From the Society for Vascular Surgery

Trends, complications, and mortality in peripheral vascular surgery

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Background: **The recent evolution in treatments for peripheral vascular disease has dated available mortality statistics for vascular intervention. Moreover, many of our current mortality statistics are derived from single-institution studies that are often not reflective of outcomes in general practice. To provide current and generalizable data regarding mortality and trends for peripheral vascular interventions, we examined two national data sets (Nationwide Inpatient Sample, 1998-2003, and National Hospital Discharge Survey, 1979-2003) and four states (New York, California, Florida, and New Jersey, 1998-2003).**

Methods: **Four procedures—abdominal aortic aneurysm repair (nonruptured), lower extremity revascularization, amputation, and carotid revascularization—were selected by cross-referencing International Classification of Diseases, 9th Revision, diagnostic and procedural codes. For significance, the *t* test was used for continuous variables, the χ^2 test was used for dichotomous variables, and the χ^2 test was used for mortality trends.**

Results: **From 1998 to 2003, there was a progressive decrease in the national per capita rate of amputations: 13.2% overall and 21.2% for major amputations ($P < .0001$). Nationally and regionally, mortality has only slightly declined. For lower extremity revascularization, after a sharp increase during the 1980s to 100,000 open procedures, the volume remained constant for 10 years and began to decline in 1998, reaching 70,000 cases in 2003. In contrast, since 1996, endovascular interventions have increased 40%. Mortality during the 1998 to 2003 period remained virtually stable at 1.5% to 2% for endovascular procedures and 3% to 4% for open procedures. The overall volume of abdominal aortic aneurysm repair has not changed substantially for the past 6 years; however, endovascular repair is now used for nearly half the cases (46.5% regional and 43.0% national). Mortality for open repair has not changed, remaining at approximately 5%, whereas for endovascular repair, mortality has declined from 2.6% in 2000 to less than 1.5% in 2003. After the rapid increase in open carotid revascularization in the early 1990s, the total volume has declined 5% nationally from 1998 to 2003. Regional data demonstrated an overall 12% reduction in carotid revascularization volume since 1998; this reduction was due to a 16% decline in open carotid revascularization. During this same period, the use of angioplasty-stent carotid revascularization doubled. Mortality for the open procedures is 0.5% and is significantly higher (2%-3%) for endovascular carotid revascularization. Stroke rates for endovascular carotid revascularization are also higher: 2.13% vs 1.28% for open procedures ($P < .0001$).**

Conclusions: **Dramatic shifts in the management of peripheral vascular disease have occurred together with an overall decline in mortality. There seems to be a significant mortality advantage for endovascular as compared with traditional surgery except for carotid endarterectomy. The increasing safety of vascular interventions should be considered when deciding which patients to treat but with the caveat that endovascular interventions are not always safer than open repair.**

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Recent years have witnessed a substantial change in the management of most common vascular diseases. Vascular surgeons have played a pioneering role in the development and introduction of new endovascular techniques, some of which have fundamentally changed the therapeutic options for these patients. At the same time, we have seen the development of new screening and diagnostic testing methodologies and strategies. The availability of these new diagnostic strategies and therapeutic regimens has affected patient selection criteria and the patient populations that ultimately receive vascular interventions.

Despite these developments, there has been little analysis of the effect of these technological changes on the regional and national volume of major vascular surgery. Moreover, even less is known about their effect on patient outcomes. Many of the often quoted mortality and morbidity rates are out of date, and because they are generally derived from single-institution or selective-series studies, they may not reflect the outcomes seen in general practice.

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Competition of interest: none.

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Table I. ICD-9 procedure and diagnosis codes

Category	*ICD-9 procedure codes*		*ICD-9 diagnosis codes*	
Carotids	Open		433.1	Carotid artery occlusion and stenosis
	38.12	Carotid endarterectomy	433.3	Multiple/bilateral carotid occlusion
			435.9	Transient cerebral ischemia
	Endo		362.3	Retinal vascular occlusion, unspecified
	39.50	Angioplasty or atherectomy of noncoronary vessel	362.8	Other retinal disorders
	39.90	Insertion of non–drug-eluting, non–coronary artery stent(s)		
AAA	Open		441.4	Abdominal aneurysm without mention of rupture
	38.34	Resection of abdominal aorta with anastomosis	441.9	Aortic aneurysm of unspecified site without mention of rupture
	38.44	Resection of abdominal aorta with replacement		
	38.64	Other excision of vessels, abdominal aorta		
	39.52	Other repair of vessels, abdominal aorta		
	Endo			
	39.71	Endovascular implantation of graft in abdominal aorta		
LER	Open		440.2	Atherosclerosis of extremities
	39.29	Other (peripheral) vascular shunt or bypass (excludes peritoneovenous shunt)	250.7	Diabetes with peripheral circulatory disorders
			443.9	Peripheral vascular disease
	38.08	Embolectomy/thrombectomy lower limb arteries	444.22	Arterial embolism and thrombosis of LE
	38.18	Endarterectomy lower limb arteries	442.3	Aneurysm of artery of LE
	38.38	Resection of lower limb arteries with anastomosis	996.74	Other complications of internal prosthetic device, implant, and graft due to other vascular device, implant, and graft
	38.48	Resection of lower limb arteries with replacement		
	38.88	Clamping/ligation/division/occlusion of lower limb arteries		
	Endo			
	39.50	Angioplasty or atherectomy of noncoronary vessel		
	39.90	Insertion of non–drug-eluting, non–coronary artery stent(s)		
Amputations	Major		445.02	Atheroembolism, LE
	84.13	Disarticulation of ankle	440.20	ASO—Native arteries/extremities unspecified
	84.14	Amputation of ankle through malleoli of tibia and fibula	440.22	ASO—Native arteries/extremities with rest pain
			440.23	ASO—Native arteries/extremities, with ulceratio
	84.15	Other amputation—below ankle	440.24	ASO—Native arteries/extremities, with gangrene
	84.16	Disarticulation of knee	440.30	ASO—Unspecified bypass graft/extremities
	84.17	Amputation—above knee	440.31	ASO—Autologous vein/bypass graft/extremities
			440.32	ASO—Nonautologous vein/bypass graft/ extremities
	All			
	84.1	Amputations of lower limb	444.22	Arterial embolism and thrombosis of LE
	84.3	Revision of amputation stump	447.1	Stricture of artery
			707.1	Ulcer of lower limb, except decubitus
			707.9	Chronic ulcer of unspecified site
			729.5	Pain in limb
			730.06	Acute osteomyelitis—lower leg
			730.07	Acute osteomyelitis—ankle and foot
			730.16	Chronic osteomyelitis—lower leg
			730.17	Chronic osteomyelitis—ankle and foot
			785.4	Gangrene
			996.74	Complication—vascular device thrombosis
			997.62	Amputation—chronic infection stump
			998.59	Postoperative wound infection
			250.7	Diabetes with peripheral circulatory disorders

ICD-9, International Classification of Diseases, 9th Revision; *AAA,* aortic abdominal aneurysm; *ASO,* atherosclerosis; *LER,* lower extremity revascularization; *LE,* lower extremity.

This article addresses this lacuna by analyzing current and generalizable data regarding mortality, morbidity, and volume for the most common vascular interventions: carotid revascularizations (CR), abdominal aortic aneurysm repairs, lower extremity revascularizations, and amputations. We examined two national data sets (the National Hospital Discharge Survey [NHDS] and the Nationwide Inpatient Sample) and four state databases (New York, California, Florida, and New Jersey) from the late 1990s through 2003. The national data sets are projections based on a sample of hospitals. The state data sets offer valuable insights because they encompass all of

Table II. List of ICD-9 codes for comorbidities and postoperative complications

Variable	*ICD-9 Code*	*Description*
Comorbidities		
Diabetes	250	Diabetes mellitus
Hypertension	401	Essential hypertension
	402	Hypertensive heart disease
	403	Hypertensive renal disease
	404	Hypertensive heart and renal disease
	405	Secondary hypertension
Emphysema	490	Bronchitis, not specified as acute or chronic
	491	Chronic bronchitis
	492	Emphysema
	493	Asthma
	494	Bronchiectasis
	496	Chronic airway obstruction, not elsewhere classified
Coronary	413	Angina pectoris
	414	Other forms of chronic ischemic heart disease
	412	Old myocardial infarction
	429.2	Cardiovascular disease, unspecified
Peripheral	443.9	Peripheral vascular disease, unspecified
	440	Atherosclerosis
Renal	585	Chronic renal failure
	403	Hypertensive renal disease
	582	Chronic glomerulonephritis with unspecified pathologic lesion in kidney
Cerebral	434	Occlusion of cerebral arteries
	433	Occlusion and stenosis of precerebral arteries
	437	Other and ill-defined cerebrovascular disease
	438	Late effect of cerebrovascular disease
Lipids	272.0	Disorder of lipoid metabolism. Pure hypercholesterolemia
Hypotension	458.2	Hypotension. Iatrogenic hypotension
	458.8	Other specified hypotension
	458.9	Hypotension, unspecified
Postoperative complications		
Cardiac	997.1	Cardiac complications. Cardiac arrest during or resulting from a procedure. Cardiac insufficiency during or resulting from a procedure. Cardiorespiratory failure during or resulting from a procedure. Heart failure during or resulting from a procedure
Perioperative stroke	997.02	Iatrogenic cerebrovascular infarction or hemorrhage. Postoperative stroke
Respiratory	997.3	Respiratory complications. Mendelson syndrome resulting from a procedure. Pneumonia (aspiration) resulting from a procedure
	518.5	Pulmonary insufficiency after trauma and surgery. Adult respiratory distress syndrome. Pulmonary insufficiency following shock, surgery, or trauma. Shock lung
Bleeding	285.1	Acute posthemorrhagic anemia. Anemia due to acute blood loss
	998.1	Hemorrhage or hematoma or seroma complicating a procedure
Infection	998.5	Postoperative infection
	998.59	Other postoperative infection. Abscess: postoperative intra-abdominal postoperative, stitch postoperative, subphrenic postoperative, wound postoperative. Septicemia postoperative
	996.62	Infection and inflammatory reaction due to internal prosthetic device, implant, and graft—due to other vascular device, implant, and graft (arterial graft, arteriovenous fistula or shunt, infusion pump, vascular catheter (arterial) (dialysis) (venous)
Shock	998.0	Postoperative shock. Collapse NOS during or resulting from a surgical procedure. Shock (endotoxic) (hypovolemic) (septic) during or resulting from a surgical procedure

ICD-9, International Classification of Diseases, 9th Revision; *NOS,* not otherwise specified.

the discharges in these four states (8 million), which constitute approximately 24% of the national hospital discharges and a population base that is approximately 30% of the US census. In addition, the evolution of treatment of peripheral vascular disease over the past 5 years was analyzed in an effort to project trends that are likely to affect training, manpower, and future research.

METHODS

Source of data. The NHDS is compiled annually by the National Center for Health Statistics. This database contains medical and demographic information from a sample of discharge records selected from a national sample of acute care hospitals. Hospitals with fewer than six beds staffed for patient use, as well as federal, military, and Veterans Administration hospitals, are excluded. Hospital discharge data are collected by means of a stratified system on the basis of the annual number of discharges and the geographic location of each institution. From the nation's approximately 6000 hospitals, approximately 500 are selected each year for inclusion in the NHDS. Discharges are weighted to reflect the 33,000,000 annual discharges across the nation. Descriptive statistics can be generated for procedures, diseases, race, sex, age, region, and payer; diagnosis and procedure codes can be determined on the basis of survey data. Such statistics are reliably valid only when the sample size is more than 30.[1]

The Nationwide Inpatient Sample (NIS), part of the Healthcare Cost and Utilization Project, is an annual database of hospital inpatient stays that is used by researchers and policymakers to identify, track, and analyze national trends in health care utilization, access, charges, quality, and outcomes. This database encompasses hospital inpatient stays from states participating in the Healthcare Cost and Utilization Project (8 in 1988, gradually increasing to 35 in 2002). Typical discharge abstracts include demographics, diagnosis (primary and multiple secondary), procedures (primary and multiple secondary), charges, length of stay, and outcomes. The NIS sample represents approximately 20% of US community hospitals, defined by the American Hospital Association as "all non federal, short term, general, and other specialty hospitals, excluding hospital units of institutions." For our analysis, we used the Inpatient Core File, which contains data for 100% of the discharges from a sample of hospitals in participating states.

The four state agencies providing regional data were (1) the New York State Health Department's Statewide Planning and Research Cooperative System; (2) California's Office of Statewide Health Planning and Development; (3) New Jersey's Department of Health and Senior Service UB92; and (4) the Florida State's Department of Health, Florida Discharges Data Abstracts. These data sets followed the Uniform Hospital Minimum Discharge Data Survey's recommendations and include: principle and multiple secondary diagnoses, and principle and multiple procedure codes (International Classification of Diseases, 9th Revision, Clinical Modification), length of stay, and outcome. Complication rates and comorbidity data were compiled from the regional databases (1998-2003 combined) to avoid the small and variable sample size projections of the NHDS and NIS. NIS rather than NHDS data were used for the national analyses when the sample sizes for the NHDS data were too small to be statistically reliable.

Patient populations. Treatment groups were identified by matching all relevant procedure codes with the primary and two secondary diagnostic codes. Four groups were analyzed: CR, abdominal aortic aneurysm repairs (excluding ruptures), lower extremity revascularizations, and lower limb amputations. The diagnosis/procedure code groupings and linkages (Table I, online only) were selected on the basis of experience from prior studies[2-4] and a survey of practitioners to ascertain which codes were most commonly used clinically. We assessed the following comorbidities (primary and all secondary diagnoses): diabetes, hypertension, emphysema, coronary disease, peripheral vascular disease, renal disease, cerebrovascular disease, and disorders of lipid metabolism. Complications included (primary and all secondary diagnoses) cardiac, postoperative stroke, respiratory complications, bleeding, infection, and shock. A list of International Classification of Diseases, 9th Revision (ICD-9), diagnosis codes for comorbidities and complications is provided in Table II (online only).

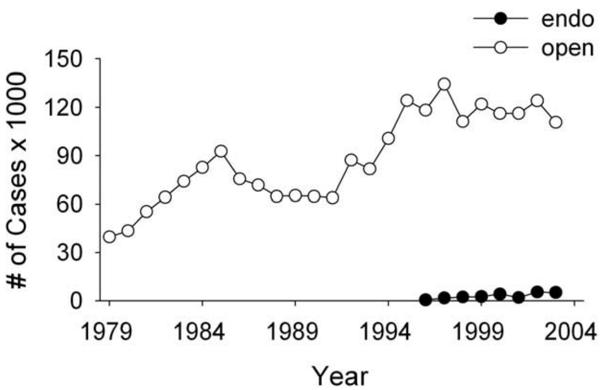

Fig 1. National change in the total number of carotid procedures (based on the National Hospital Discharge Survey). *endo,* Endovascular.

Statistics. For the per capita calculations, annual nationwide census information was obtained from the National Census Bureau for the years 1979 to 2003, and results were expressed as the rate of the variable per 100,000 population. Univariate analyses were conducted by using *t* tests for continuous variables and the Fisher exact test for dichotomous variables. We used χ^2 test for trends to analyze mortality data over time. Confidence intervals for rates were calculated by using normal approximation to the binomial distribution. Data sets were analyzed with SAS version 9.1 (SAS Institute, Cary, NC).

RESULTS

Carotid revascularizations. After a rapid increase in the volume of CR in the early 1990s (>50%) that was related, perhaps, to the outcome of several large randomized trials,[5,6] the national volume of CR after 1998 slightly decreased, reaching a rate of 120,000 cases per year (Fig 1). Regional data demonstrated an overall 12% reduction in CR volume since 1998; this was due to a 16% decline in open CR (Table III and Fig 2A). The total volume, nationally, declined 5% (Table III and Fig 2C). During this same period of time, the use of angioplasty-stent CR more than doubled (state data, 773 in 1998 to 1959 in 2003; national data, 3233 in 1998 to 7518 in 2003; Table III). In summary, despite the increasing use of angioplasty-stent procedures, carotid interventions, overall, seem to be declining.

Mortality, conversely, has been quite steady for open CR, at a rate of 0.5%, but continues to evolve for angioplasty-stent procedures (Fig 2B and D). In 1998, the

Table III. Change in volume of vascular procedures

	NIS			States		
Variable	*1998*	*2003*	*% Change*	*1998*	*2003*	*% Change*
AAA*						
Open	36,172	21,515	−40.5	8,424	4,512	−46.4
Endo	2,287	16,211	608.8	532	3,917	636.3
Total	38,459	37,726	−1.9	8,956	8,429	−5.9
Carotids						
Open	143,643	131,565	−8.4	36,087	30,324	−16.0
Endo	3,233	7,518	132.5	773	1,959	153.4
Total	146,876	139,083	−5.3	36,860	32,283	−12.4
LER						
Open	104,457	81,729	−21.8	26,580	20,313	−23.6
Endo	28,806	44,069	53.0	7,155	10,038	40.3
Combined	11,166	11,221	0.5	2,768	2,646	−4.4
Total	144,429	137,019	−5.1	36,503	32,997	−9.6
Major amputations	65,560	55,574	−15.2	15,243	12,860	−15.6
All amputations	123,983	115,749	−6.6	30,519	28,757	−5.8

NIS, Nationwide Inpatient Sample; *AAA,* abdominal aortic aneurysm; *LER,* lower extremity revascularization; *Endo,* endovascular.
*Years for AAA: 2000 to 2003.

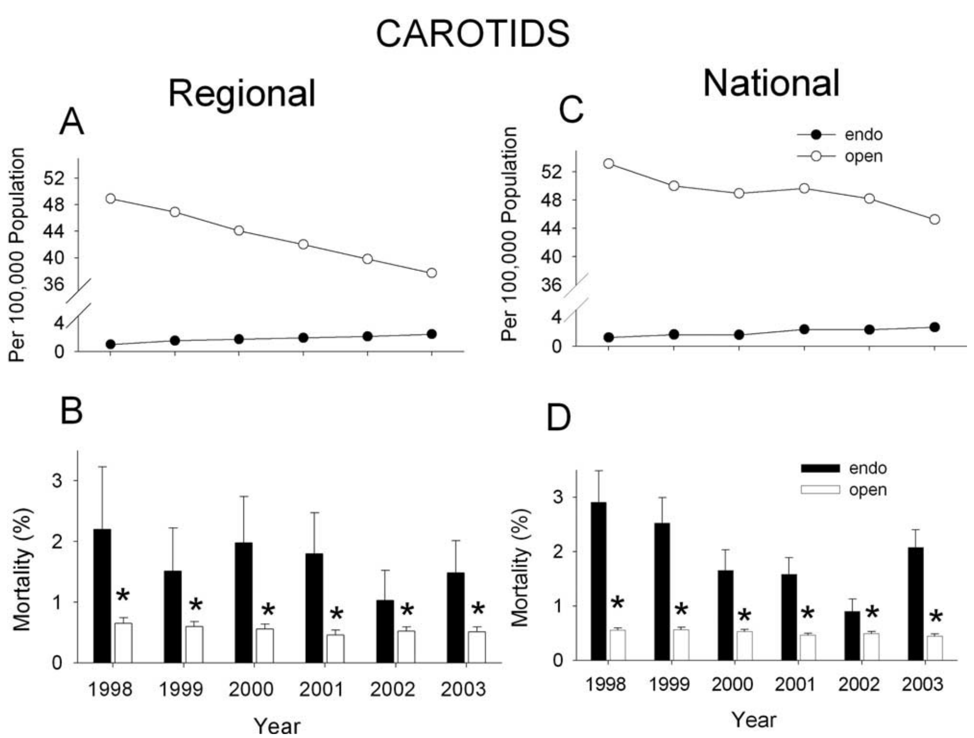

Fig 2. Per capita use (**A** and **C**) and mortality (**B** and **D**) of open and endovascular carotid procedures. Regionally, the number of cases from 1998 to 2003 was 36,087, 35,020, 34,053, 32,966, 31,622, and 30,324 for open procedures and 773, 1124, 1316, 1496, 1653, and 1959 for endovascular procedures, respectively. Nationally (based on the Nationwide Inpatient Sample), the number of cases from 1998 to 2003 was 143,643, 136,287, 137,752, 141,483, 138,731, and 131,565 for open procedures and 3233, 4396, 4410, 6567, 6518, and 7518 for endovascular procedures, respectively. *$P < .05$, open cf endovascular procedures for each year.

mortality for angioplasty-stent procedures was approximately 2% regionally and 3% nationally. These rates decreased to approximately 1% in 2002 but again increased in 2003.

Analysis of comorbidities (Table IV) reveals a similar percentage of diabetics in both groups (25%). Hypertension, chronic obstructive pulmonary disease (COPD), and generalized cerebrovascular disease were more common in

Table IV. Comorbid conditions*

Comorbidities	*Endo (%)*	*Open (%)*	P *value*
Carotids			
Diabetes mellitus	25.36	25.69	.4967
Hypertension	64.84	68.01	<.0001
COPD	11.60	15.49	<.0001
CAD	41.87	40.02	.0007
PVD	25.31	13.27	<.0001
Renal	3.77	2.09	<.0001
Cerebral	97.70	99.95	<.0001
Lipids	22.77	16.40	<.0001
AAA			
Diabetes mellitus	14.29	10.50	<.0001
Hypertension	63.33	59.97	<.0001
COPD	28.94	33.26	<.0001
CAD	45.96	40.16	<.0001
PVD	14.84	17.30	<.0001
Renal	3.68	4.06	.0676
Cerebral	3.75	4.11	.0945
Lipids	16.39	12.14	<.0001
LER			
Diabetes mellitus	39.68	43.90	<.0001
Hypertension	58.76	61.75	<.0001
COPD	14.78	20.86	<.0001
CAD	39.22	38.35	.0007
PVD	79.82	76.88	<.0001
Renal	12.38	10.12	<.0001
Cerebral	7.39	6.69	<.0001
Lipids	11.10	9.47	<.0001
Major amputations			
Diabetes mellitus		65.95	
Hypertension		57.43	
COPD		16.31	
CAD		32.50	
PVD		73.13	
Renal		22.07	
Cerebral		10.16	
Lipids		3.59	

Endo, Endovascular; *AAA,* abdominal aortic aneurysm; *COPD,* chronic obstructive pulmonary disease; *CAD,* coronary artery disease; *PVD,* peripheral vascular disease; *LER,* lower extremity revascularization.
*Based on regional data.

Table V. Postoperative complications*

Variable	*Complications*	*Endo (%)*	*Open (%)*	P *value*
Carotids				
	Cardiac	1.79	2.07	.0784
	PO stroke	2.13	1.28	<.0001
	Respiratory	0.55	1.32	<.0001
	Bleeding	5.32	3.85	<.0001
	Infection	0.36	0.13	<.0001
	Shock	0.02	0.02	.544
AAA				
	Cardiac	2.83	7.75	<.0001
	PO stroke	0.22	0.53	<.0001
	Respiratory	3.54	15.36	<.0001
	Bleeding	8.00	17.10	<.0001
	Infection	0.59	2.23	<.0001
	Shock	0.13	0.50	<.0001
LER				
	Cardiac	0.86	3.05	<.0001
	PO stroke	0.19	0.32	<.0001
	Respiratory	0.70	2.94	<.0001
	Bleeding	7.30	11.07	<.0001
	Infection	1.06	3.20	<.0001
	Shock	0.08	0.14	.0005
Major amputations				
	Cardiac		2.15	
	PO stroke		0.28	
	Respiratory		3.04	
	Bleeding		8.39	
	Infection		4.52	
	Shock		0.12	

Endo, Endovascular; *PO,* perioperative; *AAA,* abdominal aortic aneurysm; *LER,* lower extremity revascularization.
*Based on regional data.

the open group, but coronary artery disease, peripheral vascular disease, and hyperlipidemia were common in the endovascular group.

The complication rates for both interventions are depicted in Table V. Cardiac complications were similar for both (1.8%-2.1%), but the perioperative stroke rate was significantly greater for the endovascular population (2.13% vs 1.28%; $P < .0001$). Respiratory complications were higher for open repairs, whereas bleeding complications were more frequent in the endovascular group.

Abdominal aortic aneurysm repairs. National and regional findings are depicted in Fig 3 and Table III. In reviewing the period from 2000 (when coding became available for separating open from endovascular repair) to 2003, there has been a decline in overall volume: national data set, from 38,459 to 37,726 (1.9%); regional, from 8,956 to 8,429 (5.9%). The proportion of endovascular repairs, now used in almost half the patients, has increased significantly (from 0.7/100,000 in 2000 to 4.9/100,000 in 2003, up 608% in regional data sets, and from 0.8/100,000 in 2000 to 5.6/100,000 in 2003, up 586% in national data sets) and is paralleled by a decline in open procedures (from 11.6/100,000 in 1998 to 5.6/100,000, down 52% in regional data sets, and from 12.8/100,000 to 7.4/100,000 in 2003, down 41% in national data sets; Table VI). Thus, the percentage of total repairs performed with endovascular procedures went from 5.8% to 46.5% regionally and from 6.3% to 43.0% nationally (2000-2003). During the same period, the mortality of open repairs did not change (state data: 5.1% in 1998 and 5.2% in 2003; national: 4.3% in 1998 and 4.8% in 2003). Conversely, endovascular repair mortality has declined from 2.6% in 2000 to less than 1.5% in 2003 regionally and from 2.1% in 2000 to 1.0% in 2003 nationally (Fig 3 and Table VII).

It is interesting to observe that important comorbidities (Table IV), such as diabetes, hypertension, coronary artery disease, and hyperlipidemia, were more common in the endovascular group. COPD and peripheral vascular disease, by comparison, were more common in the open group. Complication rates (Table V) were significantly higher in the open repair population: cardiac (7.8% vs 2.8%), stroke (0.5% vs 0.2%), respiratory (15.4% vs 3.5%), bleeding (17.1% vs 8.0%), infection (2.2% vs 0.6%), and shock (0.5% vs 0.1%).

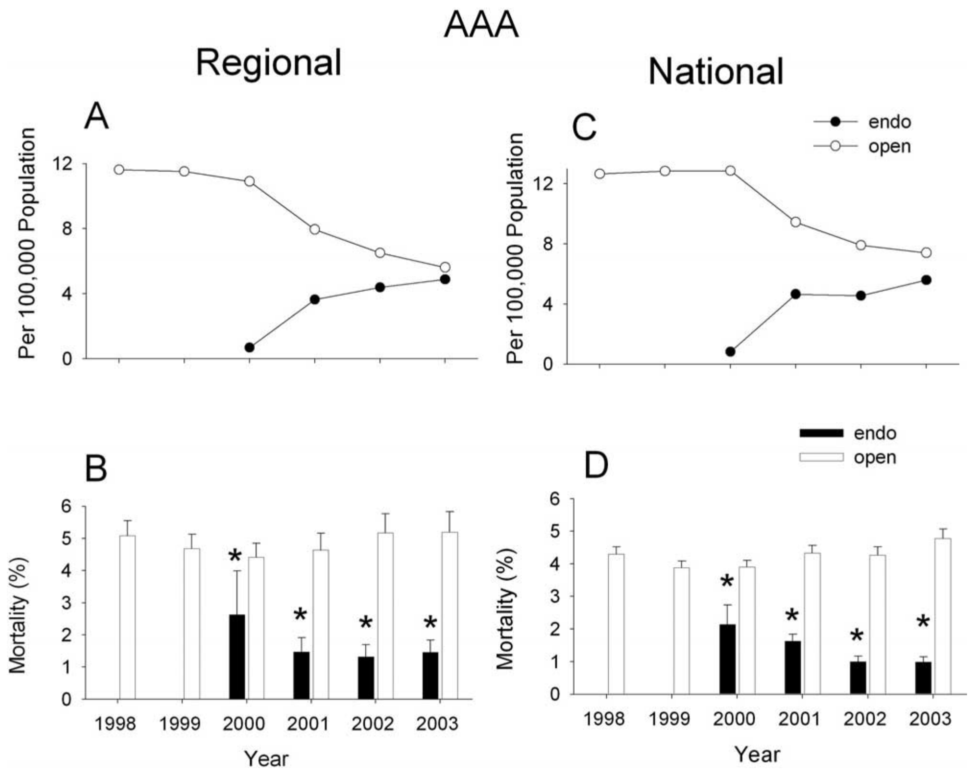

Fig 3. Per capita use (**A** and **C**) and mortality (**B** and **D**) of open and endovascular abdominal aortic aneurysm *(AAA)* procedures. Regionally, the number of cases from 1998 to 2003 was 8582, 8589, 8424, 6236, 5166, and 4512 for open procedures and for years from 2000 to 2003 was 532, 2857, 3488, and 3917 for endovascular procedures. Nationally (based on the Nationwide Inpatient Sample), the number of cases from 1998 to 2003 was 34,190, 34,983, 36,172, 26,886, 22,728, and 21,515 for open procedures and for years from 2000 to 2003 was 2287, 13,248, 13,069, and 16,211 for endovascular procedures. *$P < .05$, open cf endovascular procedures for each year.

Table VI. Change in per capita use of vascular procedures from 1998 to 2003

	NIS		*States*	
Variable	*% Change*	P *value*	*% Change*	P *value*
AAA				
Open	−41.52	<.0001	−51.66	<.0001
Endo*	585.95	<.0001	607.93	<.0001
Carotids				
Open	−14.87	<.0001	−22.73	<.0001
Endo	116.14	<.0001	133.03	<.0001
LER				
Open	−27.28	<.0001	−29.73	<.0001
Endo	42.20	<.0001	29.00	<.0001
Major amputations	−21.21	<.0001	−31.77	<.0001
All amputations	−13.23	<.0001	−13.36	<.0001

NIS, Nationwide Inpatient Sample; *AAA,* abdominal aortic aneurysm; *Endo,* endovascular; *LER,* lower extremity revascularization.
*Years for endovascular AAA: 2000 to 2003.

Table VII. Mortality change for vascular procedures from 1998 to 2003

	NIS		*States*	
Variable	*% Change*	P *value*	*% Change*	P *value*
AAA				
Open	0.48	.0073	0.11	.7941
Endo*	−1.15	<.0001	−1.18	.0422
Carotids				
Open	−0.11	.0086	−0.13	.0235
Endo	−0.84	<.0001	−0.72	.1884
LER				
Open	−0.49	<.0001	−0.57	.0011
Endo	−0.57	<.0001	−0.14	.5098
Major amputations	0.03	.839	−0.80	.014
All amputations	−0.46	<.0001	−0.81	<.0001

NIS, Nationwide Inpatient Sample; *AAA,* abdominal aortic aneurysm; *Endo,* endovascular; *LER,* lower extremity revascularization.
*Years for endovascular AAA: 2000 to 2003.

Lower extremity revascularization. Over a two-decade period from 1979 to 1998, open lower extremity reconstructive procedures (including infrainguinal, direct, and extra-anatomic) more than doubled (Fig 4). Over the subsequent 6 years (through 2003), despite a substantial increase in the number of lower extremity endovascular interventions (40% regional and 53% national), there was an overall decline in the total number of lower extremity

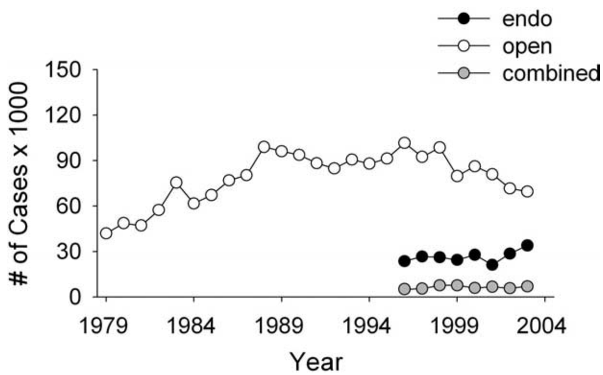

Fig 4. National change in the total number of lower extremity revascularization procedures (based on the National Hospital Discharge Survey). *endo,* Endovascular.

procedures performed (5.1% decrease nationally [NIS] and 9.6% according to state data; Table III and Fig 5A and C). From the 1980s to the mid 1990s, there was a significant decline in mortality, from approximately 7% to 4% nationally (data not shown). However, mortality during 1998 to 2003 remained virtually stable at 1.5% to 2% for endovascular procedures and 3% to 4% for open and combined procedures (endovascular together with open; Table VII and Fig 5B and D). Cardiac, stroke, respiratory, bleeding, and infection complications were all significantly greater for both the open procedures group and the open with endovascular procedures group as compared with patients who received endovascular interventions alone. These differences in complication rates occurred despite a relatively similar overall incidence of comorbidities in the three populations (Tables IV and V).

Amputations. The volume for major amputations nationally and the volume of major and minor amputations regionally have both declined (Table III and Fig 6). For the period 1998 to 2003, regional state data reveal a 5.8% overall decrease in volume; nationally, the decrease over the same period was 6.6% (Table III). More significantly, however, there has been a 15.6% (state) and 15.2% (national) decrease in major amputations in what continues to be a high-risk group of patients: ie, those with diabetes (65.9%), hypertension (57.4%), large-vessel peripheral vascular disease (73.1%), coronary artery disease (32.5%), renal insufficiency (22.1%), cerebrovascular disease (10.2%), and COPD (16.3%) (Table IV). Overall mortality is declining, but slowly, and remains more than 6% for major amputations nationally (Fig 6 and Table VII).

DISCUSSION

Our data support the general perception that dramatic shifts toward endovascular treatments have occurred in the management of peripheral vascular disease. Moreover, our data demonstrate that there has been an overall decline in treatment-related mortality, amputation rates, and complications. Given the growth and aging of the US population (24% overall increase from 1980 to 2000; 43% increase in the age group >65 years; and 67% increase in the age group >75 years; http://www.census.gov) and the increasing utilization rate of vascular interventions in the elderly,[2] it is not surprising that we observed more than a doubling in the number of vascular procedures from 1979 to 2003 (358,000 to 785,000).[2] Less clear is the more recent (last 5 years of the analysis) stabilization or decline of volume in vascular interventions. Possible explanations for this change include greater public awareness and improved risk factor management, a swing of the pendulum back toward conservative management of small aneurysms and asymptomatic carotid disease,[7-12] or the effect of cost-containment policies on utilization levels.

The decreased mortality and improved results with endovascular aneurysm repair have been observed by others and perhaps could be anticipated with improved device technology, increasing experience, and the less invasive nature of the procedure.[2,13-16] The higher, and possibly increasing, mortality of open aneurysm repair since 2000 (Fig 3B and D; Table VII) likely reflects the shift toward treating more complex and morbid (juxtarenal and suprarenal) aneurysms, because infrarenal aneurysms are more commonly treated with endovascular techniques.

In addition, many patients who previously would have been considered to represent good risks for open repair have undergone, instead, endovascular aneurysm repair. This would favorably influence the mortality/morbidity rate for endovascular aneurysm repair in its recent period of use (2000-2003) compared with its earlier use in predominantly higher-risk patients. One of the limitations of large data sets is the inability to define arterial anatomy. Presumably, aneurysms are selected for endovascular repair because they are not pararenal or lack significant iliac disease; both factors increase the risk of open repair.

Other studies have noted that the increased use of vascular interventions has led to improved limb salvage rates.[17-20] It is interesting to note that, for the period 1998 to 2003, our analyses demonstrate a decline in amputation rates (Fig 6A and C) in parallel with the increasing application of endovascular interventions (Fig 5A and C) and despite a decrease in the overall number of lower extremity revascularization procedures (Table III). Because patient morbidity has not substantially changed, it is interesting to speculate about whether the shifts toward endovascular treatment and the possible attendant earlier interventions might be a significant factor in this apparent outcomes improvement. Another variable that affects these results is the increasing application of endovascular interventions to femoropopliteal disease, an area in which it had not previously been thought or have durable results. Of course, other variables are operative, including changes in medical and risk factor managements, as well as the current heightened focus on newer and more specialized wound care treatments and methodologies. These issues merit further analysis and study.

The major unexpected finding in this study is the higher mortality (total and per capita, national, and regional) and the higher stroke rate for carotid angioplasty-

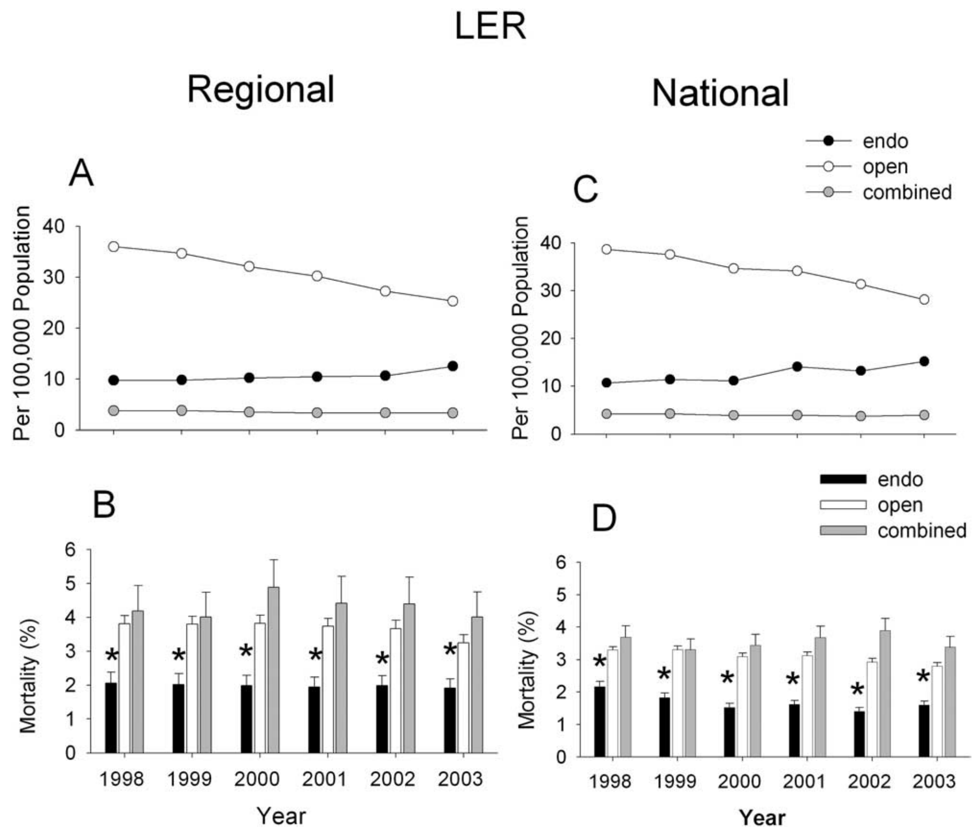

Fig 5. Per capita use (**A** and **C**) and mortality (**B** and **D**) of open, endovascular *(endo)*, and combined lower extremity revascularization *(LER)* procedures. Regionally, the number of cases from 1998 to 2003 was 26,580, 25,852, 24,760, 23,685, 21,625, and 20,313 for open procedures; 7155, 7299, 7857, 8194, 8429, and 10,038 for endovascular procedures; and 2768, 2817, 2701, 2602, 2640, and 2646 for combined procedures, respectively. Nationally (based on the Nationwide Inpatient Sample), the number of cases from 1998 to 2003 was 104,457, 102,457, 97,387, 97,247, 90,301, and 81,729 for open procedures; 28,806, 30,947, 31,242, 40,068, 37,882, and 44,069 for endovascular procedures; and 11,166, 11,319, 10,771, 11,029, 10,515, and 11,221 for combined procedures, respectively. $*P <$ .05, open cf endovascular procedures for each year.

stent procedures compared with carotid endarterectomy, despite the near equivalence of comorbidities in the two groups (Fig 2B and D; Table IV). These findings are at odds with other studies that have demonstrated equivalence or improved results for angioplasty-stent treatment compared with open carotid endarterectomy, particularly in higher-risk patients.[21-24] The logical explanation would be that carotid angioplasty and stenting were performed preferentially on high-risk patients and that carotid endarterectomy was performed on a large number of low-risk and some high-risk patients. There seems, however, to be substantial risk equivalence among the various treatment groups[25,26] (Table IV).

While acknowledging that there are constraints imposed by the complexities of working with large data sets, we believe that we have indeed identified, through ICD-9 procedure and diagnostic codes, the subset of patients who were treated with carotid stents. The ICD-9 procedure code for carotid stenting was not created until 2004. Thus, identifying patients who had undergone carotid stenting before the specific procedure code was issued required a two-step process: first, finding patients who underwent an intravascular stent procedure, and second, by using a disease code, identifying the subset of those patients who had carotid disease and therefore were most likely to have had the procedure performed in the carotid vasculature. We accomplished this by first identifying a cohort of patients who underwent both noncoronary angioplasty and stent insertion (ICD-9 procedure codes 35.50 and 35.90) and then selecting out a subset of those patients who had either a carotid occlusion or a cerebral ischemic event as their primary, secondary, or tertiary diagnosis (ICD-9 codes 433.1, 433.3, 435.9, 362.3, and 362.8).

The relative merits and outcomes for the treatment of carotid stenosis are a shifting dynamic, which may soon change with the recent increase in endovascular training and the growth of experience of its various practitioners, as well as the more ubiquitous use of embolic protection devices. This is evident in the gradually decreasing mortality with carotid stenting from 2000 to 2002 (Fig 2B and

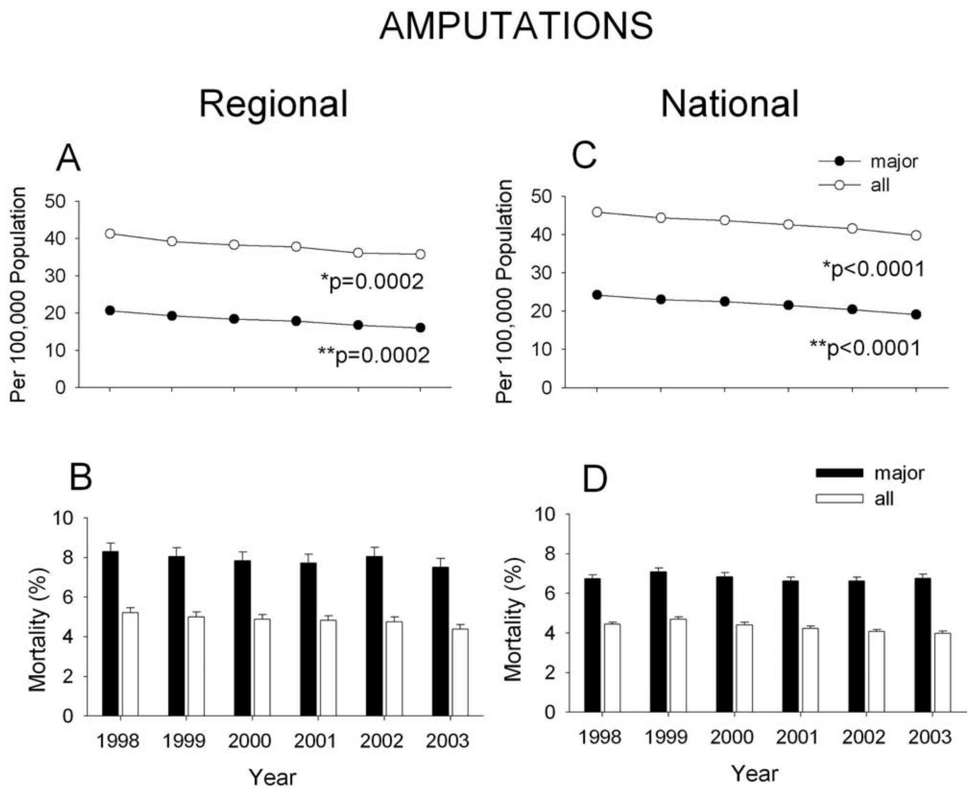

Fig 6. Per capita use (**A** and **C**) and mortality (**B** and **D**) of major and all amputation procedures. Regionally, the number of cases from 1998 to 2003 was 15,243, 14,378, 14,211, 14,021, 13,302, and 12,860 for major and 30,519, 29,243, 29,566, 29,645, 28,686, and 28,757 for all amputations, respectively. Nationally (based on the Nationwide Inpatient Sample), the number of cases from 1998 to 2003 was 65,560, 62,875, 63,242, 61,457, 58,952, and 55,574 for major and 123,983, 120,942, 123,004, 121,505, 119,782, and 111,143 for all amputations, respectively. **P* value for trend of all amputation procedures. ***P* value for mortality trend of major amputation procedures.

D); the unexpected increase again in 2003 could well coincide with a new wave of entering novice practitioners and extension of the procedure to patients who traditionally would have received no treatment.

Of course, one of the weaknesses of large data set analysis is that fine-grained clinical detail and physiological variables (eg, blood pressure, ejection fraction, and anatomic characteristics of the aneurysm) are not included; this hampers our ability to assess the severity of illness and, thus, make unbiased comparisons between treatment groups. Other weaknesses of this type of data set include variabilities and lapses in coding, missed cases, and procedural "contaminations," such as including coronary or intracerebral endovascular interventions with the carotid and lower extremity groups. In addition, a limitation of claims data is that we can analyze only conditions that were diagnosed and records of care received: we know little about the outcomes of patients for whom treatment was not initiated. Because these data bases identify only inpatient admissions, procedures performed in an outpatient setting are not captured. Finally, we did not have access to patient identifiers, and thus we cannot conduct a longitudinal analysis or characterize their baseline health on the basis of preexisting diseases.

To help minimize the effect of these problems, we examined the two major and widely used national data sets, as well as four separate state data sets. We compared the findings among all these data sets for significant disparities. We linked diagnosis and procedure codes. For example, in extracting endovascular extremity cases, procedure codes for extracoronary angioplasty and stenting were combined with diagnosis codes specific for extremity arterial occlusive disease. State data were deemed most reliable because, unlike the national surveys, these record actual numbers, rather than projections from a sample of hospitals. For these reasons, to avoid projection distortions related to small and highly variable sample sizes, the morbidity and complications data were based on the regional rather than the national surveys. The data from the four states and the national data, where sample sizes permitted reliable analysis, were consistent in overall trends.

Making predictions about future volume trends on the basis of this analysis can be somewhat hazardous. Our current review and previous reviews[2-4] have documented unexpected, sudden shifts in practice patterns. The future of surgical and nonsurgical therapies will be clinical variables, including medical management of atherosclerotic disease, biological and genetic engineering advances, and the use of vascular growth factor and endothelial progenitor cells, as well as public policy and economic changes in patient screening, device approvals, and reimbursements. However, what seems quite clear from this analysis is the increasing use and utility of the less invasive procedures and, in general, their effectiveness and safety.

CONCLUSIONS

Despite a dramatic shift from open to less invasive and less morbid endovascular interventions, the total procedure volume has recently stabilized or declined in all categories. Endovascular approaches are supplanting open surgery. Although significant systemic comorbidities seem, overall, not greatly disparate between the two groups, mortality and major complications are, except in the case of carotid patients, markedly reduced with endovascular treatment. For carotid interventions, whereas cardiac, pulmonary, and bleeding complications are decreased with balloon angioplasty and stenting, both mortality and stroke rates have been, at least until recently, significantly higher with stenting vs carotid endarterectomy. This argues for the creation of a clinical registry that would address some of the shortcomings of large data set analysis and would provide a real-time look at the evolution of carotid interventions in everyday clinical practice.

AUTHOR CONTRIBUTIONS

Conception and design: RN, NE, GG, PA, AG, M, M, M.KCK
Analysis and interpretation: RN, E, G, A, G, M, M, M, CK
Data collection: RN, E, G, A, G, M, CK
Writing the article: RN, E, G, A, G, M, CK
Critical revision of the article: RN, E, G, G, M, CK
Final approval of the article: RN, E, G, AG, M, M, M, CK
Statistical analysis: NE, G, G, M
Obtained funding: KCK, G, M
Overall responsibility: RN, KCK

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DISCUSSION

Dr Gregorio A. Sicard *(St Louis, Mo)*. I'm a little curious about the carotid data. Are these primarily New York data?

Dr Nowygrod. The carotid data go through 2003 and are consistent for the four regional states' data, which comprise about a third of the national population, as well as the two major national surveys, the NHDS and NIS. So across the board, at least through 2002 to 2003, the endovascular approach does not compare favorably.

Now, this doesn't look at the last 2 years' data, and it does not include the more recent experience with increasing utilization of embolic safety devices. And again, if we can focus on that second curve depicting the national data trends, the difference between the endovascular and open mortality does appear to be narrowing.

Dr Peter Lawrence *(Los Angeles, Calif)*. My question has to do with the accuracy of the coding. In carotid artery stenting there is currently no reimbursement, so I'm wondering whether or not there might be more carotid artery stenting performed than your data would show?

Dr Nowygrod. The coding issues were the most nettlesome in putting these data together, but in the last 5 to 6 years' experience, in looking at the 1998 through 2002 to 2003 data, the coding and the numbers appear to be reasonable, accurate, and reflective of actual data experience. If you look at the earlier data, in the national surveys, the sample sizes are too small. For that reason, we focused for most of the assessments, and for the endovascular procedures in particular, on the recent (the 1998 through 2003) period. That's one reason we felt it necessary to use several different data sets. In addition to the two major national data sets, we used, as an internal control, the regional, four states', data, where the numbers, since they're not based on probability projections from sample sizes, are most accurate and reliable.