

Role of Cardiopulmonary Bypass in Single Vessel Coronary Revascularization: Implications for MID-CABG

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ABSTRACT

Background: Minimally invasive direct coronary artery bypass grafting (MID-CABG) is being utilized for the treatment of coronary artery disease in selected patients. This innovative procedure has generated numerous technical issues relating to coronary revascularization, including whether to perform the revascularization with or without cardiopulmonary bypass (CPB).

Methods: We addressed this issue indirectly by analyzing the 1995 New York State CABG registry, comparing patients who had single vessel bypass without CPB (Non-CPB Group) to a similar cohort of patients who had CABG performed on CPB (CPB Group). The database showed stratification of patients selected for bypass grafting without CPB to a significantly higher risk group, as shown by increased age, higher incidence of reoperation, transmural MI, congestive heart failure, carotid/cerebrovascular disease, and peripheral vascular disease.

Results: Patients in the Non-CPB Group had a higher incidence of postoperative malignant ventricular arrhythmias and heart block requiring pacemaker insertion. Otherwise, the incidence of postoperative complications was similar between the two groups.

Conclusions: There were no statistical differences in the hospital mortality or the length of hospitalization between the two groups. In conclusion, the data showed a definite trend toward doing higher risk cases off CPB. These cases had an acceptable early morbidity and mortality outcome. The results were comparable to a group of lower risk patients with single vessel CABG done on cardiopulmonary bypass. However, further follow-up are required to evaluate long-term outcomes and confirm the utility of this surgical option.

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INTRODUCTION

Surgical revascularization provides satisfactory graft patency rates, freedom from angina and excellent long-term survival in ischemic heart disease [Loop 1984, Boylan 1994]. During the early postoperative period, much of the morbidity and mortality associated with coronary artery bypass grafting (CABG) have been attributed to the use of cardiopulmonary bypass (CPB), arrest of the heart during aortic cross-clamping, hypothermia and the median sternotomy incision. This led to the recent introduction of minimally invasive direct CABG (MID-CABG) which can be performed without the use of CPB or approached through smaller incisions [Benetti 1985, Subramanian 1995, Oz 1997, Boonstra, 1997], therefore avoiding the disadvantages of conventional CABG. The application of minimally invasive cardiac surgery is a natural evolution in video-assisted thoracoscopic surgery of the chest. Early single-center reports on MID-CABG have demonstrated feasibility of the procedure and encouraging short-term results [Calafiore 1996, Arom 1997]. These reports have stimulated widespread application of this new technique in coronary revascularization.

Minimally invasive revascularization can be performed either with or without cardiopulmonary bypass. Despite an emerging interest in MID-CABG, there is a paucity of information on the role of cardiopulmonary bypass in single vessel revascularization. We address this issue by analyzing the data from the 1995 New York State CABG registry, a large multicenter patient registry. The objectives of this study are to determine the profile of patients selected for revascularization without CPB and to evaluate the effects of CPB on patient outcome.

MATERIALS AND METHODS

Patients and Methods

The New York State Cardiac Surgery database is a mandatory registry for all adult patients who had cardiac surgery including CABG at 31 hospitals in New York State. The database is collected and compiled by the Bureau of

Table 1.

	Non-CPB (N = 52)	CPB (N = 548)	p Value
Age (years)	65.9±1.4	61.8±0	<0.05
Male/Female	36/16	351/197	NS
Reoperations	18 (34.6%)	96 (17.5%)	<0.005
Left Ventricular Ejection Fraction	47.2±2.4	50.4±0.6	NS
Preop MI (<21 days)	35 (67.3%)	314 (57.3%)	NS
Preop Transmural MI	24 (46.2%)	140 (25.5%)	<0.005
COPD	8 (15.4%)	61 (11.1%)	NS
Congestive Heart Failure	13 (25%)	78 (14.2%)	<0.05
Renal failure (Cr > 2.5 or dialysis)	3 (5.8%)	13 (2.4%)	NS
Stroke	4 (7.7%)	29 (5.3%)	NS
Carotid/cerebrovascular disease	10 (19.2%)	42 (7.6%)	<0.01
Aorto-iliac/fem-pop disease	10 (19.2%)	50 (9.1%)	<0.05
PTCA this admission	6 (11.5%)	50 (9.1%)	NS
PTCA previous admission	16 (30.8%)	146 (26.6%)	NS
Thrombolytic therapy (< 7 days)	3 (5.8%)	16 (2.9%)	NS

Health Care Research & Information, New York State Department of Health.

Statistical Methods

Continuous variables were examined using the Kruskal-Wallis test (nonparametric ANOVA), with a nonparametric post test for individual comparisons. Discrete variables were compared using Fishers exact test. Data is reported as mean ± SEM unless otherwise noted, and values of p < 0.05 were considered statistically significant. Length of stay data more than two standard deviations above the mean were excluded from final analysis. Statistical analysis was performed using InStat v2.01 (GraphPad software) and SAS v6.12 (SAS Institute) on a Macintosh personal computer (PPC 604e/233).

RESULTS

In 1995, CABG was performed as the sole procedure in 19,224 patients at 31 hospitals by 106 surgeons in New York State. Single vessel revascularization was performed in 600 patients (3.1%). Of these patients, 52 (9% of single vessel CABG, 0.3% of all CABG) had bypass grafting without CPB (Non-CPB Group), while 548 patients (91% of single vessel CABG, 2.9% of all CABG) underwent single vessel CABG with the use of CPB (CPB Group). These 52 Non-CPB operations were performed by 19 surgeons at 13 institutions. The mean cases for these 13 institutions were 4.0±6.4 (s.d., median 1, range 1- 24 cases). The mean cases per surgeon was 2.7±5.3 (s.d., median 1, range 1-23 cases). The CPB Group had a mean CPB time of 46.2±1.1 minutes with a mean aortic cross-clamp time of 24.3±0.8 minutes, as compared to a zero CPB and cross-clamp time for the Non-CPB Group.

Demographic data including the preoperative risk factors for both patient groups are shown in Table 1. The following risk factors were significantly associated with the Non-CPB Group: age (p < 0.05), previous cardiac operations (p < 0.005), preoperative transmural myocardial infarctions (p < 0.005), congestive heart failure (p < 0.05), carotid/cerebrovascular disease (p < 0.01) and aorto-iliac/femoropopliteal disease (p < 0.05). The remaining risk factors were not significantly associated with either group.

Postoperative length of stay for the entire study group was 8.0±9.0 days (mean±SD, range 2-131 days). Data greater than or equal to 26 days (mean+2SD) for 19 patients (3.2% of total data, range 26-131 days) were excluded from final length of stay analysis. Two of the excluded patients were from the Non-CPB Group (2/52, 3.8%) and 17 were from the CPB Group (17/548, 3.1%) with mean length of stays of 33 and 47 days, respectively. Both groups had similar postoperative length of stays (6.7±3.5 days vs. 6.8±3.2 days, p = NS) (Table 2). Length of stay was further evaluated by comparing the two groups according to the priority of revascularization (elective, urgent or emergency), age (less than 70 years versus 70 years or older), gender and preoperative ejection fraction (ejection fraction less than 40% or greater or equal to 40%). Patients in both groups had a similar length of stay when matched for surgical priority, sex, and ejection fraction. Patients in the Non-CPB Group younger than 70 years had a longer length of stay as compared to patients in the CPB Group: 7.4 days versus 6.2 days (p = 0.049), however, patients older than 70 years in the CPB Group had a longer hospital stay as compared to patients in the Non-CPB Group: 8.3 days versus 6.2 days (p = 0.013).

Postoperative complications were similar between the two groups (Table 3). The Non-CPB Group had a higher incidence of postoperative heart block requiring pacemaker insertion (2/52 vs. 2/548, p = 0.04) and malignant ventricular arrhythmias (4/52 vs. 10/548, p = 0.03). Overall mortality for the Non-CPB Group was 3.8% (4/52), slightly higher than the 2.4% (13/548) seen in the CPB Group, but this did not reach statistical significance (p = 0.0512).

Table 2.

	Non-CPB (N = 52)	CPB (N = 548)	p Value
Total population	6.7±3.5	6.8±3.2	NS
Priority 1 (elective)	5.76±0.87	6.09±0.21	NS
Priority 2 (urgent)	6.72±0.65	7.18±0.21	NS
Priority 3 (emergency)	10.17±3.02	7.28±0.39	0.09
< 70 years old	7.42±0.98	6.26±0.14	0.049
≥ 70 years old	6.09±0.61	8.39±0.35	0.013
Ejection fraction < 40	7.27±1.22	8.84±0.25	NS
Ejection fraction ≥ 40	6.29±0.49	6.42±0.14	NS
Male	6.21±0.77	6.67±0.18	NS
Female	8.13±0.87	7.11±0.25	NS

Table 3.

	Non-CPB (N = 52)	CPB (N = 548)	p Value
Mortality	4 (3.8%)	13 (2.4%)	0.0512
Stroke	0	5	NS
Transmural MI	0	2	NS
Non-Transmural MI	0	5	NS
Deep sternal wound infection	0	2	NS
Reop bleeding	0	3	NS
Return to OR	1	2	NS
Heart block requiring pacemaker	2	2	0.04
Sepsis/endocarditis	0	3	NS
GI bleed/Perforation/Infarct	0	4	NS
Renal failure/dialysis	0	2	NS
IABP inserted in OR	1	10	NS
Respiratory failure	3	17	NS
Brachial plexus impairment	1	0	0.08
Phrenic nerve palsy	0	0	NS
Malignant ventricular arrhythmia	4	10	0.03

DISCUSSION

Less invasive cardiac surgery has emerged as a new and significantly different approach to the treatment of a variety of cardiovascular diseases. There are two issues surrounding the use of CPB in single vessel CABG. One issue relates to the adverse effects of cardiopulmonary bypass, especially among high risk patients. The second issue is whether the coronary artery anastomosis can be performed precisely without CPB and cross-clamping the aorta. The availability of a new generation of mechanical stabilization hardware has made the coronary anastomosis feasible on a beating heart.

The adverse effects of CPB have been well documented and include complement and neutrophil activation and microembolism [Kirklin 1983]. Inadequate myocardial protection during aortic cross-clamping can also contribute to significant morbidity and mortality following a revascularization procedure [Allen 1997]. The adverse effects of CPB are of even greater importance among high risk patients. This is reflected in the New York State CABG Registry which showed that higher risk patients were being selected to undergo CABG without CPB. This cohort of patients was significantly older, more likely to be undergoing a reoperation, had a prior history of transmural myocardial infarction, had a greater incidence of congestive heart failure, and had more peripheral vascular disease. The Non-CPB group was stratified to a higher risk category preoperatively, suggesting a preference by some surgeons to perform higher risk cases without the use of CPB. Despite this bias in patient selection, the Non-CPB group had similar morbidities except for two complications when compared to the CPB group. We attribute the higher incidence of ventricular arrhythmia and heart block in the Non-CPB group to the fact that this was a "sicker" patient population. There was no significant difference in post-

operative length of stay or in-hospital mortality between the two groups.

Questions regarding the technical aspects of beating-heart anastomosis and subsequent graft patency remain an issue in MID-CABG. The excellent patency rate of grafting the left internal mammary artery to the left anterior descending artery as reflected in the 10 year patency rates of 85% to 95% is well established [Cameron 1996]. Whether MID-CABG can duplicate a similar patency rate is not known at this time. However, several studies have reported excellent short-term and mid-term patency rates following MID-CABG of 91% to 95% both by angiography and by Doppler ultrasound techniques [Gill 1997]. Undoubtedly, the use of regional cardiac wall immobilization is widely felt to facilitate the coronary anastomosis and will likely have an impact on graft patency rates [Subramanian 1997]. Reports of less salutary results have also been published [Lazzara 1997].

The New York database showed that a significant number of single vessel CABG was being performed without cardiopulmonary bypass in 1995. There was no evidence that these patients had a significant problem with early graft occlusion, as shown by similar rates of postoperative myocardial infarctions, requirement for early reoperation, the need for intra-aortic balloon pump placement, and in-hospital mortality when compared to those receiving CABG using CPB.

There are several limitations of the present study. First, there are always concerns with underreporting of complications and completeness of data collection with multi-center registries; however, the New York State Department of health performs periodic audits of participating centers in this mandatory database. This database does not provide angiographic and long term follow up regarding the patency of the grafts. No information is given regarding the type of incision (sternotomy vs. thoracotomy), or the use of mechanical or pharmacologic agents for ventricular stabilization employed during revascularization. It should be noted that the database will also not capture failed MID-CABG patients who are intraoperatively converted to conventional CABG on CPB. The data does not offer any direct opportunity for cost analysis or quality of life; both driving forces in the widespread acceptance of new surgical techniques. 1995 also represents an early period in the development of minimally invasive CABG techniques. Several changes have occurred since, including improved techniques of regional cardiac wall immobilization and expanding indications for the use of MID-CABG. Analysis of more recent data from various multicenter registry reports, when available, will more clearly define the role of CPB in single vessel coronary revascularization.

Early outcomes after MID-CABG shows that it is a safe approach to achieve satisfactory revascularization in selected patients with acceptable morbidity and mortality; the use of MID-CABG in high risk situations makes it's use even more attractive. Analysis of this large nonvoluntary database which includes hard risk factor data will be a valuable resource as the field evolves. Results from this

early experience suggest that higher risk patients are being selected for MID-CABG. The short-term benefits from MID-CABG have been acceptable, but in the end it will be the fundamental issues of long term graft patency and overall morbidity and mortality which will determine the role of MID-CABG in the future of cardiac surgery. Only through continued evaluation of these longer term goals will we truly be able to objectively analyze the data surrounding new surgical techniques.

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REVIEW AND COMMENTARY

1. Editorial Board member SC389 writes:

1. There is no mention of Dr. Frederico Benetti's work. He certainly is the surgeon who pioneered the left anterior thoracotomy MIDCAB and should be acknowledged.
2. There is no specific description of the technique, particularly if Adenosine or other pharmacological agents were used, which hopefully explains the heart block and ventricular arrhythmias which is not common in beating heart surgery.
3. The data is not risk stratified which from my understanding can be done with the New York database.
4. 1995 is an early time in MIDCAB history and there is probably a large learning curve and no consistency in who was doing the surgery.
5. There is no follow up data on these patients as to repeat revascularization and reintervention. Since this is an observational study, perhaps it might be better to give a followup on the 52 off pump patients as they are now 3 years out from surgery.

Authors' Response by Asim Choudhri:

- 1- A reference to the following article has been added: Benetti FJ. Direct Coronary Surgery with Saphenous Vein Bypass Without Either Cardiopulmonary Bypass or Cardiac Arrest. *Journal of Cardiovascular Surgery*. 26(3):217-22 May-Jun. 1985
- 2- As added to paragraph 5 of the discussion section, "No information is given regarding the type of incision (sternotomy vs. thoracotomy), or the use of mechanical or pharmacological agents for ventricular stabilization employed during revascularization."
- 3- Multivariable statistics cannot be performed with such a small group (n = 52).
- 4- The number of Surgeons and Centers involved has been added to paragraph one of the results section. Several mentions are made of 1995 being the early Non-CPB experience.
- 5- Unfortunately, followup information is not available, as stated in paragraph five of the discussion section.

2. Editorial Board member AR11 writes:

I have reviewed the manuscript mentioned below and found it interesting reading. The authors seem to be trying to define the place of CPB in single vessel revascularizations, using data from the New York state database of cardiac surgery.

While the use of the database was intended to be used for research purposes such as this, as well as to monitor surgeon performance, numerous questions regarding its accuracy/completeness/relevance have arisen over the years. Testifying to this is the fact that the database ques-

tionnaire changes each year with various additions and deletions of risk factors, complications, and other parameters as staticians deem them relevant. The use of the database as a source of information for this manuscript may not, therefore, provide an accurate reference source.

Assuming the data are correct, however, I think the authors should do more to clarify the information. For example, the number of surgeons performing the procedure off cpb as well as the number of cases each surgeon has done might be cited to account for a "learning curve" associated with any new technique. Additionally, the vessels bypassed are not listed—presumably all were LADs or other anteriorly-located vessels but this should be defined.

The authors, in their discussion section, state that there is no evidence that the patients grafted off cpb had a significant problem with early graft occlusion as shown various similar rates of complications between the two groups, yet there were significantly higher rates of malignant post-operative ventricular dysrhythmias in the off-cpb group. Cannot rhythms disturbances signify graft closure and were these patients studied to determine that closure was in fact not the problem?

I believe the authors thesis is interesting and merits further investigation but I also believe that the data as presented should be further refined.

Authors' Response by Asim Choudhri:

- The data collection sheet used in New York State has remained unchanged since 1992. Regardless, only data from 1995 was analyzed for this study.
- The number of Surgeons and Centers involved has been added to paragraph one of the results section
- While the specific target was not listed for individual patients, all patients presented with significant LAD lesions, presumably all requiring isolated LAD revascularization.
- No postoperative angiographic data is available to assess either early or late graft patency, as discussed in paragraph five of the discussion. We cannot directly comment on the cause of the ventricular arrhythmias in the four patients, however these four patients did not require return trips to the operating room for revision of grafts.

3. Editorial Board member YK794 writes:

This retrospective study based on the 1995 New York State CABG registry tries to address the question whether to perform the revascularization in single vessel disease with or without cardiopulmonary bypass. Based on the described data I find it difficult to answer this question because of the following limitations:

1. 548 patients(91%) were operated using CPB and only 52 pts (9%) without CPB. It was not stated how many centers were involved in this 52 pts. Its possible that each center did just a few non CPB pts, meaning that most of them were on the initial phase of the learning curve and it makes it difficult to draw conclusions in this situation. I believe that if the study will involve 1997 database the

ratio between CPB and non CPB will be different and presumably also the results.

2. Table #1 shows different characteristics of the two groups of patients in regards to their risk factors. Therefore it is hard to compare this groups of patients.

3. The surgical techniques of the non CPB patients were not described. How many were MIDCABs, sternotomies etc. We don't know if mechanical stabilization was used. All this techniques reflect on Lima patency and probably on the overall results.

4. The non CPB patients had higher incidence of heart block and malignant ventricular arrhythmias. This is hardly seen in series of Midcabs from other centers. I think that the main value of this manuscript is that it gives us the demographics of single vessel coronary surgery in N.Y State in 1995. It will be interesting to see the evolution of this surgery by analysing the 1997 data.

Authors' Response by Asim Choudhri:

- The number of Surgeons and Centers involved has been added to paragraph one of the results section. The impact of this being the "early learning curve" for MID-CABG is mentioned in paragraph five of the discussion section "1995 also represents an early period in the development of minimally invasive CABG techniques". We as well look forward to future data sets from this and other multicenter registry reports.
- As mentioned in paragraph six of the discussion ("Results from this early experience suggest that higher risk patients are being selected for MID-CABG."), the unequal distribution of risk factors is described.
- As added to paragraph 5 of the discussion section, "No information is given regarding the type of incision (sternotomy vs. thoracotomy), or the use of mechanical or pharmacological agents for ventricular stabilization employed during revascularization."
- Analysis of future datasets will be done when available, as well as multicenter prospective databases collecting data specifically on MID-CABG.

4. Editorial Board member XA5 writes:

I think reviewing the NY State data base to try to answer some of the questions that we all have about single vessel bypass techniques is a good idea. One would anticipate that this would result in 'looking through the glass darkly' and indeed the article submitted as a result of that review is understandably hampered by the nature of the data. I do not think it is too hampered for use in the journal, however (with some revisions as discussed below).

I was surprised and intrigued to see that the lengths of stay were about the same for the 2 groups despite the assertion by advocates of the less invasive approach that hospital time is reduced to an average of 2 to 3 days. Clearly that assertion didn't hold true in this data base.

It was also interesting to see the higher incidence of postop heart block and arrhythmias in the off pump cases, since these complications have been asserted by some as being less common in the off pump group.

I was also interested to see that the mortality of the off pump cases was 3.8%. This mortality rate is nearly double the rate for all cases of CABG done in some institutions!!

The authors state that the higher mortality of the off pump case was not statistically worse than the pump case with a p value of 0.0512. Technically they are correct in that assertion but not by much (this number means that there is a 94.88% chance that there is indeed a higher mortality in the off pump cases, just barely missing the traditional requirement of there needing to a 95% level of confidence that this difference did not occur by chance alone).

Thus, I think these data are interesting, though I'm not sure they support the first sentence of the last paragraph: "Early outcomes after MID-CABG show that it is a safe approach to achieve satisfactory revascularization..."

The primary attraction of the off pump cases to me is the avoidance of CPB and its complications, such as stroke, bleeding, and renal impairment. The authors must have had access to data about these issues. I would encourage them to include some comparison of these issues if they can.

Finally, I would encourage the avoidance of assertions that are unsupported either by the data presented or by data from the literature such as the statement that "inadequate myocardial protection can also contribute to significant morbidity and mortality..." The *ease* of achieving adequate myocardial protection for standard aortocoronary bypass is one of the reasons why many surgeons have been uncomfortable with the off pump techniques.

Authors' Response by Asim Choudhri:

- Length of stay was likely similar between the two groups for several reasons: this data is from early in the non-CPB experience, representing the learning curve in this technique. Also, the Non-CPB group had a higher distribution of risk factors.
- Regarding the difference in mortality in the Non-CPB group
 - Comparisons of mortality are difficult with a small group (n = 52)
 - The Non-CPB group was older and had more risk factors

-1995 is early in the Non-CPB experience

While $p = 0.0512$ is technically not-significant, we included this number (as opposed to typing $p = \text{NS}$) so that readers can make their own judgements. A decrease in the mortality of the Non-CPB group by one would change the p value to 0.1539, and an increase by one would change it to 0.0145. With such volatility, more data is required for an accurate comparison between the groups.

- Table three compares the incidence of post-operative complication between these two groups, including stroke, renal failure, and reoperation for bleeding. No significant differences were found for these three complications.
- The sentence has been changed to read "Inadequate myocardial protection during aortic cross-clamping..."

5. Editorial Board member YE186 writes:

This manuscript represents a review of the New York State data base for single vessel CABG. It provides very useful information and is well written. The increased incidence of co-morbid risk factors in the MID_CAB group needs to be stressed, especially in the abstract as the abstract make it sound like the MID_CAB group has a greater degree of post-op complications only. The risk factor differences are in the most important factors that lead to mortality and morbidity in the STS data base. It would be useful to have predicted risk as well, although this info may be misleading.

Authors' Response by Asim Choudhri:

- The abstract has been revised to include "The database showed stratification of patients selected for bypass grafting without CPB to a significantly higher risk group, as shown by increased age, higher incidence of reoperation, transmural MI, congestive heart failure, carotid/cerebrovascular disease, and peripheral vascular disease."

As more data becomes available in the future, multivariate analyses can be used to predict postoperative complications for each group, and allow comparisons independent of preoperative risk-factors.