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Does Avoidance of Cardiopulmonary Bypass Decrease the Incidence of Stroke in Diabetics Undergoing Coronary Surgery?

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ABSTRACT

Background: The adverse effects of diabetes mellitus on the coronary circulation and the higher incidence of cardiovascular events in diabetic patients are well documented [Johnson 1982]. Improvements in myocardial protection, revascularization techniques, and anesthetic management have had favorable impacts on coronary artery bypass grafting (CABG) outcome in diabetic patients. Despite that, diabetic patients are significantly more likely to have a prior history of myocardial infarction, congestive heart failure, peripheral vascular disease, and hypertension, as well as having a significantly greater baseline serum creatinine. The aim of our study was to record, compare, and analyze the stroke rate among patients with a history of preoperative diabetes undergoing "off-pump" CABG (OPCAB) with conventional cardiopulmonary bypass (CPB) CABG to determine whether the stroke rate in this higher risk population could be decreased by off-pump techniques.

Methods: The records of 1,227 patients with a pre-operative history of diabetes undergoing conventional CABG (973 patients, 79.3%) using cardiopulmonary bypass and off-pump CABG 254 (20.7%) were analyzed from 1995 through 1999. There were no differences in age, sex, or elective/urgent status of patients. Preoperative risk factors (gender distribution, carotid disease, ejection fraction, CHF, hypertension, previous MI) were identical in both groups. The goal of the operations were complete revascularization, which was achieved via median sternotomy in both groups.

Results: Our reported series reveals a stroke rate of 3.6% in the CPB group and 1.2% in the off-pump group. This evidence alone was not statistically significant, but two other high-risk criteria for stroke, re-do CABG and calcified aortas, revealed that the off-pump series had a higher percentage of each (26.4% redos in off-pump vs. 8.7% CPB redos, $p < 0.005$; 7.1% calcified aorta cases in the off-pump group vs. 2.9% in the CPB group, $p < 0.004$). The threefold reduction in stroke may be clinically significant in light of the higher-risk profile of the off-pump group. The limitations of this study are that it was retrospective, there were a small number of events, and different surgeons were involved in the two different approaches to these patients.

Conclusions: Improvements in myocardial protection, revascularization techniques, and anesthetic management have made significant, favorable impacts on CABG outcome in diabetic patients. New diagnostic and therapeutic strategies must be developed to lessen the medical and economic implications of stroke. A larger series or a more effective way of analyzing preoperative risk may well have shown a statistically significant difference in the stroke incidence given the differences in preoperative risk factors/stroke predictors. Until such advances occur, a threefold reduction of stroke incidence using OPCAB certainly makes this technique a favorable one for high-risk diabetics requiring coronary revascularization.

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INTRODUCTION

The adverse effects of diabetes mellitus on the coronary circulation and the higher incidence of cardiovascular events in diabetic patients are well documented [Johnson

1982]. Improvements in myocardial protection, revascularization techniques, and anesthetic management have had favorable impacts on coronary artery bypass grafting (CABG) outcome in diabetic patients. Despite that, diabetic patients are significantly more likely to have a prior history of myocardial infarction, congestive heart failure, peripheral vascular disease and hypertension, as well as having a significantly greater baseline serum creatinine [Stewart 1998]. Diabetic patients have overall longer ICU and hospital stays, and Herlitz [Herlitz 1996] and Morris [Morris 1991] agree with Stewart [Stewart 1998] that diabetes is an independent risk factor for mortality following CABG.

Stroke is the third leading cause of death in the United States and continues to be a challenging problem as the population ages. Stroke and neurologic complications occur in up to 6% of patients following CABG. The incidence of cognitive and neuropsychological complications are much higher and may exceed 60% [Almassi 1999]. Patients who undergo myocardial revascularization procedures, now more than 800,000 per year throughout the world, are particularly prone to stroke, encephalopathy, and other neurologic dysfunction because they are relatively old and have atherosclerotic heart disease. With longer ICU stays, hospitalization, and overall increased consumption of resources, estimates worldwide of the added in-hospital cost are upwards of $800 million annually [Roach 1996]. These patients are also subject to marked hemodynamic fluctuations, cerebral embolization of atherosclerotic plaque, air, fat, and platelet aggregates, cerebral hyperthermia after discontinuation of cardiopulmonary bypass (CPB), and other inflammatory and neurohormonal derangements associated with surgery [Roach 1996]. Hodgman and Eversman [Hodgman 1981] found a stroke incidence of 4.6% in diabetics versus 1.6% in nondiabetics. Johnson et al. [Johnson 1982] observed five fatal strokes in their series of patients concluding that diabetic patients may be more susceptible to stroke.

The aim of our study was to record, compare, and analyze the stroke rate among patients with a history of preop diabetes undergoing off-pump CABG (OPCAB) with conventional CPB CABG to determine whether the stroke rate in this higher risk population could be decreased by off-pump techniques. Stroke was defined as any new global or focal neurological deficit lasting more than 24 hours that was confirmed by head CT scan and/or neurology evaluation during that hospital stay.

PATIENTS AND METHODS

The records of 1,227 patients with pre-operative history of diabetes undergoing conventional CABG (973 patients, 79.3%) using cardiopulmonary bypass and "off-pump" CABG 254 (20.7%) were analyzed from 1995 through 1999. The goal of the operations was complete revascularization, but in the early phase of OPCAB surgery this goal was not always accomplished. Since 1997, complete revascularization was accomplished routinely in the OPCAB patients. Revascularization was achieved via median sternotomy in both groups. Aortic calcification was assessed primarily by chest x-ray and CT scan and intraoperative palpation. Chest CT was utilized only if the chest x-ray was suspicious for extensive lesions. Data was compared to the NY State database.

RESULTS

There were no differences in age, sex, or elective/urgent status. A higher proportion of the off-pump group were "re-do" cases compared to the CPB group (26.4% off-pump vs. 8.7% CPB, $p < 0.005$), and the incidence of calcified aorta was higher in the off-pump group (7.1% off-pump vs. 2.9% CPB, $p < 0.04$). Preoperative risk factors (gender distribution, carotid disease, ejection fraction, CHF, hypertension, previous MI) were identical in both groups. There was a higher percentage of patients in the off-CPB group with preoperative congestive heart failure (CHF) (18.5% off-pump vs. 12.8% CPB, $p = 0.025$) and who were also on IV nitroglycerin 24 hours pre-op (21.3% off-pump vs. 15.2% CPB). The risk-adjusted mortality for both groups was statistically the same (1.8% off-CPB vs. 2.6 % CPB, p = NS). There was no significant difference in postoperative stroke rates (1.2% off-pump vs. 3.6% CPB, p = NS). While the off-pump stroke rate represents one-third of the stroke rate in the CPB group, the difference was not statistically significant. Postoperative complications (transmural MI, deep sternal wound infection, bleeding, renal and respiratory failure) were identical in both groups.

It is important to keep in mind some of the technical milestones [Bergsland 1998], such as stabilizers (1997) and the LIMA stitch [Bergsland 1999], that took place during the time frame of this study. Median sternotomy was the exposure technique of choice in most instances for complete myocardial revascularization in both groups. Revascularization of the marginal branches of the circumflex artery was not considered a contraindication to off-pump coronary grafting. Technical considerations included the use of the single suture (LIMA) stitch technique in the oblique sinus of the posterior pericardium to obtain exposure [Herlitz 1993] and mechanical stabilization with an epicardial foot plate to reduce heart motion. Ischemic preconditioning, especially of the LAD vessels, was routine for 3-5 minutes and this was the first vessel grafted during off-pump cases. Intracoronary shunts were used to reestablish flow during construction of the distal anastamoses, the details of which have been previously described [Rivetti 1998]. A CO_2 blower/saline aerosolizer was used to maintain a bloodless field of vision [Bergsland 1999]. All off-pump grafts were evaluated via transit time flow meter [Bergsland 1999].

All relevant information, which included demographic data, preoperative risk factors and comorbid conditions, angiographic data with severity and distribution of significant coronary artery disease, and morbidity and mortality rates were recorded [Bergsland 1998]. The severity of angina was categorized according to the Canadian Cardiovascular

Society (CCS) classification. The left ventricular ejection fraction (LVEF) was determined in all cases by left ventriculography during coronary angiography. The type of operative priority was defined as emergent when severity and distribution of coronary pathology in combination with hemodynamic instability mandated immediate intervention. The management of some of these patients had included vasopressors, intra-aortic balloon counterpulsation, and cardiopulmonary resuscitation. Patients in whom surgical intervention was promptly undertaken in the face of ongoing ischemia, or failed angioplasty, or as a result of unfavorable anatomy (i.e., left main disease), were referred to as urgent.

The data collected from both study groups were statistically analyzed and compared. Statistical analysis was conducted using Epi Info, version 6. Continuous normally distributed variables were contrasted using the Student's t test. The Fisher exact test was used when the expected value of a cell was less than 5. Differences between variables were considered significant when the p value was less than 0.05.

COMMENT

The negative impact of diabetes on survival following coronary angioplasty was demonstrated by the Bypass Angioplasty Revascularization Investigation (BARI) [BARI 1996]. Five-year survival in diabetics assigned to multivessel angioplasty (65.5%) was significantly lower than five-year survival in non-diabetics treated similarly (91.1%). In addition, a reduced five-year survival was observed in diabetics assigned to CABG (80.6%) versus that seen in non-diabetics undergoing CABG (91.4%) [BARI 1996].

Not all diabetics are the same. Lawrie et al. reported that diabetics controlled through diet had a prognosis indistinguishable in all respects from non-diabetics [Lawrie 1986]. Those receiving insulin had a substantially worse long-term survival, although their early prognosis was identical. Patients receiving oral hypoglycemic agents had an intermediate prognosis. Controlled diabetes is not sufficient reason to avoid surgery for severe coronary artery disease. Five-year survival in diabetics after coronary surgery still exceeds survival of any reported series of medically treated patients with comparable disease [Johnson 1982].

An increasing proportion of high-risk patients are offered revascularization because of signs and symptoms of ischemic heart disease. Patients with a history of diabetes constitute one such high risk group. While we did not observe a statistically significant difference in the mortality rate between the off-CPB and the CPB diabetic cohorts, others have reported very high mortality rates among diabetics [Herlitz 1993, Zuanetti 1993, Herlitz 1996]. Herlitz et al. found that diabetics required more reoperation and had a higher incidence of peri- and post-operative neurological complications [Herlitz 1996]. They also concluded that the mortality rate during the two-year period after CABG was approximately twice that of non-diabetic patients. The mechanism underlying higher mortality in diabetic patients is thought to be existence of more extensive coronary artery disease, which compromises myocardial function. From these and other similar studies, diabetes, after multivariate analysis, still appears to be an independent predictor of mortality. Diabetics have a higher risk of reinfarction compared to non-diabetics, and the risk of thromboembolic complications in patients with diabetes was higher in comparison to non-diabetic cohorts [Herlitz 1993, Herlitz 1996].

Advanced age is associated with an inhomogeneous reduction in gray matter flow, and this progressive reduction in regional blood flow and cerebrovascular collateral reserve may play a role in the increased incidence of post-operative stroke in the elderly, especially when hypotension or a low flow state occurs during or after CPB [Calafiore 1997]. In an ever-aging population presenting for CABG surgery with a myriad of medical problems, understanding the physiology and pathophysiology of cerebral blood flow and the factors that may compromise it is essential.

Advances in surgical technique, anesthesia management, and CPB have all contributed to reductions in morbidity and mortality during cardiac surgical procedures. However, the incidence of neurologic injury, in particular neuropsychologic impairment, remains high after CPB [Taylor 1999]. Several studies have reported that 50%-70% of patients exhibit cognitive deficits one week after coronary bypass operations and approximately 30% of patients exhibit long-term neuropsychologic impairment. The possibility of a lower threshold to ischemic insult of any kind—whether microemboli, low flow, or other—suggests a more tenuous state that precludes safe use of CPB with its inherent sources of emboli and hemodynamic changes, as demonstrated by Taylor et al. [Taylor 1999]. In the same paper, Taylor et al. observe one-third of patients exhibiting long-term cognitive deficits after CPB. The principal cause of neuropsychologic impairment was thought to be diffuse microischemia secondary to cerebral microemboli. Taylor et al. studied interventions on-pump and correlated cerebral microemboli with transcranial doppler studies. They identified at least nine sources/points from which patients were at risk of showering emboli and found the greatest number of emboli occurring during interventions by the perfusionist (blood sampling and drug injections), although these were often correctable when detected.

Various authors and investigators have attempted to identify risk factors and preoperative predictors of perioperative stroke following CABG, and at least two authors [Higgins 1992, Mickleborough 1996] have proposed and developed severity scores and indices. Of the many risk factors examined by investigators, preoperative stroke demonstrates the highest risk of development of postoperative neurologic events. Causes of stroke are multifactorial. Some generally accepted risk factors are age, length of CPB and cross-clamp time, urgency of operation, calcified aortas/generalized atherosclerosis, combined valve repair (especially mitral) and CABG, and hypertension. Factors that are less generally accepted as predictors for stroke include female gender, atrial fibrillation, and pulmonary disease [Higgins 1992, Mickleborough 1996, McKhann 1997, Almassi 1999, Taylor 1999].

Central nervous system complications of CPB are very common. These range from subtle neuropsychiatric abnormalities detected only with sophisticated tests (e.g., saccadic eye movements) to frank and clinically evident neurologic deficit. A permanent neurologic deficit or stroke occurs in up to 6% of patients undergoing cardiac surgery Lynn 1992, Roach 1996, Almassi 1999]. Hodgman and Eversman [Hodgman 1981] found a stroke incidence of 4.6% in diabetics versus 1.6% in non-diabetics and observed five (1.9%) fatal strokes in their 261 patients. They concluded from this evidence that diabetic patients are more susceptible to stroke.

Our reported series reveals a stroke rate of 3.6% with CPB and 1.2% in the off-pump group. This evidence alone was not statistically significant, but two other high-risk criteria for stroke, re-do CABG and calcified aortas, revealed that the off-pump series had a higher percentage of each (26.4% redos in off-pump vs. 8.7% CPB redos, $p < 0.005$; 7.1% calcified aorta cases in the off-pump vs. 2.9% in the CPB group, $p < 0.004$). There was also a higher incidence of CHF on admission in the off-CPB group (18.5% vs. 12.8% in the CPB group, $p = 0.025$). This threefold reduction in stroke, therefore, is clinically significant in light of the higher risk profile of the off-pump group.

The limitations of this study are that it was retrospective, there were a small number of events, and different surgeons were involved in the two different approaches to these patients. Clearly, as this field of study broadens, more accurate risk stratification (NIH, Mathews', Murkins' scales) [Higgins 1992, BARI 1996] can be utilized as well as uniform definitions and applications of neuropsychological injury applied and followed long-term. More sensitive and consistent means of identifying aortic lesions (CT or epi-aortic scanning) may also identify high-risk individuals [Rao 1995, Calafiore 1997].

CONCLUSION

Improvements in myocardial protection, revascularization techniques, and anesthetic management have made significant, favorable impacts on CABG outcome in diabetic patients. New diagnostic and therapeutic strategies must be developed to lessen the medical and economic implications of stroke. To that end, we have explored the use of coronary revascularization techniques without extracorporeal circulation (i.e., off-pump or beating heart surgery) to determine the extent to which neurologic events and their consequences can be attenuated. A larger series or a more effective way of analyzing preoperative risk may well have shown a statistically significant difference in the stroke incidence given the differences in preoperative risk factors/stroke predictors. Such analytical tools might include computer matching and subsequent logistic regression, and identifying hazard criteria with appropriate confidence intervals from univariate and multivariate analysis. Until such advances occur, a threefold reduction of stroke incidence using OPCAB certainly makes this technique a favorable one for high-risk diabetics requiring coronary revascularization.

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APPENDIX

	Pre-Op Diabetes				
	With Pump		Without Pump		
	n	%	n	%	p value
Total patients	973	100.0	254	100.0	
Total grafts	3406		83		N.S.
Grafts per patient	3.50		1.90		N.S.
Mortality rate – Crude	34	3.5	10	3.9	N.S.
Mortality rate – Expected		3.3		5.2	N.S.
Mortality rate – Risk adj.		2.6		1.8	N.S.
Male	580	59.6	167	65.7	N.S.
Female	393	40.4	87	34.3	N.S.
Age – Average	64.4		65.7		N.S.
Age – Minimum	34.0		35.0		N.S.
Age – Maximum	86.0		86.0		
EF – Average	48.3		97.7		N.S.
EF – Minimum	15.0		18.0		N.S.
EF – Maximum	88		80		N.S.
Elective	486	489.9	130	51.2	N.S.
Urgent	437	44.9	116	45.7	N.S.
Emergency	50	5.1	8	3.1	N.S.
Length of stay – Avg. (adm.-dis.)	14.1		13.4		N.S.
Length of stay – Avg. (surg.-dis.)	9.3		9.1		N.S.
CCS Class I	30	3.1	4	1.6	N.S.
CCS Class II	17	1.7	11	4.3	0.030
CCS Class III	265	27.2	79	31.1	N.S.
CCS Class IV	665	67.9	160	63	N.S.

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APPENDIX (CONTINUED)

	Pre-Op Diabetes				
	With Pump		Without Pump		
	n	%	n	%	p value
Complications					
None	801	82.3	224	88.2	0.029
Stroke (new neurologic deficit)	35	3.6	3	1.2	N.S.
Transmural MI	24	2.5	6	2.4	N.S.
Deep sternal wound infection	14	1.4	3	1.2	N.S.
Bleeding requiring reoperation	11	1.1	5	2.0	N.S.
Sepsis or endocarditis	12	1.2	1	0.4	N.S.
G-I bleeding, perf., or infarction	16	1.6	1	0.4	N.S.
Renal failure, dialysis	29	3.0	9	3.5	N.S.
Respiratory failure	42	4.3	8	3.1	N.S.
Pre-op Risk Factors					
Previous open heart	85	8.7	67	26.4	<0.005
Previous MI 1 or more days	632	65.0	157	61.8	N.S.
Transmural MI	352	36.2	69	27.2	<0.007
Stroke	96	9.9	36	14.2	N.S.
Carotid/Cerebrovascular	259	26.6	68	26.8	N.S.
Aorto-iliac	45	4.6	13	5.1	N.S.
Femoral/Popliteal	136	14	39	15.4	N.S.
Unstable	18	1.8	2	0.8	N.S.
Shock	4	0.4	0	0	N.S.
More than one previous MI	180	18.5	35	13.8	N.S.
Hypertension history	786	80.8	212	83.5	N.S.
IV NTG within 24 hours pre-op	148	15.2	54	21.3	0.023
ECG evidence of LVH	105	10.8	30	11.8	N.S.
CHF, the admission	125	12.8	47	18.5	0.025
CHF, before this admission	176	18.1	29	11.4	0.010
Malignant ventricular arrhythmia	19	2.0	2	0.8	N.S.
COPD	265	27.2	73	28.7	N.S.
Myocardial rupture	0	0	0	0	0.05
Ext. calcified ascending aorta	28	2.9	18	7.1	0.004
Diabetes requiring medication	973	100.0	254	100.0	N.S.
Hepatic failure	2	0.2	0	0	N.S.
Renal failure, creatinine >2.5	36	3.7	12	4.7	N.S.
Renal failure, dialysis	18	1.8	8	3.1	N.S.
Immune system deficiency	11	1.1	10	3.9	<0.005
IABP pre-op	34	3.5	3	1.2	N.S.
Emer xfer to OR after DX cath.	10	1.0	1	0.4	N.S.
Emer xfer to OR after PTCA	3	0.3	0	0.0	N.S.
Previous PTCA, this adm.	9	0.9	2	0.8	N.S.
PTCA before this admission	97	10.0	34	13.4	N.S.
Thrombolytic therapy within 7 days	28	2.9	6	2.4	N.S.
Smoking history, in past 2 weeks	149	15.3	30	11.8	N.S.
Smoking history, in past year	63	6.5	16	6.3	N.S.
Vessels Diseased					
LMT: 50 – 69%	61	6.3	9	3.5	N.S.
LMT: 70 – 89%	42	4.3	12	4.7	N.S.
LMT: 90 – 100%	33	3.4	15	5.9	N.S.
Prox. LAD: 50 – 69%	87	8.9	18	7.1	N.S.
Prox. LAD: 70 – 100%	745	76.6	173	68.1	0.007
Mid./Dist. LAD: 50 – 69%	58	6.0	10	3.9	N.S.
Mid./Dist. LAD: 70 – 100%	414	42.5	71	28.0	<0.005
RCA: 50 – 69%	69	7.1	15	5.9	N.S.
RCA: 70 – 100%	733	75.3	176	69.3	N.S.
LCX: 50 – 69%	71	7.3	17	6.7	N.S.
LCX: 70 – 100%	720	74.0	142	55.9	<0.005