Left subclavian artery coverage during thoracic endovascular aortic repair and risk of perioperative stroke or death

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Introduction: **Left subclavian artery (LSA) coverage during thoracic endovascular aortic repair (TEVAR) is often necessary due to anatomic factors and is performed in to up to 40% of procedures. Despite the frequency of LSA coverage during TEVAR, reported associations with risk of periprocedural stroke or death are inconsistent in reported literature. We examined the 2005-2008 American College of Surgeons National Surgical Quality Improvement Program Participant Use Data file to determine associations between LSA coverage during TEVAR and risk of perioperative stroke or death.**

Methods: **Current procedural terminology (CPT) codes were used to identify patients undergoing TEVAR, LSA coverage, and subclavian revascularization. Patients undergoing coronary bypass, ascending aortic repair, abdominal aortic aneurysm repair, or nonvascular intra-abdominal procedures during the same operation were excluded. Perioperative stroke and mortality associations with LSA coverage were examined using logistic regression models for each outcome. Significance was assessed at $\alpha = 0.05$, with univariable $P < .05$ required for multivariable model entry.**

Results: **Eight hundred forty-five TEVAR procedures were identified, of which 52 patients were excluded due to additional major procedures performed with TEVAR. Seven hundred thirty-three of the remaining 793 procedures included CPT codes indicating primary placement of an initial thoracic endograft and form the basis of this analysis. LSA coverage occurred in 279 procedures (38%). Thirty-day stroke and mortality rates were 5.7% and 7.0%, respectively. LSA coverage was associated with increased 30-day risk of stroke in multivariable modeling (odds ratio [OR], 2.17 95% confidence interval [CI], 1.13-4.14; $P = .019$). Other significant multivariable risk factors for stroke included proximal aortic cuff placement during TEVAR (OR, 2.58; 95% CI, 1.30-5.16; $P = .007$) and emergency procedure status (OR, 3.60; 95% CI, 1.87-6.94; $P < .001$). No significant association between LSA coverage and perioperative mortality was identified (univariable OR, 1.70; 95% CI, 0.98-2.93; $P = .0578$).**

Conclusion: **LSA coverage during thoracic endovascular repair is associated with increased risk of perioperative stroke following TEVAR. Further evidence is needed to determine whether procedural modifications, including LSA revascularization, reduce the incidence of stroke associated with TEVAR. (J Vasc Surg 2011;54:979-84.)**

Thoracic endovascular aortic repair (TEVAR) has become increasingly utilized for treatment of a variety of aortic pathologies since the introduction of commercially available devices.[1-3] Left subclavian artery (LSA) coverage during TEVAR is often necessary due to anatomic factors and is performed in to up to 40% of procedures.[2,4] Despite the frequency of LSA coverage during TEVAR, reported associations with risk of periprocedural stroke or death are inconsistent in reported literature. Sample size limitations, heterogeneity in patient selection criteria, and individualized device utilization patterns make generalization of findings related to the clinical impact of LSA coverage from single-center retrospective and industry-sponsored prospective studies challenging. The role of left subclavian revascularization during TEVAR likewise remains controversial. A 2009 consensus statement from the Society of Vascular Surgery described quality of existing evidence to guide performance of subclavian revascularization in patients undergoing TEVAR as "very low."[3] This same conclusion was also reached by the authors of a recent meta-analysis examining morbidity and mortality effects of LSA coverage during TEVAR, who suggested that improvement of the evidence base will require expansion of multicenter collaborative efforts to obtain sufficient numbers of patients and events necessary for more powerful analyses.[5]

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Competition of interest: Dr Kasirajan has received research and educational grants from Medtronic and W.L. Gore & Associates. Dr Chaikof has received research and educational grants from Boston Scientific, Medtronic, and W.L. Gore & Associates. The American College of Surgeons, National Surgical Quality Improvement Program and the hospitals participating in the ACS-NSQIP are the source of the data used herein; they have not verified and are not responsible for the statistical validity of the data analysis or the conclusions derived by the authors.

Presented at the 2010 Vascular Annual Meeting of the Society for Vascular Surgery, Boston, Mass, June 10-13, 2010.

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The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a competition of interest.

0741-5214/$36.00
Published by Elsevier Inc. on behalf of the Society for Vascular Surgery.
doi:10.1016/j.jvs.2011.03.270

Table I. Procedure designation based on CPT codes

Procedure designation	*CPT codes*
TEVAR	33880
	33881
	33883
	33884
	33886
Placement of initial thoracic aortic endoprosthesis[a]	33880
	33881
Left subclavian artery coverage during TEVAR	33880
Placement of proximal thoracic aortic extension endoprosthesis	33883
	33884
Placement of distal thoracic aortic extension endoprosthesis	33886
Subclavian artery revascularization in combination with TEVAR	33889
	33891
	33875
	33877
Brachial artery exposure for delivery of endoprosthesis	34834
Iliac artery exposure for delivery of endoprosthesis	34820
	34833

TEVAR, Thoracic endovascular aortic repair.
All available code fields (n = 21) were queried for each procedure.
[a]Placement of initial thoracic aortic endoprosthesis required for inclusion in mortality and stroke models.

In this context, we analyzed TEVAR procedures from the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP) Participant Use Data File to further characterize the influence of LSA coverage on 30-day risk of stroke or death. The ACS-NSQIP collects patient-level preoperative, procedural, and postoperative data, including 30-day mortality and morbidity outcomes; data are captured by surgical clinical reviewers at participating sites and entered into a Web-based collection system.[6] Surgical clinical reviewers receive formal training, and inter-rater reliability audits are conducted periodically for all sites to ensure data quality.

METHODS

Procedure identification and categorization. Current Procedural Terminology (CPT) codes were used to identify TEVAR procedures from the 2005-2008 ACS-NSQIP Participant Use Datafile (Table I). The ACS-NSQIP collects patient-level preoperative, procedural, and postoperative data, including 30-day mortality and morbidity outcomes. Data are captured by formally trained surgical clinical reviewers at participating sites and entered into a Web-based collection system, and inter-rater reliability audits are conducted periodically for all sites to ensure data quality.[6] All available CPT code fields (maximum of 20 codes per procedure) were queried to identify both TEVARs and any other procedures performed during the same anesthetic, including subclavian artery revascularization. CPTs 33880 or 33881 were considered indicators of placement of an initial thoracic aortic endoprosthesis, and CPT 33880 was used as an indicator of LSA coverage. Postoperative diagnoses were categorized as aneurysm, dissection, or other using the "PODIAG" variable, indicating the postoperative diagnosis based on the appropriate International Classification of Diseases, Ninth Revision-Clinical Modification (ICD-9-CM) code designated as corresponding to the operative report and/or pathology results.

Patients undergoing simultaneous coronary artery bypass, ascending aortic repair, abdominal aortic aneurysm repair, or other major nonvascular procedures not routinely performed in conjunction with TEVAR were excluded from analysis. Procedures involving placement of proximal and/or distal extension endoprostheses without placement of an initial endoprosthesis were included in descriptive analyses; these procedures were not included in models of perioperative mortality or stroke, however, because we could not discern whether they resulted in coverage of the LSA.

Data analysis. Descriptive statistics are reported as mean ± standard deviation for continuous variables and number (%) for categorical variables. Group-wise comparisons were performed using χ^2 or Fisher's exact test for categorical variables and t tests for continuous variables depending on data distributions; when appropriate, continuous variables were log-transformed prior to group-wise comparisons to satisfy normality assumptions. Significance was assessed at an α level of 0.05, and adjustment for multiple group-wise comparisons of preoperative and procedural factors was performed using the Bonferroni method.

Associations between LSA coverage during TEVAR and 30-day risk of stroke and mortality were examined using uni- and multivariable logistic regression. Preoperative laboratory variables that were ≥10% incomplete were excluded from consideration as candidate covariates. Multivariable models were constructed using a forward selection approach with $P < .05$ required for model entry. Odds ratios are expressed per standard deviation change for continuous covariates. All statistical analyses were performed with SAS version 9.2 (SAS Institute, Cary, NC).

RESULTS

Patient and procedural characteristics. Eight hundred forty-five TEVAR procedures were identified, of which 52 were excluded from analysis due to additional major procedures performed during the same anesthetic, including: abdominal aortic aneurysm repair (n = 47), bowel resection (n = 4), coronary bypass (n = 2), splenectomy (n = 1), and ascending aortic repair (n = 1). Seven hundred thirty-three of the remaining 793 TEVAR procedures included placement of an initial thoracic endograft, while 60 involved placement of a proximal and/or distal extension prosthesis without a code indicating placement of an initial thoracic endograft during the same procedure. A single perioperative mortality and no perioperative strokes were observed in this latter group of procedures involving placement extension prostheses in a separate procedure from primary endograft placement, which were not included in stroke and mortality models.

Table II. Comparison of preoperative and procedural characteristics based on left subclavian artery coverage status

Variable	*Left subclavian artery coverage*		P
	No (n = 454)	*Yes (n = 279)*	
Demographic/anthropometric factors			
Age >80	24.0%	20.4%	.260
Male	57.9%	59.9%	.607
Body mass index	26.8 ± 6.0	27.7 ± 6.0	.052
Medical history			
Hypertension	88.5%	86.7%	.467
Current smoker	32.8%	35.8%	.402
Chronic obstructive pulmonary disease	19.8%	17.9%	.525
Diabetes	11.2%	13.6%	.337
Stroke	11.0%	11.5%	.849
Myocardial infarction[a]	2.2%	0.7%	.146[c]
Angina	3.7%	5.4%	.294
Preoperative hemodialysis	3.1%	5.4%	.122
Congestive heart failure[b]	1.5%	3.2%	.130
Dependent functional status	13.7%	16.9%	.239
Acute preoperative conditions			
Renal failure	1.3%	1.8%	.611
Sepsis	2.6%	4.7%	.145
Pneumonia	1.8%	2.2%	.709
Ventilator-dependent	3.5%	7.5%	.016
Preoperative laboratory data			
Serum creatinine (mg/dL)	1.1 ± 0.6	1.1 ± 0.5	.365
Hematocrit (%)	36.2 ± 5.6	36.0 ± 6.4	.678
White blood cell count (1000/mL^3)	8.6 ± 3.8	9.3 ± 4.8	.145[d]
Procedural characteristics			
Emergent procedure	15.0%	22.2%	.013
Aortic dissection (vs other diagnosis)	19.1%	25.5%	.045
General anesthesia	91.2%	90.0%	.579
Brachial and/or iliac access	15.2%	8.2%	.006
Units packed red blood cells transfused	0.8 ± 1.9	1.1 ± 2.4	.628[d]
Operation time (minutes)	165.7 ± 103.1	173.6 ± 100.8	.219
Proximal aortic cuff placement	18.7%	15.4%	.252

$P < .002$ required for significance at $\alpha = 0.05$ after adjusting for multiple testing (Bonferroni method).
[a]Within 6 months prior to procedure.
[b]Within 30 days prior to procedure.
[c]Fisher's exact test.
[d]Nonparametric (Wilcoxon) method.

Among TEVARs with CPT codes indicating placement of an initial thoracic endoprosthesis, postoperative diagnosis was identified as aneurysm in 74% of patients undergoing TEVAR, while 22% had ICD-9-CM codes indicating dissection pathology. TEVAR procedures consisted of a single thoracic endograft placement in 82.3% of procedures, while the remaining 17.7% also had codes indicating placement of proximal aortic cuffs during the same procedure. CPT codes indicating LSA coverage were identified for 279/733 procedures (38.1%), and 28 patients with LSA coverage (3.8%) had subclavian revascularization performed during the same anesthetic as TEVAR. Preoperative demographic, comorbidity, laboratory, and procedural data categorized by LSA coverage status are summarized in Table II. Preoperative and procedural factors were generally similar between groups. Patients undergoing LSA coverage during TEVAR had higher rates of preoperative ventilator dependence (7.5% vs 3.5%), emergent procedure status (22.2% vs 15%), and postoperative diagnoses indicating dissection pathology (25.5% vs 19.1%). Patients undergoing LSA coverage during TEVAR also had lower rates of CPT codes indicating iliac or brachial access for endograft delivery (8.2% vs 15.2%). These group-wise differences based on LSA coverage status were not significant, however, after adjustment for multiple testing.

Perioperative stroke. Forty-two strokes occurred within 30 days of TEVAR for an overall perioperative stroke rate of 5.7%. The median time interval between TEVAR and diagnosis of stroke was 2 days, and 75% of perioperative strokes were diagnosed within 7 days. Among patients undergoing LSA coverage, 24/279 (8.6%) had perioperative strokes vs 18/454 (4.0%) patients without LSA coverage during TEVAR. No association was identified between past medical history of stroke and risk for perioperative stroke following TEVAR (univariable odds ratio [OR], 1.35; 95% confidence interval [CI], 0.55-3.31). LSA coverage was associated with increased 30-day risk of stroke in univariable analysis (OR, 2.28; 95% CI,

Table III. Associations with 30-day stroke risk following thoracic endovascular aortic repair

	Univariable		*Multivariable*	
Risk factor	*Odds ratio (95% confidence interval)*	P	*Odds ratio (95% confidence interval)*	P
Left subclavian artery coverage	2.28 (1.21-4.28)	.010	2.17 (1.13-4.14)	.019
Left subclavian artery revascularization	3.32 (1.21-9.13)	.020	—	—
Emergent procedure	3.97 (2.09-7.53)	<.001	3.60 (1.87-6.94)	<.001
Proximal aortic cuff placement	2.53 (1.29-4.96)	.007	2.58 (1.30-5.16)	.007
White blood cell count (1000/mL^3)	1.34 (1.08-1.68)	.010	—	—
Units packed red blood cells transfused	1.12 (1.01-1.24)	.033	—	—

Displayed covariates represent those with univariable $P < .05$ used as criterion for consideration for entry into multivariable model using forward selection.

Table IV. Associations with 30-day mortality risk following TEVAR

	Univariable	
Covariate	*Odds ratio (95% confidence interval)*	P
Left subclavian artery coverage	1.70 (0.98-2.93)	.0578
Units packed red blood cells transfused	1.35 (1.24-1.48)	<.0001
White blood cell count (1000/mL^3)	1.67 (1.36-2.05)	<.0001
Preoperative serum creatinine (mg/dL)	1.40 (1.07-1.83)	.0135
Emergent procedure	4.39 (2.49-7.74)	<.0001
Brachial or iliac access	2.56 (1.34-4.90)	.0045
Preoperative sepsis	6.47 (2.66-15.76)	<.0001
Preoperative acute renal failure	4.74 (1.22-18.38)	.0245
Preoperative ventilator dependence	7.11 (3.35-15.10)	<.0001
Operative time (minutes)	1.67 (1.28-2.18)	.0002

TEVAR, Thoracic endovascular aortic repair.
Covariates displayed in addition to left subclavian artery coverage represent those with univariable $P < .05$ used as criterion for multivariable model entry.

1.21-4.28; $P = .010$) and remained a significant risk factor in multivariable modeling (OR, 2.17; 95% CI, 1.13-4.14; $P = .019$). Other significant multivariable risk factors for stroke included proximal aortic cuff placement during TEVAR (OR, 2.58; 95% CI, 1.30-5.16; $P = .007$) and emergency procedure status (OR, 3.60; 95% CI, 1.87-6.94; $P < .001$; Table III).

Perioperative mortality. Fifty-six deaths occurred within 30 days of TEVAR for an overall perioperative mortality rate of 7.0%. Thirty-day mortality occurred in 28/279 patients (10%) with LSA coverage vs 28/454 patients (6.2%) without LSA coverage during TEVAR. Univariable analyses of 30-day mortality showed highly significant associations between 30-day mortality and a number of risk factors (Table IV), including: use of brachial and/or iliac artery exposure for device delivery (OR, 2.56; 95% CI, 1.34-2.50; $P = .0045$), preoperative ventilator dependence (OR, 7.11; 95% CI, 3.35-15.10; $P < .0001$), units of blood transfused intraoperatively (OR, 1.35; 95% CI, 1.24-1.48; $P < .0001$), preoperative white blood cell count (OR, 1.67; 95% CI, 1.35-2.05; $P < .0001$), preoperative sepsis (OR, 6.47; 95% CI, 2.66-15.76; $P < .0001$), log-transformed operative time in minutes (OR, 1.67; 95% CI, 1.28-2.18; $P = .0002$), and emergent procedure status (OR, 4.39; 95% CI, 2.49-7.74; $P < .0001$). The increased mortality rate in patients undergoing LSA coverage was not significant in univariable modeling (OR, 1.70; 95% CI, 0.98-2.93; $P = .058$; Table IV). Because LSA coverage did not meet the significance criterion for multivariable mortality model inclusion and the intent of our analysis was to evaluate associations between LSA coverage and clinical outcomes, mortality analyses were therefore limited to univariable models.

DISCUSSION

Since the initial description of TEVAR by Dake and colleagues,[7] introduction of commercially available devices has been followed by expanding use for management of thoracic aortic pathology has stimulated interest in the influence of left LSA coverage on perioperative outcomes. In our analysis of TEVAR procedures within the ACS-NSQIP Participant Use Datafile, 30-day stroke and mortality rates among patients undergoing primary TEVAR were 5.7% and 7.0%. respectively. Left subclavian artery coverage was associated with increased 30-day stroke risk among patients undergoing primary TEVAR in our multivariable model accounting for other predictive risk factors, but no significant association between LSA coverage and perioperative mortality was observed. Other independent risk factors for stroke were emergent procedure status and proximal aortic cuff placement. All perioperative strokes and 98% of perioperative mortalities were observed in patients undergoing primary TEVAR, while these adverse events were much less frequent following proximal and/or distal extension prostheses placement performed as a separate procedure from the initial thoracic endograft procedure.

Lower 30-day stroke and mortality rates than those observed in this analysis have been reported from recent prospective, industry-sponsored US trials evaluating TEVAR with specific devices (2%-4% and 1%-2%, respectively).[8-10] Because clinical trials are often defined by a single aortic pathology, uniformly include anatomic enroll-

ment criteria based on the proximal device landing zone, and predominantly enroll from high-volume centers of excellence, rates of LSA coverage and adverse events within trials likely differ from clinical practice outside of study protocols. TEVARs analyzed in this study were performed at multiple centers for a variety of pathologies using heterogeneous patient selection criteria; perioperative adverse event rates associated with these procedures therefore may be more representative of outcomes associated with broader clinical application commercially available devices. Contemporary single-center retrospective analyses of TEVAR outcomes reported perioperative stroke and mortality rates of 3% to 10% and 0% to 10%, respectively,[2,4,11-17] are comparable with the rates we observed and likely also reflect influences of broader patient selection criteria and a wider range of clinician experience.

Several prior authors have attempted to ascertain the etiology of perioperative stroke after TEVAR and found similar determinants as were described in our analysis. For instance, associations between proximal extent of aortic coverage during TEVAR and perioperative stroke risk were reported by Feezor et al in their single-center analysis as well as Fairman et al from the Medtronic Vascular Talent Thoracic Stent Graft System for the Treatment of Thoracic Aneurysms (VALOR) Trial.[8] Other authors also identified LSA coverage as a risk factor for perioperative stroke[5,18] Moreover, prior studies failed to clearly identify whether LSA revascularization protected patients from stroke. Cooper et al identified a higher incidence of stroke in patients undergoing LSA coverage, including both patients treated with preoperative subclavian revascularization (pooled OR, 3.18; 95% CI, 1.17-8.65) and patients managed with LSA coverage alone (pooled OR, 2.28; 95% CI, 1.28-4.09). The association we observed between perioperative stroke and emergent procedure status in multivariable modeling is consistent with the findings of Cambria and colleagues, who observed a 15.3% incidence of perioperative stroke associated with TEVAR performed for acute catastrophes of the thoracic aorta.[19]

Reported rates of subclavian revascularization in the setting of TEVAR-related coverage are 15% to 25%, with the majority of revascularizations performed as a separate procedure prior to anticipated coverage during TEVAR.[2,8,11] Although associations between LSA coverage and perioperative adverse neurologic events have been identified in this study and others, it is not clear that routine revascularization would result in a reduction in perioperative stroke complications. We identified a univariable association between simultaneous LSA revascularization and increased 30-day stroke risk, but this association was not significant in multivariable modeling; these observations resemble those of Kotelis et al, who noted lower stroke rates in the setting of LSA coverage without versus with revascularization.[2] Image-based evaluations of post-TEVAR neurologic complications have revealed anterior circulation stroke distributions in a significant proportion of patients[4,13,17]; these anterior infarcts are presumably embolic in nature and therefore not necessarily avoided by pre-emptive revascularization. These inferences are supported by the findings of Cooper et al, who concluded that pre-emptive subclavian revascularization offers no protection against stroke associated with TEVAR.[18] Riesenman and colleagues observed partial LSA coverage in 10 out of 24 patients with preservation of antegrade subclavian flow following TEVAR,[14] demonstrating that identification of LSA coverage based on CPT codes and/or operative reports should not be considered uniformly consistent with endograft-induced subclavian artery occlusion. We observed a low rate of subclavian revascularization performed at the time of TEVAR in the current study and did not detect any association between simultaneous revascularization and stroke or mortality risk among patients with LSA coverage. However, the ACS-NSQIP data file lacks sufficient detail regarding vertebral artery anatomy and location of the proximal landing zone, limiting our ability to determine whether strokes occurred because of increased manipulation within the arch, or whether the strokes occurred due to ischemia secondary to left subclavian artery coverage. Furthermore, we were only able to identify LSA revascularizations associated with TEVAR in the ACS-NSQIP datafile if both procedures were performed during the same anesthetic. Several series have reported performance of LSA revascularization as a separate procedure done prior to TEVAR in the majority of patients,[2,9,12] so it is probable that an unknown number of the TEVAR procedures we analyzed were performed on patients who underwent an initial LSA revascularization that could not be identified. The true incidence of LSA revascularization within this series is therefore unknown, leaving us unable to conduct a valid analysis of the effects of revascularization on stroke risk.

Although we observed a higher perioperative mortality rate in patients undergoing LSA coverage during TEVAR (10% vs 6.2%), this difference did not meet the significance criterion selected for multivariable model inclusion. Despite the relative sample size advantage of our analysis over some of the largest previously published studies, evaluating the impact of LSA coverage on TEVAR outcomes, low event rates limited our ability to conduct robust multivariable analyses.[20] These power limitations related to assessment of TEVAR outcomes have been described previously[5] and further illustrate the need for future multicenter collaborative efforts to expand existing evidence. Given the increasing number of studies demonstrating associations between LSA coverage and adverse events (including spinal cord injury and upper extremity ischemia in addition to stroke), randomized evaluations of LSA revascularization may be difficult to conduct, and meaningful expansion of existing evidence therefore will likely depend on comparative effectiveness studies.

Several other limitations of this analysis deserve specific mention. First, the ACS-NSQIP was not specifically designed for analysis of TEVAR outcomes and therefore lacks preoperative anatomic variables (such as vertebral artery anatomy) and additional postoperative outcomes relevant to LSA coverage (such as spinal cord injury and upper extremity ischemia). Second, because patients with acute

trauma diagnoses are not captured in ACS-NSQIP, our findings cannot be generalized to TEVAR procedures performed for traumatic aortic injury. Also, because trauma cases are specifically excluded from ACS-NSQIP, our findings cannot be generalized to TEVAR procedures performed for traumatic aortic injury. Finally, the coding-based methods for identification of cases and diagnoses utilized for this analysis are subject to potential errors related to misclassification, although the potential for this type of bias may be lowered by the standardized data collection training and reliability audits conducted by ACS-NSQIP. Despite these limitations, the number of TEVAR procedures included in this analysis compares favorably with some of the largest series published to date[2,10,11,21] and validates the association between LSA coverage and risk of perioperative stroke reported by others. Stroke and mortality rates from this analysis also provide an informative comparison between outcomes of contemporary clinical practice and published results of clinical trials.

CONCLUSION

Left subclavian artery coverage during thoracic endovascular repair is associated with increased risk of perioperative stroke; other observed risk factors for perioperative stroke include proximal aortic cuff placement and emergent procedure status. Additional evidence is needed to elucidate the mechanism of stroke during TEVAR and ultimately help prevent this devastating adverse event. Due to low event rates and the rapid evolution of thoracic endograft technology, multicenter collaborative efforts focused on TEVAR-specific endpoints will be critical for overcoming power limitations of existing evidence.

AUTHOR CONTRIBUTIONS

Conception and design: MC, JC
Analysis and interpretation: MC, KK, JC
Data collection: N/A
Writing the article: MC, JC
Critical revision of the article: MC, KK, RV, AS, TD, EC
Final approval of the article: MC, KK, RV, AS, TD, EC
Statistical analysis: MC
Obtained funding: Not applicable
Overall responsibility: MC

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Submitted Jan 30, 2011; accepted Mar 23, 2011.