

Cover Page:

VISION and VQI Paclitaxel Safety Analysis

Document date 12/16/2019

VISION and VQI Paclitaxel Safety Analysis

Version: 1.5

Updated: December 16, 2019

Steering Committee

Daniel Bertges MD, Jens Jorgensen MD, Philip Goodney MD MS, Art Sedrakyan MD Ph.D., Danica Marinac-Dabic MD Ph.D., Misti Malone Ph.D., Roseann White Ph.D., Aaron E. Lottes Ph.D. MBA, Josh Smale, Melissa Young, Jennifer Hansen

1 Background:

In December 2018, a meta-analysis of randomized trials published by Katsanos *et al.* identified an association between the uses of paclitaxel-coated balloons (DCB) or eluting stents (DES) in the treatment of femoral-popliteal arterial disease (PAD) and increased mortality at two and five years after treatment, when compared to patients treated with non-paclitaxel devices.¹ After further investigation of the available data, the FDA issued a communication to health care providers to inform patients of this reported risk and later to consider alternatives to paclitaxel devices in the treatment of PAD.^{2,3} The FDA convened an Advisory Panel on June 19-20 confirming the presence of a safety signal, recommended modification of the labeling and incorporation of enhanced patient informed consent into the decision to use these devices.⁴

1.1 Vascular Quality Initiative (VQI)

Since 2004, the Society of Vascular Surgeons has collected detailed clinical data regarding the treatment of PAD through the Vascular Quality Initiative (VQI). Today, VQI collects data from over 550 hospitals in North America with a variety of specialists participating, including vascular surgeons (54%), cardiologists (20%), and interventional radiologists (17%), general surgeons (5%) and others (5%). The VQI Peripheral Vascular Intervention Registry (PVI) module was launched in 2010 and contains over 630,000 individual procedure records and began capturing device identifier information in the fall of 2016 with linkage to the Global Universal Device Identifier (GUDID). The PVI registry has validated linkage to the Social Security Death Index file in order to ascertain vital status in a longitudinal manner.

1.2 Vascular Implant Surveillance and Interventional Outcomes Network (VISION)

VISION has proven methodology for linkage of Medicare claims to other data sources, including the VQI.^{4,5} VISION is a coordinated registry network (CRN) supported by MDEpiNet with the mission to improve the evaluation of vascular devices throughout the total product lifecycle.

2 Objectives

1. The VQI-VISION Paclitaxel Device Safety Analysis seeks to assess the comparative safety of paclitaxel-coated balloons and stents in the treatment of PAD through analysis of the Vascular Quality Initiative (VQI) Peripheral Vascular Intervention (PVI) registry module with linkage to claims. By linking VQI patients to Medicare claims retrospectively from 2012 to 2016, we will be able to identify additional paclitaxel devices enabling longitudinal follow-up of mortality out to 5 years for paclitaxel-eluting stents and 3 years for paclitaxel-coated balloons.
2. To analyze factors associated with mortality, specifically comparing paclitaxel patients surviving vs. paclitaxel patients with mortality. The goal is to identify independent factors predictive of mortality in US pivotal trials and model registry data exposures with sufficient factors to track competing risk paradox and show emulation or not of mortality outcomes with both PTX and PTA exposures.
3. To confirm the effectiveness of paclitaxel devices by comparing reintervention for paclitaxel and non-paclitaxel devices. In-hospital mortality from open and percutaneous target vessel revascularization (TVR) will be reported to determine the impact of subsequent revascularizations on survival. Major amputation will be compared for patients with chronic limb-threatening ischemia.

3 Data Source and Limitations:

All proposed analyses will be performed using the VQI PVI dataset to maximize the consistency of outcome and clinical covariate definitions. Limitations include incomplete linkage to the SSDI because social security numbers are not universally available to the VQI PVI registry. This limitation will be countered by the ability to ascertain survival status through Medicare claims through direct and indirect matching. Based on a recent analysis of over 108,000 patients the match rate is 74%. The cohorts will be comprised only of patients greater than 65 years of age.

While the capture of patient, lesion, and treatment variables is generally complete in the registry for the index procedure, some covariates may have missing data. While the VQI mandates consecutive procedure capture there is obligate time lag for centers to perform audits against their claims data.

4 Scientific Oversight Committee

At the initiation of the project, a study oversight committee will be established including two representatives from VQI (Drs. Eldrup-Jorgensen and Bertges) and two representatives from the VISION Coordinated Registry Network (CRN) (Dr. Philip Goodney and Dr. Art Sedrakyan), representatives from FDA (Drs. Misti Malone and Dr. Danica Maranic-Dabic), an independent statistician (Roseanne White, PhD) and representatives from the peripheral vascular device

manufacturer industry (Aaron E. Lottes, PhD, MBA Cook Medical; Josh Smale, BD Peripheral Intervention; Melissa Young and Jennifer Hansen Boston Scientific Corporation).

The study oversight committee will be responsible for the approval of the study protocol, will have oversight of the overall performance and execution of the study, will propose any additional exploratory (post-hoc) analyses, and approve any proposed publications resulting from the project.

5 Devices of Interest

The proposed safety analyses will evaluate two types of paclitaxel-coated interventional devices used to treat PAD and compare patient outcomes with propensity score-matched patients of similar risk who receive non-paclitaxel devices.

The primary outcome will be freedom from all-cause death using propensity-matched survival analysis.

Three principle analyses are planned:

- a. Paclitaxel DCB (including the Bard Lutonix, Medtronic In.Pact Admiral, and Philips Spectranetics Stellarex DCB's) as compared with propensity-matched patients treated with plain balloons.
- b. Paclitaxel delivering DES (Cook Zilver PTX) as compared with propensity-matched cases using bare-metal stents (BMS).
- c. Patients treated with either Paclitaxel DCB or Paclitaxel DES compared with propensity-matched controls (with DCB patients matched to patients treated with plain balloons, and DES patients matched to patients treated with BMS).

Note that this analysis is planned at the device class level and is not intended to compare early or late mortality between specific devices or brands.

6 Missing Data

Based on previous data quality audits of VQI Registry, it is anticipated that less than 3% of all data to be used in the VQI-VISION Paclitaxel study will be missing from the dataset. If missing data represents less than 3% of the total dataset, simple imputation methods will be used, substituting missing data with median gender-specific values for continuous variables, and assuming "negative" results for dichotomous variables. If missing data represents >3.0% of any covariate used in the propensity score match model (see below), the Study Oversight Committee will determine the most appropriate manner to handle missing data, including consideration of multivariate imputation methods or case-wise deletion.

7 Patient Inclusion and Exclusion Criteria:

All patients, aged 65 or older, who underwent endovascular interventional treatment of the femoral or popliteal arteries for symptomatic PAD between 10/1/2012 and the latest available CMS dataset (12/31/2016) will be included.

In an effort to focus this safety evaluation on those patients being treated in accordance with accepted ‘best practice’ endovascular intervention strategies and ‘on-label’ use of devices, patients will be excluded from either exposure cases or controls if they received an expandable balloon stent or a balloon-expandable stent-graft in the treatment of femoral or popliteal disease. Balloon expandable stents were excluded because these stents have historically shown inferior patency, and current best practice favors placement of self-expanding nitinol stents, which were engineered for the femoral-popliteal segment and tested in multiple trials for this indication.^{6,7,8}

Additionally, patients will be excluded (as either potential cases or controls) if their index procedure was performed for acute limb ischemia due to the different etiologies (embolism, in-situ thrombosis) as compared with chronic conditions and different treatment paradigms and higher major amputation and mortality rates.^{9,10,11,12,13}

Control patients for each of the exposure groups will be selected as follows. For the DCB, control patients will be selected from patients treated with “plain balloon” therapies and will exclude those patients treated with any form of a stent (including non-Paclitaxel DES, self-expanding, or covered stents). Control patients for the Paclitaxel DES analyses will be selected from those patients receiving bare-metal self-expanding stents (BM-SES) with or without concomitant plain balloon angioplasty.

7.1 Patient Inclusion and Exclusion Criteria:

Inclusion:

- Age \geq 65 years old
- Date of index procedure is within 10/1/2012 to 12/31/2016
- Symptomatic disease ranging from intermittent claudication to chronic limb-threatening ischemia (including ischemic rest pain and/or tissue loss)
- Elective or urgent procedures

Exclusion:

- Aneurysmal disease of the superficial femoral or popliteal artery
- Treatment for acute limb ischemia
- Treatment of common femoral artery or profunda femoral artery occlusive disease
- Emergency procedures
- PVI and concomitant femoral endarterectomy, suprainguinal or infrainguinal bypass

7.2 Treatment identification using claims data

Before 2016, the VQI identified whether the patient receives POBA, stent, or atherectomy. The database did not necessarily identify whether the balloon was a paclitaxel-coated balloon or a paclitaxel-eluting stent. Claims data matched to a patient could be used to identify whether balloon was plain, or paclitaxel coated, or the stent was bare or paclitaxel-eluting

The process will include these steps:

- A list of in-patients, out-patient and ambulatory center ICD 9-10, and HCPCS codes that identify whether a balloon was paclitaxel-coated or plain and whether a stent was paclitaxel-eluting or bare will be pre-specified (Table 1, Appendix 1).
- Medicare claims data will be matched to the patient using either their social security number or a probability matching algorithm.

Using the device information in the VQI and the Medicare matched claims data, the treatments will be categorized as to the treatment type:

- Plain Balloon Angioplasty alone
- Paclitaxel-Coated Balloon Angioplasty alone
- Bare Metal stent alone
- Bare Metal stent with Plain Balloon Angioplasty
- Bare Metal stent with Paclitaxel-coated Balloon Angioplasty
- Paclitaxel-eluting stent alone
- Paclitaxel-eluting stent with Plain Balloon Angioplasty
- Paclitaxel-eluting stent with Paclitaxel-coated Balloon Angioplasty
- Atherectomy alone
- Atherectomy with Plain Balloon
- Atherectomy with Paclitaxel-coated Balloon Angioplasty

Procedures frequently include more than one treatment modality. The following Table 1 lists the assignment of treatment groups accounting for more than one device type.

Table 1. Categorization of the four treatment groups accounting for more than one treatment modality.

POBA	BMS	Paclitaxel DCB	Paclitaxel DES
Plain Balloon Angioplasty alone	Bare Metal stent alone	Paclitaxel-Coated Balloon Angioplasty alone	Paclitaxel-eluting stent alone
Atherectomy with plain balloon angioplasty	Bare Metal stent with Plain Balloon Angioplasty	Bare Metal stent with Paclitaxel-coated Balloon Angioplasty	Paclitaxel-eluting stent with Plain Balloon Angioplasty
	Atherectomy with bare-metal stent	Atherectomy with Paclitaxel-coated Balloon Angioplasty	Paclitaxel-eluting stent with Bare Metal stent
			Atherectomy with a paclitaxel-eluting stent

8 Second and later procedures

The primary analysis will consider the first procedure recorded in the VQI PVI registry as the qualifying index procedure. Any additional femoral-popliteal artery interventions on the index or opposite leg will be considered in a sensitivity analysis. In particular, patients with a first treatment that is not paclitaxel based and have a subsequent paclitaxel device treatment will be considered as “cross-overs” and will be analyzed as a pre-specified subgroup.

If a control subject crossed over by receiving a drug-coated device (on the target or any other ipsilateral or contralateral femoral-popliteal lesions) during the follow-up period, Day 0 would be the day of the drug-coated device treatment. Otherwise, Day 0 will be the day of the index procedure.

9 Endpoint Definitions

The primary safety outcome of interest is survival (freedom from death from any cause) at 2 and 5 years post-intervention in three cohorts of patients:

- a. Patients treated with paclitaxel DCB versus plain balloon angioplasty
- b. Patients treated with paclitaxel DES versus bare-metal self-expanding stenting
- c. Patients treated with either paclitaxel DCB or DES analyzed together versus plain balloon angioplasty or bare metal self-expanding stenting

Secondary efficacy endpoints will include target vessel revascularization (TVR) and major amputation.

Mortality from open and percutaneous TVR will be reported to determine the impact of subsequent revascularizations.

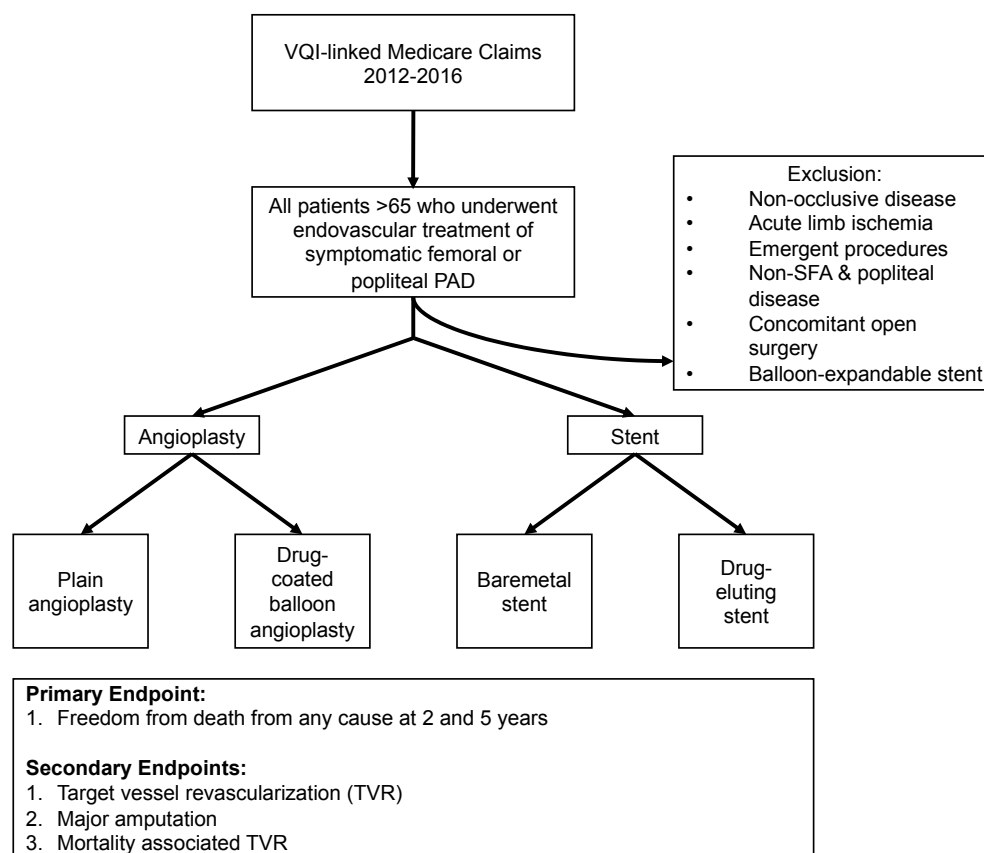


Figure 1: Flow diagram demonstrating planned schema for identification of patient cohorts.

10 Statistical Methodology

10.1 General Approach

The analyses will be performed using SAS®, and Stata®. Continuous variables will be summarized by mean, 95% confidence interval, median and interquartile range will be estimated for continuous variables. Categorical variables will summarize by the rate and its 95% confidence interval. The 95% confidence interval for the differences will be used for comparisons among treatment groups.

10.2 Propensity Score Model Development and matching

10.2.1 Variable Selection

Covariates will be included in the propensity score model if they were available to the treating physician at the time the index intervention, are considered to be associated with the outcomes of interest-based on prior published research, or plausibly related to the selection of the interventional device (based on expert opinion).

Variables to be considered for inclusion in the propensity score match model include:

- Age
- Male Gender
- Current smoker
- Body Mass Index (BMI)
- History of hypertension
- History of diabetes
- History of coronary artery disease (CAD)
- History of congestive heart failure (CHF)
- History of COPD
- Renal Insufficiency (defined as creatinine > 1.5 mg/dL)
- Dialysis dependence
- Poor pre-operative functional status
- Poor pre-operative ambulation
- Procedural indication for chronic limb ischemia
- Presence of active infection in the treated limb
- Emergent procedural status
- Treatment length
- Treatment for chronic occlusion

10.2.2 Developing the Propensity Model:

A propensity score (i.e., probability of receiving the interventional device of interest) for each patient will be calculated using the propensity score model via logit estimation.

To remove potential bias when performing the matching, those that are involved with the variables selection process and the endpoint analysis will be involved in the calculation of the propensity score and the matching. In addition, propensity scores will be estimated using logistic regression for both cohorts using the data without outcome information by an independent statistician that is naive, i.e., has not been involved in analyses using this or similar analysis cohorts.

Variables will be excluded if they are found to be co-linear with covariates already included in the propensity score model (after any necessary imputation is performed). To guard against the possibility of the model being unable to converge due to quasi-complete (or complete) separation, we will calculate linear Variance Inflation Factor (VIF) for each candidate covariate, excluding from the model any covariate with $VIF > 8$, and further assessing any covariate with a $VIF > 4.15$. For this latter group, we will review the correlation to identify those covariates that were highly correlated (with correlation coefficient > 0.80) and eliminate one of the two highly correlated covariates.

The goodness of fit of the model will be assessed by doing the following:

- Calculating the chi-square test for goodness of fit
- Examine the residuals for evidence of non-linearity

The sensitivity of the model to each of the covariates will be evaluated by dropping each variable and recalculating the model with the remaining covariates and report the c-statistic.

Matched controls will be selected as the nearest-neighbor in a 1:1 ratio from all patients who underwent endovascular treatment of PAD during the same half-year as the interventional treatment of interest (either DCB or DES), using a fixed caliper width of 0.2 SD of the logit of propensity score using a greedy matching algorithm.¹⁴ Separate propensity score (and matches) will be developed for each endpoint.

Balancing diagnostics will be performed. Standardized mean difference (SMD) is the most commonly used statistic to examine the balance of covariate distribution between treatment groups. Because SMD is independent of the unit of measurement, it allows comparison between variables with a different unit of measurement. SMD will be reported by plotting the mean difference versus each covariate. See Figure 2 below for an example:

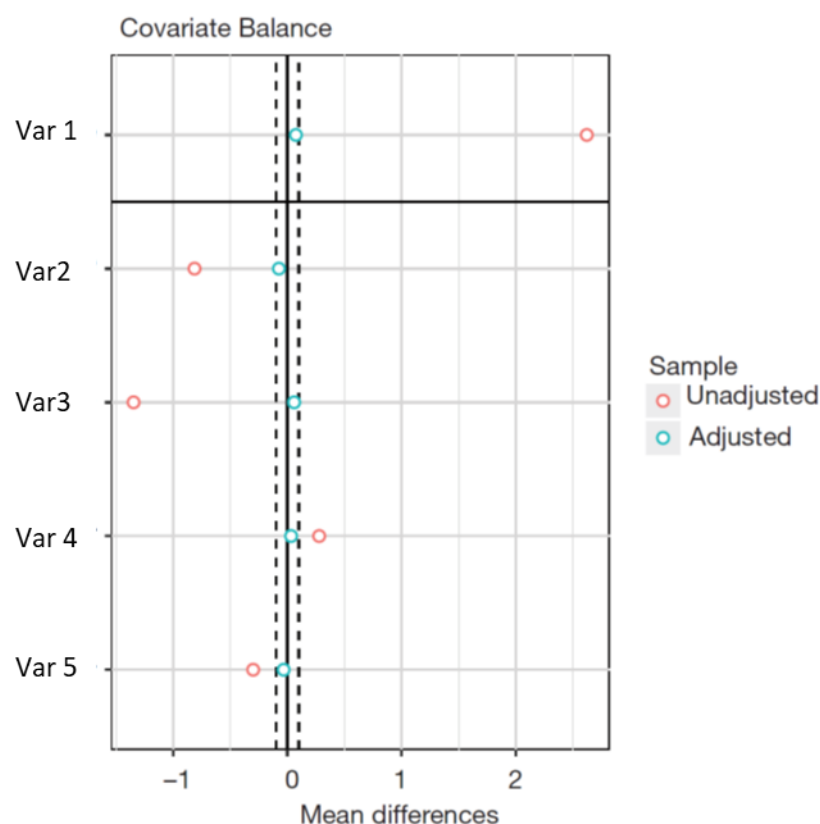


Figure 2: Covariate balance measured by standardized mean difference.

The variance will be compared by estimating the variance ratio before and after matching for each variable. A variance ratio > 1.2 will be used to indicate an imbalance.

If there is evidence of imbalance between treated and untreated the propensity score model will be modified by including by adding interactions between covariates that are already in the model, or by modeling the relationship between continuous covariates and treatment status using nonlinear terms.

10.3 Survival Analysis

For each analysis data set, a Cox proportional hazards model will be implemented to predict survival developed with the following covariates:

- time-dependent covariate will be created when a post-index interventional procedure (PTA, DCB, Stent, Atherectomy, or Surgery) is performed on the SFA/Popliteal vessel in either leg of the subject. If there is one procedure post index, then during the time interval before the new procedure, the indicator variable will be set to 0. After the new procedure, the indicator variable will be set to 1. If there is more than one procedure post-index procedure, then the indicator variable will be 0 until the first procedure, 1 for until the second procedure, 2 until the third, etc.
- Treatment Type
- Indication for treatment (Critical Limb Ischemia or not)

Survival curves by treatment group will be generated categorized by whether there were post-index procedures or not, and indication. In addition, number at-risk patients and the Hazard Ratio estimates will be generated for every 6 months of follow-up available.

10.4 Checking Assumptions

The assumption of proportional hazards will be evaluated using scaled Schoenfeld residual plots and tests of the non-zero slope developed by Therneau and Grambsch.¹⁵ If there is evidence of a lack of proportionality transformations, then the analysis will be stratified by type of follow-up treatment in the target vessel and applying the restricted mean survival times methodology.¹⁶

The global goodness of fit statistic proposed by M Parzen, et al. will also be applied.¹⁷ If there is evidence of lack of fit, the process outlined in G. Heinz, et al.¹⁸ will be followed for adding additional covariates where the events per variable and clinical knowledge are incorporated into the choice of additional variables.

If there is evidence of lack of fit, there several options to address the lack of fit

- Evaluate the model using restricted mean survival(RMS) to see if the results are similar to the proportional hazards
- Adding a dummy time covariate to the model

10.5 Pre-specified subgroups and sensitivity analysis:

Subgroups: Patients who have a history of prior femoral-popliteal endovascular treatment, which subsequently undergoes treatment with a paclitaxel device (DCB or DES), will be analyzed a subgroup from among the primary cohorts, but without rematching. Similarly, the three primary analyses will be further explored through analysis of the subgroup of patients treated for critical limb ischemia will be analyzed separately from those patients treated for intermittent claudication (without rematching).

Sensitivity Analyses: The association between discharge medications and treatment with Paclitaxel devices will be explored, as well as the potential relationship between treatment with optimal medical therapy (discharge medications including statins, aspirin +/- P2Y12 inhibitor agent) and mortality. Separately, the association between target limb revascularization and mortality will be explored in the matched sample.

Lastly, instead of the 1:1 matched cohort, the propensity scores will be stratified into quintiles. The primary endpoint analysis will be re-run with the entire cohort using the propensity stratification as a covariate in the model.

11 Human Subjects Institutional Review

Human Subjects Institutional Review was waived based on SVS VQI as a patient safety organization.

12. References

- ¹ Katsanos K, Spiliopoulos S, Kitrou P, Krokidis M, Karnabatidis D. Risk of Death Following Application of Paclitaxel-Coated Balloons and Stents in the Femoropopliteal Artery of the Leg: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. *J Am Heart Assoc.* Dec 18 2018;7(24):e011245.
- ² <https://www.fda.gov/MedicalDevices/Safety/LetterstoHealthCareProviders/ucm629589.htm> Accessed January 18, 2019
- ³ <https://www.fda.gov/medical-devices/letters-health-care-providers/update-treatment-peripheral-arterial-disease-paclitaxel-coated-balloons-and-paclitaxel-eluting> Accessed March 15, 2019.
- ⁴ <https://www.fda.gov/media/127698/download>. Accessed June 10, 2019.
- ⁵ Columbo, J. A., Kang, R., Hoel, A. W., Kang, J., Leinweber, K. A., Tauber, K. S., . . . Goodney, P. P. (2019). A comparison of reintervention rates after endovascular aneurysm repair between the Vascular Quality Initiative registry, Medicare claims, and chart review. *Journal of Vascular Surgery*,69(1). doi:10.1016/j.jvs.2018.03.423.
- ⁶ Schillinger M, Minar E. Past, present and future of femoropopliteal stenting. *J Endovasc Ther.* Feb 2009;16 Suppl 1:I147-152.
- ⁷ Dick P, Wallner H, Sabeti S, et al. Balloon angioplasty versus stenting with nitinol stents in intermediate length superficial femoral artery lesions. *Catheter Cardiovasc Interv.* Dec 1 2009;74(7):1090-1095.
- ⁸ Chowdhury MM, McLain AD, Twine CP. Angioplasty versus bare metal stenting for superficial femoral artery lesions. *Cochrane Database Syst Rev.* Jun 24 2014(6):CD006767.
- ⁹ Eliason JL, Wainess RM, Proctor MC, et al. A national and single institutional experience in the contemporary treatment of acute lower extremity ischemia. *Ann Surg.* Sep 2003;238(3):382-389; discussion 389-390.
- ¹⁰ Earnshaw JJ, Whitman B, Foy C. National Audit of Thrombolysis for Acute Leg Ischemia (NATALI): clinical factors associated with early outcome. *J Vasc Surg.* May 2004;39(5):1018-1025.
- ¹¹ Howard DP, Banerjee A, Fairhead JF, Hands L, Silver LE, Rothwell PM. Population-Based Study of Incidence, Risk Factors, Outcome, and Prognosis of Ischemic Peripheral Arterial Events: Implications for Prevention. *Circulation.* Nov 10 2014;132(19):1805-1815

- ¹² Baril DT, Ghosh K, Rosen AB. Trends in the incidence, treatment, and outcomes of acute lower extremity ischemia in the United States Medicare population. *J Vasc Surg.* Sep 2014;60(3):669-677 e662.
- ¹³ Gerhard-Herman MD, Gornik HL, Barrett C, et al. 2016 AHA/ACC Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol.* Mar 21 2017;69(11):1465-1508
- ¹⁴ Oakes D, Feng C. Combining stratified and unstratified log-rank tests in paired survival data. *Stat Med.* Jul 20 2010;29(16):1735-1745.
- ¹⁵ PM Grambsch and TM Therneau, Proportional Hazards Tests and Diagnostics Based on Weighted Residuals, *Biometrika* 1994, 81(3): 515-526, <https://doi.org/10.1093/biomet/81.3.515>
- ¹⁶ P. Royston and MKB Parmar, Restricted mean survival time: an alternative to the hazard ratio for the design and analysis of randomized trials with a time-to-event outcome, *BMC Medical Research Methodology* 2013, 13: 152 <https://doi.org/10.1186/1471-2288-13-152>
- ¹⁷ M Parzen and SR Lipsitz, A Global Goodness-of-Fit Statistic for Cox Regression Models, *Biometrics* 1999 55: 580-584 <https://doi.org/10.1111/j.0006-341X.1999.00580.x>
- ¹⁸ G Heinze C Wallisch and D Dunkler, Variable selection – A review and recommendations for the practicing statistician, *Biometrical Journal* 2018, 60(3): 431-449 <https://doi.org/10.1002/bimj.201700067>

Appendix 1.

Table 1. ICD-9 and ICD-10 Codes of Femoropopliteal Artery Revascularization

Treatment	ICD-9	ICD-10
Drug-coated balloon (DCB)	3950*	047K3Z1, 047L3Z1, 047M3Z1, 047N3Z1
Drug-coated balloon (DCB) + drug-eluting stent (DES)	3950* 0060 Added codes for # of stents: 00.45=2. 00.46=3. 00.47=4.	047K341, 047L341, 047M341, 047N341
Drug coated balloon (DCB) + bare-metal stent (BMS)	3950* 3990	047K3D1, 047L3D1, 047M3D1, 047N3D1
Uncoated Percutaneous Transluminal Angioplasty Balloon (PTA)	3950*	047K3Z6, 047K3ZZ, 047L3ZZ, 047L3Z6, 047M3Z6, 047M3ZZ, 047N3Z6, 047N3ZZ
Drug-eluting stent (DES)	0060 Added codes for # of stents: 00.45=2 00.46=3 00.47=4	047K346, 047K34Z, 047K356, 047K35Z, 047K366, 047K36Z, 047K376, 047K37Z, 047L346, 047L34Z, 047L356, 047L35Z, 047L366, 047L36Z, 047L376, 047L37Z, 047M346, 047M34Z, 047M356, 047M35Z, 047M366, 047M36Z, 047M376, 047M37Z, 047N346, 047N34Z, 047N356, 047N35Z, 047N366, 047N36Z, 047N376, 047N37Z

Bare metal stent (BMS)	3990 Added codes for # of stents: 00.45=2 00.46=3 00.47=4	047K3D6, 047K3DZ, 047K3E6, 047K3EZ, 047K3F6, 047K3FZ, 047K3G6, 047K3GZ, 047L3D6, 047L3DZ, 047L3E6, 047L3EZ, 047L3F6, 047L3FZ, 047L3G6, 047L3GZ, 047M3D6, 047M3DZ, 047M3E6, 047M3EZ, 047M3F6, 047M3FZ, 047M3G6, 047M3GZ, 047N3D6, 047N3DZ, 047N3E6, 047N3EZ, 047N3F6, 047N3FZ, 047N3G6, 047N3GZ
Atherectomy	1756	04CK3ZZ, 04CL3ZZ, 04CM3ZZ, 04CN3ZZ

*if 3990 and 3950 are coded together from 2012 to 10/1/2015, we do not know if procedure involved plain balloon angioplasty or drug-coated balloon angioplasty. We will utilize claims data matched to the patient in order to identify whether the balloon was plain or paclitaxel coated.