Peripheral Vascular Intervention (PVI) Device Utilization and Patient Outcomes

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Goal:

Peripheral Arterial Disease (PAD) is a prevalent disease in the population. Peripheral Vascular Intervention (PVI) is a catheter-based intervention commonly used for arterial atherosclerotic disease in the aorta and lower extremity circulation. In 2018, ACC/AHA/SCAI/SIR/SVM released a publication regarding appropriate use criteria for Peripheral Artery Intervention. Indiana University Health (IUH) Methodist Hospital (MH) sought to understand procedural treatment strategies and the impact to patient outcomes outside of hospitalization. IUH desired to analyze the amount and type of devices used in femoral-popliteal disease treatment. This includes the immediate and long-term outcomes of the procedures with intention to determine efficacy of treatment at follow-up timeframes.

Method:

The MH interprofessional and interdisciplinary process improvement team utilized Vascular Quality Improvement (VQI) PVI Registry data, including the type and number of PVI devices and patient outcomes, to understand how internal treatment strategies affects outcomes for the patients. This was a retrospective analysis for procedures reported in the VQI database during the timeframe of 2012-2018. Limitations in the results are due to the data review including patients lost to long-term follow up (LTFU) and reporting capability for procedural devices and lesions.

For the purposes of this analysis, noncritical limb ischemia (NCLI) was defined as asymptomatic and claudicant cases; and critical limb ischemia was defined as rest pain, ulcers, non-healing amputations, and acute ischemia. Target lesion revascularization (TLR) included percutaneous PVI and or open bypass graft (related to the area initially treated). Major amputations were defined as above the knee (AKA) or below the knee (BKA) amputation. Outcomes were defined as improvement in patients presenting symptoms such as change from critical limb ischemia to non-critical limb ischemia or resolution/no change in symptoms. Outcomes were defined as worsened when reintervention, amputation or progression of symptoms developed.

Results:

- A total of 1108 vessels were treated during the study period in 1012 patients. LTFU information was available for 620 vessels.
- When a single device was used (27% of the cases 303/1108), percutaneous transluminal angioplasty (PTA) alone was utilized in 81% (245/303) of the interventions.
- When analyzing the type of device used during the 2012-2018 timeframe, 77% involved percutaneous transluminal angioplasty (PTA) alone or with concomitant devices: 31% with stents, 15% with atherectomy, 15% with specialty balloon, and 9% with stentgraft. This data shows a shift of PTA usage from its highest 86% (2014) to a 61% (2018) with an increase in utilization of specialty balloons from 2% (2014) to 41% (2018). For the purpose of this review, specialty balloons included the following devices: drug coated balloons, cryoplasty, and cutting balloons.
- With the release of the expanded PVI Registry (V1.44), the rate of cases with three or more devices used was 41%, utilization of two devices 27%, and procedures with one device used was 31% (2017-2018 data). When only one device was used, the preferred method was PTA (81%) followed by specialty balloons (12%), stentgraft (2%), atherectomy (1%) and stents (1%). A failure to wire was observed in 3% of the procedures, with no failed wire placement since 2016.
- Procedural success rate was observed in 95% of cases with <=30% residual stenosis, 1% of cases with a >30% or 10mm gradient and in 3% of cases classified as failure to treat and/or abort. In 2018, the success rate increased to 98% for lesion stenosis rates of <=30% residual stenosis.
- Analyses of outcomes at follow up, regardless of type of device used and quantity of device used, demonstrated 60% of cases did not require target lesion revascularization (TLR) or amputation. A total of 75 new TLR, and a total of 43 major amputations were performed for disease progression or failure of TLR at time of LTFU (N = 620 vessels). TLR alone with no amputation was demonstrated in 10% of cases, incidence of TLR plus amputation was demonstrated in 2% of cases, and amputation without TLR occurred in 4% of cases.
- Additional analysis of device utilization and patient outcomes at index procedure and long term follow up are summarized in Figure 1-4.

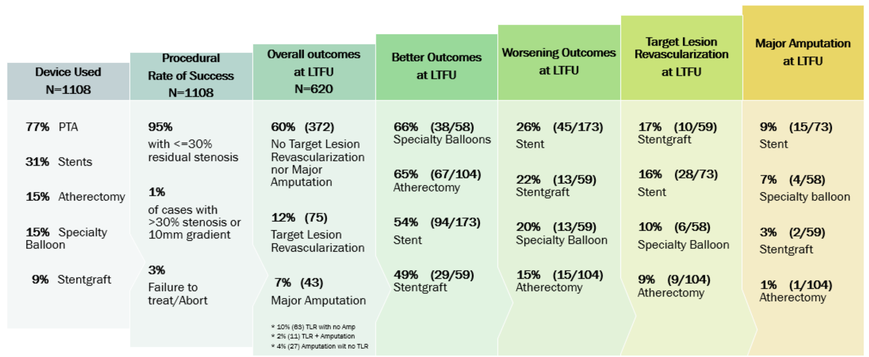

Figure 1: Cumulative Outcomes Summary 2012-2018ytd (above)

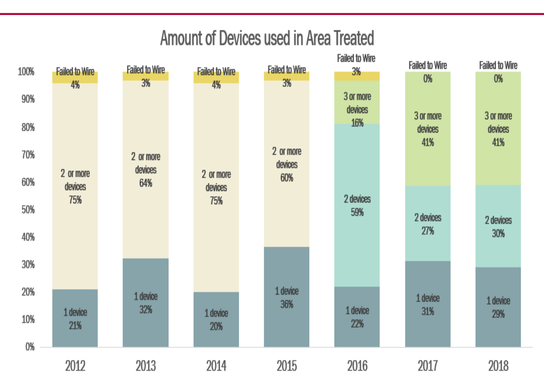

Figure 2: Quantity of Device Trends over the years (above)

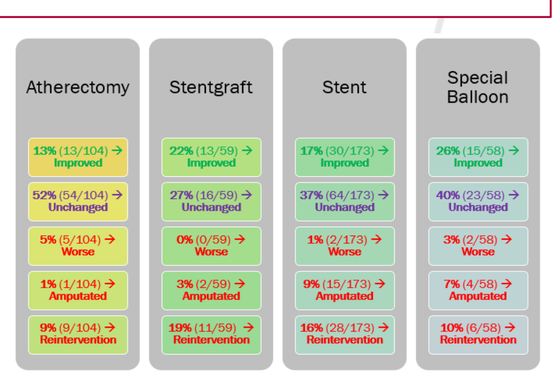

Figure 3: 2012-2018ytd Device Utilization Outcomes at LTFU (above)

Challenges / Lessons Learned:

The robust interprofessional team brought unique perspectives to the project. Preconceived notions of individual and institutional bias of device performance could not be reproduced in our analyses as all devices performed well when compared to each other. Increased frequency of specialty balloon use was noticed over time. Project limitations, including incomplete/missing data, and patients lost to long-term follow up were challenges that occurred. Despite an underestimated time needed to complete this review, a deep dive analysis was possible using VQI raw data available within the PVI module. Other limitations included inability to collect more than 3 devices per vessel treated and single center data. For continued monitoring, insights from the initial review will guide continued tracking.

Success Factors:

The MH interprofessional and interdisciplinary process improvement team found value in analysis of VQI data to review internal treatment strategies and patient outcomes. The intensive review supports the adoption of current practices to align with the recently published PVI guidelines.

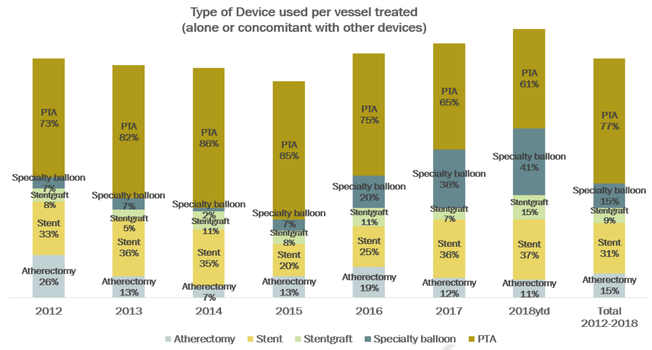

Figure 4: Device Utilization Trends over the years (above)

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Citations:

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