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A quality study of coronary artery bypass graft (CABG) surgery in Asians in California, 2003-2005

Author
Lau, Suet-Yim Diana

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A Quality Study of Coronary Artery Bypass Graft (CABG) Surgery in Asians in California

by

Suet–Yim Diana Lau

DISSERTATION

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Abstract

Asian Americans constitute one of the fastest growing groups in the United States. This dissertation study explores healthcare disparities in Asian Americans (Asians) through the window of examining those who had coronary artery bypass graft (CABG) surgery in California. The mandatory clinical data registry for CABG surgery, the California CABG Outcomes Reporting Program (CCORP), when linked to California's Patient Discharge Data (PDD), offers a unique opportunity to study Asians. Though the data did not show a significant difference in the overall observed or risk-adjusted operative mortality between Asians and Caucasians, a marginal significant difference was found between Asian females and Asian males (OR, 1.4, $p=.057$).

More significant differences in preoperative clinical characteristics existed between Asians and Caucasians and within genders in Asians. Twice as many Asians had a very low body mass index (BMI) <18.5 and developed heart disease at a lower mean BMI than Caucasians. Asians suffered more diabetes, hypertension, cerebrovascular disease, renal disease, heart failure, multivessel disease, and mitral insufficiency than Caucasians. Upon further analysis, Asian females were found to contribute to the aforementioned differences more so than Asian males. The finding that significantly fewer Asians had previous CABG surgery or other procedures than Caucasians may indicate problems in disease detection, denial, and referral, as well as access to care.

A significantly higher percentage of Asians compared to Caucasians had CABG surgery performed in the low-volume hospitals, while the converse was true for Caucasians. Significant differences were found for operative mortality between the low-

volume and high-volume hospital groups when both racial groups were examined jointly, But these differences became not significant when Asians were examined alone.

Major limitations in this study include lack of information on postoperative complications, ambiguity in the identification of the Asian race, and the absence of other process and outcome data in relation to language and cultural traits. Longitudinal mortality follow-up and quality of life data to assess the cost/benefit ratio of surgery are also lacking. Despite these limitations, this is an important study that employed a large clinical dataset to study CABG surgery with a dedicated focus on Asians. The results provide critical health information that clinicians can use to improve access and clinical outcomes for Asian patients needing CABG surgery.

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Chapter 1: Introduction

This dissertation study explored healthcare disparities between Asian Americans ("Asians") and Caucasians using secondary analysis on the clinical data on coronary artery bypass graft (CABG) surgery in patients in California from 2003 to 2005.

Few cardiovascular disparities studies have been published regarding Asians (Davis, Vinci, Okwuosa, Chase, & Huang, 2007). Despite the availability of large clinical datasets for CABG surgery, many of the studies published from them were about Caucasians, less on African Americans, much less on Hispanics, and very few on Asians. Through the lens of isolated CABG surgery, this study dedicated its focus on Asians, in the hope that the findings will help contribute to the sparse clinical knowledge about this growing racial group, and assist clinicians to obtain a better understanding of the health disparities present, if any.

Significance of the study

A number of factors may contribute to an expected increase in the incidence of heart disease in Asians in the United States. Until the economic tsunami at the beginning of 2009 which slowed down the immigration trend slightly, the Asian population in the United States was expected to double in the next couple of decades, mostly via immigration. The incidence of coronary heart disease in Asia is increasing as the westernization of lifestyles lead to less healthy habits, and the same can be expected of the large numbers of Asians who assimilate the American lifestyle after immigration to the United States. Without more Asian-specific studies on CABG surgery, primary care physicians and cardiac specialists will be forced to give advice for this group basing on the available medical and surgical treatments from their experience with Caucasian patients, which may not address the specific needs of Asians. Hence, having more racially-distinct clinical data should yield evidence-based information to enable physicians to provide more appropriate, efficient, and cost-effective care to Asian patients who have undergone CABG surgery. In the end, the new insights gained can help to improve the quality of care to Asian patients undergoing CABG surgery, and hopefully may also contribute towards helping Asians in other clinical areas besides CABG surgery.

Study purpose and aim

This dissertation explored healthcare disparities in Asians having CABG surgery by analyzing the linked clinical data from the California CABG Surgery Outcomes Reporting Program (CCORP) and the California Patient Discharge Data. These data were obtained from California's Office of Statewide Health Planning and Development (OSHPD) for the 2003 to 2005 period. The aim of the study was to examine the CCORP data with a focus on Asians in an effort to identify any healthcare disparities. The Donabedián health care delivery framework of structure, process, and patient outcomes was used (Donabedian, 2003).

Donabedián's model considers patients' demographic and preoperative characteristics, risk-adjusted mortality, and hospital surgery volume as elements of "structure", number and use of internal mammary artery as bypass conduits and use or non-use of the cardiopulmonary bypass machines as elements of "process," and operative mortality as an element of "outcome". Thus, this dissertation study addresses all three elements within Donabedián's healthcare model for quality assessment, though with an emphasis on the "structural" elements due to the disproportionately larger number of data elements in that area. Because patients who had surgery in the same hospital may be more similar than patients in different hospitals, statistical methods were chosen in particular to take into consideration the clustering effect of hospitals for the statistical analyses. Research questions were explored at both the patient group and hospital-volume group levels.

Research questions

- On Donabedián's "structure":

  Research question 1: Did preoperative characteristics differ between Asians and Caucasians presenting for CABG surgery?

  Research question 2: How did preoperative characteristics differ by race (Asians versus Caucasians) between gender, and by gender between races respectively?

  Research question 3: Were there differences in the proportion of Asians having CABG surgery in the high- and low-volume surgery centers/hospitals?

- On Donabedián's "outcome" ─ Unadjusted operative mortality

  Research question 4: Were there any differences in the unadjusted operative mortality between Asians and Caucasians?

  Research question 5: Were there any differences in the unadjusted operative mortality rates between gender within race, and between races within gender respectively?

Research question 6: Were there any differences between Asians and Caucasians in the unadjusted operative mortality between the high- and low-volume hospital groups?

- On Donabedián's "outcome" ─ Risk-adjusted mortality

Research question 7: After adjusting for the clinical predictors, were there any differences in the risk-adjusted operative mortality between Asians and Caucasians?

Research question 8: After adjusting for the clinical predictors, did the risk-adjusted operative mortality differ between the genders by race, and between races within gender respectively?

Research question 9: Were there any differences between Asians and Caucasians in the risk-adjusted operative mortality between the high- and low-volume hospital groups?

Overview of research design, data source, sample, and analyses

Research design

This is a descriptive (Questions 1-6) and analytic (Questions 7-9) comparative study between Asians and Caucasians, which uses linked data from the California CABG Outcomes Reporting Program (CCORP) and the Patient Discharge Data (PDD).

Data sources: California CABG Outcomes Report Program (CCORP) and the California Patient Discharge Data (PDD)

The dataset by CCORP (California Office of Statewide Health Planning and Development, 2007a and 2007b) is a mandatory clinical data registry of all patients undergoing heart surgeries in California since 2003, with those done in the Veterans

Affairs Medical Centers being the only exceptions that are not required to comply with the mandatory reporting. The PDD is an administrative dataset intended for billing purposes. The CCORP includes a rigorous data verification process with on-site audits that contains few missing data, and has good validity and reliability. The one important drawback of CCORP data is that the race categories have been merged into only two categories, Caucasians and non-Caucasians. Merging the CCORP data with the PDD which contain the racial information thus enabled distinguishing Asians from the other non-Caucasians. Linking with the PDD data also enable verification of patient mortality, a key outcome variable in this study.

California is especially suitable for the study of Asians because of their large numbers residing in the state. Data from 2003 to 2005 were chosen for this study because the same data collection instrument was used during this period. The data collection instrument was expanded in 2006 to include postoperative complications. Finally, and importantly, public access of patient-level data from these two datasets enables aggregation of data at the patient-level.

Population and sample

The units of analysis in this study were the Asians and Caucasians in California who had undergone isolated CABG surgery between 2003 and 2005. Because the CCORP has been a mandatory reporting program since 2003, the dataset actually contains the entire CABG surgery population in California except those from the VA system. However, the CCORP investigators prefer to treat these data as a sample to enable random errors to be taken into consideration.

Analysis methods

The main statistical tools used to study most questions, except for question 3, utilized different types of the generalized estimating equations (GEE). I examined the demographic and clinical characteristics of Asians presenting for surgery, built risk-adjusted models (Iezzoni, 2003), and compared operative mortality rates, clinical characteristics and volume-outcome relationships in hospitals. Caucasians were used as the reference group. Operative mortality was the ultimate outcome elements used to measure the quality of care in CABG surgery in the Asians.

Chapter 2: Review of Literature

Introduction

Coronary artery disease (CAD) remains one of the leading causes of death in the United States (Center for Disease Control and Prevention, 2008a; 2008b). From its début in the early 1960s through mid-1990s, CABG surgery has been touted as the gold standard of treatment for patients with CAD. Being one of the most popular treatments to revascularize blocked coronary arteries, CABG surgery saves lives and reduces angina to improve the quality of life. The cost of surgery, however, is high, and equal access to this type of surgery is therefore especially under scrutiny. The average cost of CABG surgery in California has increased from $78,000 in 1997–1998 to $129,770 in 2001 per CABG surgery case (Damberg, Danielsen, Parker, Castles, & Steimle, 2003). In light of the sparse clinical information available on Asians, any healthcare disparities learnt from studying CABG surgery for this group should underscore the need for further investigation and ways to eliminate disparities.

In the mid 1990's, newer, less–invasive revascularization procedures such as percutaneous transluminal coronary angioplasty (PTCA) and stenting have been developed. The volume of these procedures has surpassed CABG surgery as the preferred treatment option for patients with acute coronary syndrome (ACS), leading to a decline in CABG surgery volumes from the late 1990s onwards (Table 2.1). The advent of drug eluting stents (DES) in 2003 caused even further declines in the CABG surgery volumes in 2003 and 2004.

Table 2.1. Isolated CABG surgery and percutaneous coronary interventions (PCIs) in California and the U.S. between 1997 – 2006

Year	Number of Isolated CABG Surgery in the U.S.	Number of Isolated CABG Surgery in California	Number of PCIs in California
1997	192,543	28,175	44,297
1998	181,774	27,986	48,633
1999	155,831	27,638	50,497
2000	146,384	27,800	51,423
2001	146,412	25,889	54,482
2002	157,324	24,557	55,932
2003	155,292	21,414	59,137
2004	151,853	19,381	60,482
2005	154,484	17,166	59,786
2006	156,128	15,028	59,793

(California Office of Statewide Health Planning and Development, 2007b, p.63)

In parallel with the advancement in PTCA and stents, improvements in CABG surgery techniques have continued to evolve, especially those that aim to minimize surgical trauma. For patients who have multiple coronary lesions or certain types of coronary lesions, or coronary anatomy that are not suitable for PTCA and stenting, CABG surgery remains as the preferred treatment of choice for coronary revascularization, and hence is important to study despite the volume decline.

The following sections include a review of literature in the development of coronary revascularization procedures, followed by reviews of literature on Asians with

CABG surgery, their preoperative risks, and postoperative outcomes data. A summary and discussion section is followed by the conclusion.

Development of coronary revascularization procedures

Between 1970 and 2000, life expectancy has increased 7.1 years from 70.8 years for those born in 1970, to 76.9 years for those born in 2000 (Center for Disease Control and Prevention, 2002; National Center for Health Statistics, 1970). Coronary revascularization is one of the most important and frequently performed treatments in the history of medicine that has been credited with approximately 7% of the cardiovascular survival benefit (Ford *et al.*, 2007).

Methods of revascularization include medical therapy, CABG surgery, and percutaneous coronary interventions (PCIs) such as PTCA and stenting. Besides medical therapy, CABG surgery is the earliest type of coronary revascularization procedures, and has been regarded as the gold standard until the development of PCIs in the mid 1990's. It is still regarded by cardiologists as the preferred procedure for the treatment of intractable or unstable angina, especially when medical therapies, angioplasties, or other less invasive revascularization procedures have failed.

Evolution of the CABG surgery techniques

The early days of CABG surgery was plagued with failure, heavy skepticism, and harsh criticism from the medical community. Within a decade, however, all that changed. Augmented by technical advances in angiography, cardiopulmonary bypass (CPB) machines, and magnification via operating glasses and surgeon headlights, CABG surgery has become "one of the greatest advances in medical history" (Connolly, 2002). Connolly gave a summary of the early evolution of CABG surgery in which he traced the trial- and-error efforts of different grafting techniques. Table 2.2 provides a timeline of breakthroughs in CABG surgery.

Mortality and morbidity outcome data in CABG surgery

CABG surgery outcomes between 1990 and 1999 nationwide

The nationwide cardiac surgery database (STS-NDB) registry created by the Society of Thoracic Surgeons (STS) is the largest dataset for cardiac surgery in the U.S. STS has contracted with the Duke Clinical Research Institute to warehouse and harvest the clinical data. However, the data and algorithms for the STS risk model are proprietary, confidential, and access to the STS-NTB data must be sponsored by one of its surgeon members. Except for published papers, results are only revealed to the constituent member hospitals (Nilsson *et al.*, 2006). None of the publications originated from the STS data have outcomes data on CABG surgery with a specific focus on Asians. The STS-NDB data have been used to demonstrate (using 766,011 patients who underwent surgery between 1990 and 1999) that while preoperative risks increased from 2.6% in 1990 to 3.4% in 1999, which corresponds to a relative increase of 30%, the observed mortality rates, instead of increasing, paradoxically decreased from 4.8% in 1990 to 2.9% in 1999, which corresponds to a relative decline of 40% (Ferguson, Hammill, Peterson, DeLong, & Grover, 2002).

Table 2.2. Early Evolution of CABG Surgery

Surgeon/Year	Procedure/Description
Beck 1934	Beck I – Non–suture method Revascularized coronaries by using pericardial adhesions – placing a piece of pectoral muscle onto the surface of the myocardium to improve blood supply
Beck 1941	Beck II – Non–suture method A two–stage procedure using a free brachial artery graft to create an arteriovenous fistula between the aorta and the coronary sinus
Vinberg Procedure 1946	Known as the Vinberg procedure – Non–suture method Implanted a freely bleeding end of the ITA (Abbreviations in Appendix II) into a myocardial tunnel.
1957	Modification to the graft: the ITA was replaced by a free SVG with end–to–side anastomosis to the descending aorta, and the other end of the SVG (Abbreviations in Appendix II) inserted into the myocardial tunnel
de Marchi 1956	Non–suture method: Used bilateral ITAs to divert blood flow into the myocardial tunnels
Goetz 1960	First successful CABG using sutures in the U.S. Anastomosed the right ITA to the RCA (Abbreviations in Appendix II)
Kolesov 1964	First successful CABG surgery using sutures in Russia
Garrett, Dennis, and DeBakey 1964	Using sutures and SVG (Abbreviations in Appendix II) grafts to the RCA
Garrett, Dennis, and DeBakey 1964	Using sutures to graft the SVG to the RCA
Favaloro 1967	Favaloro and his Cleveland Clinic team: Using sutures to graft the SVG onto the RCA
Johnson 1967	Suture techniques Graft the SVG onto the left coronary system
Bailey, Hirose, and Green 1968	Suture techniques Graft the SVG onto the LIMA (Abbreviations in Appendix II)

(Connolly, 2002, Dee, 2003)

Several factors may have contributed to the increase in preoperative risks over time: Patients' mean age at the time of surgery has increased from 63.7 to 65.1, 11.6% more females had CABG surgery, and the proportion of CABG surgery patients with chronic illness also has increased: More increases were also found in the following areas: Pulmonary hypertension by 275%, cardiogenic shock by 243%, stroke by 84.9%, Class IV heart failure by 75%, chronic obstructive pulmonary disease by 71%, diabetes by 52.7%, renal failure by 51.8%, myocardial infarction <21 days by 46.3%, hypertension by 35.9%, and triple-vessel coronary disease by 22.7% (Ferguson, Jr., Hammill, Peterson, DeLong, & Grover, 2002).

On the other hand, there has been a paradoxical decrease in operative mortality, which can be explained by the multiple and continuous quality efforts in surgical and technical improvements in performing CABG surgery, new and more effective pharmacologic agents, and logical reconfiguration to develop more efficient cardiovascular care systems. The latter included dedicated surgical teams and service lines, improved critical care pathways allowing early extubation, fast-track care of patients, as well as implementation of clinical data registry programs for CABG surgery such as the STS-NDB (see Abbreviations, Appendix II), which enables quality comparison of surgical outcomes across the nation (Ferguson, Jr. *et al.*, 2002).

CCOMP and CCORP: CABG surgery outcomes between 1997 and 2004 in California

In addition to the STS-NDB, there are other regional clinical datasets, such as the Cardiac Surgery Reporting System of the Department of Health in the State of New York, which was one of the earliest regional clinical data system set up for CABG surgery. Similarly, the Office of Statewide Health Planning and Development in

California, supported by the Pacific Business Group, also set up a clinical database program for heart surgery, the California CABG Mortality Reporting Program (CCMRP), in 1997. CCMRP remained a voluntary reporting program until 2003, when it became mandatory, and was renamed the California CABG Outcomes Reporting Program (CCORP). Data from the CCORP between 2003 and 2005 were used in this study.

Operative mortality was the ultimate and sole outcome variable for CABG surgery collected in CCORP. The average risk-adjusted mortality rates (RAMR) for CABG surgery in California have increased from 2.80% in 1997 to 3.18% in 2005 (Damberg, Danielsen, Parker, Castles, & Steimle, 2003). Nationally, the operative mortality rates for the same period decreased from 2.90% in 1999–2002 to 2.40% in 2003 and 2004 (California Office of Statewide Health Planning and Development, 2003; 2006). Verification against the Vital Statistics data, an important step to verify mortality data, is conducted as a regular part of the data checking process by the CCORP, but not the STS, thus yielding greater accuracy of the California mortality data. This is an important consideration when evaluating the higher mortality rates in California as compared to that from the STS.

Asian Americans – Heart disease and coronary artery bypass surgery

Similar to the overall U.S. population, cardiac disease is one of the top killers among both Asian males and females, second only to cancer (Center for Disease Control and Prevention, 2008a; Center for Disease Control and Prevention, 2008b). Because of the growing Asian population at risk, there is much to be gained by examining the Asians' outcomes of CABG surgery, a high impact surgery in terms of both cost and volume. Identification of healthcare disparities contributes to the selection of effective early primary or secondary preventive interventions.

Demographic and immigration trends for a growing Asian American population

Since the economic tsunami in early 2009, immigration trend to the U.S. has slowed down from previous predictions, though the magnitude of the slowing is still too early to tell. But previous projections has indicated significant increases: In 2000, foreign-born immigrants accounted for 69% of the 11.9 million Asians in the U.S. (Reeves & Bennett, 2004), which have been projected to nearly double to 22 million in 2025, and nearly triple to 35.8 million in 2050 (U.S. Bureau of the Census, 2001). In reviewing the total number of immigrants between 2000 and 2007, almost 30% (2.64 million) of all U.S. immigrants came from Asian countries (Table 2.3) (Office of Immigration Statistics, 2007, and Asian Americans constitute one of the fastest growing ethnic groups in the U.S. (Table 2.3 and Figure 2.1) (Office of Immigration Statistics, 2007). The Asian countries of origin with the highest number of immigrants in descending order in 2007 were: China and Taiwan, the Philippines, East India, Vietnam, Korea, and Japan (Office of Immigration Statistics, 2007). California has the largest Asian immigrant population, with Chinese being its largest group (Reeves & Bennett, 2004).

Figure 2.1. Immigration from 2000-2007 in the United States

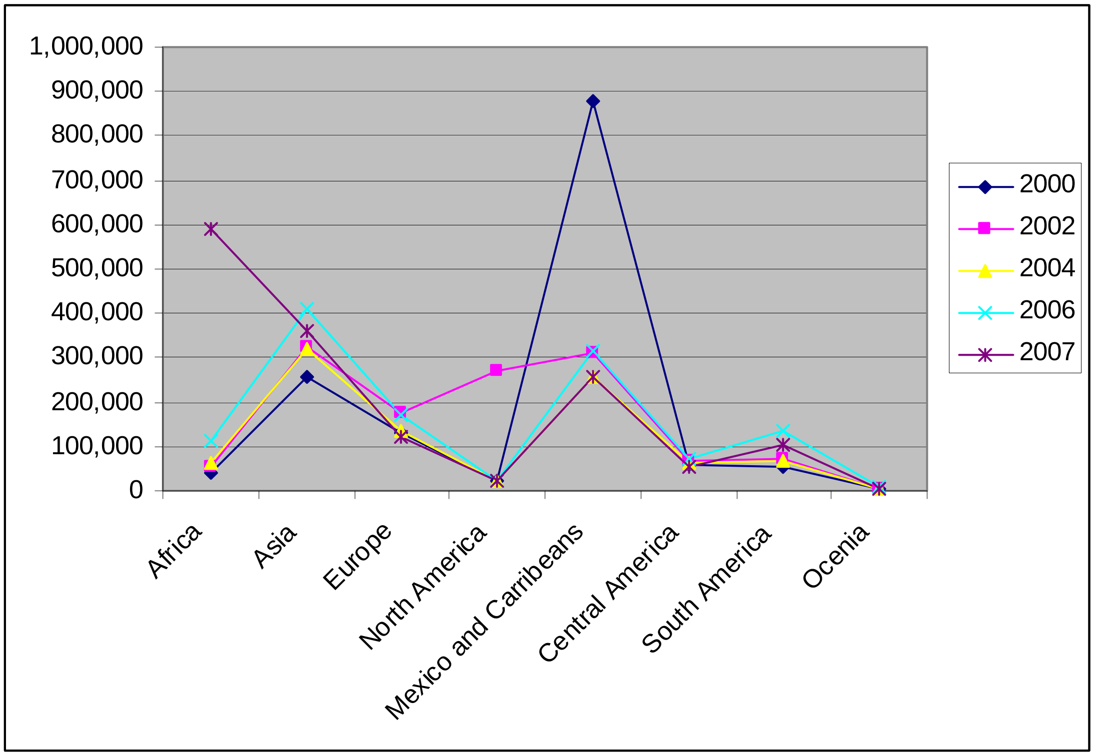


Table 2.3. Immigration Trend from 2000 to 2006

Country of Origin	2000	2001	2002	2003	2004	2005	2006	2007	Total
Africa	40,790	50,009	56,002	45,559	62,623	79,697	112,100	589,277	1,036,057
Asia[1]	254,932	336,112	325,749	235,339	319,025	382,707	411,746	359,387	2,624,997
Europe	131,920	176,892	177,059	102,546	135,663	180,396	169,156	120,759	1,194,391
North America[2]	21,289	29,991	27,1429	16,447	22,439	29,930	23,913	20,324	435,762
Mexico and Caribbean	876,913	300,416	310,838	182,256	255,827	249,363	314,519	257,498	2,747,630
Central America[3]	60,331	72,504	66,298	53,283	61,253	52,629	74,244	53,834	494,376
South America[4]	55,143	67,880	73,082	53,946	69,452	100,803	136,134	102,616	659,056
Oceania	5,928	7,201	6,495	5,076	5,985	6,954	8,000	6,639	52,278
Unknown	14,971	17,894	16,688	9,086	24,646	39,299	19,315	42,081	183,980
Total	1,462,217	1,058,899	1,303,640	703,538	956,913	1,121,778	1,269,127	1,552,415	9,428,527

[1] Asia includes China, Hong Kong, India, Iran, Israel, Japan, Korea, Philippines, Syria, Taiwan, Turkey, Vietnam, and other Asia
[2] North America includes Canada and Newfoundland
[3] Central America includes Belize, Costa Rica, El Salvador, Guatemala, Honduras
[4] South America includes Argentina, Bolibia, Brazil, Chile, Colombia, Ecuador, Guyana, Paraguay, Peru, Uruguay, Venezuela, others

Language discordance

U.S. immigrants from European countries that use a Latin-based language do not have the same linguistic challenges as immigrants from the Asian countries. According to the 2000 Census, one-third of Asians in California were foreign-born with limited English proficiency (LEP). Another survey showed that 48% of Chinese and 62% of Vietnamese spoke “English less than very well” (Asian Pacific American Legal Center of Southern California, 2005). Since communication between patients and their healthcare providers is essential to effective healthcare delivery, language barriers can negatively impact the quality of care (Green *et al.*, 2005), possibly influencing CABG surgery outcomes and causing healthcare disparities. Since few cardiac surgeons can communicate effectively with their foreign-born LEP Asian patients, medical interpreters provide a vital link, and an inadequate provision of them may hamper providers' communication with the LEP patients and families, negatively impacting surgical outcomes, and possibly leading to healthcare disparities.

For CABG surgery, factors incorporated in the risk models suggest that immediate or short-term operative mortality outcomes are more likely to be influenced by patients' personal and clinical risks. Commonly included in the CABG surgery risk adjustment models are mainly personal and clinical patient attributes such as age, gender, ejection fraction, diabetes, peripheral vascular disease, cerebrovascular disease, and chronic obstructive lung disease, to name a few (Nilsson, Algotsson, Hoglund, Luhrs, & Brandt, 2004; Tu *et al.*, 1997; Yeo, Li, and Amsterdam, 2007). Long-term outcomes of CABG surgery, such as cardiac mortality, quality of life, or angina control, are affected by individual risks, personal health behaviors, as well as social determinants of health as described by indicators such as race or ethnicity, socioeconomic status, other positions of social disadvantage, or living conditions (Metzler, 2007). Unfortunately, published studies relating to long-term outcomes and social determinants of health for Asian Americans undergoing CABG surgery are largely absent.

Existing literature on CABG surgery in Asian Americans

A literature search with the key terms “Asians AND cardiac surgery” yielded 206 articles, but most of them were not about Asians in the U.S. Rather, they were overseas studies conducted on Asians living in Asia and Europe. For CABG surgery studies published in the U.S., few include information related to ethnic differences; and of the limited ones that do, most of them are about the comparison of African- and Hispanic Americans to Caucasians. Controversies exist in the area of race. While a few studies have identified race as a significant factor in CABG surgery (Bridges, Edwards, Peterson, & Coombs, 2000; Gray, Nessim, Khan, Denton, & Matloff, 1996; Hartz, Rao, Plomondon, Grover, & Shroyer, 2001), some have not (Peterson *et al.*, 2000).

Table 2.4 gives a comparison of the CABG surgery operative mortality between Asians and Caucasians. Other than mortality outcomes, there are only a few articles addressing a limited number of areas: access to cardiac procedures (Carlisle, Leake, & Shapiro, 1997; Rothenberg, Pearson, Zwanziger, & Mukamel, 2004, Taira, Seto, & Marciel, 2001) and preoperative risks (Yeo, Li, and Amsterdam, 2007). Most of these studies compared several groups, sometimes including Asians, but Asians were not the main focus of the study. The summary below highlights findings specific to Asian Americans by extracting information from studies whose primary focus was on African Americans and/or Hispanics.

Table 2.4. Operative Mortality Rates in Asians versus Caucasians

U.S. CABG Surgery Data / Period	Number of Asians Mortality Rates or O.R.	Number of Caucasians Mortality Rates	Reference
Hawaii Administrative Claim Data* 1997–1999	2,266 Asians Odds ratios for mortality: Chinese 4.4 (0.81–21.1) Japanese 4.0 (0.92–17.4) Filipino 3.0 (0.56–16.0) No significant interracial differences among men and women.	569 Caucasians	Taira, Seto and Marciel, 2001
HCUP (administrative data) 1998–2002	20,353 Asians total Asian females 1.42 times more likely to die than Caucasian males.	1,040,641 Caucasians total	Becker and Rahimi, 2006
California CABG Outcomes Reporting Program (CCORP) (clinical data) 2003	1,772 3.5% operative mortality rate	15,069 2.8% operative mortality rate	Yeo, Li and Amsterdam, 2007

* Only 2962 (54%) of 5514 patients had the ethnicity information

Is access to cardiovascular procedures evenly distributed across different ethnicities?

Access to procedures based on race and insurance types. In CAD patients, the availability of different types of health insurance affects choices among cardiac procedures. Carlisle, Leake, & Shapiro (1997) used administrative data from the California Hospital Discharge dataset from 1986 to 1988 to identify 105,000 residents of the Los Angeles (LA) County who underwent several cardiac procedures that included 28,356 angiographies, 10,604 CABG surgeries, and 9,190 percutaneous coronary interventions. Asians in this study were more likely to be male (61.6%), younger (15.1% >75 years old), had an emergency admission (40.9%), and had MediCare (28.8%) or private insurance (24.3%). This study does not find any health disparities. Asians were as likely as Caucasians to undergo cardiac catheterization (28.2%), CABG surgery (12.7%), or PTCA (8.9%) within each of the insurance categories. Importantly, this study did not identify patients with ACS who did not go to a hospital. The negative finding between the Asian and Caucasian groups might be the result of this selection bias. Smaller differences were found in those with private health insurance than those with HMOs. Having three or more bypassed coronary vessels and emergency types of CABG surgery among Asians may imply possible late hospital admission. The unadjusted mortality rates for Chinese and Japanese men were much higher than for Caucasians in the study, and Asian males undergo more CABG surgery than PTCA. The latter can be interpreted as indirect evidence that Asian men might have multi–vessel disease that is more amenable to CABG surgery than PTCA for revascularization.

Access to procedures: CABG surgery versus PTCA. The only study that examines Asian subgroups was conducted in Hawaii. Similar to Carlisle, Leake, & Shapiro (1997), Taira, Seto, and Marciel, (2001) found that Asian males had more CABG surgery than PTCA, with odds ratios being 1.8 (1.2 –2.7) for Hawaiian men, 1.9 (1.3 – 2.9) for Chinese men, and 1.7 (1.3 – 2.2) for Japanese men. Filipino males and Asian females showed no significant differences compared to Caucasians. Additionally, both the unadjusted and adjusted mortality rates for revascularization were higher in Asians compared to Caucasians, but statistical significance was achieved only in the unadjusted OR for Chinese men: 6.4 (1.2–33.2) and Japanese men: 5.0 (1.2–21.4). The reasons why Asian males underwent more CABG surgery than PTCA and why the unadjusted mortality rates for Chinese and Japanese men were so much higher than those of Caucasians require further exploration.

Accessing high quality surgeons. Using administrative data from the New York State (NYS) hospital discharge data for patients undergoing CABG surgery from 1996 and 1997, Rothenberg *et al.* (2004) demonstrated racial disparities in accessing high–quality surgeons. Asians were found to be more likely than Caucasians to have surgery performed in hospitals and treated by surgeons with higher risk-adjusted mortality rates and lower surgical volumes. The data show that Asians tended to be younger (mean age of 62 in Asians versus 67 in Caucasians), had more diabetes (28% Asians vs. 22% Caucasians), and were less likely to have a prior CABG. An interesting inverted U-effect was found in that patients with mid level income actually had more poor quality surgeons (with higher risk adjusted mortality rates and lower volumes) than those with low or high incomes. Possible confounders may include health insurance data, geographic limitations, presence of an established relationship and referral pattern between cardiologists and cardiac surgeons, and the availability of high quality surgeons in hospitals in which patients were admitted.

Access to high volume hospitals. Nallamothu *et al.*, (2001) examined CABG mortality outcomes in Native Americans compared with other ethnic groups, including Asians. Using administrative data (HBSI EXPLORE) to examine 18,061 subjects with CABG surgery from 25 healthcare facilities across the U.S., 960 Asians (5.3%) were found. Hospitals were stratified into those with more than 200 annual cases and those with fewer than 200. The overall observed in-hospital mortality rate was 2.0% for Asians, with a risk-adjusted in-hospital mortality rate of 3.3% (1.9% for Caucasians). Only 1.7% Asians compared to 18.7% Caucasians had surgeries performed in hospitals with <200 annual cases, and none were performed in rural hospitals. These data seem to match the immigration pattern of Asians to large cities.

Mortality outcomes

Study results on mortality are mixed. The small effect size for mortality outcomes (2% - 4%; Becker and Rahimi, 2006) makes it difficult to demonstrate statistical significance across racial groups despite the relatively large sample size.

National mortality rates. Becker and Rahimi (2006) examined in-hospital mortality disparities in race and gender in patients who had CABG surgery from the Health Care Utilization Project (HCUP), a dataset from the Agency for Healthcare Research and Quality (AHRQ), from 1998 to 2002. HCUP is a large administrative dataset, and it has 1.2 million CABG inpatients from nearly 1,000 hospitals during that time period. Only slightly over 20,000 (1.7% of total) Asians had undergone isolated CABG surgery, compared with slightly over 1 million Caucasians (87.3%). The average adjusted in-hospital mortality was 2.87% for Asians and 2.68% for Caucasians, 3.65% for Asian females, and 2.56% for Asian males. Asian females had a 42.6% increase in mortality compared to Asian males. Compared to Caucasians, Asian females were almost 1.5 times more likely to die in the hospital (OR 1.42, CI 1.20–1.68). The authors admitted that the HCUP data was limited in scope and did not contain other data representative of the underlying disparities. The omitted data included patients' clinical data, their surgical preferences for the type of revascularization methods (CABG surgery or angioplasty), surgeons' intention to treat, hospital type, and quality of surgeons.

Regional operative mortality for CABG surgery in California. Unlike other studies based on administrative data, Yeo, Li and Amsterdam (2007) used clinical data to examine CABG surgery in Asians. Using data from CCORP, the authors examined clinical characteristics and 30-day mortality among different racial groups, including Asians. Examination of the 2003 CCORP data revealed no significant difference in the observed operative and predicted mortality between Asians and Caucasians. Operative mortality was 3.5% for Asians, and 2.8% for Caucasians, whereas the predicted operative mortality was 3.3% for Asians and 2.8% for Caucasians.

Preoperative risks and other clinical predictors

Verderber, Castelfranco, Nishioka, & Johnson (1999) conducted a small study to examine differences among Caucasian, Japanese, and Pacific Island subjects in Hawaii. They examined CABG risk factors and surgical outcomes using a random sample of 60 patients (19 Caucasian, 18 Japanese, and 23 Pacific Island/Hawaiian subjects). The preoperative clinical and demographic characteristics in Japanese and the Pacific Islanders were quite different, as were the difficulties experienced in their postoperative course. Pacific Islanders had the worst difficulty, followed by Caucasians and then Japanese. This study suggests intra-group differences between the Asian (Japanese in this study) and Pacific Islander subgroups. Studies that aggregate Asians and Pacific Islanders into one group run the risk of losing important information that differentiate the subgroups.

Yeo, Li, and Amsterdam (2007) found no significant differences between Asians and Caucasians in the following clinical predictors for surgery: surgery status, hepatic failure, atrial flutter/fibrillation, myocardial infarction <6 hours, cardiogenic shock, left main disease, 3 or more vessel disease, and severe mitral regurgitation. However, the following preoperative risk factors were worse in Asians than Caucasians: a smaller BMI of 25.6 (28.7 in Caucasians), 83% with hypertension (75% in Caucasians), 47% with diabetes (33% in Caucasians), mean creatinine level of 1.33 (1.28 in Caucasians), 4% on dialysis (1% in Caucasians), and 10% with ejection fraction <30% (8% in Caucasians). On the other hand, a few risk factors were worse in Caucasians than Asians: 27% had prior CABG surgery (25% in Asians), 15% with peripheral arterial disease (9% in Asians), 3% sustained ventricular tachycardia/ ventricular fibrillation (2% in Asians), and 27% with NYHA Class IV (22% in Asians).

Conclusion

A main criticism is that most of the published studies on Asians utilized administrative data, many of which have a large fraction of the race data missing – a serious problem that can lead to uncertainties about any of the findings by race. Nevertheless, administrative data are available without much additional effort or cost, and can help to shed some lights on the state of healthcare in Asians which would have otherwise been impossible. A common criticism has to do with the confusion with the Asian race category itself. The 2000 Census forms have Asians and Pacific Islanders separated. Most of the administrative datasets were developed before 2000, and the data forms have not been updated to reflect changes in race designations in the census. While some cultural habits and languages can be similar among the Asian immigrants from different Asian countries of origin, many are distinctively different (Taira, Seto, and Marciel, 2001).

Results of studies on healthcare disparities with regard to CABG surgery in Asians have been controversial. Studies on the effect on CABG surgery outcomes by insurance types and income levels (Carlisle, Leake and Shapiro, 1997, Rothenberg *et al.*, 2004), access to hospitals with different surgery volumes, and between urban and rural hospitals (Nallamothu *et al.*, 2001) show mixed results.

The mortality results in Table 2.4 are a summary of operative mortality of Asian Americans. The literature has shown that significant improvements have been made in CABG surgery overall. The high early operative mortality rates from CABG surgery have declined to around 2% to 4%. This small effect size of the mortality outcome measurement makes it difficult to detect statistically significant differences between Asians and Caucasians. While mortality rates for CABG surgery have experienced a dramatic 31% decline over the ten year period between 1993 and 2002, Becker and Rahimi (2006) found a higher mean in-hospital mortality for Asians as compared to Caucasians, with Asian females particularly at risk. Asian females were over 1.4 times more likely to die from CABG surgery than Caucasian males and had a substantially higher mortality rate than their Asian male counterparts. Chinese males were 4.4 times, Japanese males 4.0 times, and Filipino men 3.0 times more likely to die compared to Caucasian males undergoing CABG surgery (Taira, Seto, and Marciel, 2001). However, they found no significant interracial differences in women of different racial groups. The 2003 CCORP data also supported the finding that the observed operative mortality was higher (3.5%) for Asians than Caucasians (2.8%), though the difference was not statistically significant (Yeo, Li, and Amsterdam, 2007).

Literature also points out that the preoperative characteristics of Asians undergoing CABG surgery seemed to indicate late presentation of the Asian patients, as evidenced by more multi-vessel coronary disease and more chronic illnesses, including more hypertension and diabetes, a higher mean creatinine level, and a higher likelihood of being on dialysis at the time of admission for the CABG surgery (Yeo, Li, and Amsterdam, 2007). These findings agree with previous studies which found that Asians who had CABG surgery were younger, had more diabetes, and were less likely to have had prior CABG surgery (Rothenberg *et al.*, 2004). Other studies showed that more Asians were being admitted for surgery on an emergency or urgent basis (Carlisle, Leake, and Shapiro, 1997, Nallamothu *et al.*, 2001), and more Asians had an ejection fraction <30% when compared to Caucasians (Yeo, Li, and Amsterdam, 2007). Asians also had the highest percent of cases at the highest risk level for mortality based on the APR-DRG (All Patient Refined Diagnostic Related Groups, See Definitions, Appendix I) classification for acuity measurement. These factors may explain why more Asians received CABG surgery rather than PTCA.

On the whole, the published research on CABG surgery in Asians in the U.S. is limited at best, and there is scant evidence-based research in this area of healthcare disparities. With increasing immigration from Asian countries and increasing incidence of cardiovascular disease reported by the developing Asian countries, this glaring lack of clinical information published about Asians in the U.S. — whether on CABG surgery, other chronic illnesses, or other clinical treatment protocols — calls for urgent action.

Chapter 3: Theoretical Framework – The Donabedián Model

"I think I have said enough to show how we have progressed and how each one of us is only a link in a chain that began long before us and will continue long after we have gone. . . . 'What is the secret of quality?' You will ask. Very simple, it is love – love of knowledge, love of man and love of God."

Avedis Donabedián (1919-2000)

(Quoted in Sunol, 2000, p. 453)

Introduction

Quality assessment in the field of medicine has garnered serious attention, not only regarding healthcare outcomes, but with respect to rising healthcare costs. The high use rate and costs of CABG surgery, as well as its possible serious surgical complications, have been the impetus for the development of quality control practices, making quality assessment in the CABG surgery area one of the best within the medical field. Paradoxically, since the advent of PCI procedures, many patients undergoing CABG surgery appear to be sicker preoperatively, which should imply worsening surgical results. Thus, it was a surprise when CABG surgical results continued to improve. The rigorous quality monitoring efforts of isolated CABG surgery were believed to have been partially responsible for both the decreasing mortality rate (Ferguson, 2006) and the dramatic improvement in surgical outcomes since the early debacles of the 1960s.

A review of the literature identified over 7,000 scientific publications on various aspects of CABG surgery in the U.S., but only a handful of these publications focused on the Asian population in the United States. The paucity of data about CABG surgery in

Asians points to the need for more dedicated and focused efforts to explore the effect of genetic, physical, and cultural differences on surgical outcomes.

Searching for a suitable framework to evaluate the existing studies on CABG surgery, I soon realized that all the studies were related, directly or indirectly, to attempts to improve the outcomes and quality of CABG surgery, or in identifying disparities in healthcare. This observation inspired the search for a suitable quality model, which quickly led me to the widely-known quality of healthcare model proposed by Avedis Donabedián more than 30 years ago. This chapter explains Donabedián's model and makes the case that this model is suitable for use as the framework in evaluating the published work on CABG surgery. Because work done in the U.S. for CABG surgery in Asians is scanty, examples will include the following oversea regions: China, Hong Kong, Japan, Singapore, and Taiwan.

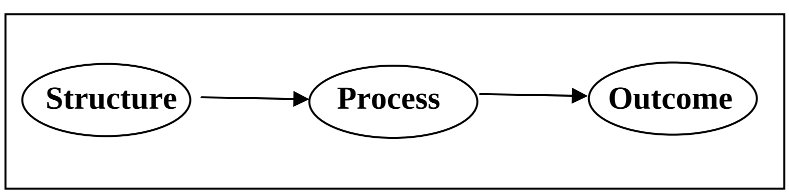
Donabedián's framework for quality in healthcare

Avedis Donabedián, dubbed the "father of quality assurance" by Best and Nauhauser (2004), first set out to organize the vast collection of existing knowledge in healthcare under the umbrella of quality in the mid 1960s. Totally underestimating the complexity of the work, what was initially estimated to be a limited, short-term project turned into a lifetime of work for Donabedián. His task was complex and seemingly endless, and he correctly predicted that quality studies would continue long after he was gone (Donabedian, 1980). Through his dedicated work, he was able to produce a coherent theoretical framework for quality, which has been widely used by different disciplines, and which can also be applied to assess the quality of CABG surgery.

What made Donabedián's work complex was his attempt to define quality, describe its many attributes, explicate the criteria to assess quality, and establish the quality assessment process within his framework. The remainder of this chapter contains a general introduction to Donabedián's quality framework and its various attributes, along with a more detailed description of the conceptual model and how CABG surgery is a good fit inside the framework. Specific criteria for CABG surgery will be aligned with the structure-process-outcome elements that form the backbone of the Donabedián model.

Donabedián's model for health care delivery has been recognized as the gold standard in health outcomes research, especially in the area of quality of care (Sunol, 2000). Donabedián argues that the real value of studying health outcomes lies in its ability to modify and improve healthcare through influencing structure and process. In Donabedián's model of health care delivery, the over-arching framework, which contains the elements of "structure → process → outcome," illustrates the necessary relationship among these three processes in the model (Figure 3.1) (Donabedian, 2003, p. 6).

Figure 3.1. A Representation of Donabedián's Model for Health Care Delivery



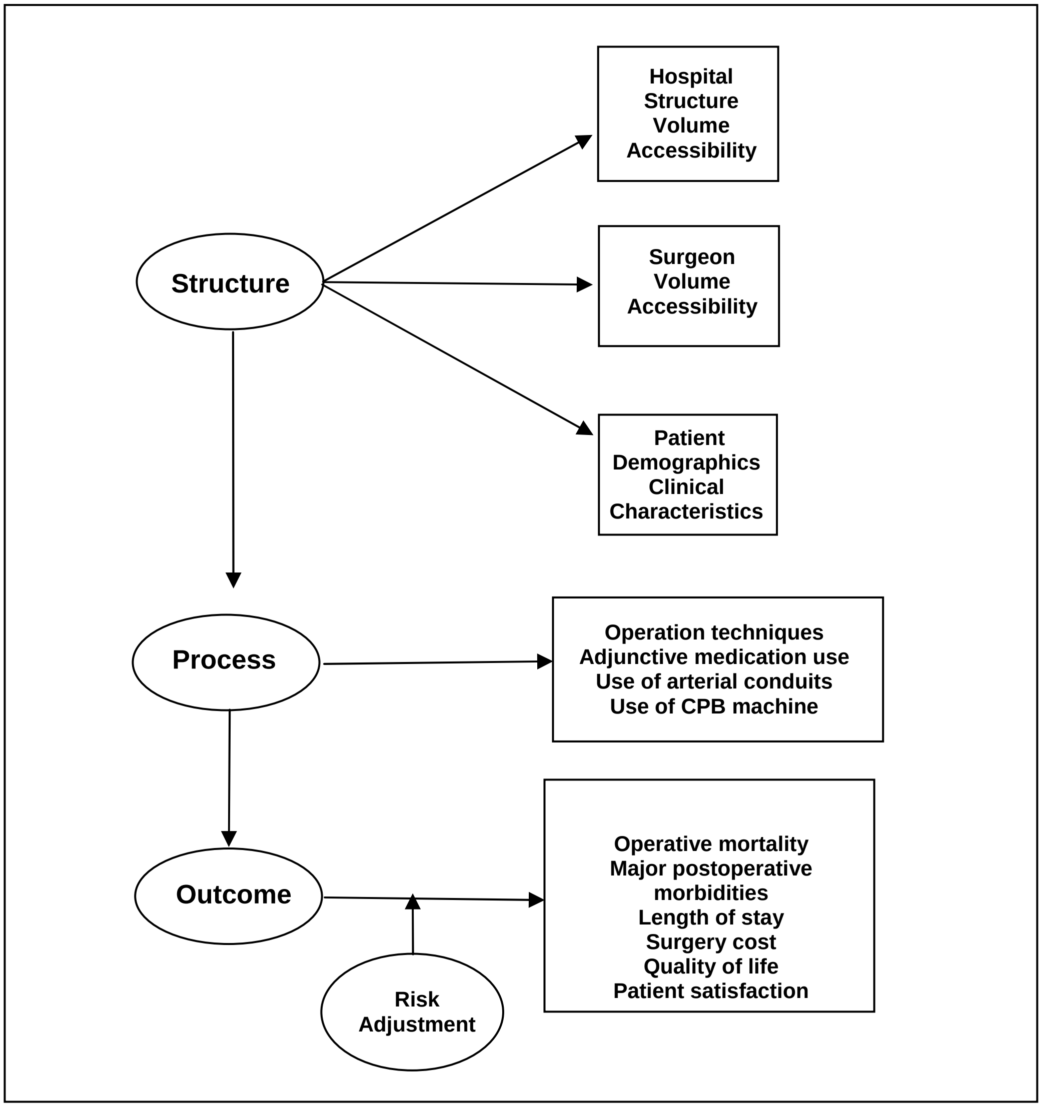
Approaches to assess performance

Donabedián states that "structure, process, and outcome" are not attributes of quality. Rather, they are steps to produce quality which can be measured according to the criteria appropriate for the specific clinical area of interest. Ultimately, one can judge if the "structure, process, and quality" of care are good, fair, or poor, or provide other quantifying terms to assess the state of healthcare (Donabedian, 2003). The following section examines the definition of the three steps within Donabedián's model and uses CABG surgery as a clinical example to examine the specific measurable criteria for each of these three steps.

The three steps to assess the quality of care — "structure, process and outcome" — have a linear representation with directional arrows between the steps, and a pre-determined cause-effect relationship among them. Figure 3.1 illustrates these relationships: structure influences process, and structure and process jointly influence outcomes (Donabedian, 2003). Through research, clinical practice, teaching, and publication, stakeholders working in clinical specialties set the "norms," the criteria for the quality of care in these relationships, which are used as benchmarks to measure the behaviors explicitly or implicitly adopted by the stakeholders (Donabedian, 1980, p. 80).

Figure 3.2 illustrates how this model can be applied to organize the studies on quality of care in CABG surgery in Asians, arguing for the appropriateness of the Donabedián framework for this present study. Figure 3.1 illustrates the interrelationships and dynamic process embedded in the model. Effects can become causes which induce other effects. All these relationships are probabilistic, such that higher probabilities of occurrence infer more credibility in the postulated paired relationships. Therefore, relationships are difficult to pre-define since the direction of causality is not absolute and may change, depending on the situation (Donabedian, 2003, p. 49).

Figure 3.2. A Representation of Donabedián's Model for CABG Surgery



Structure – Donabedián defines structure as the relatively stable conditions under which care is rendered: material and human services, caregiver and patient characteristics, resources and tools, physical and organizational settings, as well as financial resources (Donabedian, 1980, p.81). Table 3.1 lists structural characteristics regarded by Donabedián as the most important elements likely to guarantee and promote quality (Donabedian, 1980, p.82).

Table 3.1. Proposed operationalization of Donabedián's Health Care Delivery Model for cardiac surgery in Asians

Data level	Structure	Process	Outcomes
Organizational level	• Annual volume of CABG surgery • Dedicated cardiovascular service line • Monthly morbidity and mortality meetings for cardiac surgeries • In-house phase I cardiac rehabilitation program and Phase II & III referral system • *Participation in a systematic cardiovascular database • Dedicated staff and computer support for database efforts • Equipment availability and maintenance • Regular staff education • Interpreter service for Asian patients with limited English proficiency	• Dedicated cardiac service line to stream work flow: preoperative to intraoperative to postoperative • Patient and family support: physical, psychological, spiritual • Interactive physician-patient decision making process	At the organization level: • Annual CABG surgery volume • Risk-adjusted morbidity • Risk-adjusted operative mortality
Physician level	• Number of years since completion of CV surgery fellowship training	• Use of IMA/arterial graft(s) • Use of cardiopulmonary bypass • Preoperative beta blockade	

Data level	Structure	Process	Outcomes
	• Annual volume of CABG surgery	• Discharge medications include: ➢ Anti-platelets ➢ Beta blockers ➢ Anti-lipids	
Patient level – Asian patients	• English-speaking proficiency • Country of origin • Social determinants of health: economic status, educational level, living environment • Health literacy level	•	• Operative mortality • Patient satisfaction of hospital stay • Participation in cardiac rehabilitation • *Major complications from surgery • Return to work • Quality of life issues: physical, psychological, social support • Long-term survival
Organizational and Physician Overlapping Functions		• Selection of antibiotics and the timing of administration	• Length of stay
Organizational and patient level overlapping areas			• Length of stay • Cost of care
Surgeon and patient level overlapping areas			• Risk-adjusted mortality • Risk-adjusted s morbidity ➢ Prolonged intubation (>24 hours) ➢ Deep sternal infection (within 30 days of surgery) ➢ Stroke/cerebrovascular accident (>72

Data level	Structure	Process	Outcomes
			hours) ➢ Postoperative renal insufficiency (creatinine> 2.0 or new start on dialysis) ➢ Surgical re-exploration (for bleeding)
Societal level	• Equity in access • Health insurance coverage • Geographical location of CABG surgery facilities		• Disparities of health and healthcare outcomes

* From the 2004 National Voluntary Consensus Standards for Cardiac Surgery (National Quality Forum, 2004)

Process – Process consists of activities that constitute a major part of the healthcare delivery system, including prevention, awareness, diagnosis, treatment, rehabilitation, and patient education. In addition to healthcare providers, clinical researchers, and support staff, patients and their families can also affect the quality care in CABG surgery through their active participation and collaboration in the process of care. It is important to note that structural characteristics can indirectly affect the quality of care through their influence on the process (Donabedian, 1980, p. 84).

Outcome – Outcome refers to both desirable and undesirable changes in health, behavior, social, and psychological functions as a result of the antecedent health care rendered. Within Donabedián's model, outcome is regarded as an indirect measurement of the quality of healthcare, based on his assumption that "not until all other possible factors that might affect quality of care can be ruled out can the direct measurement of quality claim be made" (Donabedian, 1980, p. 83).

While these three elements offer an abstract and parsimonious structure for describing the confusing concept of quality of care, it is less clear-cut when one tries to differentiate the means from the ends, as the ends may become the means to yet another end. These components of the model should be treated more as a "guide and not a straightjacket" (Donabedian, 1980, p. 89). To illustrate the complexities and circularities: A series of diagnostic tests aiming to yield diagnostic outcomes may lead to an intervention process resulting in therapeutic outcomes which then give rise to other diagnostic processes with more diagnostic outcomes (Donabedian, 1980).

Attributes of quality

Donabedián described his early findings on quality of care as “varied in quality” and “uneven in content,” “a muddy torrent of information” with “an indiscriminate jumble of the new and the derivative, the meticulous and the careless, the honest and the manipulative, the well-informed and the unknowing, the wise and the perverse” (Donabedian, 1980, p. iv). The abundance of negative descriptive terms imparted a strong impression of the disorganized state, which, fortunately, did not deter Donabedián from the challenge to organize the tangled mass into the well-known *“structure-process-outcome*” model of healthcare delivery (Donabedian, 1980).

The ultimate goal of monitoring quality is to improve healthcare outcomes. Specifically, Donabedián hoped to “transform” healthcare into a “cutting edge that is meant to reshape everyday practice” (Donabedian, 2003, p. xiii). The availability of clinical databases in CABG surgery has enabled quality monitoring efforts that can help to fulfill Donabedián’s aim to “reshape everyday practice”. The relatively high mortality rate of CABG surgery in its very early days prior to the establishment of the regional and national CABG surgery data registries has dropped to between 2% to 4% in the U.S. (Society of Thoracic Surgeons, 2007) and less than 1% in some other countries such as Japan (Sezai, Y., Orime, Y., and Tsukamoto, S., 2007). With surgical mortality rates under control, attention has shifted to finding methods to minimize the physical trauma and invasiveness associated with CABG surgery. Through vigorous, disciplined, and collective efforts to harvest and analyze the CABG surgery data, cardiovascular surgeons were able to monitor the quality of surgery closely and reshape their practice. Novel surgical techniques and new cardiac anesthetic medications have helped to minimize surgical trauma, achieve early extubation, and shorten intensive care (ICU) stay as well as postoperative length of stay. Data collected for the preoperative, intraoperative, and postoperative structures, process, and outcomes supplied surgeons with the needed evidence to support their innovations, and enable CABG surgery to become emblematic of the transformation process advocated by Donabedián.

A distinctive feature of Donabedián's concept of quality has to do with building "criteria," an established clinical standard against which practitioners can compare and judge their clinical results. Donabedián believed that the monumental task of developing a single set of criteria to which all practitioners would agree was possible, arguing that the concept of quality could be "rather precisely defined, and that it is amenable to measurement," such that it should not be difficult to develop consensus (Donabedian, 2003, p. xxxii).

The nationally-based Society of Thoracic Surgeons and regional cardiac groups have assumed a leading role in demonstrating and improving the quality of CABG surgery. With patients' best outcomes in mind, they collaborated to set an outstanding example of quality by consensus and formed a national clinical databases (STS-NDB) to monitor the various quality aspects of CABG surgery, a feat that has been difficult for other medical and surgical specialties to follow. In 2004, the National Quality Forum (NQF), with the help of a selected group of cardiothoracic surgeon leaders, chose 21 criteria, mostly from the STS-NDB, through a consensus process. Seventeen of the 21 criteria (Table 3.2) specifically target measures associated with isolated CABG surgery (National Quality Forum, 2004).

Table 3.2. 17 National Voluntary Consensus Standards for CABG Surgery

CABG Surgery Performance Standards	Source of Measure	Donabedián's Model
1. Participation in a systematic database for cardiac surgery	STS	Structure
2. Surgical volume for isolated coronary artery bypass graft (CABG) surgery	CMS	Structure
3. Timing of antibiotic administration for cardiac surgery patients	CMS	Process
4. Selection of antibiotic administration for cardiac surgery patients	CMS	Process
5. Pre-operative beta blockade	STS	Process
6. Duration of prophylaxis for cardiac surgery patients	CMS	Process
7. Use of internal mammary artery	CMS	Process
8. Prolonged intubation	STS	Process
9. Deep sternal wound infection rate	STS	Outcome
10. Stroke/cerebrovascular accident	STS	Outcome
11. Post-operative renal insufficiency	STS	Outcome
12. Surgical re-exploration	STS	Outcome
13. Anti-platelet medications at discharge	STS	Process
14. Beta blockade at discharge	STS	Process
15. Anti-lipid treatment at discharge	STS	Process
16. Risk-adjusted inpatient operative mortality for CABG	CCMRP	Outcome
17. Risk-adjusted operative mortality for CABG	STS	Outcome

From the 2004 National Voluntary Consensus Standards for Cardiac Surgery (National Quality Forum, 2004)

Nonetheless, in order to more fully appreciate Donabedián's model of health care delivery and its application to CABG surgery, it is important to understand some fundamental underpinnings within Donabedián's model as described in the following sections. Through the strong grounding of rationales behind model development efforts, one can gain an understanding why Donabedián's model has not only withstood the test of time, but also remains the most widely-accepted model in quality assessment. This parsimonious model has established a strong foundation upon which quality measurement efforts in CABG surgery for all individuals, including Asians, can be organized.

Who defines quality?

The assessment of quality in medical care depends on how quality is defined. Searching for a definition for "quality" reveals the ephemeral nature of such attempt. Similar to the expression that "beauty is in the eyes of the beholder," quality is also assessed from the perspective of its judges. And so, depending on who the judges are, the definition of what constitutes quality varies. The traditional definition of quality for CABG surgery has usually been made by surgeons and mostly relates to surgical outcomes. However, the broader concerns of other healthcare team members, as well as administrative and healthcare system issues or society's wellness as a whole, have not been well-addressed. Quality of life after surgery, which is an important issue to patients contemplating surgery, is much costlier to examine on a longitudinal basis. Lacking definitive definitions of quality became quite an issue, which remained until Donabedián defined quality from different evaluators' perspectives, along with corresponding different methods of measurement.

Donabedián crystallized the definition of quality by examining it from three different perspectives: the “absolutist”, the “individualized,” and the “social” viewpoints (Donabedian, 2003, p.5). Each perspective maintains a different definition for quality, though some areas overlap.

In the “absolutist” view, quality is assessed from the practitioners’ (physicians’) perspective, evaluating clinical benefits and harm resulting from CABG surgery in patients, based on the beliefs and values of the practitioners. The financial implication of healthcare, in general, has not been an important part of physicians’ considerations. In contrast, the “individualized” view perceives quality from an individual patient’s standpoint, evaluating the pros and cons of undertaking the surgery, short- and long- term benefits and risks, and out-of-pocket costs of the procedure. In the “social” view, quality is viewed from a broader perspective that includes the financial costs of care, which is weighed against the expected benefits and harm to the health—not of the individual patient—but of the society as a whole. From the social perspective, fair and equitable distribution among different social strata and the consequences of this distribution in the general population become part of the definition of quality. From this angle, disparities in health and healthcare become an important area of concern.

There can be overlapping and conflicting areas among these three viewpoints, of course. For example, absolutist and individualized definitions can be similar to each other in the quality of clinical outcomes, but differ in terms of monetary considerations. This difference often becomes a point of contention between individualized and social definitions, especially in light of inadequate funding of medical care, and the seemingly imminent bankruptcy of the Medicare system. From a health system management standpoint, difficulties often arise in having to find limited resources to conduct preventive public health programs, such as vaccination or wellness programs, when the bulk of available resources have been spent on curative care for a small subset of sick patients. The struggle between quality, quantity, and high procedural costs becomes most apparent when resources are limited, and practitioners and policy makers must decide whether to spend the resources on expensive treatment options for one individual patient versus balancing the larger preventative health needs of the society as a whole.

Definition of quality in CABG surgery

The practitioner, individual patient, and societal perspectives imply different standards for the quality of care specific to CABG surgery. The National Voluntary Consensus Standards for Cardiac Surgery, for example, has provided the first set of national standardized performance measures to assess performance and outcomes of cardiac surgery, albeit that they all came from physicians' perspectives (National Quality Forum, 2004). Seventeen of the 21 standards, directly related to isolated CABG surgery, reflect the overwhelming interest of surgeons in the immediacy of surgical and clinical outcomes. One can see that significant gaps in this limited set of NQF quality measures remain when compared to those listed in Table 3.2, which list standards from all three evaluators' perspectives.

Organizational standards

Organizational standards include the entire structural process from admission to pre-surgical care, surgery, post-anesthesia recovery, intensive care stay, postoperative care, and ultimately, discharge from the hospital. However, the organizational components needed to execute CABG surgery are not included in Table 3.1. These may include dedicated cardiovascular service lines with specially-trained staff and equipment and data collection systems that enable participation in national or regional databases to help track data and enable benchmark comparisons to guide quality improvement efforts. In particular, since Asian patients, many of whom have limited English proficiency, were the focus of this CABG study, the presence of an interpreter program to help improve communication between healthcare providers and Asian patients is an important structural element unique to this population and others with language challenges.

Process level quality of care standards

These standards relate to the surgical process, such as type of incisions, use of cardiopulmonary bypass, use of medications (anesthetics, antibiotics, beta blockers, ACE inhibitors, and statins) and use of arterial conduits as grafts. While it is beyond the scope of this paper to specify benchmarks ─ the criteria specific to each standard ─ benchmarking is an important step in quality monitoring to enable comparisons of what is considered to be good, acceptable, or mediocre for each standard.

Patient and healthcare consumer level standards

Furthermore, patients have additional standards beyond immediate survival after surgery, including patient satisfaction of the surgical experience, out-of-pocket health care costs, lost wages related to surgery, quality of life issues, recuperation, secondary prevention issues, and long-term survival benefits.

These may be the overlapping areas of quality concerns between both patients and practitioners, who should also be concerned about the long-term survival benefits and quality of life after surgery, even though the corresponding data were not collected in most of the existing CABG clinical databases.

From a societal standpoint

Definition of quality from the societal angle might include equity in access to care, health insurance, surgery costs, as well as disparities in healthcare outcomes among different groups, whether defined racially, culturally, or by gender. Other important considerations include whether the benefits of CABG surgery justify its high cost and frequent usage, or if alternative procedures such as PCIs can be a better choice.

These broad definitions of quality from the three evaluators' perspectives highlight limitations of the existing clinical databases for purposes to evaluate quality or identify disparities. For that reason, fitting the existing literature within Donabedián's model helps to identify areas with adequate information, and gaps that still exist in an organized manner, as illustrated in Table 3.3. As usual, a dilemma exists between the need for more data which enables more meaningful analysis, and the need for a practical and fiscally-manageable dataset and data collection efforts.

The art and the science of measuring quality of care

Another important quality attribute embodies both technical and interpersonal aspects: the application of science and technology in the practice of medicine and the interpersonal relationship between healthcare providers and patients. The technical part is often labeled as "science" and the interpersonal part is often labeled as "art", but these two domains have no clear-cut boundaries. Donabedián highlighted the important interconnections: interpersonal relationships can influence the success of a medical procedure and, conversely, the success of a medical procedure can positively influence the interpersonal relationship – suggesting a dynamic, interactive process that partially explains why it is difficult, if not impossible, to derive a perfect predictive model for the quality of medical care. The relationship between the art and science of medicine is of great importance, yet few studies could be found to help substantiate the connection between the two, especially in relation to Asian patients with CABG surgery.

Quality, quantity, and costs of care

Donabedián also highlighted the complex and interwoven relationship among quantity, quality, and costs of care, and how they are entangled in ways that make them difficult to separate. For example, he noted, “care must be adequate in quantity if its quality is to be good” (Donabedian, 1980, p. 4). Quantity and quality of care are often used as outcome variables in studies on access to care, and they are often also directly related to the costs of care. However, access to care ultimately diverts the focus of attention from individuals to systems in some studies, which include examining the full spectrum of health care access, from “no utilization” on one end to “excessive utilization” on the other. Not only is the quality of care assessed against the resultant benefit or harm, it is also judged on the reduction of resources due to unnecessary care. Access to expensive procedures, including CABG surgery, may increase societal costs if they are performed unnecessarily, but can harm patients who do not have access to the procedure when needed. Within any quality framework, the “need/no need” and “supply/demand” continuums are important and complex issues that call for continuous monitoring and evaluation.

CABG surgery offers a classic scenario to illustrate the quantity-quality duality, as well as how policy can affect access and utilization. Donabedián alludes to the delicate relationship between quality and quantity of care when he noted that “quality costs money, since it presupposes quantitative adequacy and often means more care”

(Donabedian, 1980, p. 7). For example, the advent of PCI as the preferred treatment in patients with acute myocardial infarctions in the past decade (Ui, Chino, & Isshiki, 2005) has led to speculation that the quality of care in CABG surgery might decrease as hospitals experience a concomitant decline in CABG surgery volumes. That fear led to several studies using hospital CABG volume as a quality indicator to test the volume-outcome relationship, and intermittent debates have arisen regarding the establishment of annual volume standards in order for hospitals to continue performing CABG surgery.

Adequacy and appropriateness of care are also important considerations to avoid systematic wastefulness of resources that may cause harm while not enhance the quality of care. For example, hospital manpower structure issues in using over-qualified medical providers or over-staffed hospitals, or conversely, using under-qualified medical providers or under-staffed hospitals, may both result in inefficiencies and costly mistakes. Injudicious use causes wasting of the limited quantity of resources available in a given community and decreases available resources for needy cases, compounding health access issues and insidiously disparities in healthcare. The costliness and high volume of CABG surgery has justifiably demanded the need to define the criteria to authorize surgery in order to avoid unnecessary surgery, with high-level scrutiny and constant monitoring by both healthcare practitioners as well as policy makers (Li *et al.*, 2008, Schneider *et al.*, 2001).

For many years, some hospitals formed specialized multidisciplinary heart-care teams to oversee the continuum of the care processes for CABG patients during the different phases of patients' hospital stay (admission, diagnostic, preoperative, intraoperative, postoperative, discharge). Often called cardiac service lines, or cardiac centers, or heart and vascular centers, these multidisciplinary teams were put in place to ensure staff quality and training, and to provide consistent, efficient, and effective care (Table 3.1). Often, sufficient surgical volume is an important factor in ensuring the practical sustainability of these special teams and operations.

Quality measurement

Quality attributes are only meaningful if they can be operationalized, that is, defined in terms that can be measured by a set of criteria with corresponding data inputs. Hence, the measurement of quality is no less important than the attributes themselves, and while quality implies all the elements of goodness, it is a broad concept and rather challenging to operationalize, since not all criteria are measurable. If the instruments are poorly chosen or inaccurate, the resulting analysis will be erroneous. The suitability, ease, and measurability of the data elements or measuring instruments, as well as the feasibility of the data collection methods, are all crucial components of the "quality paradigm. The ability to evaluate attributes, with resources and practicality in mind to decide on which criteria to include or exclude and to provide the justifications for doing so, helps to set the foundation to assure or, more optimistically, improve quality (Donabedian, 2003, p. 40-43).

However, it is impractical, if not impossible, to embrace the measurement of "all" the attributes of goodness. Thus, Donabedián underscored the need to prioritize the important, suitable, identifiable and measurable attributes (predictor variables) in the quality assurance paradigm, which unfortunately highlights the under-specification (the omission of important predictor variables) or over-specification (the inclusion of too many predictor variables) of the model. These are the very same issues with which experts struggle in building the risk-adjusted model for CABG surgery. What to measure ultimately rests on the definition of quality of care, which in turn rests on the perspectives of the stakeholders who set the criteria for quality assurance, as limited by the resources available.

Organizing CABG surgery knowledge within Donabedián's quality paradigm

Most of the quality of care or disparities studies related to CABG surgery have come from secondary analysis of large clinical and administrative CABG surgery datasets in the United States (Hannan, EL *et al.*, 1997), or from smaller retrospective chart review studies conducted by medical institutions to find answers to specific questions of concern (Parker *et al.*, 2006). Organizing the body of existing studies into Donabedián's model enables a systematic way to review the information available within the quality of care paradigm for CABG surgery, and provides an overall sense of the direction of the developments in this surgical arena, as well as identifying prominent concerns.

These studies examine clinical outcomes, surgery costs, and access from different perspectives, including those of surgeons, administrators, health policy or healthcare advocates. These points of view serve as reference points for the comparison of different surgical methods and adjunctive medical and cardiac rehabilitation treatment approaches. There are also a few healthcare disparities studies that compare groups of different gender and ethnicities (Yeo, 2007).

Where are the knowledge gaps for CABG surgery in Asians?

Despite the growing presence of Asians in the United States, studies that examine Asians as the targeted population in the CABG surgery arena are limited. Due to only the handful of existing studies published on CABG surgery in Asians in the U.S., the quest for knowledge in this area compelled examination of data on Asians in Asian countries as well as the U.S. The literature for CABG surgery in several major Asian locales was surveyed included those from China, Japan, Korea, Taiwan, and Hong Kong. The studies found were placed within Donabedián's framework as a classification exercise to identify gaps in the existing knowledge. Table 3.3 organizes these studies in Donabedián's framework. The areas covered in the joint set of American and East Asian publications are quite limited and primarily relate to surgical process and medical outcomes that are of most interest to surgeons. Studies relating to other structures, including institutional practices, communication, patient care issues, longitudinal outcomes, quality of life, or patient satisfaction outcomes, have been done only in a few Asian countries, but not in the U.S. Table 3.1 shows specific examples of CABG surgery studies done in the five geographical areas in Asia organized within Donabedián's model (Table 3.3). Most of these studies seem to have been patterned after studies in the U.S. and relate to the immediate surgical outcomes or the technical aspects of surgery (Amano, Hirose, Takahashi and Nagano, 2001; Huang, Lai, and Weng, 2001; Huang *et al.*, 2004; Ishida *et al.*, 2002; Ishida et al, 2003; Ji, Feng, Liu, and Long, 2002; Kim, *et al.*, 2007; Lin *et al.*, 2003; Ochi *et al.*, 2003; Sezai, Orime, and Tsukamoto, 2007). There are, however, a few studies which examine long-term survival benefits or quality of life (Arima *et al.*, 2005; Hsiung *et al.*, 2006; Ku, Ku, and Ma, 2002; Lopez, Sek, Poon, and Wai, 2007).

One salient difference between these studies and the ones performed in the U.S. is with respect to their data sources. Many of the CABG studies from the U.S. came from analyzing large registry or administrative databases such as the STS-NDB, while overseas studies primarily used data from individual hospitals, or a small group of hospitals, with some large studies in Japan (Sezai, Y., Orime, Y., & Tsukamoto, S., 2004). The main disadvantage of many of the overseas studies lies in their smaller samples, and correspondingly reduced statistical power.

Discussion

Coronary artery bypass surgery is arguably one of the best proxies in clinical medicine to illustrate quality measurement efforts. The existence of excellent clinical and administrative databases enables relatively easy and economical comparisons of risk-adjusted outcomes in patient care. The 17 NQF criteria in CABG surgery were meant to establish a uniform set of benchmarks that can be used to compare the quality of care in CABG surgery in different hospitals, regions, or groups across the nation. Though the adoption of the NQF criteria has been sluggish and not uniform, these criteria can be relatively easily aligned with the “structure-process-outcome” elements within Donabedián’s model of healthcare delivery (Table 3.1 and Table 3.2), which also enables the existing CABG surgery studies in Asians to be mapped accordingly in an organized manner to identify the areas studied and knowledge gaps with relative ease (Table 3.3).

Table 3.3. Existing Asian studies fitted into Donabedián's Model of Healthcare Delivery

Donabedián's Model	Studies	Year/Authors
Structure		
Structure: Access	Clinical characteristics of acute ischemic syndrome in China	2002 Tan, HQ., Liang, Y., Zhu, J., Liu, LS
	Comparing risk-adjusted hospital mortality for CABG and AMI patients	2005 Park, HK *et al.*
Structure: Surgery volumes	An attempt to analyze the relation between hospital surgical volume and clinical outcome	2007 Committee for Scientific Affairs
	Association of case volume with mortality of Chinese patients after coronary artery bypass grafting: Taiwan experience	2005 Wu, SC *et al.*
Structure: Surgery training	Learning curve of coronary surgery by a cardiac surgeon in Japan with the use of cumulative sum analysis	2005 Song, MH *et al.*
Structure: Cardiac rehabilitation	Effects of phase I cardiac rehabilitation on anxiety of patients hospitalized for coronary artery bypass graft in Taiwan	2002 Ku, SL, Ku, CH, & Ma, FC
Structure: Patient characteristics: gender	Operative results of coronary artery bypass grafting in women	2004 Huang, CH *et al.*
Structure: Patient characteristics: race	The effect of race on coronary bypass operative mortality	2007 Yeo, KK, Li, Z and Amsterdam, 2000 Bridges *et al.*
Structure: Patient characteristics: age	Coronary artery bypass grafting in the elderly	2000 Hirose *et al.*
	Clinical outcome and quality of life of octogenarian patients following percutaneous coronary intervention or surgical coronary revascularization	2007 Kamiya *et al.*

Donabedián's Model	Studies	Year/Authors
Structure: Patient characteristics: risk factors	Risk factors for mortality in primary isolated coronary artery bypass grafting surgery	2001 Huang, Lai, & Weng, 2001
Structure: Patient clinical risk factors: diabetes	Does diabetes affect the postoperative outcomes after total arterial off-pump coronary bypass surgery in multivessel disease?	2005 Choi, JS, Cho, KR, and Kim, KB
Structure: Patient clinical characteristics: retinopathy	The beneficial effect of coronary-artery-bypass surgery on survival in patients with diabetic retinopathy	2006 Ohno, T *et al.*
Structure: Patient clinical characteristics: Kawasaki disease	National survey of coronary artery bypass grafting for coronary stenosis caused by Kawasaki disease in Japan	2004 Tsuda, E & Kitamura, S.
Patient clinical characteristics: s/p renal transplantation	Coronary artery bypass grafting in the acute phase after renal transplantation: report of a case	1999 Katoh *et al.*
Structure: Patient clinical characteristics: Risk factors of sternal wound infection	Risk factors of deep sternal wound infections in coronary artery bypass graft surgery	2000 Wang, FD & Chang, CH
Process		
Process: Minimally-invasive direct CABG surgery (MIDCAB)	Current status of minimally invasive coronary artery bypass grafting in China	2001 Shengshou, H
	Safety and effectiveness of minimal-access versus conventional coronary artery bypass grafting in emergent patients	2002 Yeh, CH
Process: Off-pump CABG surgery	Perioperative advantages of off-pump coronary artery bypass grafting	2002 Ishida, M *et al.*
	Off-pump technique in coronary artery bypass grafting in elderly patients	2003 Lin, CY *et al.*

Donabedián's Model	Studies	Year/Authors
	Coronary artery bypass grafting without cardiopulmonary bypass: a five-year experience	2003 Ochi *et al.*
	Less invasive coronary artery bypass without cardiopulmonary bypass	1998 Shiono, M & Sezai, Y
	Avoiding cardiopulmonary bypass in multivessel CABG reduces cytokine response and myocardial injury	1999 Wan, S et
Process: Arterial conduits -	Sequential bypass using the right gastroepiploic artery for coronary artery bypass grafting	2003 Ishida, M *et al.*
Process: Gastroepiploic artery graft	Use of arterial grafts for coronary revascularization. Experience of 2987 anastomoses	1999 Tomizawa *et al.*
	Beating heart coronary artery bypass grafting: results from 402 patients and the usefulness of gastroepiploic artery composite grafting	2003 Takemura, H *et al.*
	Bypass to the distal right coronary artery using in situ gastroepiploic artery	2004 Hirose, H, Amano, A. & Takahashi, A
	Sequential bypass using the right gastroepiploic artery for coronary artery bypass grafting	2003 Ishida, *et al.*
Process: Radial artery	Coronary artery bypass grafting using the radial artery: midterm results in a Japanese institute	2001 Amano, A, Hirose, H., Takahashi, A. & Nagano, N.
Process: Extubation	Immediate extubation in the operating room after cardiac operations with thoracotomy and sternotomy	2007 Lin, TY *et al.*
Process: Cardiac anesthesia	Investigation and analysis of incidence of awareness in patients undergoing cardiac surgery in Beijing, China	2005 Wang, Y *et al.*
Process: Cardioplegic solutions	Myocardial protection related to magnesium content of cold blood hyperkalemic cardioplegic solutions in CABG	2002 Ji, B, Feng, Z, Liu, J & Long, C
Process: Propofol use	Pharmacokinetics of propofol infusion in Asian patients undergoing coronary artery bypass grafting	1995 Lee, HS *et al.*

Donabedián's Model	Studies	Year/Authors
Process: Harvesting techniques of radial arteries	Skeletonized harvesting improves the early-term and mid-term perfect patency of a radial artery graft	2006 Miyagi, N, Oshima, N, Shirai, T & Sunamori, M
Process: Harvesting techniques of veins	Endoscopic harvest of saphenous vein graft for coronary artery bypass grafting: Saitama-Olympus technique	1998 Kyo, S *et al.*
Process: Hemodialysis filtration	Hemodiafiltration during cardiac surgery in patients on chronic hemodialysis	2006 Fukumoto, A *et al.*
Process: Biatrial pacing	Effects of biatrial pacing in prevention of postoperative atrial fibrillation after coronary artery bypass surgery	2000 Fan *et al.*
Outcomes		
Outcomes: Mortality studies on RAMR	Percutaneous coronary intervention versus coronary artery bypass grafting for diabetics with multivessel coronary artery disease: the Korean Multicenter Revascularization Registry (KORR)	2005 Gwon, HC *et al.*
	Clinical outcome and quality of life of octogenarian patients following percutaneous coronary intervention or surgical coronary revascularization	2007 Kamiya, M *et al.*
Outcomes: Outcome studies in Japan	Coronary artery surgery results 2002 in Japan	2004 Sezai, Y, Orime, Y and Tsukamoto, S.
	Coronary artery surgery results 2005 in Japan	2007 Sezai, Y, Orime, Y and Tsukamoto, S.
Outcomes: Outcome studies in Singapore	Trends in mortality, incidence, hospitalization, cardiac procedures and outcomes of care for coronary heart disease in Singapore, 1991-1996	1999 Ng, TP, Mak, KH, Phua, KH, & Tan, CH
Outcomes: Stents or surgery outcome studies for diabetes in Korea	Percutaneous coronary intervention versus coronary artery bypass grafting for diabetics with multivessel coronary artery disease: the Korean Multicenter Revascularization Registry (KORR)	2005 Gwon, HC *et al.* .

Donabedián's Model	Studies	Year/Authors
Outcomes: Stents or surgery outcome studies for diabetes in China	Coronary artery bypass surgery versus percutaneous coronary intervention with drug-eluting stent implantation in patients with multivessel coronary disease	2007 Yang, ZK *et al.*
Outcomes: Outcome studies in China – long term survival	Long-term survival and prognostic implications after coronary artery bypass grafting in Chinese patients with coronary artery disease	2006 Hsiung, MC *et al.*
Outcomes: Outcome studies in China – Octogenarians	Clinical outcome and quality of life of octogenarian patients following percutaneous coronary intervention or surgical coronary revascularization	2007 Kamiya, M et al
Outcomes: Urgent surgery	Clinical outcome of urgent coronary artery bypass grafting	2007 Kim, DK *et al.*
Outcome: Morbidity studies -delayed pleural effusion	Prevalence of symptomatic large pleural effusions first diagnosed more than 30 days after coronary artery bypass graft surgery	2007 Peng, MC *et al.*
Outcome: Morbidity studies - deep-seated infected mediastinitis	Deep-seated infective mediastinitis in post-coronary artery bypass grafting patients	1994 Khoo, AK, Tan, KC, & Ong, KK
Outcome: Morbidity studies - central nervous system (CNS) complications	Intracranial cerebral artery disease as a risk factor for central nervous system complications of coronary artery bypass graft surgery	2001 Yoon, BW *et al.*
Outcome: Morbidity studies - Vessel patency rates	Serial angiographic follow-up beyond 10 years after coronary artery bypass grafting	2005 Arima, M *et al.*
	Evaluation of coronary artery bypass grafts using multidetector-row CT with Japanese patients	2006 Murai, S *et al.*
Outcome: Quality of life studies in octogenarians: stents / surgery	Clinical outcome and quality of life of octogenarian patients following percutaneous coronary intervention or surgical coronary revascularization	2007 Kamiya, M et al

Donabedián's Model	Studies	Year/Authors
Outcome: Quality of life studies in Hong Kong	Physical, psychological and social recovery patterns after coronary artery bypass graft surgery: a prospective repeated measures questionnaire survey	2007 Lopez, V, Sek Ying, C, Poon, CY, and Wai, Y
Outcome: Quality of life studies – Gender differences in Taiwan	Gender differences in quality of life for post Coronary Artery Bypass Grafting patients in Taiwan	2007 Tung, HH, Wei, J, and Chang, CY

Whereas clinical or administrative CABG surgery datasets have been used to conduct secondary analysis, one must be cognizant of the following three core issues related to Asians pertaining to data usage.

First, the race designation of Asians within these databases is not consistent with that used by the Census Bureau. According to changes in the 2000 U.S.Census, “Asians” have been separated from the Pacific Islanders, and is a conglomerate term used to designate all Asians born in the United States as well as immigrants from Asian countries. Asians in the clinical databases, however, may still include Pacific Islanders in the same racial category, even though Pacific Islanders generally have clinical characteristics distinctively different from Asians. Because of the habitual melding of Asians and Pacific Islanders in census statistics in the past, even if the CABG databases only list “Asians,” data from Pacific Islanders have been included in the Asian category. The high percentage of missing data in the race field in some administrative databases (Becker and Rahimi, 2006.) and the confusion inherent in racial designations both put in clear limitations in the use of these datasets to study ethnic and racial differences in CABG surgery.

A second important issue is that the dataset, except the STS-NDB, may not be in alignment with the consensus criteria recommended by the NQF. Many of the clinical datasets were established prior to the existence of the voluntary NQF consensus criteria which were originally extracted from the larger STS-NDB dataset which contained over 200 data elements. Other clinical datasets may not contain all of the 17 NQF criteria. Therefore, in order to capture the NQF criteria, changes will have to be made to these databases (Table 3.1). But that will not happen unless the NQF criteria are accepted by the physician stakeholders of each of the regional clinical datasets, such as the CCORP.

The third issue relates to the uniqueness of different racial groups. Some important and unique quality criteria specific to Asians have not been captured by the data elements in the current databases. Given the large percentage of Asian immigrants with limited English proficiency (LEP), the language and cultural concordance with healthcare providers and potential communication issues associated before, during, and after CABG surgery are important dimensions to study. It would be helpful if data fields such as ‘birthplace,’ ‘number of years residing in the U.S.,’ and ‘primary language spoken at home’ were added to further characterize Asians. Particularly with the rising trend of coronary artery disease in Asians and the continuous influx of immigrants from Asian countries, it is likely that an increasing number of LEP Asians will undergo CABG surgery in the future. Capturing the primary language spoken by patients and the presence of an interpreter program as variables in the structural component in Donabedián’s model (Table 3.2) would be helpful. Other social determinants such as education and income levels, and patients’ health literacy and cultural behaviors, may also be important dimensions influencing quality of care. At this time, while many administrative datasets include language, many clinical databases lag behind. The absence of language spoken at home may hamper the measure of how limited English proficiency affects healthcare outcomes.

Conclusion

The 17 NQF consensus quality criteria for CABG surgery can be aligned with the Donabedián model (Table 3.1), thus establishing a coherent, systematic, and logical set of criteria to assess the quality of care. This correspondence helps to develop a specific framework in which the “principles and categories of thought” can be used to organize the subject matter for it to be” defined, classified, and understood” (Donabedian, 2003, p. xiii). Adoption of these NQF consensus criteria at the regional levels, such as in CCORP, may create a need to redesign data collection instruments for the NQF criteria.

Quality monitoring in CABG surgery — when established as a regular protocol within an organization (hospital) and uniformly implemented and accepted by those being monitored (surgeons and administrators)— can be a continual process of improvement. By organizing the array of different data elements into Donabedián’s “structure, process and outcome” framework, quality assessment is elevated to a higher level of refinement.

Quality monitoring of CABG surgery, especially for Asians in the United States, still has a long way to go. The adoption of Donabedián’s healthcare delivery model for quality measurement for Asians as well as for other ethnic groups is an appropriate theoretical model to use, and enables a quick and easy assessment of the existing knowledge gaps. As Donabedián states: “Without it [quality monitoring], we do not know where we are coming or where we are going” (Donabedian, 2003, p. xxvii).

Chapter 4

Measurement of Clinical Characteristics and Outcomes of Isolated Coronary Artery Bypass (CABG) Surgery in Asian Americans

In addition to external societal forces demanding more information on CABG surgery, cardiothoracic surgeons' internal initiatives to achieve better clinical outcomes have also been instrumental to the development of sophisticated clinical databases for coronary artery bypass graft surgery. This study took advantage of the availability of these valuable clinical databases to help illuminate more clinical information on Asians, an understudied ethnic group. One surgery type, isolated CABG surgery, was selected in this study to ensure uniformity in the surgical procedure. Doing so helped to make the pre-operative risk adjustment more specific to the surgery type and enable the interpretation of outcomes more meaningful.

Research questions formulated in this study were based on the outcomes of previous studies using mostly administrative datasets (see Chapter 2). Yeo and colleagues (2007) were the first to include Asians in their study using a large clinical dataset, the same CCORP clinical dataset used in this dissertation study. Of the 122 hospitals in this dissertation study, some hospitals may have dedicated cardiac service lines while others do not; some may have experienced surgeons while others have a young surgical staff; some may attract certain types of patients – those with higher socioeconomic status or more severely ill. Some hospitals may be preferentially chosen for by either the more privileged patients, or the sicker patients. Also, the geographic location of some hospitals may attract patients of a certain socioeconomic level who live in the vicinity. In consideration of these un-estimated as well as other unaccounted-for differences, it is highly likely that patients in the same hospital may be more alike than those from different hospitals, and that there may be some unique characteristics affecting outcomes within individual hospitals that are unknown and not included in the risk-adjusted model. Thus, clustering effects of hospitals cannot be ignored, as have been the case in most previous CABG studies. By using the generalized estimating equations procedure (GEE), a relatively newer type of statistical method of analysis, to account for the clustered data within individual hospitals, it is able to reflect the standard errors more accurately than without using it, therefore rendering the conclusions drawn to be more accurate.

The following sections provide an overview of the methodology issues in conducting the secondary analysis, which include a review of the research questions first, to be followed by a discussion of the overall research design, important considerations in using the CCORP and PDD linked datasets, the variables in the database, statistical analyses used to obtain answers for each research question, and conclusions.

Review of research questions

From Chapter 1, the research questions to be explored in this study have been organized into Donabedián's "structure" and "outcome" elements, to be in alignment with the theoretical model chosen for this study.

- On Donabedián's "structure" ─ Preoperative characteristics

  Research question 1: Did preoperative characteristics differ between Asians and Caucasians presenting for CABG surgery?

  Research question 2: How did preoperative characteristics differ by race (Asians versus Caucasians) between gender, and by gender between races respectively?

Research question 3: Were there differences in the proportion of Asians having CABG surgery in the high-volume and the low-volume surgery centers/hospitals?

- On Donabedián's "outcome" ─ Unadjusted operative mortality

Research question 4: Were there any differences in the unadjusted operative mortality between Asians and Caucasians?

Research question 5: Were there any differences in the unadjusted operative mortality rates between gender within race, and between races within gender respectively?

Research question 6: Were there any differences between Asians and Caucasians in the unadjusted mortality between the high- and low-volume hospital groups?

- On Donabedián's "outcome" ─ Risk-adjusted mortality

Research question 7: After adjusting for the clinical predictors, were there any differences in the risk-adjusted mortality between Asians and Caucasians?

Research question 8: After adjusting for the clinical predictors, did the risk-adjusted operative mortality differ between the genders by race?

Research question 9: Were there any differences between Asians and Caucasians in the risk-adjusted mortality between the high- and low-volume hospital groups?

Overview of research design, data source, sample, and analyses

This was a descriptive, comparative study to examine disparities in Asians with coronary artery disease (CAD), using Caucasians as the control group with the same clinical treatment: isolated CABG surgery. The comparative design enables the comparison of groups where every subject had the same treatment, isolated CABG surgery in this case, and where randomization is not possible (Cook & Campbell, 1979, p. 6).

Choosing the CCORP database and the Patient Discharge Data for the analysis

The quality of the results found in this comparative study depends to a large extent on the database used, and hence which database to use is an important consideration for this study. After deliberation, the decision was made to use the linked datasets from CCORP and the California Patient Discharge Data (PDD) for this study – basing on their feasibility, accessibility, cost, reliability, validity, and appropriateness to the purpose of the study (Shwartz & Ash, 2003). CCORP was found to be a superior choice compared to other regional or national databases such as the National Database from the Society of Thoracic Surgeons (STS-NDB). With California being the most populous state for Asians (U.S. Bureau of the Census, 2002), the CCORP dataset has a relatively large percentage of Asians. Also, the mandatory nature of the CCORP makes it more preferable to use than those of a voluntary submission nature, such as the STS-NDB. The non-participation of the Kaiser Permanente system in the voluntary STS-NDB program but in the mandatory CCORP makes a strong argument to use CCORP data in the study of Asians, because the Kaiser Permanente system contains a significant number of Asian patients which would have been omitted in the STS-NDB.

With the general understanding that there are no perfect databases, other criteria, such as timeliness and availability of data, data access, and data accuracy and validity, were examined to further substantiate the choice of use of the 2003 – 2005 CCORP dataset for this Asian-focused study.

Timeliness and availability of data

The data chosen for 2003 – 2005 period signify the time span in which the same data collection tool was used. In 2003, CCORP was changed from voluntary to mandatory data submission, and 2006 started the use of a new data collection tool which has been revised to include postoperative complications. Unfortunately, the more informative 2006 dataset was still not available for public release for the study.

Data access

Ease of data access is an important consideration. The California Office of Statewide Planning and Development (OSHPD) provides patient-level CCORP data to researchers without cost, and also provides data linking to the PDD. It does have a fee charge when the requested PDD data are 3 years older than the last set of published data. The process to obtain the raw data files took a few months. Despite that, it was still more accessible and less expensive than trying to obtain proprietary data, such as the STS-NDB, After obtaining approval for the study from the Committee for the Protection of Human Subjects from the State of California, the data request was made directly to California's Office of Health Planning and Development (OSHPD) to link the CCORP data with PDD for the 2003-2005 period.

Data accuracy and validity

Being a state mandatory program for all CABG surgeries done in California, the CCORP staff designed the CABG surgery database with help from a panel of clinical experts and have conducted regular training programs on data collection. The CCORP serves as a data depository and harvest site. Participating hospitals usually assigns designated clinical staff to do retrospective chart reviews to collect and submit the CABG surgery data to the CCORP on a regular basis. By design, the CCORP staff audit part of the data received, and audit all deaths, all outliers, as well as conduct on-site auditing on almost 1 out of 3 patients in the hospitals chosen. Onsite auditing is considered the "gold" standard for data verification. The STS-NDB, in comparison, contracts with an outside service (the Duke Clinical Research Institute) as a data warehouse, and does not conduct any on-site auditing, and is not linked with the national vital statistics to verify mortality data. The lack of on-site auditing may inadvertently encourage one type of "gaming" – exaggerating preoperative risk factors to obtain more favorable coefficients to weigh in the risk-adjusted models. So although the STS-NDB contains a more extensive dataset, the reliability of its un-audited data is a real concern. The CCORP also routinely sends preliminary summary reports back to hospitals to enable them to check for invalid, or missing data and abnormally high or low values. This practice gives participating hospitals a chance to make data corrections and thus improves data reliability further.

Variables in the study

Outcome variables in CABG surgery

There are at least four possible categories of outcome variables of interest in the assessment of quality outcome in CABG surgery:

- mortality (operative mortality)
- serious morbidity (such as stroke, myocardial infarctions, deep sternal wound infections, bleeding requiring surgical re-explorations, kidney failure requiring dialysis, prolonged intubation)
- resource utilization (length of stay, surgical costs), and
- patient satisfaction (physical ability and other quality of life issues) (Nilssen, 2005)

Each one of these outcomes requires use of risk adjustment methodology using a stipulated, unique set of patient, physician, and perioperative prediction factors and characteristics. However, most datasets, including the STS-NDB which is arguably the largest clinical dataset in CABG surgery, do not contain all the variables needed to obtain these four outcomes. And few, almost no clinical CABG surgery databases contain any patient satisfaction index variables. It is important to note that some of these outcome variables, such as major postoperative complications and resource utilization, can be highly correlated to each other.

Independent predictor variables indicating the severity of patients' risk can influence both the direction as well as magnitude of the outcome variables, as the sicker the patients are before CABG surgery, the more likely they are expected to be die, have complications, be associated with a higher utilization of resources, have a longer length of hospital stay, and have less satisfaction with the surgical experience. Many of these predictors are cardiovascular risk factors that can also correlate among each other.

Variables specific to the CCORP dataset

Most of the variables in the CCORP dataset are a subset of the data elements in the STS-NDB set, and include both outcome and predictor variables. The 2003-2005

CCORP-PDD linked datasets provided only mortality as an outcome variable, but starting from 2006, CCORP has included major morbidity outcomes into its database. The main outcome variable used from this 2003-2005 dataset was operative mortality (alive, dead). The predictor variables in the dataset can be categorized into demographic and clinical predictors. Demographic variables include facility identification numbers (coded), surgeon's name (coded), age, and gender (female and male). Clinical predictor variables include isolated CABG surgery (yes, no), date of surgery, date of discharge, body mass index, height and weight, status of surgery (elective, urgent emergency, salvage), last serum creatinine level preoperatively, hypertension (yes, no), dialysis (yes, no), peripheral vascular disease (yes, no), cerebrovascular disease (yes, no), timing of cerebrovascular accidents (none, ≤2 weeks before date of surgery, >2 weeks from date of surgery), diabetes (yes, no), chronic lung disease (none, mild, moderate, severe), on immunosuppressive treatment (yes, no), arrhythmia (none, sustained atrial fibrillation, heart block, sustained ventricular tachycardia or ventricular fibrillation), myocardial infarction (yes, no), timing of previous myocardial infarction (none, >21 days, 8-21 days, 1-7 days, >6 hours but <24 hours, 1- 6 hours, and ≤6 hours before surgery), New York Heart Association Classification (Class 1, 2, 3, and 4), cardiogenic shock (yes, no), congestive heart failure (yes, no), previous CABG surgery with cardiopulmonary bypass (yes, no), previous CABG surgery without cardiopulmonary bypass (yes, no), previous percutaneous coronary interventions (yes, no), interval from PCI to surgery (>6 hours, ≤6 hours), % of ejection fraction, % of left main coronary artery stenosis, number of diseased coronary vessels (1 or 2, 3 or more), and mitral insufficiency (none, trivial, mild, moderate, severe). The variables above that have no specified categories are continuous valuables. The only process variable in the CCORP dataset is use of internal mammary artery (yes, no).

Variables in the PDD

The PDD was linked to the CCORP dataset by the data management staff at the OSHPD using the patients' encrypted social numbers as the primary key. Two main variables were chosen from the PDD for use: the race variable (Caucasian, black, Hispanic, Asian, Native Hawaiian/Pacific Islanders, Others) and discharge status (alive, dead), Because the race variable was re-categorized as white and non-white in the CCORP database received (in order to protect the identity of patients by the CCORP staff), PDD helps to provide the critical race variable information on Asians and Caucasians, the two racial groups of interest in this study. The patient's discharge status helped to verify the operative mortality from the CCORP dataset.

A description of the sample

Because the CCORP is a mandatory reporting program (except for the Veterans Administration Medical Centers), the data included all the heart surgeries conducted for the entire population in California. This study only examined data on the 57,316 patients >18 years old who had the isolated CABG surgery (see Definitions in Appendix I) between 2003 and 2005 in California. Clinical and demographic data were collected by the participating hospitals and submitted to OSHPD, and these data were used to conduct the secondary analysis. There were no direct subject contacts. Of the 57,316 patients, 48,464 Asian and Caucasian subjects were qualified for inclusion in this study. Within this group, 11% were Asians and 89% were Caucasians. The data have been treated by the CCORP as a sample to make error estimates.

Procedure – Data analyses steps

Data analysis steps include the data application process, preparation of data, and the statistical analysis.

IRB application and OSHPD data application

The IRB and OSHPD data applications were sent to the Health Information Department (HID) of the Office of Statewide Health Planning and Development (OSHPD) in April, 2008. It was the first application that OSHPD has ever received from an external source for the California CABG Outcomes Reporting Program (CCORP) raw data request. The CCORP data were requested to be linked to the PDD before they were cut and released, and the two linked datasets finally arrived in mid January, 2009. These data were reviewed and coded into the proper format to enable the analyses.

Data cleaning and preparation

Because the CCORP dataset has gone through its strict internal verification process, it was relatively complete with no missing data for most variables except for six of them, 3 continuous and 4 categorical variables (Table 4.1). Unfortunately, in the CCORP dataset, the most important variable in this study, race, was only coded as "white" and "non-white" and CCORP refused to release data on the race variable. Fortunately, the PDD also contain the race variable, and so the "Asian" category was obtained from the PDD instead of the CCORP, a less desirable alternative. Further review of the data found that two variables ('previous CABG surgery on cardiopulmonary bypass', and 'previous CABG surgery without cardiopulmonary bypass'), contained errors, and so another round of inquiry occurred with the CCORP office. Finally, the new data disc containing corrections to these two variables was received in March.

Table 4.1. Variables with missing data

Total number of cases: 48,464

Variable names	Number of cases with missing data	Variable type
Ejection fraction	1,418	Continuous
Body mass index	10	Continuous
Last serum creatinine level prior to surgery	25	Continuous
Percentage of stenosis in the left main artery (created two categories)	1,710	Categorical
Number of diseased coronary vessels	57	Categorical
New York Heart Association Classification	920	Categorical
Operative mortality	6	Categorical

Mirroring the practice of many other ethnic and racial comparison studies in CABG surgery, this study, with the focus on Asians, also uses Caucasians as the control group. Thus, Asians and Caucasians were extracted to form a new data subset to help define the focus of the analyses.

The datasets that were originally sent out by the OSHPD as a SAS data file format were exported to SPSS version 17.0 to set up the data properly and to conduct most of the preliminary analysis. The SPSS dataset was then exported to SAS version 9.1 for the rest of the analysis, including the linear and ordinal logistic GEE models.

The CCORP staff sent a CD disc containing the linked data, and most of the data came in as string variables. Setting up the data in the correct format was a necessary step to enable statistical analyses. The following were the data transformation, recoding, and other preparative work that needed to be done prior to the data analyses.

Data transformation, recoding, and, aggregating using SPSS version 17.0:

- Recoded string variables into numeric variables
- Created a new database with only data for Asians and Caucasians
- Created a continuous variable from the height and weight variables for the body mass index (BMI) variable, and then created a categorical BMI variable with cut-points at ≤18.5 and >40.
- Aggregated data to create a new hospital volume group variable: A new 'ncases' variable was first created by aggregating the hospital ID into its total number of CABG surgery cases. Then a frequency table was run to assess the distribution of the cases among the 122 Californian hospitals.
- Created a new 'hospital volume' variable with a near 50^{th} percentile cut-point at 300 surgeries for the three year period with 2 groups: a 'low-volume' group with ≤300 surgeries and a 'high-volume' group with >300 surgeries.

Statistical methods

The statistical tests carried out for this study were based on SPSS version 17.0 for the descriptive analysis, StataIC 10 for the logistical 2-level (individual and hospital levels) analysis, and SAS version 9.1 for most of the final analyses using the GEE methodology. Preliminary analyses of the CCORP data conducted include:

- Simple logistic regression for each predictor with race as an interaction term was run to check if the coefficient for the predictor was significantly different between the two races, instead of just assuming that each predictor has the same effect on the two races.

- Correlations among the predictor variables themselves were assessed.

Generalized estimating equations (GEE) models

Generalized estimating equations (GEE) models were developed in the 1980s as an extension of the generalized linear models (Zeger and Liang , 1986), and is a method of estimation designed to obtain the mean response by using a regression model. GEE is often used with correlated data to account for the within-subject association among the repeated measures or clusters. The data from the CCORP have come from different hospitals, and patients who had surgery in the same hospital cluster differ from those who had surgery in other hospital clusters. The GEE method enables adjusting for the unknown, un-estimated, and correlated effects within individual hospital clusters that might contribute to the mortality outcome. So the GEE method enables within group and between group comparisons, as well as within hospital and between hospital comparisons, and is a correction of the variance or design effects common to cluster samples. It can also handle discrete, mean responses with continuous, binary, and count outcomes. Other advantages of the GEE include the following (Fitzmarurice, Laird, & Ware, 2004, Vittinghoff, 2005):

- It can accommodate unbalanced data and does not require that each hospital have the same number of patients, which the repeated-measures ANOVA would require.
- It also does not require a common set of measures be measured at a common set of occasions.

- The observations within hospitals can be correlated, which will not violate the independence assumptions that other more commonly used analyses such as simple regressions would require. Data from different patients at the same hospital are correlated and violate the independence assumptions.

The only limitation for GEE (which is true with Maximum Likelihood estimation methods in general and not unique to GEE) is that the model require convergence, which does not always happen as was experienced during my data analysis, The calculations, when using all 26 variables in the regression for Asians only, did not converge to a solution. In the end, some variables were deleted in order for the Asians-only model to converge.

Comparing using GEE and mixed models as the preferred methodology to study the questions

Mixed models might have been an alternative approach, but the GEE method was deemed to be more appropriate in this study. The focus of mixed models is on individuals, not populations. The GEE method yields population-averaged values, which mixed models do not. Further, with the SAS software, using the GEE method can be more convenient and simpler to handle both continuous and dichotomous variables by using one single procedure (PROC GENMOD), whereas with the mixed models, it will take two procedures (PROC MX for continuous and PROC NLMX for dichotomous variables) to handle the two types of variables. The hierarchical linear models (HLM), which is a type of mixed models, could have worked, but just not as efficiently in this study.

Statistical tests used for the research questions

In the following section, the statistical tests used are listed alongside with each of the research questions in alignment with the domains of Donabedián's "structures" and "outcomes" framework. Most of the analyses included statistical methods capable of accounting for some unknown, un-estimated clustering effects of individual hospitals that are not part of the risk-adjusted model by using the appropriate types of generalized GEE models (linear and binary logistic)On Donabedián's "structure":

- *Research question 1:* Did preoperative characteristics differ between Asians and Caucasians presenting for CABG surgery?

Method of analysis for research question 1:

In order to assess if dependency within each hospital is a significant factor affecting results, the intraclass correlation (ICC) on the variable on patient age was tested. The ICC is significantly large (~2.7%) given the sample size of >48,000 and group size of 121 hospitals (excluding one hospital that did not have the full 3-year data). Because the effects of heterogeneity across hospitals and dependency within hospitals could not be ignored in some variables, it rendered the use of the traditional t-tests or chi-square analysis inappropriate.

Instead, adjustment for the clustering effect of being from the same hospital was made by using the linear and binary logistic GEE models in the SAS 9.1 statistical software for both the continuous and dichotomous outcome variables. The GEE analysis was carried out in turn for each of the demographic and clinical characteristics as the outcome variable with 'race' as the only predictor in the model, while adjusting for the clustering of hospitals. The only exception was for the NYHA variable, an ordinal variable which cannot be done in the GEE method in SAS as its proportional odds routines do not handle the clustering. So this ordinal variable was done using the 'ologit' function in StataIC 10 instead.

- *Research question 2:* How did preoperative characteristics differ by race (Asians and Caucasians) within gender, and by gender within race?

Method of analysis for research question 2:

The same SAS 9.1 version statistical software was used to conduct the analyses for this question using the GEE linear and binary logistic models for both the continuous and dichotomous outcome variables to adjust for the clustering effect of hospitals. The GEE analysis was carried out in the same manner as was done in research question 1, using each of the demographic and clinical characteristics as the outcome variable, but this time putting 'race', 'gender' and the interaction term 'race*gender' in the model with a post estimation statement. The only exception was for 'NYHA', an ordinal variable, using the 'ologit' function in StataIC 10, because the GEE model does not handle ordinal logistic models.

- *Research question 3:* Were there differences in the proportion of Asians having CABG surgery in the high volume versus low volume surgery centers/hospitals?

Methods of analysis for research question 3:

Preliminary analysis was conducted by examining the distribution of the aggregated surgery volumes on the hospital variable to identify and choosing a reasonable cut-point to dichotomize the hospitals into two groups. Cut-points chosen from previous studies were deemed inappropriate, as hospital surgery volumes have continued to drop. For this study, the median of the CABG surgery volumes, around

300 cases in 3 years, was deemed to be a reasonable cup-point. Hospitals were thus dichotomized into two groups (high-volume and low-volume) by creating a new binary 'hospital-volume' variable: Hospitals operating <300 cases were designated as 'low volume', and those operating 300 and more cases as 'high volume'. These volumes represent the total surgical volumes of hospitals in the 3-year period between 2003 and 2005.

To find out the proportion of Asians in the high- versus low-volume hospital groups, a crosstab table with the chi-square analysis was performed.

Because the range of values for the proportion of Asian within each hospital varies between 0 and 1 and is too constricted, a logit transformation of the proportion (p) 'log [p/(1-p)]' was performed to spread the range from negative infinity (log 0) to infinity (log 1/0).

In order to seek the mean proportions of Asians within the high and low volume hospital groups, additional analyses were performed. Because the effect of the same proportion of Asians in a low-volume hospital differs from that of a high-volume hospital, the weighted t-test, instead of the unweighted t-test should have been performed. (In this case, the hospital is the unit of analysis, and the weight of the variable is the aggregated number of patients in each hospital.) However, the weighted t-test makes the assumption of equal variance which was seriously violated in this case. Therefore, both the unweighted t-test and the Mann-Whitney test were performed instead, and their results were similar, thus indicating that normalizing the transformation did a good job.

On Donabedián's "outcome":

- *Research question 4:* Were there any differences in the unadjusted operative mortality rates between Asians and Caucasians?

Method of analysis for research question 4:

The GEE function of SAS 9.1 was used to obtain the unadjusted operative mortality without taking the different clinical characteristics of patients into consideration. 'Operative mortality' was used as a dichotomous outcome variable, with 'race' as the only main effect in the GEE model, while adjusting for the clustering effect of hospitals using the hospital ID number. No other clinical predictors from patients were used in this model to obtain the unadjusted mean for operative mortality.

- *Research question 5:* Were there any differences in the unadjusted operative mortality between gender within race, and between races within gender respectively?

Method of analysis for research question 5:

To obtain the unadjusted operative mortality without taking the clustering of the hospitals into consideration, the data file was first sorted by race. Then the 2X2 chi square analysis was used to tabulate the 'operative mortality' by 'race' and 'gender'.

Taking the clustering of the hospitals into consideration by using the 'GEE' function of SAS 9.1, 'operative mortality' was used as a dichotomous outcome variable, with 'race' and 'gender,' along with the interaction term 'race*gender' in the GEE model, The post estimation statement was also conducted, No other clinical predictors of patients were used in this model, and thus the mortality outcome is considered “unadjusted.”

- *Research question 6:* Were there any differences between Asians and Caucasians in the unadjusted operative mortality rates between the high- and low-volume hospital groups?

Method of analysis for research question 6:

The GEE function in SAS 9.1 was used to assess the mortality outcomes in the volume-race relationship, by using the binary ‘hospital-volume’ variable as the outcome, and ‘race’ as the only predictors in the model while adjusting for the clustering effect of hospitals.

- *Research question 7:* After controlling for all the clinical predictors in the model, were there any differences in the risk-adjusted operative mortality between Asians and Caucasians?

Method of analysis for question 7:

The GEE function of SAS version 9.1 statistical software was used for this analysis. The same set of 26 predictor variables chosen by the CCORP, including the ‘race’ variable, was used in the GEE model, adjusting for the clustering effect of hospitals, with ‘operative mortality’ as the dependent variable. In doing so, the effects of the chosen demographic and clinical risks factors were taken together to model the mortality outcome. The main effect by race, adjusting for all the other risk predictors, can be estimated in this model.

- *Research question 8:* After adjusting for the clinical predictors in the model, did the risk-adjusted operative mortality differ between genders by race?

Method of analysis for research question 8:

The GEE function of the SAS version 9.1 statistical software was again used for this analysis, but this time, it is used to make estimations for the Asians and Caucasians separately. Using the same 26 predictor variables as above, but adding the interaction term 'race*gender' and adjusting for the clustering of hospitals, the model was re-run for the subset of Asians and Caucasians separately. Unfortunately, the model was not able to converge for the Asians subset of data. Hence, the model was reduced to 19 clinical characteristics by including only variables that were significantly different between the two races from previous analysis. After reducing the predictors, the model was re-run again for both racial groups. This time, the Asian model was able to converge. If this interaction term was found to be significant, then the post estimation using the 'lincom' function would be used to find the actual difference between the genders.

- *Research question 9:* Were there any differences between Asians and Caucasians in the risk-adjusted operative mortality for CABG surgery between the high- and low-volume hospital groups?

Method of analysis for research question 9:

Using the GEE procedure of SAS version 9.1, the 'hospital-volume' variable and the interaction term "race*hospital-volume' were added to the GEE model with the same set of 26 variables as for research question 7. The hospital volume effect on mortality, adjusting for all other predictors, could be first obtained as a main effect, and the interaction term would reveal if any significant differences exist between race and the two hospital volume groups.

Conclusion

This chapter has provided a review of the research questions, followed by a discussion of the research design, sample, data source, data validity, data preparation, and statistical tools used for the analysis for each of the nine research questions relating to CABG surgery in Asians. This secondary analysis study was selected because of the available valid and reliable CCORP clinical database, which provides a feasible and economical way to expand our clinical knowledge of the subset of Asians with coronary heart disease who had undergone CABG surgery.

The important difference in the analysis of this study, as distinct from many previous CABG studies, lies in its use of the GEE model to account for the clustering effects within individual hospitals. Since there are 122 hospitals in the dataset, choosing the GEE method to make estimations enables adjusting for the un-estimated or unknown clustering effects of hospitals, thus helping to yield more accurate results.

However, how good the secondary analysis results are depends largely on the source of the data from which the analysis is based. After considerations from multiple angles, the CCORP dataset was deemed to be the most appropriate dataset to use in this study, given its primary focus on Asians. Given the mandatory nature of the dataset, with inherent methods to verify and validate data as well as deal with the missing data, and the increased power from the higher percentage of Asians contained in the data as compared to other CABG databases, results from this study should be more accurate.

Donabedián's health delivery quality model: "structure → process → outcome" underpins this proposed CABG study for Asians. The use of the concept of risk adjustment, a staple in outcome research, is in full alignment with Donabedián's model of healthcare delivery, as many of the predictors used in risk modeling are the “structure” elements described within Donabedián’s model. Unfortunately, the only outcome variable available from the CCORP dataset is ‘operative mortality’, yielding wide gaps in other important quality outcome assessment areas.

Chapter 5: Findings

Results obtained from the isolated CABG surgery data provided answers to the research questions framed by the "structures" and "outcomes" concept within Donabedián's quality of care model. The goal is to see if the results demonstrate health and healthcare disparities between race (Asians and Caucasians), genders, and between hospital with high and low surgery volumes. The study's results are displayed in a set of 8 tables: Tables 5.1, 5.2a and 5.2b are results from the GEE models related to the clinical characteristics as outcomes for the model, adjusted to race and genders. Tables 5.1 gives the comparison of demographic and clinical characteristics between Asians and Caucasians, and Tables 5.2a and 5.2b compare the same set of characteristics between genders in the two racial groups. Tables 5.3 and 5.4 are multivariate GEE models for mortality. Table 5.3 gives two multivariate GEE models (a full model containing 26 predictors, and a reduced model containing 19 predictors) for mortality, and Table 5.4 gives a direct comparison between Asians and Caucasians for each of the 19 predictors. Tables 5.5 to 5.7 list mortality results on the race and hospital volume relationships. Table 5.5 compares the multivariate GEE models for operative mortality in Asians and Caucasians using 26 predictors and 19 predictors, whereas Table 5.6 compares the unadjusted and risk-adjusted mortality of Asians and Caucasians between the high- and low-volume hospital groups. Table 5.7 is another multivariate GEE model of 28 predictors, including hospital volume and the interaction term of 'race*hospital volume'.

A general description of the sample

The CCORP-PDD data contain a total of 57,316 patients undergoing isolated CABG surgery for the three year period between 2003 and 2005. The extracted data subset contains a total of 48,464 patients: 5,332 (9.30% of the total dataset) Asians and 43,132 (75.3% of the total dataset) Caucasians. Females contributed to about a quarter of the CABG surgery volume within both racial groups: 1,469 Asian females (27.6% of Asians) and 10,894 Caucasian females (25.3% of Caucasians).

Specific findings

- *On Donabedián's 'structures' relating to CABG surgery:*

Research question 1: Did preoperative characteristics differ between Asians and Caucasians presenting for CABG surgery?

Findings on preoperative characteristics by race

Using the GEE method, each clinical characteristic was examined as a dependent variable, with race as the independent variable and adjusting for the clustering effect by using the hospital ID. This analysis helped to check out the extent of influence of the dependency of hospitals on each of the clinical characteristics by race. The within cluster association [intraclass correlation (ICC)] of the effect of different hospitals on these clinical characteristics were found to be small, e.g. only 2.7% for age, but still needed to be taken into consideration due to the large sample size. These findings helped to justify using statistical tools that can account for the clustering effect of hospitals.

General features. Overall, Asians were ~1.4 years younger than Caucasians upon presentation for surgery, and ~17% less likely than Caucasians to present for surgery on an emergency or salvage status. Asian patients undergoing CABG surgery were ~1.3 times more likely to have 3 or more vessel coronary artery disease compared to Caucasians. For the body mass index (BMI), Asians were ~2 times more likely than

Caucasians to have very low BMI (<18.5), and ~70% less likely than Caucasians with a very large BMI (>40.0) (Table 5.1).

Chronic disease. Compared with Caucasians, Asians had more certain types of chronic illnesses than Caucasians upon presentation for surgery, especially renal disease. Their mean serum creatinine level estimate was, on average, ~0.18 mmol/L higher than that of Caucasians, and Asians going for CABG surgery were more likely to be on dialysis treatment (OR 2.2). They also had more diabetes (OR 1.6). On the other hand, they were ~30% less likely to have had immunosuppressive therapy, and ~25% less likely to have chronic lung disease (Table 5.1).

Cardiovascular disease profiles. Asians were more likely than Caucasians to have hypertension (OR 1.6), cerebrovascular accidents (OR 1.2), mitral insufficiency (OR 1.1), and congestive heart failure (OR 1.1). In contrast, they had a ~1% higher ejection fraction, and were ~40% less likely to have peripheral vascular disease, ~30% less likely to have arrhythmias, ~15% less likely to have had myocardial infarctions, and ~13% less likely to have left main coronary artery blockages >50% (Table 5.1).

Previous coronary interventions. Asians, compared to Caucasians, were about ~30% less likely than Caucasians to have had any previous percutaneous coronary interventions (PCIs), and only ~50% as likely to have had any previous CABG surgery for both the ‘on-pump’ or ‘off-pump’ types. ‘Off-pump’ surgery is a relative new surgical technique within the history of CABG surgery, and so the total numbers of previous off-pump CABG surgery were low in both groups. But even so, over twice as many Caucasians (1.0%) had off-pump CABG surgery as compared to Asians (0.4%) (Table 5.1).

Table 5.1. Univariate GEE analyses of clinical characteristics by race - CABG surgery in California (2003-2005)

(5,332 Asians, 43,132 Caucasians)

Characteristics	Asian	Caucasian	Estimate* or OR	P-values	95% Confidence Intervals	Standard error estimates
Patient age (years), mean	66.3	67.6	–1.23	<.001	–1.90 – (–.56)	.33
Preop creatinine level (mmol/L), mean	1.35	1.16	.19	<.001	.15 – .23	.02
Ejection fraction (%), mean	53.8%	53.1%	.79	.004	.25 – 1.34	.27
Body mass index – >40.0 kg/m^2	1.2%	3.6%	.32	<.001	.24 – .42	
Body mass index – <18.5 kg/m^2	1.8%	0.8%	2.22	<.001	1.73 – 2.84	
Surgery status – Emergency/salvage	4.7%	5.9%	.83	.001	.74 – .93	
Hypertension	85.1%	78.3%	1.6	<.001	1.52 – 1.75	
Diabetes mellitus	49.7%	36.0%	1.63	<.001	1.54 – 1.74	
Dialysis	4.7%	2.0%	2.18	<.001	1.89 – 2.54	
Peripheral vascular disease	9.1%	14.3%	.60	<.001	.54 – .67	
Immunosuppressive treatment	1.5%	1.9%	.73	.013	.57 – .94	
Cerebrovascular disease	11.9%	12.9%	.93	.137	.85 – 1.02	
Cerebrovascular accidents	8.9%	7.6%	1.18	.004	1.06 – 1.32	
Chronic lung disease	14.0%	18.5%	.74	<.001	.67 – .82	
Arrhythmias	8.6%	10.6%	.69	<.001	.63 – .76	

*These were ICC adjusted results. For the OR test, Caucasian is the control. The mean was used for continuous variables and OR for dichotomous variables.

Characteristics		Asians	Caucasians	OR	P-Value	95% Confidence Intervals
Prior PTCA		14.0%	20.1%	.69	<.001	.62 – .76
Myocardial Infarction		43.2%	48.0%	.86	<.001	.80 – .93
Cardiogenic shock		2.4%	2.3%	1.00	.975	.84– 1.20
Congestive heart failure		18.9%	16.9%	1.09	.027	1.01 – 1.18
Previous CABGs requiring CPB		2.4%	5.1%	.50	<.001	.43 – .58
Previous CABGs without CPB		.4%	1.0%	.52	<.001	.38 – .73
Ejection fraction <30%		9.7%	9.7%	.98	.742	.85 – 1.12
Left main >50%		24.7%	26.6%	.87	<.001	.80 – .95
3 or more diseased coronary vessels		80.2%	77.9%	1.27	<.001	1.17 1.36
Mitral insufficiency		22.1%	21.0%	1.08	.012	1.02 – 1.19
NYHA	Class 1	20.5%	17.9%	.82	.056	.67 – 1.01
	Class 2	24.7%	22.9%			
	Class 3	31.6%	31.2%			
	Class 4	23.2%	28.0%			
Use of internal mammary artery (graft)		88.7%	88.5%	1.02	.723	.93 – 1.11
Operative mortality		3.13%	3.01%	1.02	.788	.85 – 1.23

Clinical characteristics with no significant difference between Asians and Caucasians. The following clinical characteristics, however, did not show any significant difference between these two groups of patients: History of cardiovascular disease, cardiogenic shock, ejection fraction <30%, and New York Heart Association classification for angina.

Research question 2: How did preoperative characteristics differ by race (Asians versus Caucasians) within genders, and by genders within race?

Findings on preoperative characteristics by race within genders and genders within race

Results from the GEE models for each of the clinical characteristics by race and gender with 'race', 'gender', and the interaction term 'race*gender', along with post estimation statements for the interaction term, were as follows:

General features. Asian females, averaged ~68 years old, were ~4 years older than Asian males, and ~.8 years younger than Caucasian females upon presentation for CABG surgery. In contrast, Asian males, averaged ~64.5 years old, were ~1.6 years younger than Caucasian males. For both Asians and Caucasians, females undergoing CABG surgery were ~30% less likely than their corresponding male counterpart to have multivessel coronary artery disease. However, within the respective genders, Asians were ~1.3 times more likely than Caucasians to have multivessel coronary disease (Table 5.2b). Asian females were ~34% less likely than Caucasian females to have the emergency/salvage type of CABG surgery (Table 5.2b). The overall interaction between race and gender was statistically significant for patients with a very large BMI (>40) (p=.05), but not patients with a very low BMI (<18.5) (p=.73). Both Asian females and males were >2 times more likely than their Caucasian counterparts to have a very low

BMI (<18.5), and females were >3 times more likely than Asian and Caucasian males to have a very low BMI (Table 5.2b). For BMI >40, there was also a higher proportion of females than males in both racial groups respectively (~1.2 times in Asians, and ~2 times in Caucasians). On the other hand, within respective genders, Asians were less likely than their Caucasian counterpart to have a BMI >40: ~60% less likely in Asian males (than Caucasian males) and ~70% less likely in Asian females (than Caucasian females) (Table 5.2b).

Chronic diseases. The chronic disease characteristics of patients upon presentation for CABG surgery were also quite significantly different between the race-gender group combinations. Compared to Asian males, Asian females seemed to have a worse clinical profile in several types of chronic diseases: They were more like to have dialysis (OR 1.8), diabetes (OR 1.7), and immunosuppressive treatment (OR 1.7) (Table 5.2b).

Comparing to the Caucasian females, Asian females' last preoperative creatinine levels were ~.21 mmol/L higher on average, and they were ~2.7 times more likely to be on renal dialysis and ~1.8 times more likely to have diabetes (Tables 5.2a and 5.2b).

Comparing the Caucasian males, Asian males' last preoperative creatinine levels were ~.16 mmol/L higher on average, about twice more likely to be on renal dialysis, and ~1.6 times more likely to have diabetes (Tables 5.2a and 5.2b).

Cardiovascular disease profiles. Compared to Asian males presenting for CABG surgery, Asian females were more likely to have hypertension (OR 2.0), congestive heart failure (OR 1.4), peripheral vascular disease (OR 1.3), cerebrovascular accidents (OR 1.2), mitral insufficiency (OR 1.2), cardiovascular disease (OR 1.2), and angina (OR 1.2) (Table 5.2b).

Compared to Caucasian females, Asian females were 1.7 times more likely to have hypertension upon presenting for CABG surgery (Table 5.2b). Compared to Caucasian males, Asian males were ~1.4 times more likely to have hypertension, and ~1.3 times more like to have had a cerebrovascular accident (Table 5.2b).

Previous coronary interventions. Asian females were about >40% less likely than Caucasian females to have had any percutaneous coronary interventions (PCIs) done prior to the CABG surgery. Asian males were about >23% less likely than Caucasian males to have had any PCIs done prior to the CABG surgery (Table 5.2b).

Compared with Asian males, Asian females were half as likely to have had a previous CABG surgery with cardiopulmonary bypass, and ~66% less likely to have had a previous CABG surgery without cardiopulmonary bypass. Compared with Caucasian females, Asian females were ~80% less likely to have had a previous CABG surgery without cardiopulmonary bypass. Asian males, compared to Caucasian males, were ~56% less likely to have had any previous CABG surgeries with cardiopulmonary bypass, and ~36% less to have had a previous CABG surgery without cardiopulmonary bypass (Table 5.2b).

Table 5.2a. GEE analyses of clinical characteristics by race and gender for continuous outcome variables

(5332 Asians: 3,863 male, 1,469 females / 43,132 Caucasians: 32,238 males, 10,894 females)

Outcome variables (Continuous)	Comparison categories	Estimate (in years)	Standard error	Comparison categories	OR* Estimate	95% Confidence interval	P-value
Age	Asian male	64.4	.3	Gender within Asians	3.82	3.04 – 4.61	<.001
	Asian female	68.2	.5	Gender within Caucasians	3.00	2.67 – 3.34	<.001
	Caucasian male	66.1	.2	Race within males	–1.64	–2.23 – (–1.47)	<.001
	Caucasian female	69.1	.2	Race within females	–.82	–1.74 – .10	.081
Last preoperative creatinine level	Asian male	1.39	.02	Gender within Asians	–.07	–.14 – .00	.065
	Asian female	1.32	.03	Gender within Caucasians	–.12	– .14 – (–.10)	<.001
(mmol/L)	Caucasian male	1.22	.01	Race within males	.17	.13 – .20	<.001
	Caucasian female	1.10	.01	Race within females	.22	.15 – .28	<.001
Ejection fraction	Asian male	52.3%	.4	Gender within Asians	3.09	2.22 – 3.96	<.001
	Asian female	55.4%	.5	Gender within Caucasians	2.72	2.38 – 3.06	<.001
	Caucasian male	51.7%	.3	Race within males	.60	.01 – 1.20	.047
	Caucasian female	54.4%	.4	Race within females	.98	.18 – 1.78	.016

**For OR: Female=1, Asian=1, Caucasian males are designated as the control group)*

Table 5.2b. GEE analyses of clinical characteristics by race and gender

(5332Asians: 3,863 male, 1,469 females / 43,132 Caucasians: 32,238 males, 10,894 females) [same q as 5.2a]

Comparison categories	P-value for 'race*gender'	Comparison categories	OR Estimate	95% C.I.	P-value
Body mass index – <18.5 kg/m^2	.902	Gender within Asians	3.29	2.16 – 5.03	<.001
		Gender within Caucasians	3.03	2.43 – 3.78	<.001
		Race within males	2.08	1.49 – 2.92	<.001
		Race within females	2.27	1.58 – 2.92	<.001
Body mass index – >40.0 kg/m^2	.056	Gender within Asians	1.21	.70 – 2.07	.307
		Gender within Caucasians	2.08	1.89 – 2.29	<.001
		Race within males	.22	.30 - .52	<.001
		Race within females	.38	.14 - .36	<.001
Surgery status_ Emergency/ Salvage	.041	Gender within Asians	.88	.68 – 1.15	.368
		Gender within Caucasians	1.19	1.09 – 1.30	<.001
		Race within males	.90	.77 – 1.04	.143*
		Race within females	.67	.54 - .83	<.001
Hypertension	.119	Gender within Asians	2.01	1.54 – 2.63	<.001
		Gender within Caucasians	1.63	1.53 – 1.74	<.001
		Race within males	1.39	1.26 – 1.54	<.001
		Race within females	1.72	1.35 – 2.18	<.001
Diabetes mellitus	.077	Gender within Asians	1.65	1.45 – 1.88	<.001
		Gender within Caucasians	1.47	1.39 – 1.55	<.001
		Race within males	1.58	1.47 – 1.70	<.001
		Race within females	1.78	1.56 – 2.02	<.001
Dialysis	.012	Gender within Asians	1.78	1.41 – 2.24	<.001
		Gender within Caucasians	1.31	1.14 – 1.49	<.001
		Race within males	1.95	1.65 – 2.31	<.001
		Race within females	2.66	2.12 – 3.32	<.001
Peripheral vascular disease	.345	Gender within Asians	1.34	1.06 – 1.69	.015
		Gender within Caucasians	1.20	1.13 – 1.28	<.001
		Race within males	.58	.51 - .65	<.001
		Race within females	.64	.53 - .78	<.001

Comparison categories	P-value for race*gender	Comparison categories	OR Estimate	95% C.I.	P-value
Immunosuppressive therapy	.372	Gender within Asians	1.74	1.09 – 2.76	.019
		Gender within Caucasians	1.38	1.18 – 1.62	<.001
		Race within males	.67	.49 - .91	.011
		Race within females	.84	.56 - .1.25	.388
Cardiovascular disease	.234	Gender within Asians	1.24	1.03 – 1.49	.025
		Gender within Caucasians	1.39	1.31 – 1.48	<.001
		Race within males	.96	.86 – 1.07	.465
		Race within females	.85	.72 – 1.01	.063
Cerebrovascular accident	.018	Gender within Asians	1.04	.83 – 1.30	.737
		Gender within Caucasians	1.37	1.26 – 1.49	<.001
		Race within males	1.27	1.12 – 1.45	<.001
		Race within females	.97	.79 – 1.18	.741
Chronic lung disease	<.001	Gender within Asians	.75	.62 - .90	.002
		Gender within Caucasians	1.11	1.02 – 1.20	.016
		Race within males	.82	.74 - .90	<.001
		Race within females	.55	.44 - .68	<.001
Arrhythmias	.788	Gender within Asians	.90	.69 – 1.17	.426
		Gender within Caucasians	.93	.86 – 1.01	.100
		Race within males	.78	.63 - .78	<.001
		Race within females	.67	.53 - .86	.002
History of percutaneous coronary interventions	.009	Gender within Asians	.77	.65 - .91	.002
		Gender within Caucasians	.96*	.91 – 1.02	.174
		Race within males	.73	.66 - .80	<.001
		Race within females	.58	.48 - .70	<.001
History of myocardial infarction	.044.	Gender within Asians	.86	.77 - .97	.016
		Gender within Caucasians	.98*	.93 – 1.03	.49
		Race within males	.89	.82 - .97	.007
		Race within females	.78	.70 - .88	<.001

Comparison categories	P-value for race*gender	Comparison categories	OR Estimate	95% C.I.	P-value
Cardiogenic shock	.206	Gender within Asians	1.00	.70 – 1.44	.980
		Gender within Caucasians	127	1.11 – 1.45	<.001
		Race within males	1.07	.86 – 1.34	.538
		Race within females	.85	.64 – 1.13	.266
Congestive heart failure	.831	Gender within Asians	1.42	1.25 – 1.61	<.001
		Gender within Caucasians	1.44	1.36 – 1.53	<.001
		Race within males	1.09	1.00 – 1.20	.055
		Race within females	1.08	.96 – 1.21	.219
Previous CABG surgery – cardiopulmo-nary bypass	.291	Gender within Asians	.50	.32 - .77	.002
		Gender within Caucasians	.63	.56 - .71	<.001
		Race within males	.53	.45 - .62	<.001
		Race within females	.42	.27 - .64	<.001
Previous CABG surgery – no cardiopulmo-nary bypass	.007	Gender within Asians	.34	.15 - .76	.008
		Gender within Caucasians	1.06	.92 – 1.22	.426
		Race within males	.64	.45 - .91	.014
		Race within females	.21	.10 - .44	<.001
Ejection fraction <30%	.397	Gender within Asians	.66	.54 - .81	<.001
		Gender within Caucasians	.73	.67 - .79	<.001
		Race within males	1.00	.87 – 1.15	.990
		Race within females	.91	.73 – 1.14	.418
Left main artery stenosis >50%	.454	Gender within Asians	.96	.84 – 1.10	.553
		Gender within Caucasians	1.01	.96 – 1.07	.612
		Race within males	.88	.81 - .96	.005
		Race within females	.84	.73 - .96	.013
Diseased coronary vessels 3 or more	.630	Gender within Asians	.72	.62 - .83	<.001
		Gender within Caucasians	.69	.66 - .72	<.001
		Race within males	1.25	1.14 – 1.38	<.001
		Race within females	1.30	1.15 – 1.47	<.001
Mitral insufficiency	.155	Gender within Asians	1.19	1.05 – 1.35	.005
		Gender within Caucasians	1.32	1.25 – 1.39	<.001
		Race within males	1.03	.91 – 1.17	.651
		Race within females	1.14	1.04 – 1.24	.005

Comparison categories	P-value for race*gender	Comparison categories	OR Estimate	95% C.I.	P-value
NYHA	<.001	Gender within Asians	1.18	1.03 – 1.35	.018
		Gender within Caucasians	1.33	1.25 – 1.42	<.001
		Race within males	.84*	.69 – 1.02	.081
		Race within females	.74	.57 - .97	.027
Use of internal mammary artery as graft	.539	Gender within Asians	.66	.55 - .79	<.001
		Gender within Caucasians	.62	.58 - .67	<.001
		Race within males	1.00	.90 – 1.11	.966
		Race within females	1.06	.90 – 1.25	.465
Operative mortality	.070	Gender within Asians	1.37	.99 – 1.91	.057
		Gender within Caucasians	1.86	1.65 – 2.08	<.001
		Race within males	.84	.66 – 1.07	.154
		Race within females	1.13	.90 – 1.43	.297

Variables that showed no difference between the racial-gender subgroups.

The following clinical characteristics did not show any statistically significant difference in the race-gender subgroup comparisons in the patients presenting for CABG surgery:

No difference in Asians between females and males: The last preoperative creatinine level, surgery status of the emergency/salvage type, morbid obesity with BMI >40, history of cerebrovascular accidents, arrhythmias, left main coronary artery stenosis >50%, and cardiogenic shock.

No difference in females between Asians and Caucasians: Immunosuppressive treatment, cardiovascular disease, cerebrovascular accident, congestive heart failure, cardiogenic shock, mitral insufficiency, and ejection fraction <30%.

No difference in males between Asians and Caucasians: Surgery status of emergency/salvage, cardiovascular disease, congestive heart failure, cardiogenic shock, ejection fraction <30%, and a history of immunosuppressive therapy.

Research question 3: Were there differences in the proportion of Asians having CABG surgery in the high-volume versus the low-volume surgery centers/hospitals?

Findings on surgery volume for Asians between high and low volume hospitals

There were 122 hospitals performing CABG surgery in California between 2003 and 2005. A wide range was found in the distribution of hospital case volumes, ranging from 5 to 2,499 CABG surgery cases per hospital over the three year period. Six low-volume hospitals only performed a combined total of over 1,000 cases for the three years, and yet, a quarter of the total number of all CABG surgery cases (>14,000 cases) were performed in only 9 high-volume hospitals for the same period. These 122 hospitals were split into two groups at ~50th percentile cut-point at 300 surgeries per three years (low volume: ≤300 cases, high volume: >300 cases).

Table 5.3 shows that a significantly lesser percentage of Asians (73%) had their CABG surgery done in high-volume hospitals as compared to Caucasians (81%), and correspondingly, a significantly higher percentage of Asians had CABG surgery done in low-volume hospitals (~27%) as compared to Caucasians (~19%).

Table 5.3. Proportion of Asian and Caucasian patients in high and low surgery volume groups

Hospitals groups by surgery volumes	Number of hospitals	Asians (%)	Caucasians (%)	P value	Estimated average % of Asians within each hospital group	SD	P value
Low volume hospital group (≤300 cases) (9,614 patients)	56	1,456 (27.3%)	8,158 (18.9%)	<.001	16.5%	.18	.026
High volume hospital group (>300 cases) (38,850 patients)	66	3,876 (72.7%)	34,974 (81.1%)		10.4%	.11	

* *One of the hospitals, San Jose Medical Center, is not present during the entire 3-year period*

Using the independent sample t-test, the means of the proportions of Asians in the high and low volume hospital groups were also compared. Within the low volume hospital group, the estimated average percentage of Asians was ~16.5%, whereas within the high volume hospital group, the estimated average percentage of Asians was 10.4% (p = .026).

- *On Donabedián's 'outcomes' – Unadjusted operative mortality:*

Research question 4: Were there any differences in the unadjusted operative mortality between Asians and Caucasians?

Findings on unadjusted operative mortality between races

Using univariate GEE models, with only the 'race' variable in the model, no significant difference could be found in the unadjusted operative mortality rates between

Asians (3.1%) and Caucasians (3.0%, $p = .788$), after adjusting for the clustering effect of hospitals (Table 5.1).

Research question 5: Were there any differences in the unadjusted operative mortality between genders within race, and between races within genders respectively?

Findings on unadjusted operative mortality between race and gender subgroups

There was no significant difference in the unadjusted operative mortality rates in race with genders ($p = .154$ for between Asian and Caucasian females, $p = .297$ for between Asian and Caucasian males). Within Asians, females were ~1.4 times more likely to die from surgery compared to males, and the result was marginally significant ($p = .057$). (Table 5.2b). Within Caucasians, females were ~1.9 times more likely to die from surgery compared to males, and the result was statistically significant ($p = <.01$).

Research question 6: Were there any differences between Asians and Caucasians in the unadjusted operative mortality rates when they have surgery between the high- and low-volume hospital groups?

Findings on unadjusted operative mortality between Asians and Caucasians in the low-volume hospitals:

Table 5.4 gives the comparison of the unadjusted mortality results from the GEE model and it shows no difference in the unadjusted operative mortality between the high- and low-volume hospital groups within Asians, and also no difference between Asians and Caucasians in the high-volume as well as the low-volume hospital groups respectively. The only significant unadjusted mortality difference between the high- and low-volume hospital groups was only found within Caucasians.

Table 5.4. GEE analyses of unadjusted and risk-adjusted operative mortality of Asians compared to Caucasians in high- and low-volume hospital groups

Operative mortality	Hospital groups	P Value	OR	95% Confidence Intervals
Unadjusted mortality	Hospital volume within Asians	.128	1.32	.92 – 1.89
	Hospital volume within Caucasians	.013	1.24	1.05 – 1.47
	Race within low volume hospitals	.953	.99	.79 – 1.24
	Race within high volume hospitals	.714	1.06	.79 – 1.42
Risk-adjusted mortality	Hospital volume within Asians	.094	1.37	.94 – 1.98
	Hospital volume within Caucasians	.050	1.22	1.00 – 1.48
	Race within low volume hospitals	.257	1.22	0.87 – 1.72
	Race within high volume hospitals	.492	1.09	0.86 – 1.38

For OR: Volume <300 = 1; Asian=1

- *On Donabedián's 'outcomes' – Risk-adjusted operative mortality:*

Research question 7: After adjusting the clinical predictors in the model, were there any differences in the risk-adjusted mortality between Asians and Caucasians?

Findings on risk-adjusted operative mortality between Asians and Caucasians

The 26 predictors included in the full model were all the clinical elements in the CCORP dataset: Race (Asian/Caucasian), age (continuous), body mass index (<18.5, 18.5 – 40, and >40), last preoperative serum creatinine level (continuous), hypertension (yes/no), dialysis (yes/no), an emergency-salvage surgery status (yes/no), peripheral vascular disease (yes/no), cardiovascular disease (yes/no), time of cerebrovascular accident (≤ 6 hours, > 6 hours) in relation to time of surgery, diabetes, chronic lung disease (mild, moderate, severe levels), immunosuppressive therapy (yes/no), arrhythmias (yes/no), New York Heart Association classification (Class I, II, III, and IV), time of myocardial infarction (<6 hours, 6-24 hours, 1-7 days, 8-21 days, >21 days) in relation to time of surgery, time of percutaneous coronary intervention (≤ 6 hours, > 6 hours) in relation to time of surgery, cardiogenic shock (yes/no), congestive heart failure (yes/no), ejection fraction<30% (yes/no), previous CABG surgery with or without cardiopulmonary bypass (yes/no), percentage of stenosis in the left main coronary artery>50% (yes/no), number of diseased coronary arteries ≥3 (yes/no), and mitral insufficiency (yes/no). These variables, deemed clinically important, were chosen for the CABG mortality model by an expert clinical panel of physicians. After adjusting for the confounding effects of all the clinical predictors, and also accounting for the clustering hospital effect, no difference in operative mortality was found between Asians and Caucasians (OR = 1.15, p = .17) undergoing CABG surgery (Table 5.5).

Table 5.5. Multivariate GEE models for operative mortality in Asians and Caucasians

Level 1 Parameters		Full Model with 26 predictors			Reduced Model with 19 predictors		
		P Value	Estimate/ Odds ratio	95% Confidence Intervals	P Value	Estimate/ Odds ratio	95% Confidence Intervals
Race	Caucasians	Reference			Reference		
	Asians	.191	1.14*	.94 — 1.39	.132	1.15*	.96 — 1.40
Gender	Male	Reference			Reference		
	Female	<.001	1.56	1.37 — 1.79	<.001	1.57	1.38— 1.79
Age		<.001	1.06	1.05 — 1.07	<.001	1.06	1.05 — 1.07
Body mass index (kg/m^2)	18.5–39.9	Reference			Reference		
	<18.5	0.002	1.86	1.25 — .2.75	.002	1.85	1.26 — 2.71
	>40	0.032	1.34	1.03 — 1.76	.026	1.37	1.04 — 1.80
Emergency/salvage status		<.001	1.80	1.43— 2.27	<.001	1.80	1.43 — 2.28
Last preoperative creatinine level (mg/dl)		<.001	1.25	1.17 — 1.33	<.001	1.30	1.25 – 1.34
Hypertension		.753	1.03*	.87 — 1.21	—	—	—
Dialysis		.205	1.34*	.85 — 2.10	—	—	—
Peripheral artery disease		<.001	1.45	1.27 — 1.67	<.001	1.53	1.34 — 1.74
Cardiovascular disease		.117	1.17*	.96 — 1.43	—	—	—
Cerebrovascular accident	None	Reference			—	—	—
	Remote (>2 wks)	.571	1.08*	.83 — 1.39	—	—	—

	Full Model with 26 predictors			Reduced Model with 19 predictors		
Level 1 Parameters	P Value	Estimate/ Odds ratio	95% Confidence Intervals	P Value	Estimate/ Odds ratio	95% Confidence Intervals
Recent (≤2 wks)	.426	1.38*	.62 — 3.08	—	—	—
Diabetes mellitus	.124	1.11*	.97 — 1.27	—	—	—
Chronic lung disease						
None	Reference			Reference		
Mild	.129	1.15*	.96 — 1.37	.117	1.15*	.97 — 1.36
Moderate	.010	1.30	1.07 — 1.59	.005	1.32	1.09 — 1.61
Severe	<.001	2.05	1.6 — 2.62	<.001	2.05	1.60 — 2.61
Previous surgery with cardiopulmonary bypass						
None	Reference			Reference		
1 or more	<.001	1.60	1.30 — 1.97	<.001	1.63	1.34 — 1.98
Previous surgery without cardiopulmonary bypass						
None	Reference			—	—	—
1 or more	.985	.99*	.54 — 1.83	—	—	—
Ejection fraction <30%	<.001	1.68	1.41 — 1.99	<.001	1.62	1.37 — 1.93
Left main >50% stenosis	.930	1.00*	.90 — 1.12	—	—	—
No. of diseased vessels						
0/1/2	Reference			Reference		
3 or more	<.001	1.50	1.29 — 1.75	<.001	1.50	1.30 — 1.74

Level 1 Parameters	Full Model with 26 predictors			Reduced Model with 19 predictors		
	P Value	Estimate/ Odds ratio	95% Confidence Intervals	P Value	Estimate/ Odds ratio	95% Confidence Intervals
Mitral insufficiency						
None	Reference			Reference		
Trivial	.433	.92*	.76 — 1.13	.538	.94*	.78 — 1.14
Mild	.878	.98*	.83 — 1.18	.866	1.02*	.85 — 1.21
Moderate	.006	1.38	1.10 — 1.74	.003	1.40	1.12 — 1.76
Severe	.585	1.15*	.70 — 1.91	.620	1.14*	.68 — 1.88
Immunosuppressive treatment	.001	1.61	1.20 — 2.15	.001	1.61	1.21 — 2.15
Arrhythmia Type						
None	Reference			Reference		
Atrial fib/flutter	<.001	1.52	1.29 — 1.80	<.001	1.55	1.31 — 1.83
Heart block	.007	1.48	1.11 — 1.96	.004	1.51	1.14 — 1.20
Sustained VT/VF	<.001	2.21	1.72 — 2.84	<.001	2.20	1.73 — 2.78
NYHA Class I	Reference			Reference		
NYHA Class II	.0542	1.08*	.85 — 1.37	.445	1.10	.86 — 1.41
NYHA Class III	.017	1.29	1.05 — 1.59	.009	1.32	1.07 — 1.63
NYHA Class IV	<.001	1.79	1.42 — 2.25	<.001	1.86	1.48 — 2.34
Myocardial infarction						
None	Reference			Reference		
>21d ago	.106	1.17	.97 — 1.41	.075	1.18	.98 1.42
8–20d ago	.011	1.40	1.08 — 1.81	.006	1.42	1.11 — 1.81

	Full Model with 26 predictors			Reduced Model with 19 predictors		
Level 1 Parameters	P Value	Estimate/ Odds ratio	95% Confidence Intervals	P Value	Estimate/ Odds ratio	95% Confidence Intervals
Myocardial infarction						
1–7d ago	<.001	1.39	1.18 — 1.63	<.001	1.40	1.19 — 1.64
>6 but within 24h	<.001	1.68	1.30 — 2.18	<.001	1.74	1.35 — 2.25
Within 6h	.002	1.83	1.25 — 2.67	.002	1.83	1.26 — 2.67
Cardiogenic shock	<.001	2.45	1.94 — 3.09	<.001	2.50	1.99 — 3.13
Congestive heart failure	<.001	1.35	1.17 — 1.56	<.001	1.37	1.18 — 1.59
Interval from PCI to Surgery None	Reference			Reference		
<=6 hours	.003	1.25	1.08 — 1.44	.001	1.26	1.09 — 1.45
>6 hours	.004	1.68	1.17 — 2.39	.009	1.59	1.12 — 2.26

* *Statistically insignificant*

Other findings from the GEE model

From the multivariate GEE model (Table 5.5), after adjusting for other variables and the clustering effect of individual hospitals, the clinical variables that contribute 1.5 times or more to operative mortality (in descending order) include patients who were in cardiogenic shock (O.R. 2.4); had ventricular tachycardia or ventricular fibrillation (O.R. 2.2); with severe chronic lung disease (O.R. 2.1); had a very low BMI <18.5 (O.R. 1.9); with an emergency/salvage surgery status (OR 1.8), with a New York Heart Association class IV (OR 1.8), had a myocardial infarction <6 hours from the time of surgery (OR 1.8), or <24 hours but >6 hours from the time of surgery (OR 1.7), a percutaneous coronary intervention in ≤6 hours, on immunosuppressive therapy (O.R. 1.7); an ejection fraction of <30% (O.R. 1.7), with a past history of CABG surgery on cardiopulmonary bypass (O.R. 1.6); being female (O.R. 1.5), or had atrial fibrillation (O.R. 1.5) or multivessel coronary disease (O.R. 1.5) (Table 5.5).

Continuous variables in the model include age and serum creatinine. For every year's age increase, the operative mortality rate from CABG surgery is increased by 6%, and having one unit (mmol) increase in the serum creatinine also significantly increases mortality by 1.25 times (Table 5.5).

In summary, 29 of the independent predictor variables in the model (including sub-categories) deemed clinically important were found to have a statistically significant difference on mortality, except for the following 17 predictors: race, hypertension, diabetes, dialysis, mild chronic lung disease, cardiovascular disease, cerebrovascular accidents regardless of timing of occurrence, mild chronic lung disease, cardiogenic shock, myocardial infarction >21 days, previous CABG surgery without cardiopulmonary bypass, left main artery disease >50% occlusion, New York Heart Association Class II, and trivial, mild, and severe mitral insufficiency.

Research question 8: After adjusting the clinical predictors in the model, did the risk-adjusted operative mortality differ between the genders by race?

Findings on the risk-adjusted operative mortality between genders by race

From the GEE model that includes risk adjusting of the 26 predictors and clustering effect of hospitals, the inclusion of the interaction term on race by gender yielded no statistical significance ($p = .132$) in the full model. When the dataset was split into Asians and Caucasian subsets, and the full GEE model was re-run, unfortunately, the Asian model did not converge, thus forcing the use of a reduced model which excluded the predictors that were found to be non-significant. After the model has been reduced (Table 5.5), the model for Asians was then able to converge.

Table 5.6 shows the multivariate reduced GEE model for mortality for both Asians and Caucasians as a side-by-side comparison. Asian females were not more likely to die from CABG surgery when compared to Asian males, after adjusting for the clinical predictors in the model and the hospital clustering effect (OR 1.2, $p=.452$).

Table 5.6. Multivariate GEE reduced model for operative mortality in Asians and Caucasians (with 19 predictors))

	Asian Model			Caucasian Model		
Level 1 Parameters	P Value	Estimate/ Odds ratio	95% Confidence Intervals	P Value	Estimate/ Odds ratio	95% Confidence Intervals
Gender Male	Reference			Reference		
Female	.452	1.16	.79 — 1.70	<.001	1.64	1.44— 1.87
Age	<.001	1.05	1.03 — 1.07	<.001	1.06	1.05 — 1.07
Body mass index (kg/m^2)						
18.5–39.9	Reference			Reference		
<18.5	0.11	1.87	.87 — .4.05	.004	1.90	1.22 — 2.95
>40	0.348	2.08	.43 — 9.58	.050	1.33	1.00 — 1.78
Emergency/salvage status	.004	2.91	1.41— 6.04	<.001	1.69	1.34 — 2.13
Last preoperative creatinine level (mg/dl)	<.001	1.16	1.06 — 1.25	<.001	1.30	1.25 – 1.34
Peripheral artery disease	.083	1.51	.95 — 2.48	<.001	1.53	1.33 — 1.76
Chronic lung disease						
None	Reference			Reference		
Mild	.094	.55	.27 — 1.11	.035	1.22	1.01 — 1.47
Moderate	.050	1.78	1.00 — 3.17	.018	1.27	1.04 — 1.55
Severe	.004	2.66	1.38 — 5.15	<.001	2.02	1.58 — 2.60
Previous CABG w CPB						
None	Reference			Reference		
1 or more	.061	2.05	.96 — 4.33	<.001	1.61	1.31 — 1.98
Ejection fraction <30%	.120	1.43	.91 — 2.37	<.001	1.64	1.37 — 1.96

Level 1 Parameters	Asian Model			Caucasian Model		
	P Value	Estimate/ Odds ratio	95% Confidence Intervals	P Value	Estimate/ Odds ratio	95% Confidence Intervals
No. of diseased vessels						
0/1/2	Reference			Reference		
3 or more	.011	1.78	1.14 — 2.77	<.001	1.47	1.25 — 1.72
Mitral insufficiency						
None	Reference			Reference		
Trivial	.518	.78	.37 — 1.64	.755	.97	.79 — 1.19
Mild	.203	1.36	.85 — 2.17	.817	.98	.80— 1.19
Moderate	.327	1.34	.75 — 2.40	.004	1.43	1.12 — 1.83
Severe	.754	.71	.08 — 6.12	.563	1.17	.68 — 2.02
Immunosuppressive treatment	.809	1.19	.28 — 5.05	<.001	1.64	1.23 — 2.21
Arrhythmia Type						
None	Reference			Reference		
Atrial fib/flutter	.54	1.15	.73 — 1.83	<.001	1.59	1.33 — 1.89
Heart block	.297	1.53	.69 — 3.43	.007	1.51	1.12 — 2.04
Sustained VT/VF	<.001	4.58	2.25 — 9.33	<.001	2.00	1.56 — 2.57
NYHA Class I	Reference			Reference		
NYHA Class II	044	2.23	1.02 — 4.87	.985	1.00	.79 — 1.31
NYHA Class III	.030	2.22	1.08 — 4.55	.069	1.24	.98 — 1.55
NYHA Class IV	.015	2.69	1.21 — 6.00	<.001	1.80	1.42 — 2.29
Myocardial infarction						
None	Reference			Reference		
Myocardial infarction	.723	1.09	.67 — 1.77	.077	1.20	.98 — 1.46

Level 1 Parameters	Asian Model			Caucasian Model		
	P Value	Estimate/ Odds ratio	95% Confidence Intervals	P Value	Estimate/ Odds ratio	95% Confidence Intervals
>21d ago						
8–20d ago	.575	1.23	.59 — 2.55	.005	1.46	1.12 — 1.90
1–7d ago	.100	1.45	.94 — 22	<.001	1.39	1.17 — 1.64
>6 but within 24h	.85	1.09	.43 — 2.76	<.001	1.82	1.40 — 2.37
Within 6h	.73	1.25	.35 — 4.45	<.001	1.93	1.33 — 2.80
Cardiogenic shock	154	1.63	.83 — .18	<.001	2.66	2.09 — 3.39
Congestive heart failure	.013	1.88	1.14— 3.07	<.001	1.31	1.12 — 1.52
Interval from Prior PCI to Surgery None	Reference			Reference		
<=6 hours	.06	1.62	.99. — 2.67	.011	1.23	1.05 — 1.44
>6 hours	.84	1.14	.312. — 4.15	.009	1.64	1.13 — 2.38

Research question 9: Were there any differences between Asians and Caucasians in the risk-adjusted mortality between the high- and low-volume hospital groups

Findings on the risk-adjusted operative mortality between Asians and Caucasians in the high- and low-volume hospital groups respectively:

From the multivariate GEE full model on mortality, there was a significant difference between high and low volume hospitals when both racial groups were considered together (OR 1.22, p=.05), but when the Asian race was considered separately with hospital volume, using the interaction term 'race*hospital volume', no significant difference in the risk-adjusted mortality could be found (OR 1.12, p=.570) (Table 5.7). In separately built risk-adjusted models for Asians and Caucasians, there were also no significant differences found in the risk-adjusted mortality between Asians and Caucasians in the high-volume (OR 1.09, p=.492) as well as low-volume (OR 1.22, p=.257) hospital groups respectively , after adjusting for the clinical predictors and the hospital clustering effect (Tables 5.4).

Additional findings on the process indicator in Donabedián's model

The use of internal mammary artery (IMA), a quality measurement for surgery, is the only finding that relates to the process element in Donabedián's model. While no significant difference was found in the use of the IMA as graft conduits for CABG surgery (Table 5.1), there was a significant difference between the Asian genders: Asian females were ~34% less likely than Asian males to receive the IMA graft (Table 5.2)

Table 5.7. Multivariate GEE full model for mortality with race by hospital volume

Level 1 Parameters		P value	OR	95% Confidence Intervals
Race	Caucasians	Reference		
	Asians	.492	1.09	0.86 – 1.38
Gender	Male	Reference		
	Female	<.001	1.57	1.37 – 1.79
Age		<.001	1.06	1.05 – 1.07
Body mass index (kg/m^2)				
	18.5–39.9	Reference		
	<18.5	.002	1.85	1.25 – 2.75
	>40	.027	1.36	1.04 – 1.78
Emergency/salvage status		<.001	1.79	1.42 – 2.26
Last preoperative creatinine level (mg/dl)		<.001	1.25	1.17 1.33
Hypertension		.760	1.03	0.87 – 1.21
Dialysis		.213	1.33	0.85 – 2.10
Previous surgery with cardiopulmonary bypass	None	Reference		
	1 or more	<.001	1.61	1.30 – 1.98
Previous surgery - no cardiopulmonary bypass	None	Reference		
	1 or more	.922	0.97	0.52 – 1.79
Ejection fraction <30%		<.001	1.68	1.42 – 2.00
Left main >50% stenosis		.968	1.00	0.90 1.12
No. of diseased vessels	0/1/2	Reference		
	3 or more	<.001	1.51	1.30 – 1.76
Mitral insufficiency	None	Reference		
Mitral Insufficiency	Trivial	.408	.92	.76 – 1.12
	Mild	.863	.98	.82 – 1.18
	Moderate	.006	1.39	1.10 – 1.74
	Severe	.566	1.16	.70 – 1.93
Arrhythmia Type	None	Reference		
	Atrial fib/flutter	<.001	1.52	1.29 – 1.80
	Heart block	.007	1.47	1.11 – 1.95
	Sustained VT/VF	<.001	2.19	1.70 – 2.82
NYHA Class I		Reference		

Level 1 Parameters		P value	OR	95% Confidence Intervals
NYHA Class II		.461	1.10	.86 – 1.40
NYHA Class III		.011	1.31	1.06 – 1.61
NYHA Class IV		<.001	1.84	1.46 – 2.31
Myocardial infarction	None	Reference		
	>21d ago	.122	1.16	.96 – 1.40
	8–20d ago	.012	1.39	1.07 – 1.79
	1–7d ago	<.001	1.39	1.18 – 1.63
	>6 but within 24h	<.001	1.69	1.30 – 2.18
	Within 6h	.002	1.84	1.26 – 2.69
Cardiogenic shock		<.001	2.43	1.92 – 3.08
Congestive heart failure		<.001	1.35	1.17 – 1.55
Interval from Prior PCI to Surgery	None	Reference		
	<=6 hours	.003	1.25	1.08 1.45
	>6 hours	.004	1.68	1.18 – 2.41
Hospital volume	High	Reference		
	Low	.050	1.22	1.00 – 1.48
Race*Hospital volume	Caucasian	Reference		
	Asian	.570	1.12	.75 – 1.69

Chapter 6: Discussion and Conclusion

In this final chapter, I will start with a recap of each research question and a summary of findings, to be followed with a discussion of the significance of the findings and the limitations of the study, then the theoretical, clinical and research implications and finally, the conclusion.

Research question 1: Did preoperative characteristics differ between Asians and Caucasians presenting for CABG surgery?

Finding: Yes, statistically significant differences were found in the preoperative characteristics between Asian and Caucasian patients who underwent CABG surgery in California. Compared to Caucasians, Asians were younger, had a relatively normal average body mass index and ejection fraction, but have a higher likelihood of multi-vessel disease and chronic illnesses such as hypertension, diabetes, end-stage renal disease requiring dialysis, mitral insufficiency, and with a history of cerebrovascular accidents. Asians were also more likely than Caucasians to have a very low body mass index (<18.5) and less likely to have morbid obesity (BMI >40.0). On the other hand, they were less likely than Caucasians to have had immuno-suppressive therapy, chronic lung disease, peripheral vascular disease, arrhythmias (atrial and ventricular fibrillations and heart blocks), myocardial infarction and left main coronary artery disease. Asians were found to have a less likelihood to have undergone an emergency/salvage type of CABG surgery, had previous interventions, including PTCAs and CABG surgery with, and without, the use of the cardiopulmonary bypass machines. No statistical significant difference was found in the use of the internal mammary artery as a bypass conduit between the two racial groups.

Research question 2: How did preoperative characteristics differ by race (Asians versus Caucasians) between gender, and by gender between races respectively?

Finding: Many of the statistically significant differences found between Asians and Caucasians were found to be contributed mostly by the Asian females, except for age, where Asian females who underwent CABG surgery were found to be about 4 years older than Asian males on average. Compared to Asian males, Asian females were found to have a higher likelihood of multi-vessel disease and chronic illnesses such as hypertension, diabetes, end-stage renal disease requiring dialysis, heart failure, peripheral vascular disease, mitral insufficiency, immunosuppressive therapy. cardiovascular disease, an ejection fraction of <30%, and angina. On the other hand, they were less likely than Asian males to have chronic lung disease, myocardial infarction, underwent an emergency/salvage type of CABG surgery, have had previous interventions, including PTCAs and CABG surgery with and without the use of the cardiopulmonary bypass machines, or use of the internal mammary artery as a bypass conduit.

Research question 3: Were there differences in the proportion of Asians having CABG surgery in the high-volume and the low-volume surgery centers/hospitals?

Finding: Statistically significant differences were found in the distribution of Asians and Caucasians between the high- and low-volume hospital groups. A significantly higher proportion of Asians were found to have the CABG surgery done in the low-volume hospital group.

Research question 4: Were there any differences in the unadjusted operative mortality between Asians and Caucasians?

Finding: No statistically significant difference could be found in the unadjusted operative mortality between Asians and Caucasians.

Research question 5: Were there any differences in the unadjusted operative mortality rates between gender within race, and between races within gender respectively?

Finding: There was a marginal statistically significant difference in the unadjusted operative mortality between Asian females and males. Statistically significant difference could also be found in the unadjusted operative mortality between Caucasian females and males. But no statistically significant differences could be found in the unadjusted operative mortality between Asian females and Caucasian females, or between Asian males and Caucasian males.

Research question 6: Were there any differences between Asians and Caucasians in the unadjusted operative mortality between the high- and low-volume hospital groups?

Finding: No statistically significant differences could be found in the unadjusted operative mortality between Asians and Caucasians in the low volume or high volume hospital groups respectively. There was also no gender differences found between Asian females and Asian males due to hospital volumes. But a statistically significant difference was found between Caucasian females and Caucasian males.

Research question 7: After adjusting for the clinical predictors, were there any differences in the risk-adjusted operative mortality between Asians and Caucasians?

Finding: No statistically significant difference in the operative mortality could be found after risk adjustment.

Research question 8: After adjusting for the clinical predictors, did the risk-adjusted operative mortality differ between the genders by race, and between races within gender respectively?

Finding: The risk-adjusted operative mortality findings were the same as the unadjusted findings above for research question 6. No statistically significant difference could be found except for between Caucasian females and Caucasian males.

Research question 9: Were there any differences between Asians and Caucasians in the risk-adjusted operative mortality between the high- and low-volume hospital groups?

Finding: After risk adjustment, operative mortality was significantly higher in the low volume hospitals when both racial groups were combined together, but not for the Asian group alone.

Significance of findings

Answers derived from the linked clinical CCORP dataset and the administrative PDD have helped to shed some preliminary findings on the health disparity issue of

Asians from a hitherto unexplored angle for those who underwent CABG surgery using CCORP-PDD data from 2003 to 2005 in California. Previous studies on disparities in CABG surgery were done mostly with African Americans (Bridges, Edwards, Peterson, and Coombs, 2000, Gillum, Gillum, and Francis, 1997, Hannan *et al.*, 1999, Gray, Mirvis and Graney, 1998). Except for a handful of studies (Yeo et al., 2007, and Marcin et al., 2008), studies about Asians have mostly come from self-reported data or administrative data sets such as those from the Health Care Utilization Project (HCUP, Becker and Rahimi, 2006). This study's findings provide new insights to Asians with heart disease, especially Asian women, by looking through a subset of those who had CABG surgery.

While findings were not conclusive that health and healthcare disparities exist because the mortality outcome was not significantly different except the marginal significance found between Asian males and Asian females, the race and gender differences found in the preoperative characteristics merit further investigation. The differences between the Asian genders were probably modified by the more advanced age of females at the time of surgery. However, findings of a higher likelihood of Asian males having more multivessel disease and at a younger age than Caucasian males were a surprising outcome against the healthy stereotyping of Asians. The limitation of only using the mortality as the only outcome variable in this study further emphasizes the need for future investigation using the 2006 CCORP dataset and beyond where other postoperative complications have been included as elements in the dataset.

One of the most important distinctions between the present study and previous ones was the statistical method employed for the analyses. This study, in utilizing the multivariate generalized estimating equations, GEE, was able to adjust for the unestimated or unknown effects of individual hospitals that were not included in previous models, rendering results more accurate than those from previous studies, most of which used simple logistic regression techniques without accounting for the clustering effect of individual hospitals.

The GEE method and t tests are sensitive to large numbers and yield statistically significant differences for even minute differences in group comparisons. It is important to keep this in mind in studies using large datasets. Consideration of the clinical relevance of statistically significant results therefore plays an important role in the interpretation of findings.

On the other hand, because this study used a dataset from a mandatory CABG surgery reporting program, the data should really be considered as the population and not a sample. In that case, the statistical findings may not really apply, and that we can consider all results to be what they were as there would be no sampling error around the point estimates. This perspective again addresses the important role of clinical relevance in the interpretation of the findings even if no statistical significance could be found.

Discussion

On mortality

Race as an adjusted main effect was non-significant in this study. In the past studies, controversies exist in the area of racial comparisons in CABG surgery between Asians and Caucasians (Bridges, Edwards, Peterson, & Coombs, 2000; Gray, Nessim, Khan, Denton, & Matloff, 196; Partz, Rao, Plomondon, Grover, & Shroyer, 2001; Peterson *et al.*, 2001). While Taira's group (Taira, Seto, and Marciel, 2001) was able to show that both the unadjusted and adjusted mortality rates were significantly higher in

Asians than Caucasians, a more recent study by Yeo *et al.* (2007) using the 2003 CCORP dataset shows the same negative results as the current study using the same CCORP dataset.

There was also no significant difference in the mortality outcomes between Asian and Caucasian males. However, a significant marginal difference (OR ~1.4, p.057) was found in the unadjusted operative mortality between Asian females and males, which dissipated after risk-adjustment with 19 demographic and clinical factors. Thus, the data indicate that the difference in the unadjusted mortality was more likely due to age and other clinical predictors in the model, but not race, and that the finding may reflect that Asians had more preoperative chronic illness or cardiovascular risk factors than Caucasians at the time of presentation for surgery.

The Health Care Utilization Project (HCUP) study (Becker and Rahimi, 2002) was the only study which demonstrated that regardless of race, females had higher in-hospital risk-adjusted mortality when compared with Caucasian males. Asian females were ~1.4 times more likely than Caucasian males to die following CABG surgery. In the current study, only a marginally significant finding was noted, but this time it was the unadjusted mortality between Asian females and Asian males (OR ~1.4, p=.057), and the difference in adjusted mortality was insignificant. Even though CABG surgery patients have multi-vessel involvement and present with an increasing number of co-morbidities, the continuous improvements made in the field of CABG surgery in the last couple of decades seem to have been able to keep the operative mortality rates low despite the sicker patient profiles (Ferguson, Hammill, Peterson, DeLong, & Grover, 2002).

On demographic and preoperative clinical characteristics

Asians and Caucasians were different in their clinical characteristics when they presented for surgery, suggesting that there might be possible healthcare differences between the two groups. Significant to note is that Asian patients, though ~1.4 years younger on average than Caucasians when presenting for surgery, were found to have more multivessel coronary artery disease, more chronic medical conditions (renal disease and diabetes) and more chronic types of cardiovascular disease (hypertension, history of previous cerebrovascular accidents, and heart failure) than Caucasians preoperatively (Table 5.1). These findings found concordance with those by in the study by Yeo *et al.* (2007), and these findings suggested possible health disparities which warrant further investigation.

The 2006 version of the CCORP dataset has improved by including major postoperative complications such as perioperative myocardial infarction, stroke, return to surgery for graft revision or bleeding, prolonged intubation, major infections, and others, in addition to operative mortality. With additional information available in the later versions of the CCORP dataset, more vigorous outcomes monitoring of racial disparities can be pursued in the future.

Fewer Asians than Caucasians had any prior percutaneous coronary interventions (PCIs) despite more coronary vessel involvement, and only about half as many of them had previous CABG surgery as compared to Caucasians. These data suggest that this subset of Asians with CABG surgery had less previous invasive interventions for their CAD, and raise suspicion to if the same situation is true for all Asians with CAD. While the ultimate outcome for CAD treatment in this group with less invasive interventions may not be worse off than that with more invasive interventions, it nevertheless raises doubts about equal access for services and questions for the seemingly different treatment discrepancies when compared with Caucasians. This finding contradicts with an earlier study (Carlisle, Leake, and Shapiro, 1997) which did not find any differences. Yeo's study (2007), however, had similar findings as this study, but did not discuss the potential implications explicitly. Another previous study found that more Asian males (but not Asian females) were referred for CABG surgery than for percutaneous coronary interventions, but it did not address the overall treatment pattern for CAD in the Asians (Taira, Seto, and Marciel, 2001).

The finding on more multivessel disease in Asians may imply that Asian patients might have experienced delays in diagnosis and/or treatment, or might have refused the invasive treatment option in the earlier course of the disease. This finding suggests possible healthcare disparities in this subset of Asians with CAD. Significant to note is that in this study, Asians have included the Pacific Islanders, and were ~1.3 years younger than Caucasians on average, emphasizing the need to separate the Pacific Islanders from the Asians and investigate the major subgroups of Asians separately to see if the age difference still exist. This approach will enable the interventions planned to be more targeted and effective.

All in all, these findings yield more questions than answers. Further investigation into the pattern of referrals for Asian patients in California for the same time period for percutaneous coronary interventions, combined with a survey on the cultural acceptance of CABG surgery in Asians may yield a clearer picture for the answers to the questions raised. Nevertheless, these findings, as they stand now, bear important clinical implications for clinicians. Given Asian males' earlier age presentation for CABG surgery than their Caucasian counterpart, that their mean BMI was in the normal range, and the existence of multiple chronic illnesses that could be managed and controlled, Asian patients should be carefully assessed by clinicians to avoid missing the earliest possible opportunity for diagnosis and intervention of heart disease and management of risk factors.

As for the emergency status of admission, findings were similar to those obtained by Carlisle and colleagues (1997) where no differences were found between Asians and Caucasians in the County of Los Angeles. This study did not find significant differences between the two Asian genders or in the males between the two races. However, it was able to show a significant difference between the Asian and Caucasian females,.

An interesting observation found regarding patients with severe mitral insufficiency and only having isolated coronary artery bypass surgery, instead of the expected combined CABG and valve procedure, is puzzling. Usually, one would have expected that patients who have severe mitral insufficiency to benefit from having combined cardiac procedures. Since this study only pertained to those with isolated CABG surgery, one would not have expected to find this relatively small number of patients with severe mitral valve disease in the data.

Gender differences

Asian females had a marginally significant difference in the observed operative mortality (OR ~1.4, p=.057) when compared with Asian males, which disappeared after risk adjustment for the clinical characteristics (OR ~1.16, p=.452), suggesting that the difference was more due to the clinical characteristics than the gender factor, unless if some of the clinical characteristics were a result of the gender differences. In the larger study using data from HCUP (Becker and Rahimi, 2006), where the Asian sample size was almost four times larger than the present study (>20,000), a significant difference was observed between Asian females and Caucasian males, but unfortunately, the analysis between gender within the Asian group was not conducted in the HCUP study.

The clinical differences between Asians and Caucasians mentioned earlier, when explored further, were found to mainly come from the Asian females, not Asian males. Some of these differences in the chronic disease profile could have been attributed to the older age of females on average (~4 years older) at the time of presentation for surgery. Asian females also experienced more angina (Class II to IV, NYHA) than Asian males. Although Caucasian females were not the focus of this study, they also were found to have higher rates of these chronic illnesses compared to their male counterparts, suggesting that there are opportunities for intervention and risk factor management for women, regardless of race, to prevent, recognize, and treat heart disease at an earlier stage. In light of the fact that CAD and stroke combined remained as the number one killer in women, these data further support the need for continual preventive efforts to increase women's awareness and advocacy in Asian women to understand their risk for heart disease and stroke, especially in a language that they can understand and in ways that are culturally appropriate and acceptable.

Asian females in this study were found to have significantly less interventional treatment done in the past compared to the Asian males, the same difference was also observed in the Caucasian females. Becker and Rahimi's study (2006) have found similar results (2006). Asian females had a lesser rate of previous PTCA (~23% less) or previous

CABG surgery (~50% less) compared to their male counterparts. There may be two possible reasons to account for these differences as discussed earlier. The first one may be a cultural trait that Asian females themselves refuse invasive interventions until later in the illness trajectory. The second one may be due to an access issue in that physicians may have overlooked females' complaints of cardiac symptoms and not referred them in a timely fashion.

Results related to the BMI indicate that even though >3 times as many Asian females compared to Asian males had a very small BMI (<`8.5), they were also 20% more likely to have a very large BMI of >40.0. However, despite the tail end differences, the mean BMI ended up surprisingly close, with 25.50 in Asian females and 25.98 in Asian males (p=0.002), when one would have expected Asian females to have a smaller BMI. This finding suggests that weight is an also important area to monitor in Asian women, on par with females in other racial groups.

Asian females had a later presentation (~4 years older) for CABG surgery compared with Asian males. In addition to the possible later manifestation of heart disease in women from the cardiac protection of female hormones, the same explanations discussed in the access section above may also apply to this group: self refusal and physician referral issues.

The only process variable measured in this study was the use of the internal mammary artery as a graft conduit, where significant differences were found between Asian females and Asian males (OR .66, p<.001), and between Caucasian females and Caucasian males (OR .62, p<.001). No difference was observed in the females or the males between the two race groups . The use of the internal mammary artery (IMA) has been endorsed by the NQF as a quality measure of CABG surgery, so very low utilization rates are associated with poor care (National Quality Forum, 2004). The reasons for the significantly lesser use of IMA grafts in Asian females may be due to the smaller vessel size of the IMA or poor flow in females, or gender bias may exist in surgeons. Surgeons used to operate in females may choose to inject papaverine in the IMAs to dilate them and improve blood flow.[1] Because IMA grafts are longer lasting than the vein grafts and improve patient survival, the reasons for the lesser use of IMA in females warrant further investigation. More recent results from the 2006 CCORP data indicated that the overall IMA usage rate has increased from 89.6% to 93.3% (California Office of Statewide Health Planning and Development, 2009a), and it will be interesting to examine if the same improvement can be found in the female gender group when the 2006 patient-level data become available for public use.

The hospital volume-outcome relationship

In past studies, the demarcation line between high and low hospital volume groups has been rather subjectively defined by different authors. In an earlier study by Nallamothu et al. (2001), hospitals were dichotomized into two groups with a cut-point set at 200 average annual cases. However, in a more recent hospital volume effect study by Marcin *et al.* (2008), the authors used 300 cases a year to separate the high-and low-volume hospitals, where ~90% of the hospitals ended up belonging to the low-volume hospital group. With the dwindling in CABG surgery in recent years, the numbers used to demarcate between high- and low volume hospitals warrant adjustment, probably shifting towards the lower end. Thus in this study, the demarcation line at 300 surgeries for the

[1] Email communication with Dr. Elaine Tseng, a cardiovascular surgeon at the UCSF Medical Center. Papaverine is a vasodilator-of-choice used by some cardiothoracic surgeons to improve flow in the IMA grafts.

entire 2003-2005 3 year period (100 cases/year) was drawn and used to define the high and low volume hospitals at ~50th percentile, which can be considered a more reasonable cut-point given the dwindling CABG surgery volumes, where further declines in CABG surgery volumes in California continued in 2006. The CCORP reported that of the 121 Californian hospitals, only 56 (46%) of them had performed 100 or more surgeries (California Office of Statewide Health Planning and Development, 2009b).

Whereas mortality partially reflects the quality of care, hospital volume infers access to CABG surgery, which can be viewed as a surrogate for measuring access to quality healthcare. In this study, a higher percentage of Asians than Caucasians were found in the low volume hospital group, with a corresponding lower percentage in the high volume hospital group. The opposite was found in the Nallamothu study (Nallamothu et al., 2001), in which a lesser percentage of Asians than Caucasians had surgery at the low volume hospitals. Viewing from another angle, this study has also shown that the low volume hospitals had a higher estimated average percentage of Asians than the high volume hospitals (Table 5.3). Interestingly, in large metropolitan cities such as San Francisco, only one hospital belongs to the high-volume hospital group as defined in this study in the CCORP data just released this year for 2006 (California Office of Statewide Health Planning and Development, 2009b). Asians may have had surgery in the low-volume hospitals based on geographical convenience.

No significant differences were found in both the unadjusted mortality and adjusted mortality in Asians in relation to hospital volumes for these mandatory reported data, a result that is consistent with the findings of Marcin *et al*. (2008) and Becker and Rahimi (2006). However, these findings should not be used to compare directly with the results of this study, for the hospital volume cut-points were not the same. Again, we will not know, until further studies are conducted, if Asians experience other adverse consequence such as more major postoperative complications, longer hospital stays and postoperative recovery periods, higher costs of surgery, or different other outcomes than Caucasians in relation to hospital volumes.

Implications

Disparities about CABG surgery have been published for the African Americans in abundance, but this is the first study dedicated to highlight and focus specifically on disparities in Asians and between Asian males and females in details. The results in this study have general theoretical implications as related to the use of the Donabedián model, as well as specific clinical and policy implications as related to the differences in findings between the Asians and Caucasians undergoing CABG surgery. The gaps in knowledge, easily appreciated from the 'structure-process-outcome' framework of Donabedián's model, help to point to future directions for research. All of these issues will be discussed below.

Theoretical implications

The parsimonious Donabedián framework has provided a relatively easy method to evaluate areas of deficiency and health disparities for Asians with CABG surgery. The model contains a disproportionate amount of quality assessment data on risk factors, clinical processes, and surgical outcomes ─ designed and collected from the surgeons' points of view or interest, but not from the patients' or from a system's standpoint, thus contributing to an incomplete assessment of CABG surgery. The missing areas include other patient outcomes such as comparison of quality of life, the recovery process and patient satisfaction. Other areas include institutional or healthcare system characteristics that could be altered to streamline the surgery, improve patient care process, and reduce hospital's length of stay. Up to this point, a large percentage of Asians are still immigrants, and studies that can add distinctive cultural and language dimensions to Donabedián's theoretical framework may help yield other important findings that will improve the medical management for this group of patients.

Clinical implications

This study shows that Asians had the CABG surgery at a younger age on average, with a lower average BMI, a higher frequency of multi-vessel disease, and higher rates of certain chronic illness and cardiovascular risk factors such as diabetes, hypertension, and renal disease as compared to Caucasians. Asian females were found to have higher risks for the above when compared to Asian males. It is also important to note that Asian patients were at risk for heart disease even with a relatively normal BMI (mean BMI for Asians was ~25, as compared to ~28 in Caucasians). These findings help inform clinicians who take care of Asian patients to become more sensitive to the earlier onset of heart disease in those with high risks, and to intervene more aggressively and in a timely manner to control their cardiovascular risk factors, lower the need for future surgical interventions, or else enhance earlier treatment access for those needing it. Cholesterol levels should be drawn in Asians as well as Caucasians on a regular basis as recommended by the American College of Cardiology (ACC)/American Heart Association (AHA) guidelines (Thomas et al., 2002). Results of this study also highlight the need for primary care physicians to increase their awareness for Asian patients who may be at risk for heart disease, even those with the absence of angina, and to refer them to cardiologists in a timely manner, so that appropriate diagnostic work-ups for heart disease can be done and effective interventions instituted. The referral pattern for CABG surgery also highlights the need for physicians' self examination of referral patterns, as this study has revealed that a disproportionately higher percent of Asians compared to Caucasians have been referred to low-volume hospitals for surgery. The finding that significantly fewer Asians had previous CABG surgery or other procedures than Caucasians may indicate problems in disease detection, denial, and referral, as well as access to care.

Policy implications

While combining Asians in the census count makes political sense, combining them for medical management reasons may mask the particular Asian groups needing particular targeted interventions. Since language is an important issue in physician-patient communications, the identification of the language of the sub-Asian groups becomes necessary in order for healthcare and health educational efforts to be delivered in culturally-sensitive and language-appropriate manners. Thus, the CCORP data should include data fields that identify Asian subgroups. A review board should be set up at the national level to monitor healthcare disparities so that they do not continue or propagate insidiously. And, public awareness campaigns for women and heart disease, such as the American Heart Association's Red Dress Campaign, to publicize women's risk for heart disease should be translated into different Asian languages to raise the awareness of Asian women of their risk for heart disease and stroke. Effective adoption, implementation, and monitoring of language policies such as SB853 that address mandatory language assistance in medical settings should help decrease disparities that may possibly arise from language difficulties. Health advocates should also raise awareness in the general public regarding the limited and disproportionate research funding available from both the public and private sectors to conduct clinical research for improving the health of Asians, inclusive of those with limited English proficiency (LEP). Policies guidelines should be set to involve LEP Asians in clinical research involving Asians, and should include funding for translations/interpreters, as sufficient resources will not be available to hire interpreters and translate related documents otherwise.

Directions for future research

The review of literature shows that few studies have been conducted on Asian Americans with CABG surgery. This study, though limited in scope to California data, is one of the largest clinical studies about Asians, and its findings point to the need for more research to address healthcare disparities in this group. It also points out the importance of utilizing the available large clinical datasets by doing secondary analysis. The significant findings further highlight the little-known clinical status of Asians, not just in those with heart disease, but also other healthcare areas, and underscore the need for both exploratory qualitative and quantitative studies. Many of the research instruments that measure quality of life for specific clinical areas can be culturally-adapted, translated, and tested for reliability for use with Asians. Studies that can be done may include those aforementioned in patient and institutional issues, such as the effectiveness of prevention strategies and health educational efforts, decision-making for surgery, comparing outcomes between CABG surgery and angioplasties, postoperative complications, treatment aimed to reduce postoperative complications and hospital's length of stay, rehospitalization, quality of life before and after surgery, the recovery process, patient satisfaction, surgery and patient care process, ways to prolong graft patency, and longitudinal follow-up on the ultimate endpoint: mortality. The interpretation and appreciation of the results of these studies will be greatly enhanced if we can identify the major Asian sub-groups such as Chinese, Filipino, Southeast Indians, Pacific Islanders, and others. In addition to the more specific information on race, adding language, communication, physician relationship, acculturation, and other cultural perspectives to any of the above studies should yield valuable information that can be used to guide, and hopefully improve, future medical and nursing disease management for Asians. While no significant differences were found for operative mortality in Asians between the low-volume and high-volume hospital groups, other major postoperative morbidities were not known and should be investigated. A significantly higher percentage of Asians compared to Caucasians had CABG surgery performed in the low-volume hospitals, while the converse was true for Caucasians. Studies to test various cut-points for high and low volume hospitals using linear or quadratic equations as guides, or to investigate the referral pattern of Asians, should help to shed light on why a higher percentage of Asians had CABG surgery in the low-volume hospitals.

Limitations

The results of this study have been based on the data collected by the CCORP and the PDD, and therefore carry with them all the limitations inherent in the CCORP and PDD databases. The following section discusses some of these limitations in this secondary data analysis study.

Lack of data alignment with the National Quality Forum

Even though the National Quality Forum (NQF) was able to achieve a consensus of 17 quality indicators for isolated CABG surgery, the CCORP did not include most of these 17 indicators in its dataset. This deviation represents fragmentation of quality evaluation standards across the nation, and devalues the quality indicators developed by the NQF by consensus.

Lack of data alignment with processes and outcomes underlying the theoretical model

In considering Donabedián model's (2003) three dimensions of structure, process, and outcomes, the limited CCORP dataset does not enable an adequate measurement of the process and outcome dimensions. The lack of data on patients' cholesterol levels in the CCORP was also glaring. The following are examples of other "process" quality of care indicators for CABG surgery that were not present in the CCORP.

- Medications (e.g. beta-blockers, ACE or ARB inhibitors, anticoagulants, antibiotics, aspirin, lipid-lowering drugs) used in association with the CABG surgery preoperatively, intra-operatively, and upon hospital discharge
- Blood product usage intra-operatively and postoperatively
- Number of arterial and venous conduits, and specifics about vessel harvest
- Specific data related to use of the ventricular assist device (VAD)
- Specific data relating to concomitant valve surgery or other procedures
- Other important discharge information, including cardiac rehabilitation referral and smoking cessation counseling
- Other highly desirable "outcome" variables including major morbidities, cost of surgery, return to work issues, patient satisfaction regarding the surgery

experience, longitudinal mortality data, angina control, activity levels, and other quality of life indicators.

The race category

The most common criticism of any Asian study is that the Asian racial designation is usually a self-reported item and represents a heterogeneous grouping of Asians from different countries in Asia and Pacific Islands. In such a grouping arrangement, the meaning of race can be diluted because of the large cultural, ethnic and language differences that exist among the many different Asian subgroups. Currently, there are no large clinical databases that identify the country of origin for the Asian immigrants, limiting use of the large clinical datasets to study Asian subgroups in the United States. In light of the lack of clinical studies on Asians, even though using the Asian race cluster is a compromise, it nevertheless presents an opportunity to study this group to yield some preliminary information. If the variables being studied show significant differences, then there may be justifiable cause to devote more resources to pursue further investigations.

The surgery itself – different surgical approaches

Different surgical techniques for CABG surgery have been continuously developed, such as non-use of the cardiopulmonary bypass (CPB) machines during surgery [often known as off-pump (OPCAB)], minimal invasive direct surgery (MIDCAB) or port-access surgery, as well as hybrid procedures combining PTCA with MIDCAB. This CCORP dataset does not distinguish the techniques employed in the CABG surgery, when in fact, the criteria for choosing patients for the different surgical procedures may differ, affecting the risk factors associated with the different surgical modalities. Li *et al*. (2008) found that patients who had the off-pump CABG surgical modality (OPCAB) had a better risk profile than those who had the traditional cardiopulmonary bypass (CPB) method, suggesting a clinical selection process for the OPCAB procedure that favors non-Caucasians and patients with less surgical risks, such as those without diabetes or recent myocardial infarction, or those with only 1= or 2= vessel coronary disease.

Data Accuracy

Another major limitation is the accuracy and reliability of the two datasets. As discussed in previous chapters, the outcomes and conclusions that can be drawn from any dataset are only as good as the data itself. Clinical data sources are, in general, more reliable than the administrative data sources. Unfortunately, despite the fact that discreet racial data have been collected by the CCORP and approval has been obtained from the State's IRB office to use the dataset, the CCORP office refused to release specific racial data in its clinical dataset. Thus, the less accurate administrative racial data had to come from the PDD data files to identify Asians and Caucasians for the analysis.

Other important missing data

Finally, all current CABG surgery datasets only collect data from those who have had the CABG surgery, and the American College of Cardiology and American Heart Association collects voluntary data on percutaneous coronary interventions. However, there was still a subgroup of Asian patients with coronary artery disease (CAD) who have either not been diagnosed, or who have been managed on the noninvasive medical regimes only. Then there were also those who have not been offered invasive treatments, or those who have refused the invasive treatments. Much about these groups is unknown.

In order to more fully assess the accessibility of healthcare services in Asians or any other groups with CAD, the inclusion of data and analysis on all Asian patients with known CAD, especially those who qualify for CABG surgery and yet do not receive any, should be meaningful.

Operative mortality

Operative mortality includes both in-hospital mortality, no matter how long until patient discharge, and 30-day all-cause mortality, no matter where death occurs as long as it is within 30 days from the date of surgery (Osswald *et al.*, 1999). Using operative mortality as the outcome to include 30-day mortality helps to avoid a type of gaming practice in the past where patients with a poor prognosis after surgery were transferred to another institution to die in order to lower the in-hospital mortality rate. In this study of Asians, it was especially important, in light of the cultural practices of some Asian patients who prefer to die at home (Wu, Chien, Ng, Chu, & Chen, 2005), to measure 30-day mortality. The routine link up with California's Vital Statistics by the CCORP to verify the self-reported mortality from institutions that perform CABG surgery was therefore an especially important step to verify the 30-day mortality data, which required additional staff and resources to do telephone follow-ups post hospital discharge.

Demarcation to distinguish high- and low-volume hospitals

Because the number of CABG surgeries has been dwindling since the advent of angioplasties, it is necessary to redefine the demarcation points for high and low volume hospitals over time. In the end, this study chose the ~50th percentile, whereas earlier studies have chosen other arbitrary data points. Thus, even though the terminology of ‘high’ and ‘low’ volumes are the same in these studies, their meanings have changed and rendered the past study results unsuitable for making comparisons.

Conclusion

Even though there was no statistically significant difference in mortality outcomes between races, the clinical significance of the difference was still significant. The findings that Asians with CABG surgery had more multivessel disease and more chronic illnesses at a younger age also merit further investigation. Given the data set did not include other postoperative complications, future studies using later CCORP datasets that includes those variables should shed more light on if any health disparities are present. This is also the first study to compare between Asian males and females presenting for CABG surgery using more reliable clinical data from a state-mandated CABG surgery registry. The marginal significance of operative mortality between genders in Asians also merits further investigation. Furthermore, the results from this study brought out some salient clinical characteristics of Asians that are different from those of Caucasian patients going for CABG surgery, and these findings suggest that the clinical pathways of developing CAD, which eventually led these patients to surgery, might be somewhat different between race and gender groups. This observation merits future investigation into the different lifestyles, eating and exercise habits of Asians. The differences in clinical characteristics and increased proportion of multivessel involvement together imply later treatment of CAD in Asians compared to Caucasians.

As >60% of Asian immigrants have limited English proficiency (U.S. Census Bureau, 2007), one wonders how much the unfamiliarity of the healthcare system and language barriers have contributed to the disparities seen in the access and outcomes of

CABG surgery. Though this study is unable to demonstrate differences in the immediate operative mortality based on racial difference, there is a trend of increasing mortality in the hospitals with <300 CABG surgeries a year. More Asians also disproportionately ended up having CABG surgery in the smaller volume hospitals, although this study did not demonstrate any difference in mortality (compared to Caucasians) in CABG surgery between small and large volume hospitals.

It is important to keep in mind that there are no perfect predictive models, and the model can only be as good as the predictors that are chosen for fitting it. The choice of the predictors and the data collected for them ultimately determine the outcomes and the questions that can be answered. In terms of outcome disparities in CABG surgery, this secondary analysis study only used operative mortality as the only outcome variable to study, and is therefore limited in scope. The research questions, when organized within Donabedián’s quality of care framework, presents a sensible, reasonable, and prudent approach to study healthcare outcomes in Asians, as well as any other racial groups. The reliability of the data and the large clinical dataset makes this an important study for the Asians.

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Appendix I

Definition of Terms

30–day mortality is death that occurs within 30 days from the date of surgery regardless of where it occurs (California Office of Statewide Health Planning and Development, 2007).

Acute coronary syndrome (ACS) – Acute coronary syndrome (ACS) is an umbrella term to cover both unstable angina and the two types of myocardial infarction: non–ST segment elevation myocardial infarction (NSTEMI) and ST segment elevation myocardial infarction (STEMI). The group of signs and symptoms associated with ACS usually arises as a result of acute myocardial ischemia caused by the abruptly decreased blood flow to the heart due to disruption of atherosclerotic plaque in one of the coronary arteries. It is a combination of new onset chest pain, chest pain with minimal exertion, or at rest, especially with increasing severity or frequency, and other features such shortness of breath, cold sweats, nausea, and radiated pain to the arms, neck, jaw, or the back.

Angiogram (also called “angiography,” or “cardiac catheterization,” or “cardiac cath”) – This procedure is regarded as the gold standard for diagnosing coronary artery disease (CAD) and quantifying the location and severity of lesions inside the coronary arteries by cannulating the coronary arteries selectively through the brachial artery (Sone’s technique, 1958–59), or through the femoral artery (Judkins’ technique, 1967). The injected radiation dye enables visualization of the blockages in the right and left coronary trees (Levin & Gardiner Jr., 1988).

Benchmarking – A quality tool for measuring performance against established standards of best practice. Often used to evaluate various aspects of their processes using measurable outcomes in relation to best practice, usually within the same sector (http://en.wikipedia.org/wiki/Benchmarking).

Expected or predicted mortality rate (E) (see "predicted mortality" below) is the sum of the predicted probabilities of death for all patients divided by the total number of patients with isolated CABG surgery cases and multiplied by 100:
Expected Mortality Rate (E) % = Number of expected deaths/Total number of isolated CABG surgery X 100 (California Office of Statewide Health Planning and Development, 2006).

Internal mammary artery (IMA) or internal thoracic artery (ITA), or other arterial conduits, is used as a measure to reflect quality of the CABG surgery, as arterial grafts have been found to provide patients with a longer life expectancy rate than vein grafts (Berger *et al.*, 2004).

In-hospital mortality is death that occurs while a patient is still in the hospital regardless of length of stay (California Office of Statewide Health Planning and Development, 2007).

Isolated CABG surgery is defined as CABG surgery performed without other major heart procedures, such as valve repair, during the same surgery. When any of the following procedures are performed concomitantly with CABG surgery (not including other major heart procedures such as valve surgery), they are still regarded as isolated CABG surgery: coronary endarterectomy, internal cardiac defibrillator (ICD) placement, Fem-fem (as distinguished from aortofemoral bypass) cardiopulmonary bypass, pacemaker implantation, pericardiectomy and excision of heart lesions, repair/restoration of the heart or pericardium, transmyocardial laser revascularization (TMR), thymectomy, and thyroidectomy. CABG surgery performed concomitantly with any other surgeries not listed above will be regarded as non-isolated CABG surgery (California Office of Statewide Health Planning and Development, 2007, pp. 65 - 66).

Observed mortality rate is the ratio of the actual number of isolated CABG deaths and the total isolated CABG surgery cases multiplied by 100. Expressed mathematically: Observed Mortality Rate (O) = Number of isolated CABG deaths/Total isolated CABG surgery cases X 100 (California Office of Statewide Health Planning and Development, 2007).

O/E Ratio is defined as the observed mortality rate divided by the expected mortality rate. At the institutional/surgeon level, the O/E ratio is often used as a quality measurement of institutional/ surgeon performance. At the regional or national level, the O/E ratio is a reflection of the level of precision of the risk model in over- or under-estimating mortality for a population. An O/E ratio of >1 implies that the risk model underestimates the actual number of deaths, and an O/E ratio of <1 implies that the risk model overestimates the actual number of deaths, which is commonly the case in risk adjustment models built to estimate CABG surgery outcomes. Theoretically, the perfect O/E ratio of 1 does not exist because one does not know what the exact predictors are.

Operative mortality is defined as “patient death occurring in the hospital after CABG surgery, regardless of the length of stay, or all-cause mortality occurring anywhere after hospital discharge but within 30 days of the CABG surgery" (California Office of Statewide Health Planning and Development, 2007, p.1).

Observed mortality rate = Number of isolated CABG deaths/Total number of isolated CABG cases X 100 (Office of Statewide Planning and Development, 2007, p. 12)

Mortality rates refer to the percent of patients who have died, and is calculated by the number of deaths among patients with CABG surgery divided by the total number of patients who have undergone the same surgery in a defined time period multiplied by 100. However, because every patient admitted for CABG surgery does not have the same risk of death, observed mortality rates generally are not a good indicator to use to compare the quality of care, nor to reflect disparities in care.

Predicted mortality, used interchangeably with "expected mortality" (E), is the probability of death for an individual patient, estimated across identical patients having the same severity of the preoperative clinical status and risk factors in a specified risk adjustment model developed from the same patient population. (California Office of Statewide Health Planning and Development, 2006).

Mean expected mortality rate = Sum of predicted deaths / Number of isolated CABG cases with predicted mortality X 100

(Office of Statewide Planning and Development, 2007, p. 12)

Expected mortality partially reflects patient's severity of illness, and can be obtained through building a multilevel logistic regression risk-adjusted model, taking the clustering effects of hospitals and surgeons into account. Since the CCORP database mostly contain only clinical variables at the patient level, demographic as well as clinical predictors for the model will be used. These predictors will be selected based on clinical judgment, and also guided by results from preliminary correlation analyses and logistic regressions. To calculate the expected mortality rate for CABG surgery for a particular group, the mean of the group's expected mortality is used. To obtain the mean, the sum of the expected mortality for all the patients in a particular group is obtained by summing up each patient's expected mortality within the group. The sum can then be divided by the total number of cases that have expected mortality and multiplied by 100 to get the average expected mortality rate for that particular group of patients. The grouping could be by race, gender, surgeons, or hospitals.

Quality assurance – According to Donabedián, one cannot "assure" or "guarantee" quality. Quality assessment involves 3 steps: obtain information about the performance, evaluate the performance in its level of quality, and take actions to improve quality (Donabedian, 2003, p. xxvi). It implies a "continuous" process to achieve better outcomes in healthcare. The quality assurance schematic design includes two parts (Donabedián, 2003, p. xxiii-xxiv):

1. System design and resources – Structure – This sets the average (mean) level of performance as well as the variance around the mean.
2. Performance monitoring and readjustment – To improve and fine tune performance by raising the mean and reducing the variance around it (Donabedián, 2003, p. xxvii).

Risk adjustment – A statistical method that helps to establish a degree of fairness, which is critically important in assuring quality and in comparing performance among physicians and medical institutions. It accounts for "patient-related factors before comparing outcomes across different patients, treatments, providers, health plans, or populations" (Iezzoni, 2003, p. 3).

Risk–adjusted mortality rate (RAMR) – The risk–adjusted mortality rate (RAMR) is the mortality rate for a group of patients after adjusting for differences in the patients' severity of illness or case-mix, and to make them identical to the mix of patients of the state – an act that has been conventionally labeled as "risk adjusted". The RAMR thus enables an across the board comparison for the different hospitals, or surgeons, after leveling the playing field with "identical" levels of severity for the clinical predictors in patients . The RAMR for a provider is computed first by dividing the provider's group of patients' averaged observed mortality rate by the corresponding averaged expected mortality rate (based on the risk model) to get the observed/expected (O/E) ratio. (An O/E ratio >1, means the provider has a higher mortality than expected based on its patient mix; whereas an O/E ratio <1 means that the provider has a lower mortality rate than expected.) The O/E ratio is then multiplied by the overall state mortality rate to obtain the provider's RAMR.

RAMR = O/E x Observed average mortality rate of the population

(California Office of Statewide Health Planning and Development, 2007, p. 12).

The risk-adjusted mortality rate (RAMR) is often used as a measure of quality of care provided by hospitals and surgeons, and represents the best estimate of the mortality rate if the patient case mix for the special group of patients of interest is identical to the patients in the dataset. However, the RAMR results have to be interpreted carefully since it is based heavily on the expected mortality obtained from the multilevel model of predictors, as there are no perfect risk–adjusted models.

Confidence interval for the RAMR - Because a point estimate of the RAMR based on a small number of cases can be attributed to chance, usually a 95% confidence interval

(CI) is established to represent the confidence in the point estimate for the RAMR. Additionally, in order to minimize the risk of misinterpretation of differences of the point estimate caused by chance variation, the 100% mandatory data is treated as a sample, so that true performance [the risk-adjusted mortality rate (RAMR)], can be assessed to fall within the 95% CI of the RAMR 95% of the time.

The CCORP published a public report on hospital data in 2005 for the 121 hospitals that conducted CABG surgery in California, in which every hospital is assessed against 3.08%, the state's observed operative mortality average in 2005, to assess if the 3.08% lies inside the range of the 95% CI of the individual hospital's RAMR (CCORP, 2007). If the 3.08% is outside of the 95% confidence interval (CI), it is either judged as "better" (if 3.08% is >95% CI), or "worse" (if 3.08% is <95% CI). An example of the hospital-level quality data in 2005 reporting hospitals with better and worse risk-adjusted performance is shown in the Appendix (CCORP, 2007).

Appendix II:

Abbreviations

ACC	American College of Cardiology
ACEIs	Angiotensin converting enzyme inhibitors
ACS	Acute coronary syndrome
AHA	American Heart Association
AHRQ	Agency for Healthcare Research and Quality
AMI	Acute myocardial infarction
ARBs	Angiotensin receptor blockers
AUC	Area under the curve
CABG	Coronary artery bypass grafting
CAD	Coronary artery disease
CCMRP	California CABG Mortality Reporting Program
CCORP	California CABG Outcomes Reporting Program
CNS	Central nervous system
CPB	Cardiopulmonary bypass
DES	Drug–eluting stents
HCUP	Health Care Utilization Project
ICDs	Internal cardiac defibrillators
ICU	Intensive care units
IMA	Internal mammary artery
ITA	Internal thoracic artery, used synonymously with IMA
LIMA	Left internal mammary artery

M.I.	Myocardial infarction
MIDCAB	Minimally invasive direct CABG surgery
NQF	National Quality Forum NQF
NS positioner	Non sternotomy positioner (made by Medtronic)
O/E ratio	Ratio of observed number of deaths (O) /Expected number of deaths (E)
OPCAB	Off–pump CABG surgery
OR	Odds ratio
PACAB	Port–access CABG surgery (system by Heartport)
PCIs	Percutaneous coronary interventions
PDD	Patient Discharge Data
PI	Principal investigator
PTCA	Percutaneous transluminal coronary angioplasty; also called “balloon angioplasty” or PCI
QOL	Quality of life
RCA	Right coronary artery
RA	Risk-adjusted
RAMR	Risk–adjusted mortality rate
ROBOCAB	Robotically–assisted CABG surgery (by Intuitive da Vinci Robotic Surgical System)
SES	Socioeconomic status
STS	Society of Thoracic Surgeons
STS–NDB	Society of Thoracic Surgeons’ National Database
SVG	Saphenous vein grafts

TECAB	Totally endoscopic CABG surgery (closed chest, off–pump CABG surgery using facilitated anastomotic devices and computer enhanced instrumentation systems)
TMR	Transmyocardial laser revascularization
U.S.	United States of America

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