Vacuum assisted and gravitational venous drainage in aortic valve surgery: A propensity-match study

Q1Q2 Vacuum assisted and gravitational venous drainage in aortic valve surgery: A propensity-match study

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Abstract

Introduction

Vacuum assisted venous drainage (VAVD) is widely adopted in minimally invasive cardiac surgery. VAVD enables the advantage of using smaller cannulae in a reduced surgical field while allowing satisfactory drainage and pump flow. The production of gaseous micro-emboli is a recognized risk associated with VAVD, however no difference in clinical endpoints have been reported between patients operated on with gravity venous drainage (GVD) or with VAVD. Due to the paucity of data on selected surgical populations, we sought to evaluate the early outcomes of patients undergoing isolated aortic valve replacement using VAVD or GVD.

Methods

Data on 521 patients between 09/2016 and 09/2022 were retrieved from our internal database. Patients were divided into two groups according to use VAVD or GVD. A propensity match analysis was performed to account for difference between the two groups.

Results

The propensity match provided two well balanced cohorts with 129 patients each. A minimally invasive access was used in 97% of the cases in VAVD group vs 98% in GVD group (p = .68). Mean cardiopulmonary by-pass (CPB) time was 71 vs 73 min (p = .74), respectively. There was no difference in lactates peak (p = .19) and urine output during CPB (p = .74). We registered two in-hospital deaths in VAVD cohort (1.6%) vs. no mortality in GVD group (p = .5). Postoperative cerebral stroke occurred in 1 patient in GVD cohort vs. 0 in VAVD (p = 1). Severe postoperative acute kidney injury complicated the course in 16 patients in GVD group and in 5 patients who had VAVD (p = .012). VAVD was associated with a higher number of patients with elevated postoperative AST (p = .07) and Troponin I (p = .01) values.

Conclusions

The use of VAVD during isolated aortic valve replacement was not associated with increased risks of postoperative complications and in-hospital mortality with results that were at least similar to those registered in a matched cohort of patients operated on with GVD.

Keywords:

cardiac surgery, minimally invasive aortic valve replacement, gravity venous drainage, vacuum assisted venous drainage, cardiopulmonary by-pass

Introduction

During Cardiopulmonary Bypass (CPB), the venous return is usually regulated by gravity using the difference in height between the levels of the patient and the venous reservoir. In case of insufficient drainage, vacuum-assisted venous drainage (VAVD) can be applied to enhance the venous return and achieve an adequate pump flow.[1] VAVD is widely adopted especially in minimally invasive cardiac surgery and is associated with some advantages such as the use of smaller venous cannulae, shorter circuit tubing, and smaller volumes of priming and heterologous blood.[2–4]

Owing to the paucity of data in literature regarding the effect of VAVD on organ function or protection in selected cardiac surgery populations, we sought to evaluate whether the use of VAVD has any impact on early outcomes in patients undergoing aortic valve replacement.

Materials and methods

Populations

We have retrieved the data of patients who underwent aortic valve replacement at the Cardiac Surgery Unit, Lancisi Cardiovascular Centre at University Hospital of Marche, Ancona – Italy, during the period September 2016 - September 2022. Exclusion criteria were the performance of any other procedure associated with aortic valve surgery, ongoing acute heart failure, hemodynamic instability requiring inotropes, emergency surgery, redo operation.

Study design, ethical approval and data retrieval

This study is a retrospective outcome evaluation of prospectively collected data from the internal database of Cardiac Surgery Unit at Lancisi cardiovascular Centre in Ancona. Approval was obtained for the use of data (CERM 2023, 83).

Several preoperative, intraoperative data and early postoperative outcomes were retrieved (Table 1).

Table 1.

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Preoperative details of the overall population.

	Overall population *N* = 521	**VAVD** *N* = 384	**GVD** *N* = 137	*p*
	mean ± SD Median [IQR 1 – IQR3] Number (%)	mean ± SD Median [IQR 1 – IQR3] Number (%)	mean ± SD Median [IQR 1 – IQR3] Number (%)	
Age (years)[a]	74 (66 – 79)	73 (65 – 78)	76 (71 – 80)	<0.001

Gender (male)	284 (55%)	216 (56%)	68 (50%)	0.17
Weight (Kg)[a]	74 (65 – 83)	75 (65 – 85)	72 (63.5 – 80)	0.027
Height (cm)	167 (160 – 171)	167 (160 – 172)	165 (160 – 170)	0.15
BSA (m^2)	1.82±0.35	1.82±0.35	1.81±0.35	0.43
Diabetes mellitus	103 (20%)	82 (21%)	21 (15%)	0.12
Dyslipidemia	264 (51%)	200 (52%)	64 (47%)	0.26
Smoking history	126 (24%)	93 (24%)	33 (24%)	0.95
Chronic kidney disease (eGFR<50)	88 (17%)	58 (15%)	30 (22%)	0.73
Creatinine	0.9 (0.74 – 1.1)	0.9 (0.74 – 1.1)	0.9 (0.73 – 1.1)	0.63
Haemodyalisis	5 (1%)	3 (1%)	2 (1%)	0.49
CVD	38 (7%)	28 (7%)	10 (7%)	0.99
PVD[a]	34 (7%)	20 (5%)	14 (10%)	0.043
LVEF (%)	60 (55 – 65)	60 (55 – 65)	60 (55.5 – 65)	0.80
AST >45U/l	15 (2.88%)	11 (2.86%)	4 (2.91%)	0.98
ALT >50 U/l	24 (4.6%)	16 (6.77%)	8 (5.84%)	0.43
Troponin I (ng/l)	15 (15 – 21.75)	15 (15 – 20)	15 (15 – 24)	0.49

ALT, alanine transaminase; AST, aspartate transaminase; BSA, body surface area; CVD, cerebrovascular disease; LVEF, left ventricle ejection fraction; PVD, peripheral vascular disease.

Table Footnotes

[a]statistically significant VAVD vs GVD.

Surgical techniques

All patients were operated through a mini-sternotomy or a full sternotomy access. The ascending aorta/aortic arch and the right atrium were commonly cannulated for CPB institution. A left ventricular vent was routinely positioned through the right upper pulmonary vein.[15]

CPB was maintained normothermic and blood cardioplegia was delivered into the aortic root or selectively into the coronary ostia. Both stented and sutureless prosthesis were used according to surgeons' preference and/or anatomical factors. Trans-esophageal monitoring was used throughout the procedure to assist the set up and to evaluate the final surgical results.

Cardiopulmonary bypass circuit

The tubing diameter of the perfusion set was 3/8 inch for the arterial line and ½ inch for the venous line. In every perfusion set, we used the centrifugal blood pump as the master pump. The centrifugal pumps used is BBAP40 made by Medtronic (Medtronic Inc., Minneapolis, MN), Revolution made by Livanova (Livanova, Mirandola, IT) and Sarns made by Terumo (Terumo CVS, Ann Arbor, MI, USA). At our institution we used Heart-Lung Machine S5 made By Stockert/Livanova and Quantum Perfusion System made by Spectrum Medical (Spectrum Medical, Mirandola, IT). In every configuration we used heat exchanger integrated with a hollow fibers membrane oxygenator.

The oxygenators used were Medtronic Affinity, Terumo Capiox FX25 Advance and Livanova Inspire 8F. The Inspire 8F is expected to require a larger priming volume, however the shortening of tubing set allowed the same prime volume as for the other oxygenators (900 mL of saline solution).

For arterial cannulation a Medtronic Elongated One Piece Arterial Cannula 20 or 22 Fr was invariably used. Venous cannulation was achieved with a two-stage 29/29 Fr made by Medtronic (MC2 91329C) or a three stage

29/29/29 Fr made by Livanova (RTS-11029). Left ventricle was vented in all the cases with a 20 Fr silicon catheter produced by Medtronic inserted through the right upper pulmonary vein.

Cardiopulmonary bypass was established and maintained at normothermia (36°C) after cannulation of the ascending aorta and right atrium allowing a cardiac index of 2.4 L/min * body surface area. Red blood cells transfusion was considered when hematocrit fell below 24%.

The cardioplegia consisted of St. Thomas solution without procaine, delivered by a syringe pump into the aortic root through a 9 Fr aortic needle or selectively into the coronary arteries with 10Fr, 12Fr or 14 Fr selective coronary cannulas manufactured by Medtronic or Livanova. The initial dose was 20 mL x weight (kg). A further half dose – 10 mL/kg – was generally delivered after and every 25-30 min thereafter.

The level of anticoagulation during CPB was controlled with active clotting time (ACT) aiming a value of at least 450 s.

Level sensor on the venous hardshell reservoir, bubble detector at the outflow of cardiotomy reservoir and aortic cannula pressure alarm were used in all the cases.

CPB was instituted by gravity venous drainage into a hard-shell venous reservoir positioned at 80–100 cm difference of the patient. Vacuum was added in case of reduced venous drainage. In these last cases, the negative pressure, as measured by a transducer, was controlled with a mean pressure of −20 to −25 mmHg and never exceeding the value of −40 mmHg. Negative pressure is measured in a port of cardiotomy reservoir.

Statistical analyses

Patients were divided into two groups according to the use of either VAVD or GVD. To minimize the effects of selection bias and generated two evenly matched cohorts of patients, a propensity match analysis with a caliper width for the logit of the propensity score less than 0.2 was performed using preoperative and intraoperative variables (Table 2).

Table 2.

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Preoperative and Intraoperative variables using for propensity match scoring.

• Gender
• Smoking
• Diabetes
• Dyslipidemia
• Renal failure pre op
• Age
• Body surface area (BSA)
• Left ventricular ejection fraction (LVEF)
• Preoperative AST value
• Preoperative ALT value
• CPB time

The adequacy of propensity score matching was evaluated on standardized mean difference values for each variable and was considered acceptable when the absolute value was less than 0.1.[16]

The continuous variables were presented by means or median with 1st and 3rd interquartile range. Categorical variables were expressed as frequencies and percentages. Univariate comparisons of preoperative, intraoperative and postoperative variables were performed between the two groups of patients using the appropriate test (Student's *t* test or Mann-Whitney U test, $\chi 2$ or Fisher's exact test).

The analysis was generated using Statistical Analysis Software (SAS), Version 3.8, SAS University Edition (SAS Institute Inc., Cary, NC).

Results

Populations and baseline characteristics

The overall population included 521 patients. Among them, 137 underwent CPB with GVD and in 384 cases VAVD was used. The VAVD group patients were older ($p < .001$) and had a higher prevalence of preoperative peripheral vascular disease ($p = .043$) when compared with patients in the GVD group.

Q3 Propensity match analysis provided two well balanced cohorts including 129 patients each ~~(Figure 1).~~ The preoperative characteristics of the overall population and the VAVD and GVD groups are summarized in Table 3. (Table 3)

Table 3.

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Preoperative characteristic of matched cohorts.

	VAVD *N* = 129	GVD *N* = 129	[SMD]	*p*
	mean ± SD Median [IQR 1 – IQR3] Number (%)	mean ± SD Median [IQR 1 – IQR3] Number (%)		
Age (years)	75 (69 – 80)	75 (70 – 79)	0.05	0.76
Gender (male)	67 (52%)	62 (48%)	0.08	0.62
Weight (Kg)	72 (62.5 – 82)	72 (63.5 – 80)	0.02	0.83
Height (cm)	165 (159 – 170)	165 (160 – 170)	0.02	0.82
BSA (m^2)	1.79±0.20	1.79±0.19	0.008	0.95
Diabetes mellitus	20 (50%)	20 (50%)	<0.001	1
Dyslipidemia	76 (59%)	63 (49%)	0.20	0.13
Smoking history	34 (26%)	31 (24%)	0.05	0.77
Chronic kidney disease (eGFR<50)	26 (20%)	25 (19%)	0.02	1
Creatinine	0.9 (0.7 – 1.1)	0.9 (0.73 – 1.1)	0.03	0.70
Haemodyalisis	2 (2%)	1 (1%)	0.08	1
CVD	13 (10%)	10 (8%)	0.06	0.33
PVD	7 (5%)	14 (11%)	0.23	0.085
LVEF (%)	60 (56 – 65)	60 (55 – 65)	0.008	0.72

AST >45U/l	2 (1.55%)	4 (3.10%)	0.008	0.92
ALT >50 U/l	6 (4.65%)	7 (5.42%)	0.05	0.19
Troponin I (ng/l)	15 (15-23)	15 (15-26.5)	0.08	0.60

ALT, alanine transaminase; AST, aspartate transaminase; BSA, body surface area; CVD, cerebrovascular disease; LVEF, left ventricle ejection fraction; PVD, peripheral vascular disease; SMD, standardized mean difference.

Intraoperative data

There was no difference in CPB time, cross clamp time and urine output during CPB between the two cohorts of matched patients. Intraoperative lactates peak was 1.4 (IQR 1.1-1.75) in VAVD group and 1.3 (1.1-1.7) in GVD group (p = .191) (Table 4).[8]

Table 4.

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Intraoperative data.

	VAVD *N* = 129	GVD *N* = 129	*p*
	mean ± SD Median [IQR 1 – IQR3] Number (%)	mean ± SD Median [IQR 1 – IQR3] Number (%)	
Minimally invasive access	125 (97%)	127 (98%)	0.68
Theoretical CPB flow (l/min)	4.3±0.5	4.3±0.4	0.93
CPB time (min)	71 (63 – 89)	73 (63 – 84)	0.74
Cross-clamp time (min)	55 (44 – 69)	57 (46 – 65)	0.60
Peak of lactates during CPB (mmol/l)	1.4 (1.1 - 1.75)	1.3 (1 – 1.7)	0.19
Urine output during CPB (ml)	200 (115 – 400)	200 (100 – 400)	0.74
Urine output during CPB (ml/kg/min)	2.28 (1.35 – 4.03)	2.33 (1.34 – 4.44)	0.616

CPB, cardiopulmonary bypass.

Postoperative outcomes

There were 2 deaths in the VAVD group (1.6%) and 0 in GVD group (p = .498). One patient in the GVD group, suffered a cerebral stroke.

Early postoperative outcomes were similar in matched VAVD and GVD cohorts. One patient (0.8%) required CVVHD in VAVD group, and 3 (2.3%) patients in GVD (p = .622). Occurrence of severe AKI was higher in GVD patients 14% vs. 4% in VAVD (p = .012).

There was no difference between the two groups in terms of postoperative mechanical ventilation time, ICU stay and overall hospital stay. Similar rates of postoperative atrial fibrillation and number of transfused units of red blood cells were found in both cohorts. Patients in VAVD group showed a higher prevalence of AST value increased over the normal range (p = .07) and significantly higher median postoperative peak High Sensibility Troponin I (Hs Troponine I) levels (p = .01) (Table 5).

Table 5.

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Postoperative data.

	VAVD *N* = 129	GVD *N* = 129	*p*
	mean ± SD Median [IQR 1 – IQR3] Number (%)	mean ± SD Median [IQR 1 – IQR3]} Number (%)	
In-hospital mortality	2 (1.6%)	0	0.50
Cerebral stroke	0	1 (0.8%)	1
AKI (eGFR<50)[a]	5 (4%)	16 (14%)	0.012
CVVHD	1 (0.8%)	3 (2.3%)	0.62
Respiratory failure	2 (1.6%)	1 (0.8%)	1
Tracheostomy	1 (0.4%)	0	1
Sepsis	2 (1.6%)	2 (1.6%)	1
Atrial fibrillation	41 (31.8%)	50 (38.8%)	0.30
PPM	2 (1.6%)	2 (1.6%)	1
Mechanical ventilation time (hours)	5 (0 – 8)	4 (0 – 10)	0.23
Drain output 12 h (ml)	160 (120 – 230)	180 (120 – 250)	0.20
ICU stay (hours)	24 (23 – 48)	24 (23 – 45)	0.57
Units of RBC transfused	1 (0 – 2.5)	1 (0 – 2.5)	0.97
AST >45U/l	48 (37.2%)	28 (21.7%)	0.071
ALT >50 U/l	17 (13.1%)	13 (10%)	0.71
Troponin I (ng/l)[a]	3350 (2121-5715)	2730 (1796-4178.5)	0.01
Hospital stay (days)	6 (5 – 7)	6 (5 – 8)	0.29

ALT, alanine transaminase; AKI, acute kidney injury; AST, aspartate transaminase; CVVHD, continuous veno-venous haemodyalisis; PPM, permanent pacemaker; RBC, red blood cells.

Table Footnotes

[a]statistically significant.

Comment

The use of GVD or the adjunct of VAVD are based on the preferences of the perfusionist and cardiac surgeon to achieve a satisfactory drainage of the heart and an adequate pump flow. Although our experience has shown that VAVD is not mandatory in minimal access aortic valve surgery, with one fourth of our patients being managed with GVD, VAVD has emerged as the primary solution in minimally invasive cardiac surgery since it allows the use of smaller cannulae, which is particularly advantageous in a reduced surgical field.[3,17,18]

While an increased occurrence of haemolysis has not ubiquitously associated with the use of vacuum-assisted drainage and seems widely preventable with vacuum pressure above −60 mmHg and/or ranging between [−40 to −30]

mmHg, the risk of generating gaseous micro-emboli in the venous circuit together with bubble transgression in the oxygenator remains the most recognized and feared complication during VAVD.[3,5,6,17–24] Nygaard et al. demonstrated an increase of micro-emboli count at the augmentation of the VAVD level.[7] A pressure not exceeding −30 mmHg was reported to be safe for all the oxygenators tested in this study. To further minimize this inconvenience and optimize VAVD, a continuous monitoring of venous blood flow using an ultrasonic flow probe was recommended.[8] In our experience, VAVD was added during CPB by application of vacuum pressure to the hard-shell reservoir using a negative pressure that never exceeded −25 mmHg, and the presence of eventual gaseous emboli was always monitored using a bubble detector on the arterial line made by the producer of the heart-lung machine. The awareness about the risk of production of emboli in the arterial line and the routinely implementation of appropriate monitoring measures contribute to the high safety of VAVD procedures. Our data showed an overall incidence of postoperative stroke of 0.4% with no case of neurologic injury registered in the cohort of patients who underwent surgery with the aid of VAVD, and fully confirmed the evidence from other large experiences that did not find any association between VAVD application and increased incidence of perioperative cerebrovascular accidents.[2,9,17,22] Furthermore, we registered no difference between our two cohorts of matched patients in terms of in-hospital mortality (p = .50), ICU and hospital stay.

The use of VAVD allows for shortening of tubing length and the reduction of clear priming volume aiming for reduced intraoperative hemodilution.[10] These measures, alongside the optimization of the intraoperative anesthesia and fluid management during CPB, have been associated with a higher hematocrit level during CPB and a decreased perioperative blood and blood products usage.[10–12,17] We were not able to confirm these findings as we did not find any difference in postoperative red blood cells transfusions in VAVD and GVD groups (p = .97).

On the contrary, although we found no difference between the two groups in the need of postoperative CVVHD – 3 patients in GVD group and 1 patient in VAVD group (p = .62) – a significantly higher number of patients in the GVD cohorts experienced acute kidney injury with worsening renal parameters and needs of adequate medical therapy and monitoring (14% vs 4% in VAVD, p = .012). Postoperative AKI is multifactorial, and its occurrence can be influenced by several perioperative variables including intraoperative venous congestion.[13] In this regard the increased outflow realized by the extra negative pressure during VAVD and the concomitant reduction of clear volume and hemodilution could play a protective role against the development of perioperative renal dysfunction.[14] Furthermore, the increase and optimization of venous return by VAVD could allow increase flow and DO2i with enhanced perfusion and oxygenation of kidneys.[25]

We found post operative AST levels increased over the normal values (cut off = 45 U/L) in 37% of patients treated with VAVD and in 22% of patients treated with GVD (p = .07) and ALT values over the higher normal cut off (50 U/L) in 13% of patients with VAVD and 10% of patients with GVD (p = .71). These data associated with a higher mean value of postoperative peak of Hs Troponin I in VAVD group (vs GVD group p = .01), may suggest a better myocardial protection achieved in patients who did not require VAVD. This finding has not been highlighted in previous studies. In the large propensity-match study by Gao et al. on patients undergoing mixed cardiac surgical operations, a higher prevalence of patients with elevated AST (p = .09) and a higher rate of postoperative MI were found in the cohort operated on with VAVD, but no data regarding Troponin sampling was available.[17] We used the same protocol for myocardial protection in all patients, and the surgical times, particularly the cross-clamp times, were similar in both groups with a slightly shorter cross-clamp time in VAVD patients. One explanation for the higher Troponin value in VAVD group could be a suboptimal drainage of the heart with the presence of some myocardial distension, being the need for VAVD application a marker of initial insufficient and unsatisfactory drainage.[26] Nevertheless, the median peak Troponin levels we recorded in both groups of our patients represent an acceptable value after on pump and cardioplegic arrest cardiac surgery and were not associated with a worse outcome.[27,28]

Limitations

Our study shares the usual limitations associated with observational retrospective studies, although all the retrieved data were prospectively collected in our internal database before patients discharge. The two populations of patients receiving VAVD and GVD during CPB presented significant differences in age and body weight. The propensity match analysis provided two well balanced cohorts of patients. The prevalence of dyslipidemia and history of peripheral vascular disease were the only preoperative variables with an absolute Standardizes Mean Difference (SMD) higher than 0.1 with no significant difference at univariate analysis.

This topic is not new as previous studies have already investigated the early outcomes using VAVD and GVD during CPB, however, with the exception of only a few larger studies, they included only small populations undergoing mixed cardiac surgery procedures.[9,17] We were able to present a large and homogenous population who underwent isolated aortic valve replacement that is widely performed by means of a minimal thoracic access and mostly invariably required the application of VAVD.

Conclusion

Patients undergoing minimally invasive isolated aortic valve replacement usually receive VAVD during CPB. VAVD and GVD techniques were found to be safe as they were used according to perfusionist and surgeon preference to improve drainage and maintain adequate flow during CPB. There was no difference between the two matched cohorts of patients who underwent VAVD and GVD surgery in terms of in-hospital mortality, postoperative stroke, ICU and hospital stay. The occurrence of postoperative AKI was higher in patients who had GVD, while a higher percentage of patients with increased postoperative AST value and a higher postoperative peak Troponin I was found in the VAVD group.

Declaration of conflicting interests

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