

EXHIBIT 18(b)

Trends in the use of diagnostic coronary angiography, percutaneous coronary intervention, and coronary artery bypass graft surgery across North Carolina

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Background Although variation in use of invasive coronary procedures has been shown, the relationship between invasive diagnostic cardiac catheterization (Cath) and subsequent revascularization with percutaneous coronary intervention (PCI) or coronary artery bypass surgery (CABG) is not known. We evaluated the temporal trends and variation in invasive Cath, PCI, and CABG across hospital systems in North Carolina.

Methods All Cath, PCI, and CABG procedures performed in North Carolina from 2003 to 2009 were identified using data reported in the annual North Carolina State Medical Facilities Plan. Rates and variation in procedure use, relative rates of PCI to Cath, CABG to Cath, and CABG to PCI were compared over the study period between hospitals that performed at least 25 Cath, 25 PCI, and 25 CABG procedures.

Results The rates of all invasive procedures per 100,000 population declined: 24% for Cath, 16% for PCI, and 35% for CABG. However, the relative rate of PCI to Cath over the study period increased by 11%, whereas the relative rate of CABG to Cath decreased by 13%. Hospital level analysis showed significant variation in the relative rate of both PCI to Cath (10%-90%, $P < .05$) and CABG to Cath (5%-35%, $P < .05$).

Conclusions Although the use of all invasive cardiac procedures declined, the relative rate of PCI to Cath increased over the study period. There was also significant variation in the mode of revascularization (CABG and PCI) across hospital systems in North Carolina. Further research is needed to understand drivers of coronary revascularization. (Am Heart J 2011;162:932-7.)

Since the introduction of coronary stents in the early 1990s, percutaneous coronary intervention (PCI) has been shown to reduce angina symptoms in stable patients and cardiovascular events in patients with acute myocardial infarction. In patients with a high burden of coronary atherosclerosis, coronary artery bypass surgery (CABG) provides revascularization that improves survival and cardiovascular outcomes. More recently, with the introduction and use of drug-eluting stents (DESs) and improved medical therapy for angina, the need for invasive diagnostic cardiac catheterization (Cath) studies and subsequent PCI and CABG procedures may be changing.¹⁻⁴

Despite improved evidence of the benefits of revascularization, improved technology, and medical therapy, wide geographic variation in the use of Cath and coronary revascularization procedures remains.^{3,5} There is significant national interest in the nature of this variation coupled with increasing awareness of the associated costs of invasive cardiac procedures for patients with coronary artery disease.⁶

Some have reviewed overall trends of Cath, PCI, and CABG to understand this variation; however, these national reports are limited by the use of Medicare data that exclude younger and privately insured patients. In addition, these prior reports have only captured inpatient procedures and may have had ascertainment bias due to the shift from inpatient to outpatient Cath that has occurred across the country. Finally, these trended data do not provide the context of use of invasive cardiac procedures by individual hospitals. In the current study, we explored the overall volume and rates of invasive cardiac procedures, relative rates of revascularization procedures (PCI and CABG) to Cath, and relative rates of PCI to CABG across North Carolina and within hospitals from 2003 to 2009. We also examined the variation in these rates across hospital systems in North Carolina.

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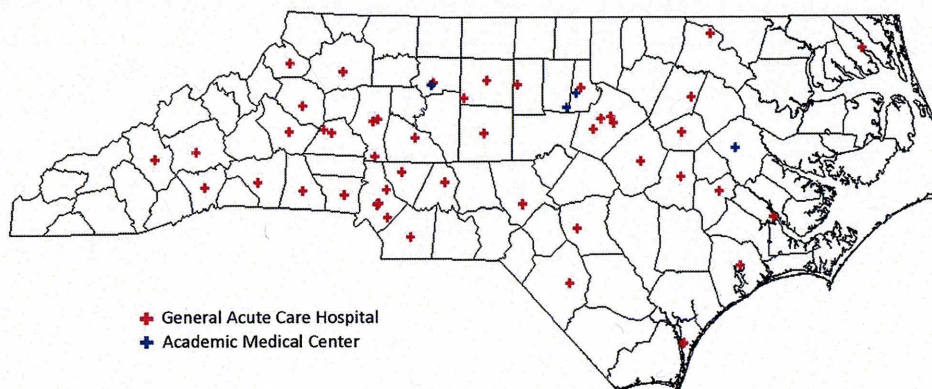
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Figure 1



North Carolina hospital map. Map of the location of all integrated academic medical center hospitals and acute care hospitals that performed invasive cardiac procedures in North Carolina during the study period.

Methods

Data sources

All North Carolina hospitals are required to submit an annual license renewal application. Data are compiled from these applications in the North Carolina State Medical Facilities Plan. In this application, the number of diagnostic and interventional cardiac Cath procedures and open-heart surgery procedures were self-reported for the prior fiscal year. Fiscal years will be referred to herein by the calendar year in which the fiscal year ended. The total number of Cath, PCI, and CABG was collected from these license renewal applications from 2003 to 2009.

Invasive procedure rates

Based on these data, volume of procedure use and relative rates of PCI to Cath, CABG to Cath, and CABG to PCI were computed. When appropriate, the volume of procedure use was converted to the rate of procedure use based on an estimated population of North Carolina that was published by the North Carolina Office of State Budget and Management from 2003 to 2009.⁷ Data from hospitals that performed at least 25 Cath, 25 PCI, and 25 CABG each year were used to compare volume, trends, and relative rates of procedure use between hospitals over time. Because this data set did not involve patient-specific information, the data will be presented as relative rates of revascularization procedures to Cath because not every revascularization procedure necessarily originated from a Cath.

Statistical analysis

Percentage change in volume and rate of procedure use was calculated for the period. Procedure rates were compared across time using the analysis of variance statistical test. The F statistic from the regression analysis of variance, which tests for a linear relationship with a nonzero slope, was used to derive the *P*-trend value. *P*-trend values < .05 were considered statistically significant.

Responsibility

No extramural funding was used to support this work. The authors are solely responsible for the design and conduct of this study, all study analyses, and the drafting and editing of the manuscript and its final contents.

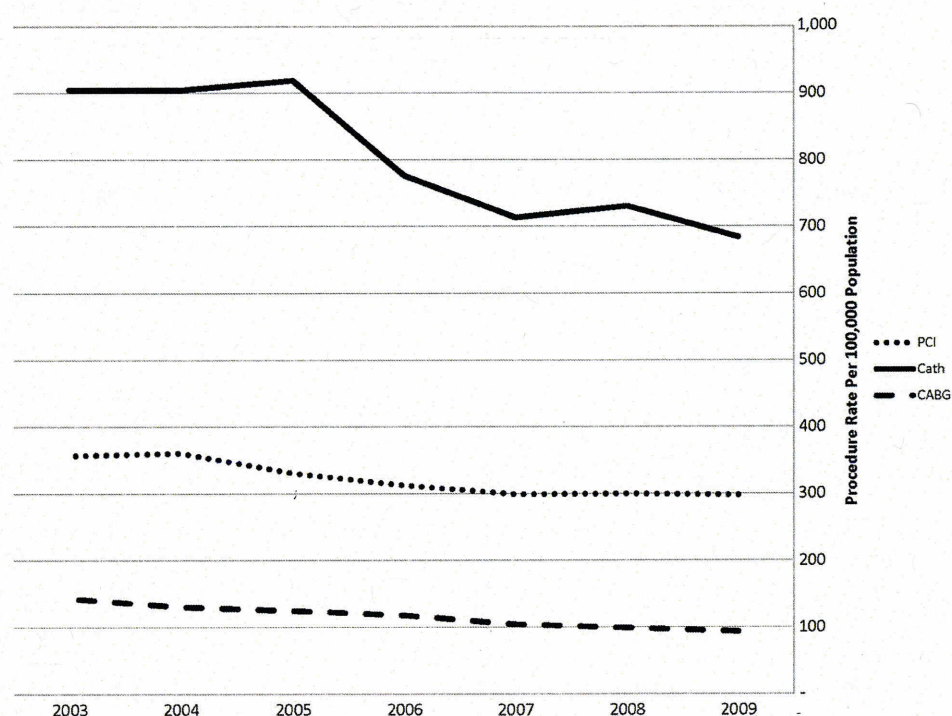
Results

There were 4 integrated academic medical center hospitals and 49 acute care hospitals (that do not meet criteria for integrated academic medical center hospitals as designated by the Association of American Medical Colleges) that performed invasive cardiac procedures across a wide geographic spectrum in North Carolina (see Figure 1).⁸ Of these 53 hospitals, 22 performed Cath, PCI, and CABG, whereas 31 performed only Cath and PCI during the study period. The absolute number of all procedures declined significantly during the study period. It should be noted that, during this period, the overall state population did increase from 8,416,671 to 9,382,609. When adjusted for the population, the rate of procedure use declined similarly: 24% for Cath (falling from 905/100,000 NC population in 2003 to 684/100,000 NC population in 2009), 16% for PCI (falling from 357/100,000 NC population in 2003 to 298/100,000 NC population in 2009), and 35% for CABG (falling from 143 CABG/100,000 NC population in 2003 to 93 CABG/100,000 NC population in 2009) (see Table 1 and Figure 2). As demonstrated in Figure 2, the absolute change in rate of procedure use was small from 2007 to 2009.

Over the study period, the relative rate of PCI to Cath increased by 11%, the relative rate of CABG to Cath decreased by 13%, and the relative rate of CABG to PCI decreased by 22% (see Figure 3). Of the 53 hospitals that reported performing invasive cardiac procedures in

Table I. Temporal trends of Cath, PCI, and CABG during the study period

	2003	2004	2005	2006	2007	2008	2009
North Carolina population	8 416 671	8 531 487	8 669 657	8 867 193	9 064 307	9 247 173	9 382 609
Cath	76 136	77 161	79 641	68 829	64 659	67 542	64 161
Rate of Cath per 100 000 population	905	904	919	776	713	730	684
PCI	30 029	30 771	28 659	27 713	27 102	27 714	27 963
Rate of PCI per 100 000 population	357	361	331	313	299	300	298
CABG	12 041	11 128	10 817	10 459	9449	9136	8762
Rate of CABG per 100 000 population	143	130	125	118	104	99	93

Figure 2

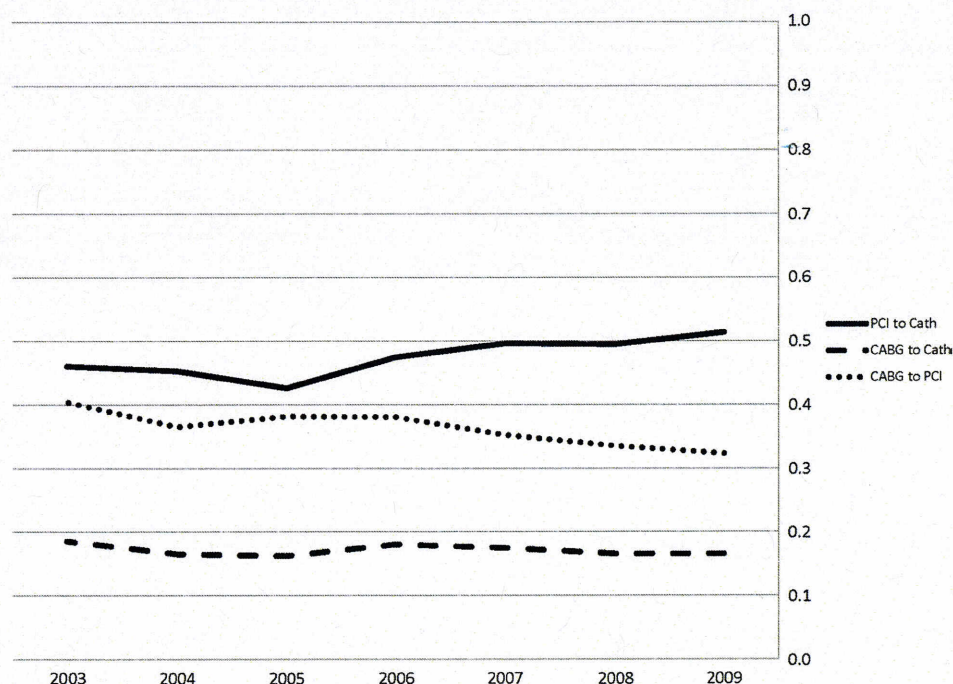
Trends in procedure use. Trends in invasive cardiac procedure rates per 100,000 population in North Carolina, 2003 to 2009. In spite of an enlarging general population in North Carolina, there was a significant decline in the volume of all invasive cardiac procedures from 2003 to 2009. The overall state population did increase from 8,416,671 to 9,382,609 during the study period. When adjusted for the population, there was a 24% decline in Cath, 16% decline in PCI, and 35% decline in CABG during the study period.

North Carolina, 21 hospitals reported performing >25 Cath, 25 PCI, and 25 CABG each year from 2003 to 2009 (1 hospital initiated a cardiac surgery program during the study period and did not perform sufficient volume during multiple years to meet criteria). Volume, rate, and trend analyses from these centers demonstrated similar findings to the total volume, rate, and trend analyses that are described above. Hospital level analysis showed evidence of significant variation in the relative rates of both PCI to Cath (10%-90%, $P < .05$) and CABG to Cath (5%-35%, $P < .05$) (see Figure 4).

Discussion

We analyzed the rates of invasive cardiac procedures over a 7-year period in North Carolina and found that the rates of all invasive cardiac procedures declined significantly despite an enlarging population in North Carolina. Although the relative rate of CABG to Cath declined, the relative rate of PCI to Cath increased steadily during the study period. Temporally, the decline in procedure use was smaller from 2007 to 2009. Of the hospitals that performed at least 25 Cath, 25 PCI, and

Figure 3



Relative rates of revascularization. Overall relative rates of revascularization procedures to diagnostic Cath and relative rates of CABG to PCI. Although the overall volume and rates of invasive cardiac procedures declined significantly, the relative rates of PCI to Cath increased by 11% from 2003 to 2009.

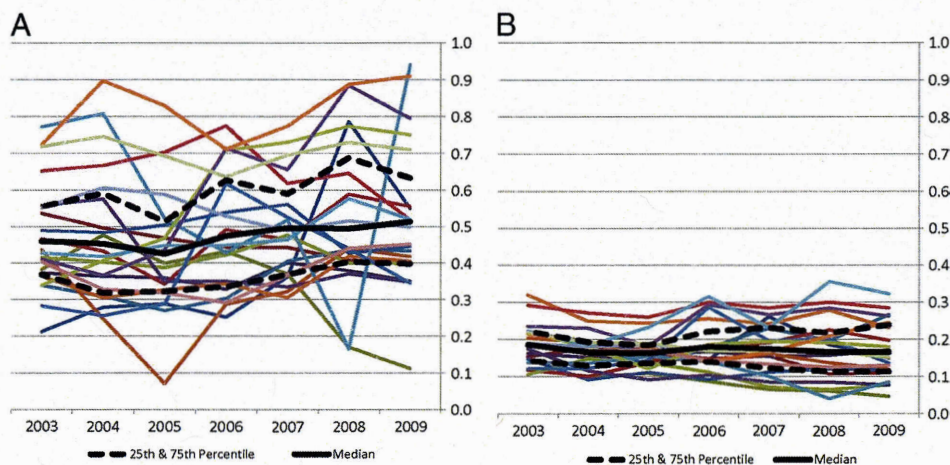
25 CABG each year, there was significant variation in the relative rate of revascularization procedure (PCI or CABG) to Cath.

Over the last decade, there have been reports of diverging trends in revascularization procedures for patients with coronary artery disease in the United States and Canada.^{2,3,5,9-11} The rates and trends in PCI and CABG use in the current study are congruent with prior reports that revascularization procedures have been declining in use since 2003.³ These prior reports are limited by completeness of data because of inclusion of only Medicare patients and exclusion of outpatients, younger patients, and patients with private insurance.^{3,4,12-14} In addition, no prior report has documented hospital-specific variation in procedure use in a region. The current data allowed broad observations on the use of cardiac procedures in North Carolina, as it is unlikely that hospitals underreported their procedure use, as the license renewal application was directly linked to annual licensure.

The decline in use of Cath, PCI, and CABG observed in this study was likely driven by several factors. First, the introduction in 2003 and increased implantation of DES may have contributed to fewer invasive procedures being performed because of less target vessel revascularization

(less in-stent restenosis). In fact, observational studies have shown that use of DES has been associated with improved cardiovascular outcomes and reduced repeat revascularization.¹⁵ Second, increased use of overall cardiovascular medical therapy, as evidenced by continuing reductions in cardiovascular mortality, may also be associated with reduced invasive procedures. Third, the performance of multivessel or complex PCI during the study period has been described,¹⁶ and this may contribute further to the decline in relative rate of CABG and the overall leveling off of procedure use in 2007. Finally, the shift from scheduled PCI to ad hoc PCI during this period may have contributed to fewer invasive procedures being performed. This shift to ad hoc PCI might also play a part in the change in the relative rate of PCI to Cath compared with the relative rate of CABG to Cath. Our study was unable to assess the impact of these factors on procedure rates in North Carolina.

In terms of hospital-specific variation, the current study has shown that hospitals' relative rates of CABG to Cath varied as much as 4-fold, whereas the relative rates of PCI to Cath varied as much as 9-fold. This has important implications when considering prior reports that suggested that patients who live in an area of high Cath rates may be more prone to receive PCI.¹² Prior reports

Figure 4

Hospital variation in relative rates of revascularization to Cath. Hospital variation in the relative rates of PCI to Cath (Panel A) and CABG to Cath (Panel B) in North Carolina hospitals performing at least 25 Cath, 25 PCI, and 25 CABG procedures from 2003 to 2009. The 25th and 75th percentiles are designated with dotted black lines, and the median relative rate is designated with a solid black line.

have shown that the rate of coronary angiography and revascularization procedures has been moderately associated with the number of Cath laboratories and the number of cardiologists, but they have not been linked to patient characteristics or the prevalence of risk factors in a region.^{5,11,12} With continued emphasis on the overall health care costs and use of procedures, some may interpret the data in this current study to imply that the relative rate of revascularization (either PCI or CABG) to Cath should be used to assess appropriateness of the use of invasive procedures. We would strongly caution against that, as the current study does not have clinical information to evaluate the appropriateness of the invasive procedures. Furthermore, as previously described, there may be significant variation in the use of noninvasive studies used to identify coronary disease that differ in the referral regions of specific hospitals.¹⁷ Despite these limitations, hospitals that are on the ends of the spectrum with regard to these rates of invasive cardiac procedures to revascularization, both high and low, should consider performing quality review to understand the nature of the local practice and ensure that there is not under- or overuse that may deprive patients of the possible benefits of revascularization or may expose them to unwarranted risks and increased cost.

These data suggest that further investigation into the geographic trends and variation in use of cardiac procedures is warranted. Specifically, there is a need to understand differences in geographic and hospital variation in terms of patient characteristics, indication

for procedures, and even coronary angiographic characteristics. Future studies should aim to determine if patients with similar characteristics or who present with similar clinical indications are more prone to undergo invasive procedures and revascularization at specific hospitals. This propensity to revascularize may be a local or regional practice pattern.

There are several limitations to our study. Our findings pertain to the population of North Carolina, and the extent to which they represent other states or the United States in general is not defined. Given the nature of the data presented, we were unable to obtain patient-specific information such as demographics, indications for invasive procedure, and need for repeat revascularization procedures. However, the current study was not subject to underreporting or miscoding issues that can occur in many administrative studies, as the source of our data is linked to annual Cath laboratory licensure, and this study included all subjects regardless of age, indication, or insurance carrier.

In conclusion, the rates of diagnostic coronary angiography and coronary revascularization via PCI or CABG declined in North Carolina from 2003 to 2009. This decline over this period is more pronounced when the number of procedures performed per 100,000 North Carolina residents is examined. This overall decline in invasive procedures may be due to improved medical therapy and improved more durable percutaneous and surgical revascularization techniques. The significant variation in the relative rates of PCI to Cath and CABG to Cath observed between hospitals in this study

warrants further investigation specifically to examine the clinical indications and evaluate the appropriateness of coronary revascularization.

Disclosures

None.

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