Original Article

A Comparison of the Benefits of Roller Pump Versus Constrained Vortex Pump in Adult Open-Heart Operations Utilizing Outcomes Research

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ABSTRACT

The purpose of this study was to compare roller pump and centrifugal pump technologies in routine adult open-heart operations to demonstrate the usefulness of applying a proven method of uniform risk stratification (outcomes research). Objective and readily available preoperative patient data was collected retrospectively on 102 non-randomized and consecutive adult open-heart operations. Group 1 consisted of 51 adult open-heart operations utilizing a roller pump for arterial blood perfusion. Group 2 consisted of 51 adult open-heart procedures utilizing a constrained vortex pump for arterial blood perfusion. A comparison between the frequency of occurrence of 53 different preoperative risk factors in the roller pump group and the centrifugal pump group found no statistically significant differences ($p < 0.05$). Outcome data for the roller pump and centrifugal pump groups included such data comparisons as intensive care unit length of stay (LOS), post operative LOS, total LOS, total patient charge, reimbursement, morbidity, and mortality, which revealed no statistically significant differences ($p < 0.05$). Further comparison studies of roller pumps versus centrifugal pumps for arterial blood perfusion should incorporate this kind of comprehensive data comparison and analysis to reasonably assure that both pump groups are very similar before outcomes research is performed.

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INTRODUCTION

A common blood pump used today is the roller pump, or kinetic displacement pump. The roller pump was originally patented by Porter and Bradley in 1855 (1). Mechanical displacement of volume is produced by compressing the wall of the tubing between the roller and the back plate within the raceway and squeezing blood out of the tubing in front of the roller. A second type of blood pump is the constrained vortex pump which was first used clinically in 1975, and originally described in 1968 (2). Blood moving through the cone-shaped vortex pump pulls the trailing blood along, creating a vortex. Low pressure develops at the inlet while high pressure develops at the outlet. If there is no obstruction, flow will occur because of these gradients. Clinical studies comparing centrifugal pumps with the roller pump during cardiopulmonary bypass (CPB) are still scarce. Claims have been made that the centrifugal pump is less traumatic to the blood than a roller pump (3) and that this will help decrease patient cost over the total hospital stay (William DeBois. Personal Communication; February 27, 1993). We decided to test the hypothesis — that patient cost is decreased using the centrifugal pump — by utilizing outcomes research that compared several factors that affected costs, including length of stay, blood product usage, and severity of patient illness.

MATERIAL AND METHODS

A total of 102 patients received standard preoperative and intraoperative anesthetic management. The operations were performed by several different surgeons and anesthesiologists. Three perfusionists were responsible for all cardiopulmonary bypass runs. Intraoperative monitoring consisted of five lead electrocardiogram, pulse oximetry, arterial and pulmonary artery pressure monitoring and end tidal CO_2 monitoring. Non-pulsatile perfusion was employed at cardiac indexes between 1.8 and 2.8 L/min/m^2. A hollow fiber membrane oxygenator[a] with a closed venous reservoir system[a] was used. Systemic temperatures during cardiopulmonary bypass ranged from 28°C to 37°C. Several of the procedures were performed under normothermic conditions (37°C) while others were performed at moderate hypothermia conditions (28°C) and still others were performed at temperatures between moderate, hypothermic and normothermic conditions. Blood cardioplegia[a] (4:1 blood to crystalloid) was utilized. Both warm and/or cold cardioplegia techniques were employed utilizing antegrade techniques or a combination of antegrade and retrograde techniques. Autotransfusion with a cell washing machine[b] was employed and ultrafiltration was used when considered necessary by the perfusionist. Mean arterial pressure was maintained between 40-70 mmHg while on cardiopulmonary bypass. Alpha-stat blood gas management was performed. Activated clotting times were maintained at or above 400 seconds and routinely measured throughout cardiopulmonary bypass.

There was only one intended difference in variables in this group of 102 patients. Cardiopulmonary bypass was performed with a roller pump[c] for arterial blood perfusion in 51 consecutive cases. Next, a constrained vortex pump[d] was employed for arterial blood perfusion in another 51 consecutive cardiopulmonary bypass cases.

Categorical data was retrospectively analyzed using Fisher's exact test. Measured data was retrospectively analyzed using unpaired, two-tailed Student t-tests and where the standard deviations were significantly different the non-parametric Mann-Whitney test was performed. Statistical significance was accepted at the $p < 0.05$ level. Statistical data was analyzed using the InStat[e] statistical computer program. Data was queried from a FileMaker Pro[f] database computer program. These computer programs were used on an Apple Macintosh[g] computer. A total of 76 data indices were analyzed for each patient.

RESULTS

Table 1 lists 53 preoperative risk factors and their frequency of occurrence (distribution) for the roller pump and centrifugal pump groups. The number in parentheses is the number of patients in each group. There were no statistically significant differences found in this data at $p < 0.05$. Total points listed at the bottom of Table 1 represents the predicted percent probability of operative mortality. This number is derived from the 53 differently weighted risk factors (4, and Dr. Parsonnet. Personal Communication; July 1991). This calculated number helps to objectively represent a certain acuity (risk) level of the patient. There was no statistically significant difference at $p < 0.05$.

Table 2 represents the distribution and frequency of the two pump groups into the five major adult open-heart surgery Medicare Diagnostic Related Groups (DRGs). There were no statistically significant differences found in each of these five categories at $p < 0.05$.

Table 3 represents measurable outcomes data that was analyzed. Statistical significance was accepted at the $p < 0.05$ level. Four different length of stay (LOS) categories were analyzed (preoperative LOS, intensive care unit LOS, postoperative LOS, and total LOS). There were no statistically significant differences in length of stay data. Furthermore, total patient charge and reimbursement categories revealed no statistically significant differences. Blood product (packed red blood cells, platelets, cryoprecipitate and fresh frozen plasma) transfusion rates that occurred intraoperatively and/or during the first 24 hours postoperatively were calculated for the two pump groups.

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b Sorin Biomedical Inc., Dideco-Shiley, Irvine, CA 92714
c Sorin Biomedical, Shiley Stockert, Irvine, CA 92714
d Medtronic BioMedicus Inc., Eden Prairie, MN 55344
e GraphPad, San Diego, CA 92121
f Claris Corp., Santa Ana, CA 95052
g Apple Computer Inc., Cupertino, CA 95014

Table 1
Categorized and Measured Preoperative Risk Data[a]

Preoperative Risk Factors	Centrifugal Pump Group (%)	Roller Pump Group (%)	p Value
Abdominal Aortic Aneurysm-Asymptomatic	0	0	NS
Active Neoplasm (leukemia, lymphoma, etc.)	0	(1) 2.0	NS
Acute Renal Failure	0	0	NS
Age (years)[b]	62.0 ± 9.2	64.1 ± 10.6	NS
AIDS, Active Disease (HIV positive excluded)	0	0	NS
Aortic Regurgitation-Acute (endocarditis)	0	0	NS
Aspirin Prescription	(20) 39.2	(23) 45.1	NS
Asthma (peak expiratory flow rate < 1 L/sec)	0	0	NS
Asthma (peak expiratory flow rate 1-2 L/sec)	(1) 2.0	(1) 2.0	NS
AVR (AV gradient less than 120 mmHg)	(6) 11.8	(4) 7.8	NS
AVR (AV gradient ≥ 120 mmHg)	0	0	NS
Cardiogenic Shock (U.O. <10 ml/hour)	0	0	NS
Carotid Disease - Bilateral Occlusion	0	0	NS
Carotid Disease - Unilateral Occlusion	0	0	NS
Chronic CHF (with peripheral edema, pleural effusion)	(4) 7.8	(3) 5.9	NS
Chronic Renal Failure (CR >2 without dialysis)	(2) 3.9	0	NS
Cirrhosis of Liver (serum bilirubin >5)	0	0	NS
Cold Agglutinins	0	0	NS
Congenital Heart Disease in Adult, Cyanosis	0	0	NS
Constrictive Pericarditis	0	0	NS
Chronic Obstructive Pulmonary Disease, severe	(2) 3.9	(4) 7.8	NS
Dialysis Dependency (PD or Hemo)	0	0	NS
Dissecting Thoracic Aneurysm	0	0	NS
Diabetes (unspecified type)	(9) 17.6	(14) 27.5	NS
Diabetes - Juvenile Onset	0	0	NS
Ejection Fraction (%)[b]	52.9 ± 16.3	58.5 ± 12.8	NS
Endotracheal Tube, preoperation	(1) 2.0	0	NS
Emergency Surg. Following PTCA or Cath Comp.	(8) 15.7	(8) 15.7	NS
Hi-Dose Steroids, active	0	0	NS
Hypertension (syst. BP >140 mmHg; history of hypertension; currently taking hypertensive medication)	(18) 35.3	(22) 43.1	NS
Hyperlipidemia (cholesterol >300, HDL <30)	(3) 5.9	(1) 2.0	NS
Idiopathic Thrombocytopenic Purpura	0	0	NS
Jehovah's Witness	0	0	NS
Left Main Disease/Unstable Angina	(17) 33.3	(20) 39.2	NS
Left Ventricular Aneurysm Resection	(2) 3.9	0	NS
Mitral Regurgitation - Acute (endocarditis, papillary muscle rupture, etc.)	0	0	NS
MVR (P.A. systolic pressure ≤ 59 mmHg)	(1) 2.0	(3) 5.9	NS
MVR (P.A. systolic pressure ≥ 60 mmHg)	0	0	NS
Neurological Disorder, severe (healed CVA, paraplegia, M.S., hemiparesis)	(3) 5.9	(5) 9.8	NS
Obesity, Morbid (≥1.5 x ideal weight)	(2) 3.9	0	NS
Pacemaker Dependent	0	(2) 3.9	NS
Preoperative Intra-Aortic Balloon Pump	(1) 2.0	(1) 2.0	NS
Pulmonary HTN (Mean PAP >30 mmHg)	(1) 2.0	(1) 2.0	NS
Peripheral Vascular Disease, severe	(4) 7.8	(4) 7.8	NS
Reoperation - 1st Time	(4) 7.8	(7) 13.7	NS
Reoperation - 2nd Time	0	0	NS
Sex - Female	(11) 21.6	(16) 31.4	NS
Substance Abuse, severe (alcohol, drugs)	0	(3) 5.9	NS
Transmural M.I. (within 48 hours)	0	(1) 2.0	NS
Tricuspid Valve Surgery	0	0	NS
Valve Surgery at the Time of CABG	(4) 7.8	(5) 9.8	NS
Ventricular Septal Defect - Acute	0	0	NS
Ventricular Tach./Ventricular Fib./Aborted Sudden Death	(3) 5.9	(1) 2.0	NS
Total Points [b,c]	11.8 ± 9.2	14.1 ± 7.8	NS

Legend: AIDS = acquired immunodeficiency syndrome. HIV = human immunodeficiency virus. AVR = aortic valve replacement. AV = aortic valve. U.O. = urine output. CHF = congestive heart failure. CR = creatinine (serum) P.D. = peritoneal dialysis. Hemo = hemodialysis. Surg. = surgery. PTCA = percutaneous transluminal coronary angioplasty. Cath. = catheterization. Comp. = complications. B.P. = blood pressure. HDL = high density lipoprotein. MVR = mitral valve replacement. P.A. = pulmonary artery. CVA = cerebral vascular accident. M.S. = muscular dystrophy. HTN = hypertension. M.I. = myocardial infarction. CABG = coronary artery bypass graft. Tach = tachycardia. Fib = fibrillation. NS = not significant.

a Number in parentheses are number of patients in each category.

b Values are shown as mean ± standard deviation.

c Total Points equals the predicted percent probability of operative mortality.

Table 2
Medicare Diagnostic Related Groups[a]

DRG Classification	Centrifugal Pump	Roller Pump	p Value
104	(4) 7.8	(5) 9.8	NS
105	(3) 5.9	(2) 3.9	NS
106	(36) 70.6	(32) 62.7	NS
107	(8) 15.7	(9) 17.6	NS
108	0	(3) 5.9	NS

Legend: 104 = cardiac valve procedure with cardiac catheterization. 105 = cardiac valve procedure without cardiac catheterization. 106 = coronary artery bypass procedure with cardiac catheterization. 107 = coronary artery bypass procedure without cardiac catheterization. 108 = other cardiothoracic procedure. NS = not significant.
a Number in parentheses are numbers of patients in each category.

Table 3
Outcome Data[a]

Description	Centrifugal Pump Group	Roller Pump Group	p value
Preoperative LOS (days)[b]	3.1 ± 4.0	2.5 ± 2.4	NS
ICU LOS (days)	3.1 ± 2.0	3.0 ± 1.8	NS
Postoperative LOS (days)	8.9 ± 4.8	9.1 ± 4.6	NS
Total LOS (days)	12.0 ± 6.9	11.6 ± 5.5	NS
Patient Charge ($)	61,626 ± 23,988	61,266 ± 19,518	NS
Reimbursement ($)	28,454 ± 17,319	31,598 ± 19,583	NS
Packed RBC's (units)[c]	1.8 ± 2.6	2.4 ± 2.8	NS
Platelets (units)[b,c]	3.4 ± 7.7	1.6 ± 3.8	NS
Cryoprecipitate (units)[c]	1.9 ± 6.0	1.3 ± 4.7	NS
FFP (units)	0.6 ± 1.3	0.6 ± 1.5	NS
Pump Time (minutes)	84.4 ± 36.5	91.0 ± 30.9	NS
X-Clamp Time (minutes)	51.5 ± 22.1	56.4 ± 26.3	NS
O.R. Time (minutes)	233.2 ± 66.5	236.9 ± 61.2	NS
Neurological Complication	(1) 2%	(0)	NS
Infection (sternal and/or leg)	(1) 2%	(2) 4%	NS
Ventilator Support > 5 days	(2) 4%	(1) 2%	NS
Mortality (within same admiss.)	0	(2) 4%	NS

Legend: LOS = length of stay. ICU = intensive care unit. RBC = red blood cells. FFP = fresh frozen plasma
O.R. = operating room. NS = not significant. admiss. = admission.
a Values are shown as mean ± standard deviation. Numbers in parentheses are number of patients in each category.
b Groups have significantly different standard deviations. Non-parametric test performed.
c Blood or blood product transfusions were measured intraoperativlely and the first 24 hours postoperatively.

There were no statistically significant differences in these four categories. Pump time, cross clamp time and operating room time (defined as the period of time from when the patient enters the room to the time when the patient leaves the operating room) were analyzed and no statistically significant differences were found in either of these three parameters. Three morbidity complications were compared and no statistically significant difference was found in their frequency of occurrence between the two pump groups. Lastly, mortality rates occurring during the same admission were not statistically significant.

DISCUSSION

Lynch, et al, (5) were the first to document a clinical study comparing the blood handling characteristics of the roller pump and Bio-Pump[d] in 1978. This was a retrospective study which evaluated hemolysis by the rise in plasma free hemoglobin and hemostasis by postoperative chest tube drainage. They found the rise in plasma free hemoglobin per hour was 25 mg % less during cardiopulmonary bypass (CPB) using the Bio-Pump. Also, the average rate of chest tube drainage over 24 hours after surgery was nearly 6 ml/hour/m^2 less when the Bio-Pump was used. Since then other investigators have expanded on Lynch's study with varying results; however, clinical studies comparing centrifugal and roller pumps remain scarce. Driessen, et al, (6), in contrast, were unable to show any differences between roller and centrifugal pumps in terms of plasma free hemoglobin or platelet count during and immediately after CPB. They attributed this to the fact

that cardiotomy suction, rather than the arterial pump, is the major cause of damage to circulating blood components due to the large blood-air interface. It should be pointed out, however, that the centrifugal pump used in their study was an impeller design rather an a constrained vortex design. As early as 1958 impeller pumps were abandoned because they were even more hemolytic than roller pumps (7). Although currently improved, impeller pumps have been shown to be more hemolytic than a constrained vortex pump (8, and C. Vane. Bio-Medicus versus Centrimed hemolysis comparison. University of Colorado health Science Center. Unpublished data.).

In order to eliminate the variable of cardiotomy suction Hoerr, et al, (8) evaluated the centrifugal pump and roller pump in a closed in vitro recirculation system. Only after 16 hours did the roller pump produce significantly greater amounts of hemolysis than the centrifugal pump. Thus, showing the roller pump not to be optimal for long term support.

For routine CPB Zirbel, et al, (9) compared the centrifugal pump with the roller pump and furthermore used a silicone membrane oxygenator with the centrifugal pump as opposed to polypropylene membrane used with the roller pump. In this study blood damage was measured by changes in plasma free hemoglobin, hematocrit, platelet counts, and blood products required for transfusion. All of these parameters were found to be similar in both groups. Furthermore, there were no significant differences noted in ICU stay, total length of stay or complication rate. The authors concluded that the results did not warrant the higher cost of the centrifugal pump system. This is one of the even fewer studies which addresses roller pump versus centrifugal pump in terms of clinical outcome and cost. It should be pointed out that Zirbel did not actually compare total patient charges. Instead Zirbel assumed a higher cost while using the centrifugal pump and silicone membrane oxygenator since all other cost factors examined were found to be equal.

Our study goes one step further and compares total patient charges as well as reimbusrement. We choose not to examine the more commonly documented factors such as plasma free hemoglobin and platelet counts. Instead we concentrated on patient outcomes which could also translate into cost savings. Like Zirbel's group, we found no significant differences in transfusion requirements, ICU length of stay, total length of stay or complication rate. We did observe two deaths in the roller pump group. One was a non-surgical death and the other may be attributed to factors other than the type of blood pump used.

Although this was a non-blinded retrospective study the two groups proved to be well matched, as illustrated in Tables 1 and 2. Table 2 insures a fair match when comparing net pay because the majority of patients were covered under capitated reimbursement insurance plans (i.e., Medicare and other managed care contracts).

In Table 3, it is important to note that the patient charges do not reflect any additional charge for use of the centrifugal pump and flow probe. We did not actually charge our patients for these disposables because they were donated for the purpose of this study. If their cost is factored into the statistical analysis the result is unchanged. This is not surprising since their cost is small in comparison to the observed patient charge variances. Unarguably, large variances make it difficult to identify real yet subtle differences, especially when many other variables could be involved. A remedy to large variances would be to increase the size of the population and eliminate as many variables as possible (10), which is difficult and not always practical in the clinical setting.

In contrast to our study a recent and similar study by DeBois, et al, (William DeBois. Personal Communication; February 27, 1993) did find a significant difference in total length of stay of one day and a cost savings of approximately $2,000 favoring their centrifugal pump group. The authors state that they cannot fully explain these observations. Also, the roller pump group demonstrated a greater 24 hour post-op weight gain (2.5 kg vs. 1.8 kg). They believe this may be do to greater complement activation in the roller pump group. Wheeldon, et al, (11) demonstrated that C3a levels (a marker for complement activation) were significantly higher throughout CPB in their roller pump group as compared to their centrifugal pump group. Cardiac and pulmonary dysfunction, renal failure, and bleeding tendencies have been related to C3a levels after CPB (12). DeBois, et al, observed no differences in red blood cell requirements, platelet counts, or blood loss 24 hours postoperatively, which would normally be expected with increased C3a levels. However, the whole body inflammatory response to CPB is complex and involves several other mediators which may lead to capillary injury and extravascular fluid permeability (12).

Another reported advantage of the centrifugal pump, not examined in our study, is that it generates fewer gaseous microemboli (2). Furthermore, the concern of microemboli generated by tubing spallation is reduced (13). Zirbel, et al, however, were unable to show any significant difference in the amount of debris generated from a centrifugal pump versus a roller pump. It would be interesting to incorporate degrees of neurological function as part of a clinical outcomes study between the two pump groups; however, degrees of neurological function are difficult to quantitate.

The inherent safety advantages of the centrifugal pump are its nonaffinity to pass macro air and its afterload dependence which can prevent line rupture (15). These safety features have been recognized by some malpractice insurance underwriters who may offer premium discounts for its use (David Moehle BS, CCP. Personal Communication; February 28, 1993). The centrifugal pump, however, is not without its own potential hazard. If the pump stops due to electrical, mechanical, or operator error, retrograde flow may occur very fast and could create a siphon which may aspirate air into the aorta from the aortic cannulation suture area (16).

In conclusion, we could not identify any significant advantages in clinical outcomes which would benefit either our patients or the hospital in our sample population of patients that experienced arterial blood perfusion utilizing the centrifugal pump. The

reason for this may be two-fold.

First, patients perfused with the centrifugal pump may need to be monitored more aggressivley than is routine (i.e., change practice patterns), during their postoperative hospital stay in order to realize and take advantage of any real benefits. Second, the average pump time was only 84 minutes for the centrifugal pump group and 91 minutes for the roller pump group. Parault and Conrad (17) compared platelet retention after CPB for a centrifugal pump versus a roller pump group of patients. In their study the centrifugal pump exhibited the best platelet retention with the most pronounced difference occuring after 120 minutes of CPB. Furthermore, their results showed that patients greater than 70 years of age and "special cases" demonstrated better platelet retention using the centrifugal pump. The difference in platelet retention between their two pump groups could be shown to be independent of pump time in the case of age but was more difficult to delineate for higher risk patients such as reoperations which commonly have longer pump times. In contrast, our patients were younger with an average age of 62 years in the centrifugal pump group and 64 years in the roller pump group.

Our justification for using Parsonnet's risk stratification was that it could effectively be used to profile our patient population's demographics and at the same time provide predicted mortalities for each pump group. We believe that since this was a non-blinded retrospective study of clinical outcomes that it was important to show the two pump groups to be equally matched in terms of preoperative risk and help eliminate the question of bias (10). Although this would not have changed the results of the patient outcome statistical analyses we believed it helped better validate the results. Also, by using risk a stratification methodology, predicted versus observed mortality can be compared when evaluating the clinical outcomes of the two different techniques. In our study we showed that both groups were well matched in regard to preoperative risk factors. Since we could not find any differences in clinical outcomes in our patient population we suggest that further studies utilize risk stratification to quantify and match populations comparing roller pumps versus centrifugal pumps. Perhaps studying only patients that fall into high risk categories would provide different outcomes.

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