Complications of Endovascular Treatment for Acute Stroke in the SWIFT Trial with Solitaire and Merci Devices

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Complications of Endovascular Treatment for Acute Stroke in the SWIFT Trial with Solitaire and Merci Devices

P.T. Akins, A.P. Amar, R.S. Pakbaz, and J.D. Fields, on behalf of the SWIFT Investigators

ABSTRACT

BACKGROUND AND PURPOSE: Treatment of patients with ischemic stroke after endovascular treatment requires in-depth knowledge of complications. The goal of this study was to make endovascular treatment for acute ischemic stroke safer through an in-depth review of the major peri-procedural complications observed in the Solitaire FR With Intention for Thrombectomy (SWIFT) trial.

MATERIALS AND METHODS: The SWIFT data base was searched for major peri-procedural complications defined as symptomatic intracranial hemorrhage within 36 hours, SAH, air emboli, vessel dissection, major groin complications, and emboli to new vascular territories.

RESULTS: Major peri-procedural complications occurred in 18 of 144 patients (12.5%) as follows: symptomatic intracranial hemorrhage, 4.9%; air emboli, 1.4%; vessel dissection, 4.2%; major groin complications, 2.8%; and emboli to new vascular territories, 0.7%. Rates of symptomatic intracranial bleeding by subtype were PH1, 0.7%; PH2, 0.7% (PH1 indicates hematoma within ischemic field with some mild space-occupying effect but involving ≤30% of the infarcted area; PH2, hematoma within ischemic field with space-occupying effect involving >30% of the infarcted area); intracranial hemorrhage remote from ischemic zone, 0%; intraventricular hemorrhage, 0.7%; and SAH, 3.5%. We did not observe any statistically significant associations of peri-procedural complications with age; type of treatment center; duration of stroke symptoms; NIHSS score, IV thrombolysis, atrial fibrillation, site of vessel occlusion; rescue therapy administered after endovascular treatment; or device. Comparing the Merci with the Solitaire FR retrieval device, we observed symptomatic cerebral hemorrhage (10.9% versus 1.1%; \textit{P} = .013); symptomatic SAH (7.3% versus 1.1%; \textit{P} = .07), air emboli (1.8% versus 1.1%; \textit{P} = 1.0), emboli to new vascular territories (1.8% versus 0%; \textit{P} = .38), vessel dissection (1.8% versus 4.5%; \textit{P} = .65), and major groin complications (3.6% versus 7.9%; \textit{P} = .48). Angiographic vasospasm was common but without clinical sequelae.

CONCLUSIONS: Understanding of procedural complications is important for treatment of patients with stroke after endovascular treatment. We observed fewer endovascular complications with the Solitaire FR device treatment compared with Merci device treatment, particularly symptomatic cerebral hemorrhage.

ABBREVIATION: SICH = symptomatic intracranial hemorrhage; TIMI = Thrombolysis in Myocardial Infarction; CEC = Clinical Events Committee

Intravenous tissue plasminogen activator has been proven to be efficacious in recanalization of occluded intracranial vessels and improvement of clinical outcome for acute ischemic stroke. A meta-analysis of 53 studies including 2066 patients with acute stroke demonstrated a 46.2% overall recanalization rate with IV fibrinolysis. However, IV tPA has limited ability to open occlusions of medium and large arteries such as the internal carotid artery, proximal middle cerebral artery, or basilar artery, with recanalization rates reported as low as 10%. Because of these limitations, catheter-based approaches for acute ischemic stroke have been developed to directly infuse thrombolytics at the site of the thrombus or mechanically extract and disrupt the clot. As with systemic thrombolytics, endovascular treatments for acute ischemic stroke carry the risk of intracranial bleeding. These treatments also carry additional risks related to vascular access, catheter placement, direct vessel injury, and the type of device deployed.

The Solitaire FR With Intention for Thrombectomy (SWIFT) trial provides additional information about endovascular ap-
proaches for acute stroke and directly compares the Solitaire FR device (Covidien, Irvine, California) with the Merci retrieval device (Stryker Neurovascular, Fremont, California) in a prospec- tive, randomized trial. Results of the primary end point for this study have been reported separately.13 Acute stroke trials have consistently highlighted the importance of achieving early reper-
fusion while keeping procedural complication risks as low as pos-
sible. The therapeutic time windows are tight, and gains achieved by flow restoration are easily erased by symptomatic intracranial bleeding caused by procedural complications. The SWIFT trial reports a significant technical advance for mechanical thrombec-
tomy by use of the Solitaire device compared with current technol-
ogy (Merci retriever); the focus of this report is an in-depth
analysis of the major procedural complications of this trial.

MATERIALS AND METHODS
The SWIFT trial was a multicenter, prospective, randomized, par-
allel-group, noninferiority study enrolling patients diagnosed
with acute ischemic stroke for which endovascular intervention
was indicated.13 After a roll-in phase in which the investigational Solitaire FR device was used for 2 patients at each participating
center, subsequent patients were randomly assigned on a 1:1 basis
for thrombectomy with either the investigational Solitaire FR de-
vice or the US Food and Drug Administration–cleared Merci re-
triever. The Solitaire device consists of a self-expanding stent in-
tegrated onto a delivery wire. The stent is deployed across the
thrombus, allowing its tines to intercalate with the thrombus, and
is then retracted into a guide catheter by traction on the wire. The
Merci retriever system has received Food and Drug Administra-
tion clearance for removal of thrombus and consists of a helical
terminus that is deployed distally to the thrombus and then pulled
back into the guide catheter. The aim of the SWIFT study was to
demonstrate substantial equivalence by obtaining prospective
clinical data on the safety and efficacy of the Solitaire FR de-
vice compared with the Merci device for patients diagnosed with
acute ischemic stroke. On the basis of the SWIFT study results, the
Solitaire FR received Food and Drug Administration clearance in
March 2012.

The primary efficacy end point of the study was arterial recan-
alization of the occluded target vessel measured by Thrombolysis
in Myocardial Infarction (TIMI) score14 of 2 or 3 after the use of
the study device. All patients received clinical evaluations at 24
hours, 30 days, and 90 days after the procedure.

Clinical and technical complications were prospectively col-
lected for patients enrolled into the SWIFT trial. These events
were independently reviewed and adjudicated by a central Clini-

cal Events Committee (CEC). The type, timing, severity, out-

come, relationship to study device or procedure, and other attri-
butes of each complication were assessed. The CEC followed
conventions and definitions established by the Common Termi-
nology Criteria for Adverse Events of the National Cancer Insti-
tute.15 Neuroimaging was independently reviewed by a core lab.
Because of early termination of the study, data were available on
31 roll-in patients treated with Solitaire FR device and 113 pa-
tients randomly assigned to either the Merci device or the Solitaire
FR device.

Definitions
A clinical or technical event was judged to be procedure- or treat-
ment-related when there was a strong temporal relationship to the
procedure or device implantation, such as bleeding from femoral
puncture site or adverse reaction to contrast administration.

The major intracranial procedural complications in this sub-
study are defined as symptomatic intracranial hemorrhage
(SICH), SAH, air emboli, vessel dissection, serious groin compli-
cation, and emboli to new vascular territory. Cerebral hemorrh-
ages were classified according to the European Cooperative
Acute Stroke Study (ECASS) criteria16 as follows:

SICH is defined as any PH1, PH2, RIH, SAH, or intraventricu-
lar hemorrhage associated with a decline in NIHSS score ≥4
within 24 hours (PH1 indicates hematoma within ischemic field
with some mild space-occupying effect but involving ≤30% of
the infarcted area; PH2, hematoma within ischemic field with
space-occupying effect involving >30% of the infarcted area;
RIH, any intraparenchymal hemorrhage remote from the isch-
emic field).

Asymptomatic intracranial hemorrhage is defined as any in-
tracranial hemorrhage within 24 hours not meeting the above
criteria for symptomatic intracranial hemorrhage.

The major extracranial procedural complications in this sub-
study are defined as extracranial vessel dissection and serious
groin complication.

Device-Related: Study Devices and Ancillary Devices
A study device–related adverse event is defined as an event with a
strong temporal relationship to the use of the device and no plau-
sible alternative etiology. An example is an arterial wall dissec-
tion caused by the study device. In some patients, the CEC was unable
to distinguish whether the study device or ancillary devices (such
as guidewires) contributed to the complication. In these circum-
stances, the CEC took a conservative view, and these events were
adjudicated to the study device.

An ancillary device–related adverse event is directly related to
the delivery catheter (system), and another cause is unlikely. An
example is a vessel perforated by a guidewire.

Adverse events classified as major access site adverse events are
defined as access site pseudoaneurysm, femoral hematoma, retro-
peritoneal hematoma, access site bleeding, access site bruising/
ecchymosis, and access site occlusion.

Statistical analysis was completed by use of SAS version 9.2
(SAS Institute, Cary, North Carolina). Descriptive statistics were
tabulated, and probability values were computed by use of the
Fisher exact test, comparing patients as assigned with their respec-
tive roll-in or randomly assigned treatment groups.

RESULTS
The SWIFT trial enrolled 144 patients. The study population con-
stituted of 31 patients treated during the roll-in phase with the Sol-
itaire FR device and 113 randomly assigned patients (58 Solitaire
FR; 55 Merci). A prespecified efficacy stopping rule triggered early
trial termination. The CEC adjudicated 644 adverse events, and
the core imaging lab reviewed neuroimaging. The overall rate for
major peri-procedural events was 12.5% (Table 1). Mortality
rates without and with major peri-procedural events were 23.8%
Table 1: Major procedural complications

<table>
<thead>
<tr>
<th>Type of Intracranial Bleeding</th>
<th>Present</th>
<th>Absent</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic cerebral hemorrhage</td>
<td>7</td>
<td>127</td>
<td>4.9%</td>
</tr>
<tr>
<td>Air emboli</td>
<td>2</td>
<td>142</td>
<td>1.4%</td>
</tr>
<tr>
<td>Emboli to new vascular territory</td>
<td>1</td>
<td>143</td>
<td>0.7%</td>
</tr>
<tr>
<td>Serious groin complication</td>
<td>4</td>
<td>140</td>
<td>2.8%</td>
</tr>
<tr>
<td>Vessel dissection</td>
<td>5</td>
<td>139</td>
<td>3.5%</td>
</tr>
<tr>
<td>Total number of patients</td>
<td>18</td>
<td>126</td>
<td>12.5%</td>
</tr>
</tbody>
</table>

Note: Total number of subjects with symptomatic cerebral hemorrhage is less than the sum of individual subtype rows because some subjects had more than 1 radiologic subtype of intracranial hemorrhage. RIH indicates any intraparenchymal hemorrhage remote from the ischemic field; IVH, intraventricular hemorrhage.

Table 2: Intracranial bleeding complications

<table>
<thead>
<tr>
<th>Type of Intracranial Bleeding</th>
<th>Asymptomatic (%)</th>
<th>Symptomatic (%)</th>
<th>Total (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PH1</td>
<td>3 (4.2)</td>
<td>1 (0.7)</td>
<td>4 (4.9)</td>
</tr>
<tr>
<td>PH2</td>
<td>5 (3.5)</td>
<td>1 (0.7)</td>
<td>6 (4.2)</td>
</tr>
<tr>
<td>RIH</td>
<td>1 (0.7)</td>
<td>0 (0)</td>
<td>1 (0.7)</td>
</tr>
<tr>
<td>IVH</td>
<td>5 (3.5)</td>
<td>1 (0.7)</td>
<td>6 (4.2)</td>
</tr>
<tr>
<td>SAH</td>
<td>6 (4.2)</td>
<td>5 (3.5)</td>
<td>11 (7.6)</td>
</tr>
</tbody>
</table>

DISCUSSION

The head-to-head comparison of peri-procedural complications observed with the Merci and Solitaire FR devices is shown in Table 5. Higher rates of SICH were observed after treatment with the Merci device compared with the Solitaire FR device (Solitaire FR 1/89, 1.1%; Merci 6/55, 10.9%; P = .013). Restoration of TIMI grade 2–3 flow was higher after treatment with the Solitaire FR device compared with the Merci device (TIMI grade 2–3 flow: Solitaire roll-in, 17/27, 63%; Solitaire randomized, 37/54, 68.5%; Merci randomized, 16/53, 30.2%; P = .0001). SICH followed successful revascularization (TIMI grade 2 or 3 flow) in 3 of 70 patients (Solitaire FR roll-in, 0/17, 0%; Solitaire FR randomized, 1/37, 2.7%; Merci, 2/16, 12.5%; P = .21). Rates of SAH trended lower with the Solitaire FR device compared with the Merci device (Table 5).

DISCUSSION

We observed important differences between complications of systemic (IV) thrombolysis and endovascular (intra-arterial) treatment (Table 6). The major risk of systemic thrombolysis is symptomatic intracranial bleeding and is generally intraparenchymal. This complication carries a 50% mortality rate. In comparison, the pattern of intracranial bleeding after endovascular therapy is more variable and carries a greater risk of SAH. Rates of symptomatic intracranial bleeding in the SWIFT trial in the Solitaire FR treatment arm (1.1%) were significantly lower compared with
Device in the SWIFT trial (10.9%) was similar to that in prior reported in other device trials (Table 6) and case series. The rate patients had symptomatic SAH and 8 (7.2%) had asymptomatic stered probably exceeds this rate. In the Multi-MERCI trial, 3 (2.7%) not reported separately in this trial; therefore the total SAH encoun-
tered of SAH compared with microcatheter delivery of intra-arterial

The lower rates of SICH observed with Solitaire FR compared with Merci (3/55, 5.5%; P = .3513). The trend toward lower rates of symptomatic SAH with the Solitaire FR device (1.1%) compared with the Merci device is encouraging (7.3%, Table 6).

Reperfusion is a double-edged sword. Early reperfusion will limit ischemic damage to both the brain and the cerebrovascu-

2.7%) and were lower than published trials that used intra-

of SAH compared with microcatheter delivery of intra-arterial

SAH was not reported in the NINDS IV tPA trial but has been reported in other device trials (Table 6) and case series. The rate of SAH was higher in this trial compared with earlier interven-
tional stroke trials but similar to rates in a recent study by UCLA and the Multi-MERCI trial (Table 6). A key difference between earlier interventional stroke trials such as the PROACT trials and more recent trials is the use of thrombectomy devices in addition to intracranial placement of microcatheters and infusion of intra-

Our hypothesis that thrombectomy devices pose a greater risk of SAH compared with microcatheter delivery of intra-arterial thrombolytics is supported by a recent analysis by the UCLA Endovascular Stroke Therapy Investigators. They reported that SAH was detected after primary intra-arterial thrombolysis (6.5%) but was numerically more likely after Merci retriever thrombectomy (14.1%). They had an overall 15.6% rate of SAH after endovascular treatment of acute ischemic stroke (20/128 procedures), and independent predictors of SAH in their study were procedure-related ves-
sion. Late reperfusion can cause cerebral hemorrhage by restora-
tion of flow. A favorable functional outcome at 3 months 
goes traction. In a preclinical model, less endovascular injury was 
thrombus, the withdrawal of the devices into the guide catheter 
SICH rate observed with the Merci device in the SWIFT trial (10.9%) was similar to that in prior studies (Table 6).

The IMS III trial results highlight the importance of rapid restoration of flow. A favorable functional outcome at 3 months (a modified Rankin Scale score of 0–2) occurred in 12.7% of patients with TICI score of 0, 27.6% with TICI score of 1, 34.3–47.9% with TICI score of 2a or 2b, and 71.4% with TICI score of 3. In this trial, treating physicians used different devices and intra-
arterial tPA doses at their discretion. Only 4 patients enrolled in this trial were treated with the Solitaire FR device.

### Table 5: Association of major procedural complications and embolectomy device

<table>
<thead>
<tr>
<th>Type of Complication</th>
<th>MERCI [% (n/N) [events]]</th>
<th>Solitaire [% (n/N) [events]]</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>SAH asymptomatic</td>
<td>5.5% [3/55] [3]</td>
<td>3.4% [3/89] [3]</td>
<td>.67</td>
</tr>
<tr>
<td>ICH PHI symptomatic</td>
<td>1.8% [1/55] [1]</td>
<td>0.0% [0/89] [0]</td>
<td>.38</td>
</tr>
<tr>
<td>ICH PH2 symptomatic</td>
<td>1.8% [1/55] [1]</td>
<td>0.0% [0/89] [0]</td>
<td>.38</td>
</tr>
<tr>
<td>IVH symptomatic</td>
<td>1.8% [1/55] [1]</td>
<td>0.0% [0/89] [0]</td>
<td>.38</td>
</tr>
<tr>
<td>ICH asymptomatic</td>
<td>27.3% [15/55] [15]</td>
<td>27.0% [24/89] [25]</td>
<td>1.00</td>
</tr>
<tr>
<td>Ischemic stroke symptomatic</td>
<td>12.7% [7/55] [7]</td>
<td>3.4% [3/89] [3]</td>
<td>.044</td>
</tr>
<tr>
<td>All symptomatic ICH</td>
<td>10.9% [6/55] [6]</td>
<td>1.1% [1/89] [1]</td>
<td>.013</td>
</tr>
<tr>
<td>Air emboli</td>
<td>1.8% [1/55] [1]</td>
<td>1.1% [1/89] [1]</td>
<td>1.00</td>
</tr>
<tr>
<td>Emboli to same vascular territory</td>
<td>5.5% [3/55] [3]</td>
<td>4.5% [4/89] [4]</td>
<td>1.00</td>
</tr>
<tr>
<td>Emboli to new vascular territory</td>
<td>1.8% [1/55] [1]</td>
<td>0.0% [0/89] [0]</td>
<td>.38</td>
</tr>
<tr>
<td>Device detachment</td>
<td>0.0% [0/55] [0]</td>
<td>0.0% [0/89] [0]</td>
<td>1.00</td>
</tr>
<tr>
<td>Vessel dissection</td>
<td>1.8% [1/55] [1]</td>
<td>4.5% [4/89] [4]</td>
<td>.65</td>
</tr>
<tr>
<td>Vessel vasospasm on angiography</td>
<td>16.4% [9/55] [10]</td>
<td>22.5% [20/89] [20]</td>
<td>.40</td>
</tr>
<tr>
<td>Vessel vasospasm symptomatic</td>
<td>0.0% [0/55] [0]</td>
<td>0.0% [0/89] [0]</td>
<td>1.00</td>
</tr>
<tr>
<td>Major access site issues</td>
<td>3.6% [2/55] [2]</td>
<td>7.9% [7/89] [8]</td>
<td>.48</td>
</tr>
<tr>
<td>Study device–related AE</td>
<td>16.4% [9/55] [10]</td>
<td>10.1% [9/89] [14]</td>
<td>.31</td>
</tr>
<tr>
<td>Ancillary device–related AE</td>
<td>3.6% [2/55] [2]</td>
<td>7.9% [7/89] [8]</td>
<td>.48</td>
</tr>
<tr>
<td>Technical difficulty with device</td>
<td>7.3% [4/55] [4]</td>
<td>10.1% [9/89] [12]</td>
<td>.77</td>
</tr>
</tbody>
</table>

Note: —IVH indicates intraventricular hemorrhage; ICH, intracerebral hemorrhage; AE, adverse event.

### Table 6: Complications of systemic (IV) thrombolysis and endovascular (intra-arterial) treatment

<table>
<thead>
<tr>
<th>Type of Event</th>
<th>NINDS</th>
<th>PROACT I</th>
<th>PROACT II</th>
<th>IMS I</th>
<th>IMS II</th>
<th>Merci</th>
<th>Multi-Merci</th>
<th>Penumbra</th>
<th>SWIFT-all</th>
<th>SWIFT-Merci arm</th>
<th>SWIFT-Solitaire arm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symptomatic ICH</td>
<td>6.4%</td>
<td>15.4%</td>
<td>10.2%</td>
<td>6.3%</td>
<td>9.9%</td>
<td>7.8%</td>
<td>9.8%</td>
<td>10%</td>
<td>4.9%</td>
<td>10.9%</td>
<td>1.1%</td>
</tr>
<tr>
<td>SAH</td>
<td>0%</td>
<td>na</td>
<td>na</td>
<td>0%</td>
<td>na</td>
<td>3.5%</td>
<td>9.9%</td>
<td>5%</td>
<td>7.6%</td>
<td>12.7%</td>
<td>4.5%</td>
</tr>
</tbody>
</table>

SAH was not reported in the NINDS IV tPA trial but has been reported in other device trials (Table 6) and case series. The rate of SAH was higher in this trial compared with earlier interven-
tional stroke trials but similar to rates in a recent study by UCLA and the Multi-MERCI trial (Table 6). A key difference between earlier interventional stroke trials such as the PROACT trials and more recent trials is the use of thrombectomy devices in addition to intracranial placement of microcatheters and infusion of intra-
arterial thrombolytics. In the MERCI trial, patients were adjudicated with symptomatic SAH (5/141; 3.5%), and the authors attributed the symptomatic SAH to vessel perforations. Asymptomatic SAH was not reported separately in this trial; therefore the total SAH encoun-
tered probably exceeds this rate. In the Multi-MERCI trial, 3 (2.7%) patients had symptomatic SAH and 8 (7.2%) had asymptomatic SAH, for a total SAH rate of 9.9% (11/111).

Air emboli 1.8% (1/55) 1.1% (1/89) 
Emboli to same vascular territory 5.5% (3/55) 4.5% (4/89) 
Emboli to new vascular territory 1.8% (1/55) 0.0% (0/89) 
Device detachment 0.0% (0/55) 0.0% (0/89) 
Vessel dissection 1.8% (1/55) 4.5% (4/89) 
Vessel vasospasm on angiography 16.4% (9/55) 22.5% (20/89) 
Vessel vasospasm symptomatic 0.0% (0/55) 0.0% (0/89) 
Major access site issues 3.6% (2/55) 7.9% (7/89) 
Study device–related AE 16.4% (9/55) 10.1% (9/89) 
Ancillary device–related AE 3.6% (2/55) 7.9% (7/89) 
Technical difficulty with device 7.3% (4/55) 10.1% (9/89) 

The lower rates of SICH observed with Solitaire FR compared with Merci devices may be related to other technical factors besides the higher and more rapid rate of reperfusion. After adv-
vancement of the embolectomy devices into the intracranial thrombus, the withdrawal of the devices into the guide catheter exerts traction on the arterial tree. These mechanical forces may contribute to SICH by direct endoluminal trauma or through shear forces on the perforating vessels as the parent vessel under-
goes traction. In a preclinical model, less endovascular injury was observed with Solitaire as compared with Merci use.

The IMS III trial results highlight the importance of rapid restoration of flow. A favorable functional outcome at 3 months (a modified Rankin Scale score of 0–2) occurred in 12.7% of patients with TICI score of 0, 27.6% with TICI score of 1, 34.3–47.9% with TICI score of 2a or 2b, and 71.4% with TICI score of 3. In this trial, treating physicians used different devices and intra-
arterial tPA doses at their discretion. Only 4 patients enrolled in this trial were treated with the Solitaire FR device.
This study has strengths and weaknesses. The strengths include the multicenter, randomized, prospective study design, independent adjudication of adverse events by a CEC, and review of neuroimaging by a core lab. This is the first endovascular stroke trial to directly compare 2 thrombectomy devices. The weakness of this study is the limited sample size (n = 144) and the variability in operator experience and skill with mechanical thromboembolotomy that is inherent to multicenter studies.

CONCLUSIONS
“Experience is what you get when you don’t get what you want.”22
Detailed knowledge of peri-procedural complications is important for the treatment of patients with stroke after endovascular treatment. The results of the IMS III trial highlight the importance of maximizing the time to restore flow while keeping procedural complication risks low for acute ischemic stroke. Fewer endovascular complications were observed with Solitaire FR device treatment compared with Merci device treatment, particularly symptomatic cerebral hemorrhage. Device registries will be helpful to gain deeper understanding of rare events. This trial illustrates a significant technical advance for mechanical thrombectomy by use of the Solitaire device compared with current technology (Merci retriever); this report has focused on the major procedural complications.

ACKNOWLEDGMENTS
Funding for the SWIFT trial was provided by ev3/Covidien. No funding was provided to the authors for data analysis and manuscript preparation and submission.

Drs Akins, Pakbaz, and Amar served on the Clinical Events Committee and received modest time-based compensation as consultants. Dr Fields served as a clinical site co-investigator in the SWIFT trial, and his institution received modest enrollment-based compensation to offset study costs.

Disclosures: Paul T. Akins—RELATED: Consulting Fee or Honorarium: ev3,* Fees for Participation in Review Activities, Such as Data Monitoring Boards, Statistical Analysis, Endpoint Committees, and the Like: ev3,* Comments: I served on the Clinical Events Committee for the SWIFT trial. I did not receive compensation directly and fees were paid to The Permanente Medical Group. Arun P. Amar—RELATED: Fees for Participation in Review Activities, Such as Data Monitoring Boards, Statistical Analysis, Endpoint Committees, and the Like: Covidien, Comments: Received market value time-based compensation to serve as chairman of Clinical Events Committee for the SWIFT trial, and his institution received modest enrollment-based compensation to offset study costs.

REFERENCES