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Vacuum Assist: Angel or Demon CON

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Abstract: Vacuum-assisted venous drainage (VAVD) to enhance venous return during cardiopulmonary bypass (CPB) was described as early as 1958 but was not widely used until the late 1990s. VAVD was initially used to facilitate the use of smaller cannulas with ministernotomy but was increasingly used to allow reduction in CPB circuit size while maintaining CPB flow rates. This innovation was made without planned consideration to CPB circuit design, most critically that of the venous reservoir. Clinical reports of prime reduction facilitated by VAVD in both adult and pediatric CPB were associated with reduced nadir hematocrit and rates of transfusion that encouraged the proliferation of VAVD in CPB. Concomitantly, investigators have reported both in vitro and in vivo significantly increased arterial emboli associated with the use of VAVD, mostly related to accelerated venous air entrainment. In vitro studies continue to confirm this association and likely underestimate the resulting embolic load as a result of flawed study design. While the evidence for VAVD is equivocal, our understanding of the clinical impact of gaseous microemboli in CPB is similarly limited, most likely confined to blood–brain barrier disruption. It is only after two decades that CPB component design is receiving serious attention in terms of air handling. The ethics of innovation in the field of CPB warrant careful consideration. The application of VAVD is not without consequence. **Keywords:** vacuum-assisted venous drainage, cardiopulmonary bypass, emboli. *JECT. 2013;45:128–132*

VACUUM-ASSISTED VENOUS DRAINAGE: THE BEGINNINGS

The concept of reducing the prime volume of the cardiopulmonary bypass (CPB) circuit is not new. Clarence Dennis (1) in the early 1950s described his requirements for an oxygenator to use a minimum amount of blood, do as little damage to the blood cells as possible, and to achieve a critical level of oxygenation without excess foaming. In the infancy of CPB Dennis was aiming to minimize prime volume as well as gaseous emboli.

Vacuum-assisted cardiotomy drainage was described by DeWall and colleagues (2) as early as 1958 using a variably controlled vacuum source as a means to rapidly remove a large quantity of blood from the heart without a proportionate increase in blood trauma. They cautioned that excessive siphoning forces tended to occlude the cavae across the drainage cannulas and observed that hemolysis was associated with turbulent mixing of air with the blood as opposed to high suction force.

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INTO THE NEW MILLENNIUM

In the late 1990s and into the new millennium, vacuum-assisted venous drainage (VAVD) as an adjunct to CPB gained serious traction after publication of its application at the Cleveland Clinic, initially to facilitate the use of smaller cannulas with ministernotomy (3,4). It was further developed to reduce the prime volume using a conventional circuit with an unprimed venous line and then used in a modified circuit with reduced tubing lengths. The authors concluded VAVD resulted in higher hematocrit during CPB and reduced blood product use, irrespective of the type of sternotomy. In addition, VAVD was found to be useful for clearing airlocks common with conventional venous drainage. Of interest they stated that as VAVD was introduced as a modification of conventional CPB, no randomized protocol was used and that "the introduction of new technology is often iterative leading in stages to a re-engineering process." On the basis of the Cleveland Clinic experience, Munster and colleagues

(5) investigated the functionality and safety of VAVD, initially in an vitro circuit with a precise vacuum regulator and then its clinical application in 54 patients undergoing coronary artery bypass grafting. Their retrospective comparison to the preceding 58 patients revealed less fluid addition to the CPB circuit and no difference in measures of blood trauma.

There are relatively few randomized controlled trials (RCTs) comparing VAVD with gravity venous drainage and the numbers of patients studied are small. These RCTs report common findings of reduced nadir hematocrit during CPB, smaller cannula use, reduced prime volume, similar levels of hemolysis, and variable transfusion requirements (6–8). Higher levels of vacuum were positively correlated with hemolysis in a recent RCT by Goksedef (9). All of these studies were conducted in adults.

At the same time as the proliferation of VAVD for adults to assist in minimally invasive surgery, there was experimental work, in vitro and in vivo, to miniaturize neonatal CPB circuits with VAVD to achieve a blood free prime (10,11). Clinical use of VAVD and reduced prime circuits in pediatric cardiac surgery have been used to permit a blood-free prime together with reduced sized volumes and transfusion requirements (12–16). These reports coincided with a period of development of smaller components of the CPB circuit and new configuration heart–lung machines, which were contributory to prime reduction. Of particular interest is the variable absence of arterial line filters in reduced prime pediatric CPB circuits in these reports.

EMBOLI AND CARDIOPULMONARY BYPASS

As VAVD was beginning to be used, investigations into emboli transmission through CPB circuits were gaining momentum. During a study of neuroprotection by lidocaine in cardiac surgery conducted at Green Lane Hospital, casual observations revealed an association of emboli in the carotid artery with reducing levels in the hard-shell venous reservoir (HSVR) of the CPB circuit (17). These observations spawned a series of in vitro studies that demonstrated both the transmission of entrained venous air through the CPB circuit as well as generation of emboli within certain HSVR designs (18–20). Given our findings of the unexpected appearance of arterial line emboli resulting from air entrained with conventional gravity venous drainage (GVD), we further investigated the influence of VAVD on entrained venous air. Venous air entrainment with VAVD at –60 mmHg resulted in a 10-fold increase in the number of arterial line emboli (21). This was corroborated in other studies with additional findings that arterial emboli from venous air were attenuated to an extent by limiting the vacuum to –40 mmHg and by design factors of different CPB circuit components (22,23). In a pro con debate on VAVD at the 2000 Key West Outcomes Meeting, the author made the comment "Cerebral emboli during CPB have been positively correlated with increasing neurocognitive deficits. The application of VAVD has been employed clinically without any significant redesign of the components of the CPB circuit. While VAVD may be efficacious in certain scenarios, a thorough understanding of its influence on CPB is essential. Advantages must be balanced against potential hazards. The safe use of VAVD necessitates refinement of perfusion techniques, judicious choice of application, and further development of the CPB circuit" (24).

So Where Have We Come to in the Last Decade with Respect of This Debate?

On one hand there has been a focus in both the cardiac surgical and perfusion literature on avoidance of red cell transfusion summarized in "evidence-based" papers (25,26). In respect of the contribution of VAVD, the recent Blood Conservation Clinical Practice Guidelines from the Society of Thoracic Surgeons (STS) Blood Conservation Guideline Task Force, the Society of Cardiovascular Anaesthesiologists Special Task Force on Blood Transfusion and the International Consortium for Evidence Based Perfusion ascribed the use of VAVD a Class IIb recommendation with Level C evidence. The accompanying comment was that "Vacuum-assisted venous drainage in conjunction with minicircuits may prove useful in limiting bleeding and blood transfusion as part of a multimodality blood conservation program" *and* "Given the potential limitations of VAVD, use of this technology necessitates caution and adjustment of perfusion techniques, but may provide benefit, especially in paediatric patients. A VAVD may or may not cause haemolysis within the CPB circuit" (27). Class II recommendations (as defined by the American Heart Association) indicate conditions for which there is conflicting evidence or a divergence of opinion about the usefulness/efficacy of a procedure or treatment. Class IIa indicates that the weight of evidence is in favor or the usefulness/efficacy. Class IIb indicates that the usefulness/efficacy is less well established by evidence or opinion—in essence the "maybes." The lowest rank of evidence (C) is assigned when expert consensus is the primary basis for the recommendation (28). In other words, the use of VAVD may be of benefit based on expert opinion but with no hard evidence.

On the other hand, there has been a proliferation of reports in the perfusion literature on the behavior of gaseous microemboli in CPB circuits. This is the result of the increased commercial availability of sophisticated multichannel emboli detection devices (29,30). Recent in vitro studies in pediatric models of current CPB circuits have demonstrated increased transmission of emboli through the CPB circuit associated with VAVD and that although

the number of emboli was attenuated by an arterial filter, they were associated with both reservoir level and higher vacuum (–40 mmHg) (31,32). Studies from the laboratory at Penn State Hershey Children's Hospital similarly show emboli distal to the arterial filter after entrained venous air are exacerbated with higher levels of VAVD and attenuated by the arterial filter. In the clinical setting, large amounts of air were seen to originate from the venous line, particularly with VAVD, with high numbers of emboli in the arterial line and variable numbers of emboli in the middle cerebral artery (33,34). The authors advocate using EDAC-type (embolus detection and classification, Luna Innovations, Roanoke, VA) technology routinely in the clinical setting to optimize use of VAVD and minimize embolic load. However, they, like other investigators, have mimicked entrained air using fixed rate in vitro entrainment models.

A fixed rate air entrainment model will limit the rate at which the air is entrained rather than it being determined by the pressure gradient. Therefore, fixed-rate air entrainment models of VAVD underestimate emboli transmission through the CPB circuit.

We have previously pointed out the importance of using an unrestricted rate of air entrainment in VAVD CPB models, because in the clinical setting air entrainment from atmosphere is unrestricted. Under VAVD, air will entrain at a greatly increased rate compared with GVD (35). In accordance with our findings, venous air entrained at a unrestricted rates under low levels of VAVD resulting in increased arterial line emboli has also been demonstrated by La Pietra and colleagues (23). Although subsequent publications have frequently cited Jones et al. (22) describing VAVD of –40 mmHg to be similar in effect to conventional gravity drainage, they overlook the fact that the work cited was flawed with respect of its use of fixed-rate air entrainment. Jones et al. conceded this point in a letter to the editor stating "This dissimilarity between studies may be due to the differences in time taken to introduce the air or it may be due to a change in the physical properties of the GME arising from unrestricted or restricted air introduction. . ." (36).

Avoidance of an arterial line filter in association with VAVD to reduce prime is still reported (14). There is a compelling case to include arterial filtration in the CPB circuit. The recent emergence of integrated arterial filters requires additional investigation and a recent in vitro comparison of the air handling capability of circuits with integrated and conventional arterial filters showing quite variable levels of filtration efficiency (37). Of interest, both this study as well as a phased clinical improvement study demonstrated that the venous screen pore size plays an important role in emboli elimination (38).

Although the literature on VAVD with respect of emboli focuses on venous air as the causal factor, there are other sources of air entrainment including drug additions to the sampling manifold, fluid additions to the venous reservoir, and cardiotomy (left ventricle vent) return (39,40). The most frequent and least visible alternative source of entrained air results from intermittent excessive negative pressure excursions (40). This may be the result of cavitation in the venous line (David A. Stump, personal communication).

EMBOLIC LOAD VERSUS REDUCED PRIME

Although the continued evidence of arterial line emboli of <40 μm transmitted from the CPB circuit using VAVD is cause for concern, we are much less able to assess the clinical impact of these emboli. Frequently quoted studies associating emboli numbers with neuropsychological deficit are now out of date and were conducted in an era of CPB circuitry that is no longer applicable (41–43). Carrier's (44) study in 2002 entitled "Vacuum-assisted Venous Drainage Does Not Increase the Neurological Risk" was retrospective with somewhat gross outcome measures of stroke, mortality, and convulsions. The CPB protocol used conservative levels of VAVD (–5 to –15 mmHg) not dissimilar to conventional GVD and aprotinin was used in the VAVD cohort. There is evidence in a small animal model associating emboli less than 30 μm in size with blood–brain barrier injury (45). Although the effect of deformable emboli such as gaseous microemboli on the blood–brain barrier is an increasing focus of attention (46), evidence of clinical injury in humans associated with gaseous embolic load from the present day CPB circuit is not currently available. The question that remains regarding VAVD is do we take the approach of what the eye does not see the heart does not grieve? Alternatively, do we heed the cautionary advice of the latest STS guidelines?

Notwithstanding the careful deployment of VAVD reported in the literature, the absence of arterial line filtration and effective emboli detection would seem ill advised.

DRIVERS OF CHANGE

A somewhat more philosophical question is how do we find ourselves, more than a decade after the introduction of VAVD for CPB, using a technique empirically used on a widespread basis with devices (the reservoirs oxygenators and filters of the heart–lung machine) that were not designed for that purpose? Moreover, CPB circuit components (especially the venous reservoir) have undergone no substantive change with VAVD in mind over the past decade. The drivers for change would appear to be a combination of surgical innovation and promotion by the manufacturers. The ethical issues of innovation in cardiac surgery are complex and infrequently referred to in the

cardiac surgical literature. The application of VAVD is an interesting example in which a prominent institution promotes the application of a good idea using equipment not specifically designed for the purpose. This concept proliferates and is applied widely, quite often with marked variation in technique, which was not intended at its conception (e.g., the wide variation in negative pressure applied, the removal of arterial filtration, the absence of safety components such as negative or positive pressure relief) (47,48). In the VAVD literature, in vitro findings of increased embolic load are referred to as a potential issue but largely dismissed without any current understanding of their sequelae. We have seen reports warning of limitations of VAVD and occasional reports of accidents attributed to the use of VAVD (49–51). Unquestionably these are the tip of the iceberg because we reliably know that perfusion incidents are significantly underreported (52). The ability to reduce the size of the conventional CPB circuit with the evolution of smaller and more efficient oxygenators, filters and heart–lung machine redesign combined with the strategies of retrograde autologous priming and cell processing has obviated the need for VAVD for routine CPB.

Peter Angelos draws our attention to our "contemporary fascination with whatever is new" and the conflicts that surgical innovation poses in respect of informed consent together with the lack of oversight of the creativity of surgeons to innovate (53). The debate between advancement and stagnation in progressing surgical technique, in this case the innovation of VAVD, has not been subject to the independent checks and balances as would the use of a new drug therapy. Even with the more rigorous control of pharmacological innovation, unforeseen badness may subsequently come to light, as in the use of aprotinin (54).

Only now, plausibly as a result of the recent commercial availability of more sophisticated emboli detection technology and the resulting publications on CPB circuit air handling, is the industry giving serious consideration to reservoir design in respect of emboli. In addition, there are a number of new-generation CPB components that include emboli reduction as an integral part of the design that are soon to become commercially available that show promise.

CONCLUSION

Vacuum-assisted venous drainage might best be described not as angel or demon, but as angel AND demon. Twelve years on from debating the relative merits of VAVD, the summary statement remains unchanged. . ."Cerebral emboli during CPB have been positively correlated with increasing neurocognitive deficits. The application of VAVD has been employed clinically without any significant redesign of the components of the CPB circuit. While VAVD may be efficacious in certain scenarios, a thorough understanding of its influence on CPB is essential. Advantages must be balanced against potential hazards. The safe use of VAVD necessitates refinement of perfusion techniques, judicious choice of application, and further development of the CPB circuit."

This is unfinished business.

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