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Vacuum-Assisted Venous Drainage: A 2014 Safety Survey

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Abstract: Despite the widespread use of vacuum-assisted venous drainage (VAVD) and case reports describing catastrophic incidents related to VAVD, there is a lack of data cataloging specific safety measures that individuals and institutions have incorporated into their VAVD practices for the prevention of these incidents. Therefore, the purpose of this study is to survey the perfusion community to gather data on VAVD practices, and to compare these current practices with literature recommendations and the American Society of ExtraCorporeal Technology (AmSECT) Standards and Guidelines. In September 2014, a survey was distributed via PerfList and PerfMail, and by direct e-mail to members of the New York State Society of Perfusionists, targeting certified clinical perfusionists in New York State. Survey topics pertaining to VAVD practice included 1) equipment, 2) pressure monitoring and alarms, 3) protocols, checklists, and documentation, and 4) VAVD-related incidents. Of ~200 certified clinical perfusionists who live and/or work in New York State (NYS), 88 responded (42%). Most respondents (90.1%) report they use VAVD. Of these, 87.3% report that they monitor VAVD pressure, with 51.6% having audible and visual alarms for both positive and excessive negative pressures. At the institutional level, 61.2% of respondents reported that there is a protocol in place at for their team limiting negative pressure in the reservoir, 28.4% document VAVD pressure in the pump record, and AmSECT's three recommended VAVD checklist items are met with 53.7%, 55.1%, and 33.8% compliance. In conclusion, the results of this study reveal that the use of VAVD has increased and has become nearly universal in 2014. There is high compliance to some of the literature recommendations and AmSECT Standards and Guidelines, however, there are still some gaps between current practices and these recommendations. Continued improvement, both at the individual and institutional levels, will help to improve patient safety by preventing untoward events from occurring while using VAVD. **Keywords:** vacuum-assisted venous drainage, VAVD, CPB, perfusion, safety, monitoring. *JECT. 2015;47:160–166*

Accompanying the rapid proliferation of minimally invasive cardiac surgery (MICS) is an increased dependence on augmented venous drainage techniques during cardiopulmonary bypass (CPB) (1). Although one of these techniques, vacuum-assisted venous drainage (VAVD), makes MICS possible by allowing for the use of smaller venous cannulae and miniaturized circuits, it also carries with it a significant risk if not practiced judiciously and safely. Aside from the myriad of data surrounding the propagation of gaseous microemboli (2–5) and increased hemolysis with its use (6,7), VAVD has also garnered attention through numerous case reports and anecdotes of catastrophic events occurring while using this technique (8–13). The paramount importance of incorporating monitoring and safety devices while using VAVD is evident in these published reports, which have evoked literature recommendations for the prevention of these events. In addition, the American Society of ExtraCorporeal Technology (AmSECT) includes VAVD-related items on their recommended institutional checklist (14), and also mentions VAVD safety, monitoring, and documentation in their 2013 revised Standards and Guidelines (15).

Despite this, there is currently a lack of data cataloging the specific safety measures that individuals and institutions have incorporated into their VAVD practices. Therefore, the objective of this study is three-fold: 1) to gather specific data on VAVD practice and safety, 2) to identify any gaps between reported practice and current literature recommendations, and 3) to assess respondent compliance to AmSECT's Standards and Guidelines and checklist items (14,15).

MATERIALS AND METHODS

This study was submitted to State Univeristy of New York (SUNY) Upstate Medical University research compliance committee and was determined to be exempt from the review of Institutional Review Board according to federal

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regulations (exemption category no. 2). The web-based survey was created using a commercial survey site (www.surveymonkey.com) and responses were collected between September 2014 and October 2014. The 28 questions in the survey covered various topics pertaining to VAVD practice including 1) equipment, 2) pressure monitoring and alarms, 3) institutional protocols, checklists, and documentation, and 4) VAVD-related incidents. The survey data security and participant confidentiality were ensured through physical protection, software devices, and hardware features. The target population of this study was certified clinical perfusionists (CCPs) who live and/or work in New York State (NYS). The survey link was distributed to members of AmSECT and Perfusion.com via the organizations' online forums (PerfList and PerfMail, respectively), and was addressed specifically to perfusionists that live and/or work in NYS. In addition, the survey link was distributed via e-mail directly to all members of the New York State Society of Perfusionists. Data from respondents that reported that they neither work nor live in NYS were excluded.

RESULTS

Response Rate and Respondent Demographics

Of the approximately 200 CCPs that live and/or work in NYS, 88 responded to the survey, for a response rate of about 42%. Although a very large number of respondents were from the New York City/downstate region (47.5%), all regions of NYS were well represented considering their respective populations (Table 1). Respondents reported a wide range of experience in the field of perfusion, with the largest number of respondents falling into the category of greater than 20 years in the field (Table 1). The majority of respondents (64.5%) identified themselves as full-time staff perfusionists, while 25.0% of respondents were chief perfusionists. Other demographic data are summarized in Table 1.

Table 1. Respondent demographic data.

Employment location	
Western NY	17.5%
Central NY	18.8%
Eastern NY	12.5%
New York City/Downstate	47.5%
Employment venue	
Hospital based—academic	50.7%
Hospital based	44.0%
Large contract group	.0%
Small contract group	2.7%
Self-used	2.7%
Job description	
Staff Perfusionist—full time	64.5%
Staff Perfusionist—part time	6.6%
Chief perfusionist/manager	25.0%
Full-time perfusion education faculty	2.6%
Locum tenens	1.3%
Retired	.0%
Years in perfusion	
0–5	21.1%
6–10	6.6%
11–15	15.8%
16–20	22.4%
>20	34.2%
Patient population	
Adult only	71.1%
Adult and pediatric	29.0%
Primarily pediatric	.0%

Prevalence and Use of VAVD

Most of the respondents (90.1%) indicated that VAVD is a technique that is performed in their practices, while 7.9% reported that they currently use kinetic-assisted venous drainage (KAVD; Figure 1). Of those respondents using VAVD, 41.9% reported that they are using VAVD in more than 75% of their cases (Figure 2). Initiation of CPB with a dry venous line was reported by 18.2% of respondents. The technique of venting the vacuum from the venous

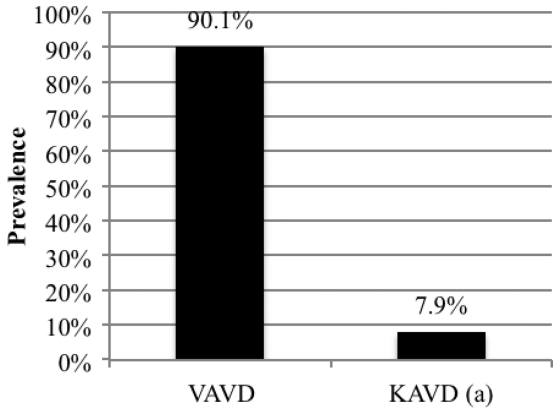

Figure 1. The use of VAVD and KAVD reported by respondents in 2014. VAVD, vacuum-assisted venous drainage; KAVD, kinetic-assisted venous drainage.

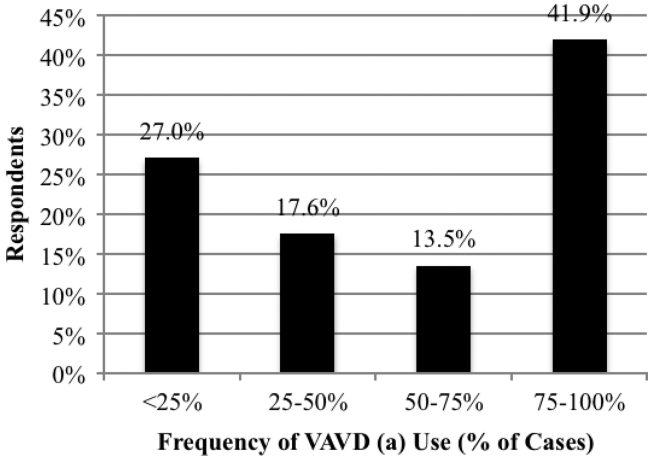

Figure 2. The frequency of VAVD use reported by respondents. VAVD, vacuum-assisted venous drainage.

Table 2. CPB equipment used.

Arterial pump	
Roller	29.6%
Centrifugal	70.4%
Venous reservoir	
Hard-shell venous reservoir	92.1%
Soft-shell venous reservoir	6.6%
Other	1.3%
Vacuum system equipment	
Approved VAVD regulator	95.5%
Vacuum line with negative pressure relief valve	50.6%
Vacuum line with "Y" atmosphere vent line	94.3%
Condensation trap	95.5%
Positive pressure relief valve on reservoir	98.6%
Negative pressure relief valve on reservoir	59.4%
One-way flow valve between reservoir and oxygenator*	56.1%
Vacuum regulator inspection and calibration as part of routine equipment maintenance	44.1%

CPB, cardiopulmonary bypass; VAVD, vacuum-assisted venous drainage.
*Data were included for centrifugal pump users only.

Table 3. Monitoring and alarms pertaining to VAVD.

Pressure monitoring	
On hard-shell reservoir	81.7%
In venous line	5.6%
None	12.7%
Stand-alone pressure monitor	22.7%
Integrated pump console transducer (without servoregulation)	51.5%
Integrated pump console transducer (with servoregulation)	25.8%
Alarms and alarm limits	
Positive pressure only	27.4%
Excessive negative pressure only	6.5%
Both positive and excessive negative pressure	51.6%
None	14.5%
Positive alarm limit (mmHg)	+1 to +50 (mean = +7.71)
Negative alarm limit (mmHg)	–40 to –100 (mean = –60.83)
Institutional protocol limiting negative pressure	
Yes	61.2%
No	38.8%
Institutional protocol limit (mmHg)	–40 to –100 (mean = –52.79)

VAVD, vacuum-assisted venous drainage.

reservoir when rapidly going down on pump flow was indicated by 78.1% of the respondents.

CPB Equipment

The type of arterial pump was reported as follows: 70.4% primarily use centrifugal arterial pumps, while 29.6% of respondents use roller pumps. The use of a hard-shell venous reservoir was reported by 92.1% of respondents. Equipment pertaining to VAVD is summarized in Table 2. In brief, approved VAVD regulators, vacuum line with a "Y" atmosphere vent line, a condensation trap, and positive pressure relief valve on the reservoir are nearly universal features in respondents' vacuum systems (>94% prevalence). Conversely, the use of a vacuum line with a negative pressure relief valve, a negative pressure relief valve on the reservoir, and a one-way flow valve between reservoir and oxygenator were all reported by roughly half of respondents (50.6%, 59.4%, and 56.1%, respectively).

Pressure Monitoring, Alarms, and Institutional Protocols

For those respondents who use VAVD, vacuum pressure is monitored by 88.1% (Table 3). Of these, 93.5% monitor pressure indirectly on the venous reservoir and 6.6% monitor pressure directly in the venous line. Of the respondents monitoring pressure, 77.3% use an integrated pump console transducer (51.5% without servoregulation and 25.8% with servoregulation), with 22.7% using a stand-alone pressure monitor. For this group of respondents monitoring pressure, the use of audible and visual alarms is also summarized in Table 3. The majority (51.6%) of respondents use alarms for both positive and excessive negative pressures while using VAVD, whereas 27.4% use alarms for only positive pressure. A very small number of respondents (6.5%) use alarms only for excessive negative pressure; in addition, 14.5% of respondents monitoring VAVD pressure that do not use alarms at all. The reported range for the positive pressure alarm was +2 to +50 mmHg (mean = +7.71 mmHg), while that for the negative pressure alarm was –40 to –100 mmHg (mean = –60.83 mmHg). A total of 61.2% of respondents indicate that they have an institutional protocol in place limiting negative pressure in the reservoir, with a reported range of –40 to –100 mmHg (mean = –52.79 mmHg).

Servoregulation

Of the aforementioned respondents monitoring VAVD pressure, 25.8% reported that they use an integrated pump console pressure transducer with servoregulation. Servoregulation techniques with selected direct quotes from respondents are shown in Table 4. In summary, these respondents' sucker and vent pumps are slowed and eventually stopped when the pressure in the venous reservoir exceeds a set positive pressure limit.

Institutional Checklist Items

Institutional checklist items pertaining to VAVD are summarized in Table 5. Of the seven checklist items that this survey inquired, the two most commonly used were "pressure transducers zeroed" (81.2%) and "alarms are on and limits are set properly" (71.0%).

Reported VAVD-Related Incidents

Incidents related to VAVD are displayed in Table 6. The most common incident reported was "a leak in the vacuum system rendering it non-functional when trying to engage it on CPB," which 52.4% of respondents have encountered. Of note, 26.2% of respondents have encountered a pressurized venous reservoir that led to retrograde

Table 4. Comments on servoregulation techniques pertaining to VAVD.

"When positive pressure in the reservoir exceeds 10 mmHg, sucker and vent pumps shut off."
"Over pressurization of cardiotomy = vent and sucker auto shut off with audible alarm and visual screen alert to rectify situation."
"Pumps that supply positive pressure to the reservoir will automatically slowed when reservoir pressure reaches 10 mmHg and will automatically be shut down when the reservoir pressure reaches 20 mmHg."
"If maximum positive pressure is met or exceeded, audible alarm sounds and vent/sump and pump sucker heads shut off until negative pressure restored."

VAVD, vacuum-assisted venous drainage.

Table 5. Institutional checklist items pertaining to VAVD.

Item	Compliance (%)
Vacuum regulator operational*	53.7
Cardiotomy positive-pressure relief valve present*	55.1
Negative pressure relief valve(s) unobstructed*	33.8
System has been engaged and tested	54.4
Pressure transducers zeroed	81.2
Reservoir pressure reading correlates with vacuum regulator's set vacuum	26.5
Alarms are on and limits are set properly	71.0

VAVD, vacuum-assisted venous drainage.
*Checklist item recommended by AmSECT (14)

Table 6. Reported VAVD-related incidents.

Incident	Prevalence (%)
Pressurized venous reservoir activating PPRV (b)	23.8
Pressurized venous reservoir leading to retrograde air up the venous line	26.2
Air pulled across the membrane during priming	21.4
Leak in vacuum system rendering it non-functional when trying to engage it on CPB	52.4
Vacuum regulator malfunction	33.3
Vacuum source (wall vacuum) malfunction	33.3
Over-administration of drugs or fluids due to increased siphon	19.1

air entrainment up the venous line. One respondent reported in the open-ended comments that he/she experienced acute de-priming of his/her arterial line filter while using VAVD and had to remove the vacuum, come off bypass, and re-prime the arterial line filter to rectify the situation.

DISCUSSION

The application of external suction to achieve adequate venous drainage is not a new technique. To the contrary, Dr. John Gibbon's earlier models of the heart–lung machine in the early 1950s used vacuum to achieve venous return (16). Blood was removed from the vena cavae using a minimal negative pressure (~40 cmH_2O or ~30 mmHg) and then entered the collection chamber (16). However, at a Minnesota conference in 1954, Dr. Clarence Dennis described his early experience with gravity venous return, stating that he simplified the removal of blood from the vena cavae by changing the orientation of the apparatus so that the collection chamber fills with gravity (17). Thereafter, the use of gravity to achieve venous return superseded vacuum, favored for its simplicity. However, around the turn of the 21st century, when MICS demanded smaller venous cannulae with increased resistance, augmented venous return made its resurgence. A 2000 practice survey by Mejak et al. (18) found that both VAVD and KAVD were being used at nearly equal prevalence at this time (23.7% reported the use of VAVD and 26.3% KAVD). An Australian and New Zealand perfusion practice survey in 2006 found that 38.0% of respondents were using VAVD, demonstrating an increase in prevalence of this technique (19). This survey of NYS perfusionists indicates that the use of VAVD has become nearly universal (90.1%), while the use of KAVD has all but disappeared (only 7.89% of respondents report that they ever use KAVD) (Figure 3). One likely reason for this shift is that VAVD is more cost effective than KAVD, since it eliminates the expense of an additional centrifugal pump head in the venous line (20). Not only do 90.1% of perfusionists report using VAVD at some frequency in their practice, but 41.9% of these respondents report using it in more than 75% of their cases (Figure 2).

Compliance to Literature Recommendations

Compliance to current literature recommendations regarding VAVD safety is summarized in Table 7. Multiple literature sources recommend monitoring real-time pressure

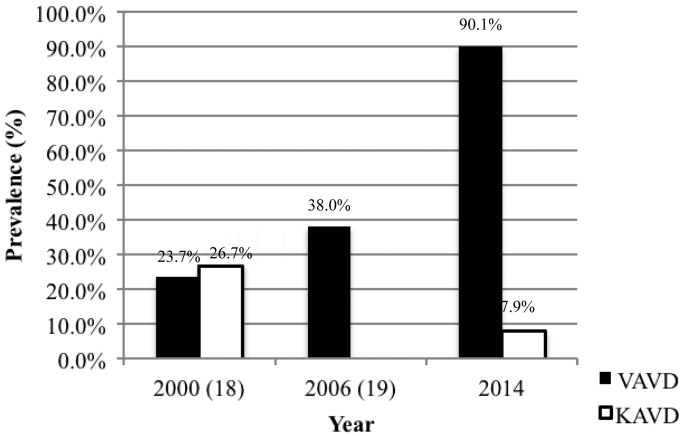

Figure 3. Comparison of the prevalence of VAVD and KAVD. VAVD, vacuum-assisted venous drainage; KAVD, kinetic-assisted venous drainage.

Table 7. Respondent compliance to literature recommendations.

Literature Recommendation	Compliance (%)
The use of a PPRV on the reservoir (1,9,10,20–23)	98.6
The use of a negative pressure relief valve on the reservoir (1,9,20–23)	59.4
The use of an approved VAVD regulator (1,9,10,20–23)	95.5
Vacuum line including a Y atmosphere vent line (9,10,20,21)	94.3
Vacuum line including a moisture trap (9,10,20,21)	95.5
Routine vacuum regulator calibration and maintenance (21)	42.9
The use of a real-time pressure monitoring system (9,10,20–23)	88.1
The use of alarms for positive pressure (9,10)	79.0
The use of alarmrs for both positive and excessive negative pressures (20,21)	51.6

VAVD, vacuum-assisted venous drainage.

in the venous reservoir, aside from the measured value on the vacuum regulator (9,10,19,20,22,23). In a 2012 case report, the authors were neither using pressure monitors nor alarms, and a proximal kink in the vacuum system caused an unidentifiable pressurization of the venous reservoir when pump suckers were turned on (10). The pressurization was unbeknownst to the clinician until the venous clamp was removed to initiate CPB, at which point a massive air embolism was transferred to the patient's right atrium (10). Fortunately, the recommendation to monitor VAVD pressure aside from just the VAVD regulator is met with 88.1% compliance (Table 7). Different locations and modes of pressure monitoring are displayed in Table 3. Interestingly, although there is a current lack of literature recommendations pertaining to servoregulation while using VAVD, there were still some respondents that reported that they incorporate servoregulation as an added safety measure (Table 4).

The incorporation of a positive pressure relieve valve (PPRV) on the venous reservoir has become nearly universal (reported by 98.6% of respondents). Although the current literature recommends using a PPRV (Table 7) and nearly all perfusionists are currently using one, it is important that perfusionists recognize the fallibility of such devices. A laboratory assessment of various PPRVs revealed that one PPRV allowed positive pressures in excess of +40 mmHg (likely large enough to overcome the negative pressure exerted by the gravity siphon) at sucker and vent flows as low as 1–2 liters per minute (LPM), despite manufacturer claims that the valve will deploy at a pressure of +5 mmHg (24). In addition, the authors of the aforementioned case report with the kink in venous tubing did in fact have a PPRV on their venous reservoir; however, they reported that it either failed or was unable to accommodate the positive pressure being generated by the pump suckers (10). Therefore, a PPRV should be used, according to the literature recommendations, but laboratory studies and case reports reveal the limitations of these devices and show that a PPRV alone is not enough to protect against pressurization of the venous reservoir.

Currently, there is 51.6% compliance to the literature recommendations to have alarms set for both positive pressure and excessive negative pressure (19,20). An additional 28.8% of respondents have alarms for only positive pressure, while 6.8% of respondents have alarms for only negative pressure. The importance of these audible and visual alarms cannot be overemphasized. In a case report by Davila et al. (9), a pressurized venous reservoir led to a de-primed venous line and massive air embolism to the right atrium of a pediatric patient, which subsequently crossed an intracardiac shunt and was ejected systemically. Although the causes of this untoward event were multifactorial, the authors stated that they only had alarms on their pressure monitor set to trigger at a large negative pressure (and none for a small positive pressure), and cite this as a preventable cause (9). In addition, a 2015 study by Beck et al. (25) demonstrated that when perfusionists were given a computer-generated visual alert to notify them of a clinical parameter outside of a set range, they identified and rectified the parameter statistically faster than those without a computer-generated alert. This further emphasizes the point that even the most vigilant clinicians can benefit from audible and visual alarms, which will subsequently translate into improved patient safety.

Of those respondents using alarms, the average positive alarm limit was +7.71 mmHg, while the average negative alarm limit was –60.83 mmHg, both of which are compliant with literature recommendations. Most CPB circuit configurations have a gravity siphon of about –20 to –30 mmHg (20); thus, a positive pressure alarm of +7.71 mmHg would likely alert the perfusionist of a pressurized reservoir before retrograde de-priming of the venous line would occur. A study by Mulholland et al. illustrated that beyond negative pressures of –120 mmHg, the relationship between negative pressure and blood trauma becomes linear (5); thus, it is recommended by the literature to limit net negative pressure (gravity siphon + VAVD pressure) to –100 mmHg (20). Another study found that the application of a VAVD pressure of –80 mmHg (a "net" negative pressure of –100 to –110 mmHg) led to greater levels of plasma free hemoglobin than VAVD pressures of –40 mmHg, further supporting this negative pressure limit (6). Reported alarm limits of –60.83 mmHg indicate that those using alarms are maintaining a maximum net negative pressure of about –80.83 to –90.83 mmHg, which will not lead to increased blood trauma according to evidence in the current literature. Thus, current alarm limits reported by those using alarms are largely compliant with the literature recommendations.

Compliance to AmSECT Standards and Guidelines

The importance of adherence to professional standards and guidelines was outlined in a 2013 Report from AmSECT's International Consortium for Evidence-Based Perfusion (ICEBP) (26). In this report, the ICEBP stated that the purpose of the revised Standards and Guidelines is to provide a framework to improve the reliability and safety of CPB, and to reflect the expectations of our profession. However, the authors also acknowledge that merely publishing these Standards and Guidelines is not enough to effect a change in practices. Rather, the implementation of institutional protocols, documentation, and checklists adhering to these Standards and Guidelines will ultimately be the vehicle through which we, as a profession, continue to improve patient care (26). Currently, 61.2% of respondents report that they have an institutional protocol in place limiting negative pressure in the venous reservoir (Table 3), highlighting an area with relatively good compliance, but with room for improvement nonetheless. Unfortunately, only 28.4% of respondents document VAVD pressure in their pump records, despite the recommendation in Appendix C of the Standards and Guidelines to do so (15) (Table 8). In addition, there is room for improvement on institutional checklist items as recommended by AmSECT, as illustrated in Table 8 (14).

The incidents reported in Table 6 shed light on the importance of adherence to the Standards and Guidelines and implementation of institutional checklist items. Most notably, roughly one in four perfusionists (26.2%) have experienced a pressurized venous reservoir leading to retrograde air entrainment up the venous line. This is actually an incredibly remarkable number, given how large of a threat this particular incident is to patient safety. While it is true that this question did not ask "when" this incident was experienced (and it could have been years ago), there are case reports as recent as 2012 that indicate that this is still occurring despite current safety measures that many institutions may have in place (10). It is important to note that three of these incidents (a pressurized venous reservoir leading to activation of PPRV, a pressurized venous reservoir leading to retrograde air entrainment up the venous line, and air pulled across the membrane during priming) could all "likely" be prevented by adherence to Standard 6.1, that VAVD pressure should be monitored and shall include an audible and visual alarm (15). A "leak in the vacuum system rendering it non-functional on CPB" was reported by 52.4% of respondents, and would likely be prevented by the implementation of institutional checklist items pertaining to the VAVD system. It is reasonable to believe that these same checklist items could identify "vacuum regulator malfunction" and "vacuum source (wall vacuum) malfunction" before CPB, which were each reported by a third of respondents (33.3% for each). A 2011 case report published by Matte et al. (11) gives credence to the importance of institutional protocols and checklists. Rather than assigning individual blame following a massive air embolism in a Fontan patient due to a pressurized cardiotomy, the authors appropriately revised their institutional checklist, so it is now in accordance with AmSECT's recommendation to include "cardiotomy reservoir vented" (11,14). This is a real-life application of the sentiment from the ICEBP that improving patient safety must begin at the institutional level, and highlights the importance of institutional adherence to evidence-based Standards and Guidelines.

Conclusions

This study has limitations, most notably the small sample size of the survey. Also, although unlikely, it could be possible for the same individual to submit a duplicate survey on different devices. In addition, although all regions of NYS were well represented considering their respective populations (Table 1), it makes the assumption that the practices of perfusionists in NYS reflect the practices of perfusionists at the national level. A future study should include a national-level survey to examine more broadly the practices of perfusionists and to reveal whether or not there are regional variations in practice.

Table 8. Respondent compliance to AmSECT Standards and Guidelines (15) and checklist items (14).

Standard 6.1	Compliance (%)
Pressure monitoring of the arterial line, cardioplegia delivery systems and venous reservoir (when augmented venous drainage is used), shall be used during CPB procedures (15).	88.1
The pressure monitor shall include an audible and visual alarm (15)	49.2
Charting	
Appendix C: Patient physiological and perfusionist practice parameters documented at a frequency determined by institutional protocol. . . .5: Vacuum assisted venous return (15)	28.4
Recommended checklist items	
Vacuum regulator operational (14)	53.7
Cardiotomy positive-pressure relief valve present (14)	55.1
Negative pressure relief valve(s) unobstructed (14)	33.8

CPB, cardiopulmonary bypass.

In summary, this study reveals that the use of VAVD has increased dramatically in the last decade and has become nearly universal in 2014. While there is relatively high compliance to some of the literature recommendations and AmSECT Standards and Guidelines, there are still some gaps between current practices and these recommendations. Continued improvement in these areas, both at the individual and institutional levels, will help to improve patient safety by preventing untoward events from occurring while using VAVD.

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