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# Vacuum-Assisted Venous Drainage does not Increase the Neurological Risk

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## ABSTRACT

**Background:** Vacuum-assisted venous drainage (VAVD) with negative pressure applied to integral sealed-hardshell venous reservoir facilitates valvular surgery through minimally invasive approaches. Despite concerns regarding air entrainment from the right atrium, cerebral microemboli of air and neurological complications, VAVD was used in patients who underwent valvular surgery throughout the last two years in our institution.

**Methods:** We compared the rate of neurological complications in patients who underwent surgery with and without VAVD from June 1997 to July 2001. VAVD was added to solid venous reservoirs with membrane oxygenators and arterial filters. Clinical results were prospectively entered in our valve database and were used for the analysis.

**Results:** Eight hundred twenty-two consecutive patients averaging 65 ± 11 years of age underwent aortic, mitral and tricuspid valve replacements including 40 redos (40/822, 5%) and 265 associated CABG (265/822, 32%) with VAVD in 1999 to 2001 compared to 723 patients averaging 63 ± 11 years of age (p = 0.01) who underwent the same procedures with 79 redos (79/723, 11%) and 177 CABG (177/723, 24%) without VAVD in 1997 to 1999. CPB time averaged 117 ± 50 minutes in VAVD patients compared to 108 ± 43 minutes in those without VAVD (p = 0.001). Thirty-day mortality averaged 5% (39/822) in patients with VAVD and 4% (30/723) in those without VAVD (p = 0.6). Seven patients of the VAVD group (7/822, 1%) and 11 patients without VAVD (11/723, 1.5%, p = 0.2) suffered from temporary or permanent neurological deficit.

**Conclusion:** VAVD is a useful adjunct to modern cardiopulmonary bypass systems. When used with appropriate care, VAVD does not appear to significantly increase air microemboli and is not associated with an increased neurological risk following valvular surgery.

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## INTRODUCTION

Vacuum-assisted venous drainage (VAVD) with negative pressure applied to an integral sealed-hardshell venous reservoir facilitates surgery in allowing the use of smaller diameter venous cannulas and in insuring an optimal venous return to the cardiopulmonary bypass system with low central venous pressure during surgery. Thus VAVD improves access to the surgical field both in standard median sternotomy and in all minimally invasive approaches. Willcox et al. have shown that VAVD can increase entrainment of venous air with the vacuum assist drainage and have raised safety issues with the system [Willcox 1999].

Despite concerns expressed in the literature regarding air entrainment from the right atrium, cerebral microemboli of air and neurological complications, VAVD has been used in patients who underwent valvular surgery throughout the last two years in our institution.

The objective of the present study is to compare the incidence of neurological complications in patients who underwent valvular surgery with and without VAVD added to a standard cardiopulmonary bypass system.

## METHODS

From June 1999 to August 2001, 822 consecutive patients undergoing valve replacement with VAVD were compared to 723 consecutive patients who underwent valve surgery between June 1997 and May 1999 without VAVD. Clinical results were prospectively entered in the Montreal Heart Institute Valve Clinic database and were used for analysis. Stroke was defined as temporary or permanent neurological deficit occurring after surgery.

The cardiopulmonary bypass circuit consisted in a solid venous reservoir with a venous filter (40-µm filter), a hollow-fiber membrane oxygenator (Sorin Biomedical), nonpulsatile roller pumps (Stockert, Shiley) and an arterial filter of 32 µm (Capiox CX AF01, Terumo). The VAVD system consisted in a Boehringer suction regulator (Boehringer Laboratories, Inc.) with a suction regulator between 0 to –100 mm Hg. In our patients, the VAVD's negative suction was maintained between –5 and –15 mm Hg during surgery.

All drugs were administered through central lines by our anesthesiologists. Carbon dioxide flooding of the surgical

Table 1. Patient characteristics

| | VAVD | No VAVD | p value |
|---|---|---|---|
| Number of patients | 822 | 723 | |
| Age (year) | 65 ± 11 | 63 ± 11 | 0.001 |
| > 80 | 46 (6%) | 26 (3.6%) | 0.006 |
| > 75 | 168 (20%) | 114 (16%) | 0.02 |
| Gender (Women/Men) | 409/413 | 342/381 | 0.4 |

VAVE = vacuum-assisted venous drainage.

field to reduce air embolism was used in most patients who underwent surgery with the VAVD [Webb 1997]. Aprotinin, a protein serase inhibitor (Bayer, Canada) was also routinely used in most patients who underwent surgery during the last two years of the present study.

Data are expressed as means, standard deviations and 95% confidence limits (CL) when specified. Statistical comparisons were done with the unpaired Student's t test, the $\chi^2$ test and the Fischer's exact test. Univariate and multiple logistic regression analysis was performed to identify the relationship between neurological complications and several clinical variables in the two groups. Data analyses were performed with the Number Cruncher Statistical System 2001 (NCSS Statistical Software, Kaysville, UT).

## RESULTS

### *Patient Characteristics and Operative Data*

Patients of the VAVD group were older, underwent CABG and associated procedures in addition to valve replacements in a greater proportion and, the cardiopulmonary bypass time was longer compared with patients who underwent valve replacements without the use of VAVD (Tables 1 and 2, ◎).

### *Mortality and Neurological Complications*

Early postoperative mortality averaged 5% (39/822) in patients with VAVD compared with 4% (30/723) in patients without VAVD (p = 0.6, Table 3, ◎). Cardiogenic shock and multiorgan failure were the cause of death in 16 (16/39, 41%) VAVD patients and in 14 (15/30, 47%) patients without VAVD. Mediastinal bleeding, sepsis, perioperative myocardial infarction and malignant arrhythmia were the causes of death in 17 (17/39, 44%) VAVD patients and in 15 (15/30, 50%) patients without VAVD. Two patients with VAVD (2/39, 5%) died from early prosthetic valve thrombosis and two other patients from multiple cerebral emboli. One patient without VAVD (1/30, 3%) died from multiple cerebral emboli. The cerebral emboli were documented at CT-scan exams and at the autopsy.

Seven patients (7/822, 1%) who underwent surgery with VAVD showed clinical evidence of a stroke in the postoperative period compared with 11 patients (11/723, 1.5%) in those without VAVD (p = 0.4). Moreover, one patient in the non-VAVD group suffered from episodes of convulsions after surgery. Overall, the postoperative incidence of neurological complications averaged 1% (7/822) in patients with VAVD compared with 1.7% (12/723) in those without VAVD (p = 0.2, Table 3, ◎).

Table 2. Operative data

| | VAVD | No VAVD | p value |
|---|---|---|---|
| AVR (number of patients) | 561 (68%) | 451 (62%) | 0.2 |
| MVR (number of patients) | 208 (23%) | 222 (31%) | 0.02 |
| DVR (number of patients) | 57 (7%) | 55 (8%) | 0.2 |
| Triple valves (number of patients) | 7 (1%) | 12 (2%) | 0.2 |
| TVR (number of patients) | 3 (1%) | 7 (1%) | 0.1 |
| Redo (number of patients) | 40 (5%) | 79 (11%) | 0.01 |
| CABG (number of patients) | 265 (32%) | 177 (24%) | 0.001 |
| Associated procedures | 129 (16%) | 73 (10%) | 0.001 |
| CPB time (minutes) | 117 ± 50 | 108 ± 43 | 0.0001 |
| Cross-clamp time (minutes) | 83 ± 33 | 79 ± 45 | 0.03 |

AVR = aortic valve replacement, MVR = mitral valve replacement, DVR = double valve replacement, Triple valve = triple valve repair or replacement, TVR = tricuspid valve replacement, redo = reoperation, CABG = coronary artery bypass grafting, CPB = cardiopulmonary bypass, VAVD = vacuum-assisted venous drainage.

### *Multivariable Analysis*

Univariate analyses performed to determine clinical factors related to neurological complications showed that longer cardiopulmonary bypass time and isolated tricuspid valve replacement increased the risk of neurological complications and that aortic valve replacement decreased the later risk compared to the other procedures. The use of VAVD had no significant effect on the occurrence of neurological complications (Table 4, ◎).

In the multivariate analysis, only cardiopulmonary bypass time and aortic valve replacement remained related to the risk of developing neurological complications following surgery (Table 4, ◎). Longer cardiopulmonary bypass time increased the risk and aortic valve replacement procedures were associated with a decrease in the risk of neurological complications.

## DISCUSSION

Vacuum-assisted venous drainage was introduced to increase visualization and drainage through smaller diameter venous cannula in minimally-invasive approaches. Our

Table 3. Mortality and neurological complications

| | VAVD | No VAVD | p value |
|---|---|---|---|
| Mortality (30 days) | 39 (5%) | 30 (4%) | 0.6 |
| Stroke | 7 (1%) | 11 (1.5%) | 0.4 |
| Convulsion | 0 | 1 | |
| Total neurological complications | 7 (1%) | 12 (1.7%) | 0.2 |

VAVD = vacuum-assisted venous drainage.

Table 4. Univariate analysis of the determinants of neurological complications

| Characteristics | Odds ratio (95% CI) | p value |
|---|---|---|
| VAVD | 0.54 (0.22-1.30) | 0.16 |
| CPB time (minutes) | 1.008 (1.005-1.01) | 0.02 |
| AVR | 0.39 (0.16-0.93) | 0.04 |
| TVR | 9.36 (1.10-77.8) | 0.04 |

Multivariable analysis of the determinants of neurological complications

| Characteristics | Odds ratio (95% CI) | p value |
|---|---|---|
| CPB time (minutes) | 1.007 (1.004-1.01) | 0.04 |
| AVR | 0.41 (0.16-1.02) | 0.05 |

VAVD = vacuum-assisted venous drainage, CPB = cardiopulmonary bypass, AVR = aortic valve replacement, TVR = tricuspid valve replacement.

experience in valvular replacement surgery suggests that VAVD does not increase the risk of neurological complications. Patients who underwent valve replacements with VAVD were older and the cardiopulmonary bypass time was longer. Yet, the overall incidence of neurological complications was not significantly different from patients who underwent similar surgery without VAVD. Although the use of aprotinin to decrease mediastinal blood loss and the flooding of the surgical field with carbon dioxide to reduce air embolism were introduced in our clinical practice during the same time period, routine use of VAVD adjusted to the need of surgeons did not result in an increase in the incidence of significant neurological complications following surgery for valve replacement.

Taylor et al. [Taylor 1999] and Borger et al. [Borger 2001] in studying perfusionist interventions during cardiopulmonary bypass in patients undergoing coronary artery bypass grafting showed that injection of drugs into a softshell venous reservoir caused a significant increase in the rate of cerebral air microemboli which could contribute to postoperative cognitive impairment. In our experience, all drugs were injected by our anesthesiologists in central venous lines and we used an integral hardshell venous reservoir, two key elements leading to a decrease in air microemboli according to the two previous studies.

Other authors [Sylivris 1998] have suggested that the highest rates of cerebral microemboli occur at the time of cross-clamp release during CPB and is associated with the development of neuropsychological deficits. Microemboli of particulate composition that occurred before aortic incision were associated with evidence of strokes. Others have suggested that elderly patients have significantly more cerebral dysfunction than younger patients but the changes do not persist into the late follow-up period [Heyer 1995]. Plöchl et al. [Plöchl 2001], showed that a reduction in $PaCO_2$ during cardiopulmonary bypass did not result in a significant decrease in cerebral emboli in humans.

Adverse cerebral outcomes after cardiac surgery are now recognized as a significant health care problem with enormous societal cost. Roach et al. [Roach 1996], in the largest prospective study on cerebral outcome after coronary artery bypass surgery found that 6.1% of the 2,108 patients, developed serious neurological complications ranging from stroke to seizures and to deterioration of intellectual function after surgery. Aortic atherosclerosis, history of neurologic disease, diabetes mellitus, hypertension, advanced age, excessive alcohol consumption and dysrhythmia were among the most significant risk factors for adverse cerebral outcomes. Patients with adverse outcomes had five to 10 times the mortality, two to four times the time spent in intensive care unit and three to six times the need for prolonged care compared with the other patients. Moreover, the same investigators identified a subgroup of patients at extraordinary risk of cerebral injury, patients undergoing left-sided intracardiac and coronary artery bypass grafting surgery [Wolman 1999]. They reported a 15.8% incidence of adverse neurologic events, 8.4% of type 1 events including stroke and coma and 7.3% of type 2 events including seizures and deterioration of intellectual function among 273 patients from 24 medical centers in the United States. In the present study, seven patients (7/442, 1.6%) undergoing left-sided valve replacement and coronary artery bypass grafting showed clinical evidence of neurological injury following surgery.

Compared to the experience of Wolman et al. [Wolman 1999], using multicenter prospective recruitment of patients, other single center retrospective data [Borger 1998] show that the incidence of stroke averages 2-3% following valve replacement. The striking difference in the rate of stroke and of cerebral injury between single center and multicenter prospective studies could be explained not only by differences in definition of events but also by the thorough completeness of neurological observation and evaluation in the later studies. Differences in patient selection could explain in part the difference, patients were older ($70 \pm 9$ vs. $69 \pm 8$ years of age) and cardiopulmonary bypass time was longer ($166 \pm 68$ vs. $136 \pm 49$ minutes) in Wolman's [Wolman 1999] report compared with the present study.

The present study has several weaknesses, the data was entered prospectively in our data bank but the study is a retrospective comparison of two series of patients undergoing surgery during two different periods of time. In the most recent cohort of patients, not only have we introduced the VAVD in our routine clinical practice, we have also used aprotinin during surgery and carbon dioxide flooding of the surgical field, two variables that could have had an effect on the incidence of neurological complications. Moreover, formal neuropsychological testing is not part of our routine clinical practice and is not available for the present study. With the above limitations in mind, the study compares two cohorts of patients who underwent valve replacements by the same group of surgeons and of nursing staff using similar definitions of neurological complications.

We conclude that the use of VAVD during CPB in patients undergoing valve replacements does not increase the risk of significant neurological injuries. We suggest that

VAVD, when used carefully and applied with the proper equipments and techniques, is a useful adjuvant to modern CPB systems. More sophisticated neuropsychological testing of these patients remains to be done to insure that there is no subclinical injury.

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