consider them to be a safety device. While it is true that chance of massive air embolism is reduced with a collapsible VRB, the current study shows that air entering the venous inlet may be transmitted to the circuit and, potentially to the patient. Therefore, it becomes critically important to know the efficiency of VRBs currently being used.

The current study attempts to answer the questions: How closely do the available VRBs come to the ideal of zero micro air transmission, and how do they relate to one another? Since ultrasonic bubble detectors are significantly limited and possibly misleading, the values presented here are intended for comparison of the VRBs and should not be considered absolute quantities. We do, however, feel that the experimental design was effective in differentiating the capabilities of each VRB tested.

In order for a VRB to be effective, it must be able to separate air from the blood before it passes through the outlet. The VRBs tested were able to adequately remove the vast majority of venous line air but, at flow rates experienced during bypass, they passed significant numbers of micro bubbles through the outlet. Since most of these bubbles are not visible in blood, it is reasonable to suggest that the perfusionist is unaware of the air embolism occurring. Although arterial filtration hopefully removes many of these bubbles, pilot studies in our laboratory have shown that arterial filters do not remove micro bubbles smaller than the screen pore size, and bubbles larger than the screen pores are seen on the outlet side of the filter. For these reasons, it seems more appropriate to never allow air to enter the main part of the bypass circuit.

Most bags rely on bubble buoyancy and favorable flow characteristics to separate the air. Recently, however, one manufacturer introduced a VRB which imposes a 200µ heparin coated screen in the blood path. As evidenced by the present study, the BMR1900 is quite efficient at removing air from crystalloid. It is unclear on the basis of this study what effect a blood
prime would have on the screen. Interestingly, the predecessor to this bag was the BMR1400 which was the worst bag in the study. This indicates an overdue response from the manufacturers and an effort to improve the VRB.

With the exception of the BMR1900, all VRBs in this study used directed flow and buoyancy for air removal. It was therefore felt that comparisons among these could be made using a crystalloid prime, and relative performance with blood could be postulated. Of these, the Shiley was clearly the best, showing significant lower bubble counts to all but the BMR1900. The Terumo1000, J & J1000, and SM1300 comprise the next group in order of efficiency. This is followed by the SM1500 and finally the BMR1400. It is disturbing to note that the SM1500 is a new model VRB, yet it produced higher bubble counts than its predecessor, SM1300 in all ranges (10—50µ, p<.013; 50—100µ. p<.001, >100µ p<.84). Interestingly, the SM1500 approximates the Shiley1500 in design and appearance, yet falls remarkably short of its performance. By far the worst bag was the BMR1400. One must wonder if any thought process was utilized in its conception. It appears to have been an afterthought to the introduction of a new HFMO. Fortunately there is now a replacement, the BMR1900. Unfortunately, it costs more than any bag on the market.

There is clearly a tremendous degree of variability among currently available VRBs. While a couple are quite good at separating air from the venous inflow, most perform marginally, and some fail miserably. As the market share for membrane oxygenators increases, manufacturers must take the responsibility to further develop and refine venous reservoirs which are capable of accepting air from the venous line without transmitting it to the extracorporeal circuit.

Acknowledgments

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References

5. Unpublished data
6. Unpublished data

Questions from the Audience

Question—Brian Lalone: I want to congratulate you on a very well-designed study and for the presentation and the abstract. I have two questions. One, could you possibly vent all these bags with an active suction line? And two, do you have any available data on introduction to cardiotomy air—because all these bags differ with respect with cardiotomy inlets?

Answer: We did not vent the bags, and currently we do not have any data on cardiotomy return air. That is, however, a very thick source of error, one that we recognize, and that we’ll probably do something about very shortly.

Question—Frank Hurley: Can one postulate any relation between blood mixing characteristics of these bags to the ability to produce air? By that I mean: is there a negative correlation? If one can assume that this bag produces more air than bag A, can you also assume that it has less of an ability to mix drugs adequately?

Answer: One thing that we did notice was the size of the bag. The larger the bag, then possibly the better the air removal there was—just because of the size and the distance from inlet to the outlet. This does create a problem in priming volume considerations for the circuit. As far as just looking at a bag, as I said, the sign read 1500 and the Shiley looked very similar. However, as we described, the bubble counts were totally different. So I’m not sure that you could actually predict on the basis of their appearance and physical characteristics—just from examination—how they would react to air in the venous line.

Question—Richard Berryessa: Most elegant presentation. I wanted to address several issues. I’m not sure everyone understood that when you talked about the injection of drugs into the extracorporeal circuit by the perfusionist or anesthesiologist, should you include the patient in the extracorporeal circuit? That
a drug given by an anesthesiologist through an IV creates air that is picked up by the venous cannulus or the venous line bag, and passed right back into the patient, and that those counts are significant. In the range of 1000s per minute of microbubbles. And that can be done with as little as a cc, for instance, of Neo-Synephrine. And that we found that you give 50 cc’s of air in the stopcock in the venous line, that the bubble counts are really not that much different than if you give 50 cc’s of saline that happens to have some bubbles in it. The large bubbles rise, the small bubbles don’t have enough bouyancy, are subject to fluid flow dynamics, and then carried out. Which then brings me to the next point—and that is, a positive air vent in a bag would have done very little good, if any. And we did study that. Because the bubbles we’re measuring are so small that they are not going to rise and be vented out, anyway. They’re extremely small bubbles.

Answer: That’s correct and a very good point. I hope everyone understands that.