Outpatient Atherectomy for IC Leads to Worse Outcomes and More Amputations Than the Natural History of the Disease: Medicare Billing Data

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Change in Policy Helped Drive Office-Based Interventions

- **2008:**
  - The Centers for Medicare & Medicaid Services (CMS) made several payment system changes that contributed to the shift of Peripheral Vascular Intervention (PVI) cases into the physician office setting
    - To spur efficiency in outpatient services, CMS began packaging ancillary services (e.g. imaging supervision, interpretation, and contract agents) with primary procedures
    - CMS also expanded the list of ASC-approved services, including some peripheral vascular Current Procedural Terminologies (CPTs)

- **2011:**
  - New PVI CPTs were introduced, including atherectomy
    - For the 1st time, non-facility practice expense Relative Value Units (RVUs) were assigned, allowing for reimbursement of in-office atherectomy
    - Office-based atherectomy reimbursement came on par with or exceeded hospital outpatient reimbursement

Favorable Medicare Reimbursement for Office-Based Atherectomy

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
<th>Physician Office</th>
<th>Hospital Outpatient</th>
<th>Phys. Office as % of Hospital Outpatient</th>
</tr>
</thead>
<tbody>
<tr>
<td>37225</td>
<td>Fem-Pop Atherectomy</td>
<td>$10,723</td>
<td>$9,542</td>
<td>112%</td>
</tr>
<tr>
<td>37227</td>
<td>Fem-Pop + Stent + Atherectomy</td>
<td>$14,555</td>
<td>$14,612</td>
<td>100%</td>
</tr>
<tr>
<td>37229</td>
<td>Tibial/Pereonal + Atherectomy</td>
<td>$10,483</td>
<td>$14,612</td>
<td>72%</td>
</tr>
<tr>
<td>37231</td>
<td>Tibial/Pereonal + Stent + Atherectomy</td>
<td>$12,976</td>
<td>$14,612</td>
<td>89%</td>
</tr>
</tbody>
</table>

Note: Medicare final payment ruling national reimbursement rates; hospital outpatient rate reflects the APC payment; physician office represents the non-facility practice expense component of the fee schedule for apples-to-apples comparison between hospital outpatient and physician office settings.

Recent Trends in Peripheral Vascular Intervention (PVI) Among Medicare Beneficiaries

Brief Review of Endovascular Treatment of Peripheral Arterial Disease (PAD)

- Explosion of endovascular PVI in the past two and a half decades
  - Growth of PVI continues to far exceed Percutaneous Coronary Intervention (PCI)
  - Atherectomy accounts for vast majority of volume increases
  - Surgical bypass now performed in only a minority (~20%)

- Vascular surgeons and cardiologists account for the majority of PVI (both have the ability to “self-refer” patients)

- **2014:**
  - Medicare expenditure for inpatient peripheral vascular cases (primary diagnosis of PVI) was ~$50 billion
Vast Majority of Atherectomy Volume Growth in Physician Office Setting

By Comparison, Far Less Volume Growth in Other PVI

Vascular Surgery and Cardiology Dominate Office-Based Atherectomy

Total Medicare Costs for PVI: 2011-2014

Our Study

A database analysis study was proposed and carried out by a single institution in collaboration with The Advisory Board Company

Objectives:
- Demonstrate the massive increase in outpatient atherectomy, particularly in office setting
- Get a better understanding of patient and clinical outcomes are poorly understood
- Report ‘downstream’ results of atherectomy in the office and hospital outpatient (HOPD) surgical setting
- Report real-world results for claudication for infra-inguinal occlusive disease as determined from billing data

Methods
- Medicare Part B procedure and claims data from 2012 to 2014 using a 5% sample
- Upstream utilization 18 months before, during, and 18 months after incident atherectomy
- Incident procedures:
  - Femoral-Popliteal Atherectomy (CPT 37225)
  - Tibial-Peroneal Atherectomy (CPT 37229)
- Calculated percent of patients receiving each downstream service -
  - Compared descriptive statistics were calculated to characterize patient population, determine number of incident and re-intervention cases, need for amputation postoperatively
  - All calculations were stratified and compared by setting of surgical procedure and anatomical location on body of procedure
Results: Femoral-Popliteal Atherectomy

- 924 patients undergoing Femoral-Popliteal Atherectomy were analyzed for repeat PVI within 18 months of incident procedure:
  - 262 (28.4%) Office
    - 42.7% underwent repeat intervention
  - 662 (71.6%) HOPD
    - 36.9% underwent repeat intervention

Results: Amputation after Femoral-Popliteal Atherectomy

- Minor amputations are defined as below the ankle (toe and foot); major refers to lower extremity limb amputation above the ankle
- Need for any lower extremity amputation:
  - 3.8% in the Office
  - 5.4% in the HOPD
- Need for major lower extremity amputation:
  - 2.3% in the Office
  - 3.2% in the HOPD

Results: Tibial-Peroneal Atherectomy

- 423 patients undergoing Tibial-Peroneal Atherectomy were analyzed for repeat peripheral vascular intervention within 18 months of incident procedure:
  - 202 (47.8%) Office
    - 46.5% underwent repeat PVI
  - 221 (52.2%) HOPD
    - 38.9% underwent repeat PVI

Results: Amputation After Tibial-Peroneal Atherectomy

- Need for any lower extremity amputation:
  - 5.9% in the Office
  - 11.3% in the HOPD
- Need for major lower extremity amputation:
  - 5.0% in the Office
  - 8.1% in the HOPD

Results: Natural History of Claudication

- Studies prior to 1980 documented a cumulative amputation rate of 11% over 10 years
  - At ~1%/year
- More recent studies show similar rates
  - ~30% patients were symptomatic deterioration over time
- Low Ankle Brachial Index (ABI) and Diabetes Mellitus (DM) associated with development of:
  - Ischemic rest pain
  - Ischemic ulceration
- All prior studies confirm low amputation rates, but high mortality rates

Discussion: Jones et al.
Discussion: BASIL-1 Trial

In BASIL-1 bypass after "endofailure" was highly significantly less successful than primary bypass

*Endovascular is not a "free shot"*

Amputation-Free Survival  Overall Survival

Discussion: DEFINITIVE Ca++ Trial

**TABLE IV. Procedure Characteristics**

<table>
<thead>
<tr>
<th>Procedure characteristic</th>
<th>Mean ± SD or % (n, N−1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total procedure time (min)</td>
<td>74.2 ± 28.4 (133)</td>
</tr>
<tr>
<td>Total fluoroscopy time (min)</td>
<td>21.1 ± 9.7 (132)</td>
</tr>
<tr>
<td>Total contrast administered (cc)</td>
<td>182.3 ± 72.4 (132)</td>
</tr>
<tr>
<td>Visible debris in filter device</td>
<td>88.4% (122/138)</td>
</tr>
<tr>
<td>Adjunctive therapy</td>
<td>53.8% (91/169)</td>
</tr>
<tr>
<td>Adjunctive (bail-out) stenting</td>
<td>4.1% (7/169)</td>
</tr>
<tr>
<td>Preservation of run-off (per angiographic core lab)</td>
<td>98.3% (113/115)</td>
</tr>
</tbody>
</table>

Discussion: Shortcomings of Atherectomy Trials

- Use of Embolic Protection Devices (EPDs) in 50% of patients in Jetstream ISR and ~25% in JET Registry and Definitive LE Trials
  - Despite this small incidence of distal embolization
- IFU does not recommend use of EPD
- Adjunctive treatment PTA in 35% in Definitive LE and ~100% in Jetstream
- Bail-out stenting in ~35% in JET Registry
  - 54.8% stenosis following JET reduced to 6.6% following stenting
  - Which is more effective?

Discussion: Shortcomings of Atherectomy Trials

- Procedure related adverse events ~22%, restenosis 38% in 1 year in Silverhawk trials
- Short follow-up (f/u) times 1 year:
  - Excite ISR reports only 6 month follow-up and underpowered
- 57 of 241 patients underwent duplex ultrasound f/u in JET registry
- *I will be presenting similar results using ICD-10 data soon*

Conclusions

- We believe this is the first time that Medicare claims-based utilization data for atherectomy procedures and repeat procedures among patients being treated for claudication have been compared across office-based and hospital outpatient-based cohorts
- Considering the high rate of amputation in both hospital outpatient and physician office settings, the data suggest that atherectomy for occlusive disease in the femoral-popliteal and tibial-peroneal segments when done for claudication results in outcomes worse than the natural history of the disease
- Our study supports the previously made observation that repeated interventions result in worse outcomes. Financial incentives may be a driving force
- *We recommend a prospective study to confirm the above mentioned findings and caution the operators that our first responsibility to the patients is " do-no-harm"*

Take Away Message

- At the end of the day this is not a crusade against atherectomy, rather an example of unintended consequences of generous re-imbursement of a procedure for PAD.
- Atherectomy the way it is being used is not making VASCULAR CARE GREAT AGAIN!
- Unless we can put ethics before greed, we will bankrupt the system and lose the ability to practice this art of vascular surgery and interventions which we all love so much.
Thank You!

References


• We have an ethical problem in the United States that goes far beyond medicine. How to solve this problem is something that none of us can simplify. However, it would be very nice if this ethical revolution, which I think is badly needed in our country, started with medicine, particularly with doctors.

Frank Veith, MD
August 2016

• We see it on Wall Street and in our insurance companies, who put profit above all other motives. And we see it in our healthcare system, tragically. Hospital executives, institutional leaders, and so forth may say that quality care is above all else, but that's not the way it works in many institutions. Instead, diagnosis-related groups, relative value units, and dollars are the motivating force for these individuals.

Frank Veith, MD
August 2016

• Finally, we see ethical problems in doctors who, as compensation is decreased, will sometimes do cases that don't need to be done or enter into fields in which they have little expertise. We see it with unnecessary superficial femoral artery endovascular treatments, even from some of the best institutions in the land. Patients who would be better off being treated conservatively who are claudicators and don't need invasive treatment get treated with expensive devices. We see this particularly with individuals who are not cognizant of the nature of vascular disease.

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August 2016

Exploring the Efficacy of Atherectomy Versus PTA ± Stent (Continued)

• Definitive LE, Definitive AR, CSI Orbital and Turbohawk Trials showed no advantage of atherectomy over PTA+/stent in 1-2 year follow-up.

• Atherectomy used in ~20% of PVI in the US vs 4.4% in Western Europe and even less in Canada, Japan and Latin America; Possible reasons:
  - No financial incentive to use atherectomy
  - Lack of efficacy data to support widespread use
Physician Office's: Now the Most Common Setting for Atherectomy

Percent of Medicare Atherectomy Cases Performed in Physician Offices

Note: Atherectomy cases defined by CPTs 37225, 37227, 37229, 37231.