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Letter to the Editor

Technology Use and Patient Safety: At the Intersection of Change

To The Editor,

I appreciated reading Potger and coworkers' response to my letter "Working toward Best Practice: Microbubble Filtration and Patient Safety During Extracorporeal Circulation." I respect and welcome their reply (1), as it adds to discussions surrounding the importance of best practice and patient safety. Their response, however, has pointed out an error in my original letter that should be corrected out of concerns to better serve the best interests of this readership.

To clarify, I made the presumption that line pressure for the Affinity NT system as reported by Potger et al. (2) must have been artificially raised to ensure volume delivery between trials. This may have given the false impression that line pressure was thought to be increased for the Affinity NT system in isolation. Understandably, this would be incorrect and may be partly responsible for the assertions made by Potger's group regarding "potential discrepancies of pressures" (1). In reference to their original work, the study design adjusted a variable clamp at the inlet of a deairing oxygenator so that "arterial line pressures were kept at approximately 80 mmHg at 3 L/min pump flow and 110 mmHg at 5 L/min pump flow" (2). If the variable clamp was to raise pressure during testing with the Affinity NT system, then the amount of resistance applied by the clamp would transmit an increase in pressure across all arterial line tubing sections and respective circuit components. This of course would include both the prearterial filter and preoxygenator tubing segments. The increased pressure carries a net effect of compressing gas bubbles, making them smaller as previously discussed elsewhere (3). If on the other hand, 110 mmHg represents the resting pressure for the Affinity NT system at 5 L/min, then applying the variable clamp for testing with the Medtronic integrated Fusion system carries the same net effect of increasing pressure. My concern is that while the integrated Fusion system is designed to take advantage of higher internal pressures, the Affinity NT oxygenator with conventional filter could theoretically be affected negatively. How do we isolate effects of the varying downstream resistance that results when line pressure is balanced, and how does this affect the unsystematic variance in the statistical model used to analyze the study outcomes?

Whether the variable clamp was used to test both systems or not, differences in pressure drop dictate that the systems be compared using different amounts of downstream resistance in order to keep line pressure constant. In the context of clinical practice, Potger et al. correctly point out that line pressure is usually a product of resistance and not the other way around (1). Since pressure drop across each device cannot be controlled, the question then is whether or not each system should be allowed to adjust pressure naturally as a function of normal operation. Using different amounts of resistance in favor of keeping pressure constant, in my opinion, is analogous to conducting comparative clinical research using two different clinical scenarios. If the intention is to pursue research capable of mimicking the clinical setting with comparative value, then it makes more sense to standardize the test patient scenario, represented here as resistance, before making the comparison. This could be achieved by simply relying on the resistance created by the deairing oxygenator alone, or by applying the desired amount of in-line resistance before introducing each test system into the circuit.

The recent advances in oxygenator design make it necessary to rethink the methods used to compare them. Taking the new integrated Fusion system as an example, a progressively tighter weave of its hollow-fiber membrane helps augment internal pressure and improve bubble absorption. It can be conceptualized that a tighter weave reduces the diffusion boundary layer and helps boost oxygen transfer, while also affecting fluid velocity and transit time through the oxygenator. This could help explain the decrease in filter performance stability seen with the integrated Fusion system as flow rate increased (4). Where transit time was once largely seen as a design constraint on oxygen transfer that was normally balanced with changes in membrane area and prime volume (5), the new integrated Fusion system seems to have shifted somewhat the focus on transit time and the elements dependent on it. Determining the lowest acceptable membrane area must now also consider performance of the integrated bubble absorbing function.

To better appreciate the relevance of this, consider the relationship between flow, pressure, and transit time through an oxygenator in an extracorporeal circuit having constant resistance. As flow rate increases, internal pressures of the in-line oxygenator also increase, whereas transit time decreases. The higher internal pressure augments the driving force promoting bubble absorption, whereas the higher flow rate limits the time available for this process to take place. The amount of free gas absorbed due to the driving pressure generated at any given flow rate is in part limited by transit time. Now consider the same relationship in an extracorporeal circuit used to compare two oxygenators with different resistance values. If line pressure were kept constant by using a variable clamp to adjust downstream resistance, then the oxygenator with the larger pressure drop would require an increased occlusion setting to balance pressure in the postoxygenator tubing segment. This scenario favors the oxygenator with the larger pressure drop, as the net effect would be to increase internal pressure without increasing fluid velocity. In other words, the oxygenator with the larger pressure drop would benefit from an increased driving pressure without a decrease in transit time.

The explanation offered here can easily be vetted by varying both downstream resistance and flow rate to test the bubble absorbing capacities of different internal pressures and flow rates in the Fusion system. According to this explanation, lower flows and higher internal membrane pressures should show improved bubble absorption over higher flows and lower internal membrane pressures. The significance of this effect should also increase as the difference between the internal pressures and flow rates being compared increases. While this may be used to help better understand the bubble absorbing performance of the Fusion system, it also raises important questions concerning best practice and patient safety. Attached to this is the perception that current advances are a step toward improvements in hemodilution and biocompatibility (2). But are these advances being used to their fullest potential to optimize this situation? Naturally, one expects any achievement in the manufacturing process that allows a decreased diffusion boundary to go hand in hand with a decrease in the membrane area needed for effective oxygenation. Given that each 0.1 m^2 of membrane area represents almost double the total surface contained in a conventional adult arterial-line filter, how do we define best practice and patient safety in this context, and what role should technology play?

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