

Preventing Critical Limb Ischemia

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DNP Quality Improvement Project

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Abstract

Background: Peripheral arterial disease (PAD) affects 10 million adults in the United States and remains a major cause of morbidity, mortality, and disability worldwide despite recent advances in medical, endovascular, and surgical therapies. After lower extremity revascularization (LER), patients are at heightened risk for developing major adverse cardiovascular events (MACE) and major adverse limb events (MALE). Current guidelines for the medical management of these conditions include antiplatelet therapy and aspirin (ASA). Upon reflection on current practice and performing an evidence-based literature review using the ACE Star Model, areas of opportunity for improved management of patients undergoing revascularization for symptomatic PAD became evident and resulted in the development of a quality improvement (QI) project.

Method: The QI project implemented the use of rivaroxaban plus ASA to reduce the primary composite outcomes that include acute limb ischemia, including major amputation, myocardial infarction, ischemic stroke, and/or cardiovascular death. The project was conducted over eight weeks and included 10 patients undergoing LER. Two patients met the inclusion criteria for the implementation of this initiative.

Results: The patients treated with rivaroxaban and ASA reported significant improvement in their symptoms. Ankle-brachial index (ABI) examination also revealed significant improvement in circulation in the lower extremities.

Discussion: The development of MALE is associated with poor prognosis among individuals diagnosed with PAD. Treatment with rivaroxaban along with ASA significantly reduced the incidence of complications and should be considered as an important therapy for this condition.

Keywords: peripheral arterial disease, claudication, revascularization, amputation, anticoagulation, antiplatelet agents, limb ischemia.

Preventing Critical Limb Ischemia

Peripheral arterial disease (PAD) affects 10 million adults in the United States (U.S.) and remains a major cause of morbidity, mortality, and disability across the worldwide despite recent advances in medical, endovascular, and surgical therapies. PAD is a clinical manifestation of systemic atherosclerosis. In PAD, atherosclerotic plaques cause progressive stenosis and occlusion of cerebral, coronary, and peripheral arteries, leading to a high risk of cardiovascular (CV) and major adverse limb events (MALE) (Søgaard et al., 2022). Hypertension, dyslipidemia, diabetes, obesity, and cigarette smoking increase the risk of PAD and can lead to a poor prognosis. Comprehensive medical management of PAD is based on tempering the processes that lead to atherosclerotic disease and focusing primarily on smoking cessation, exercise therapy, cholesterol reduction, and antiplatelet and/or anticoagulation therapy, as well as the application of peripheral vasodilators and blood pressure control as indicated (Dittman et al., 2022). Symptomatic PAD can present with atypical symptoms on exertion, claudication, critical limb ischemia (CLI), and acute limb ischemia (ALI) (Hess et al., 2020). Treatment modalities include revascularization or surgical interventions. Guidelines recommend single antiplatelet therapy with either Aspirin (ASA) or clopidogrel to reduce risks of developing a MALE or major CV events in patients with symptomatic PAD, regardless of whether they receive conservative medical treatment or undergo a revascularization procedure (Søgaard et al., 2022).

In advanced PAD, patients may experience disabling claudication, pain at rest, or tissue loss that requires endovascular or open surgical intervention (Dittman et al., 2022). Clinical presentation of this condition includes cool and discolored skin, prolonged capillary refill time, pallor on elevation, dependent rubor, and nonhealing wounds of the lower extremity that frequently progress to necrosis. A patient with suspected PAD will require a thorough vascular

examination of lower extremities including an assessment of dorsalis pedis and posterior tibial pulses followed by an ankle-brachial index (ABI) test to establish the diagnosis. The ABI is a noninvasive test that uses a Doppler device to measure systolic blood pressure in the arms (brachial arteries) and ankles (dorsalis pedis and posterior tibial arteries). The ABI of each leg is calculated by dividing either the dorsalis pedis or posterior tibial pressure (whichever is higher) by the higher of the two blood pressure measurements taken in the right and left arm (Gerhard-Herman et al., 2017). An ABI result of ≤ 0.90 is considered indicative of PAD. For symptomatic patients with ABI or toe-brachial index (TBI) confirmed PAD who are under consideration for a revascularization procedure, the results of duplex ultrasonography, computed tomography angiography (CTA), or magnetic resonance angiography (MRA) imaging studies may be used to develop an individualized treatment plan. These methods might be used for assistance in the selection of vascular access sites, identification of significant lesions, and determination of the feasibility of and modality most appropriate for invasive treatment (Gerhard-Herman et al., 2017).

Because PAD is both detectable and treatable, it is especially important to monitor trends, risk factors, and complications in diverse populations (Aponte, 2012). As noted above, PAD affects millions of adults world-wide and is a common chronic disease process among adults living in the border cities of El Paso, Texas in the U.S., and Ciudad Juarez Chihuahua in Mexico. Disparities in access to health care, employment status, income level, education status, and ethnicity all contribute profoundly to individual patient outcomes. El Paso is a unique area in west Texas that is home to individuals from many different backgrounds. According to Quick Facts El Paso County, Texas (2022), 867,947 individuals reside in the county of El Paso; 82.9% of these individuals are Hispanic. Furthermore, 20% of the residents of El Paso live in poverty,

which creates difficulties when attempting to obtain appropriate prevention and treatment interventions. Because of various obstacles, patients with PAD frequently seek treatment only at the late stages of the disease and as a result undergo limb amputation at an unnecessarily high rate.

PAD remains underdiagnosed and under-treated to an extent greater than that observed for manifestations of atherosclerosis elsewhere in the body, e.g., coronary artery disease and cerebrovascular disease (Dittman et al., 2022). While engaged in evaluating patients with PAD, we became aware of the need to implement immediate change due to countless hospitalizations. For example, a recent retrospective cohort study published by Anand et al. (2018) that enrolled 1,085 acute care hospitals in the U.S. and 31,538 patients with PAD and CLI who underwent peripheral artery revascularization reported that 21.3% of patients experienced unplanned hospital readmission within 30 days of discharge. Among those readmitted, 25% underwent repeat revascularization or amputation and 5.2% died. This was clearly a significant problem that we had already recognized in our medically underserved community. As noted by Anand et al., (2018), reasons for readmission included procedure-related complications, complications from diabetes and/or sepsis, and ongoing limb ischemia. In addition to the dramatic reduction in the patient's quality of life, readmission to the hospital was quite expensive, with an average cost of \$12,394 in U.S. dollars (Anand et al., 2018).

Upon reflection of current practice and evidence-based literature review, areas of opportunity for improving the management of patients undergoing revascularization for symptomatic PAD became evident. This ultimately resulted in the development of a quality improvement (QI) project. This QI project focuses on improving outcomes, reducing complications, and prolonging healthy lives in individuals suffering from PAD who receive care

at a local not-for-profit hospital. Among our initial findings, Hess et al., (2020) reported that symptomatic PAD could present with atypical symptoms on exertion, claudication, CLI, or ALI. In patients reporting symptomatic PAD after LER, nearly one in five will ultimately develop cardiovascular or limb ischemic events within three years. This risk is even higher (1 in 4) among those who have undergone surgical LER (Debus et al., 2021).

Our review of the available literature, including publications that featured results from the COMPASS and VOYAGER PAD trials, revealed that our PAD patients might be managed more effectively with anticoagulation in combination with antiplatelet therapy. COMPASS is a randomized, double-blind placebo-controlled study that investigated (1) if hospitalizations, MACE, amputations, and deaths occurred more frequently after the first episode of MALE compared with patients with PAD who experienced no MALE; and (2) the impact of low-dose rivaroxaban and ASA treatment compared with ASA alone on the incidence of MALE, the need for peripheral vascular interventions, and all peripheral vascular outcomes among patients with PAD (Anand et al., 2018). Anand et al. (2018) also reported that the combination of rivaroxaban (2.5 mg twice daily) and ASA significantly reduced the incidence of MALE and its related complications. The VOYAGER PAD (Vascular Outcomes Study of ASA Along with Rivaroxaban in Endovascular or Surgical Limb Revascularization for Peripheral Artery Disease) trial demonstrated the superiority of rivaroxaban plus ASA *versus* ASA alone as a therapy to reduce major cardiac and ischemic limb events after LER (Hiatt et al., 2020). Thus, this combination should be considered an important potential therapy in patients with PAD who have undergone an LER procedure.

The goal of this project was to decrease the risk of limb ischemia leading to amputation after an endovascular intervention. This will be achieved by treating these patients with daily

dose of ASA and rivaroxaban (Xarelto[®]) at a dose of 2.5 mg twice daily. Exclusion criteria included planned long-term dual antiplatelet therapy with clopidogrel (>6 months); another condition requiring for therapeutic anticoagulation; recent ALI (within two weeks of the qualifying revascularization procedure) or acute coronary syndrome; medical conditions that could increase the risk of major bleeding; significantly impaired renal function at baseline (estimated glomerular filtration rate < 15 mL/min/1.73 m²); or any documented history of intracranial hemorrhage, stroke, or transient ischemic attack (Bauersachs et al., 2021). The implementation of anticoagulation was done carefully and thoughtfully considering the heightened risk of major bleeding. According to Dittman et al. (2022), no increase in fatal or critical organ bleeding was observed among participants in the VOYAGER PAD trial that enrolled patients who had undergone a recent peripheral revascularization procedure. In this study, combination therapy provided superior reductions in adverse composite cardiovascular and limb adverse events compared with ASA alone.

The goal of this project was to improve patient outcomes and the delivery of health care. Several aims were identified for patients struggling with PAD, including reductions of the risk of outcomes such as ALI, major amputation secondary vascular disease, myocardial infarction, ischemic stroke, and cardiovascular death. In addition to improving functional outcomes, efforts aimed at reversing activity restriction associated with substantial disability among patients with PAD was also important. Thus, the overall aim of this project was to reduce morbidity including profound disability resulting from an amputation. Among our goals for the providers, efforts to increase awareness of long-term risks and to guide efforts aimed to improving post-procedural outcomes were important clinical goals of this QI project. Our final aim was to reduce the high healthcare costs associated with major amputation and ALI.

Methods

Context

The QI project was conducted at a local hospital overseen by the Division of Vascular and Endovascular Surgery at UMC in El Paso, Texas, that provides medical care for individuals from the Texas, New Mexico, and the Mexico border. The vascular surgery group in this division includes two vascular surgeons, two board-certified nurse practitioners, one patient navigator, two wound care certified nurses, one ultrasound technician and two medical assistants. The service provides traditional, minimally invasive, and endovascular surgical treatments for atherosclerosis, aneurysms, and venous diseases (Vascular & Endovascular Surgery, 2023). The vascular surgeons include the Division Chief and an assistant professor at Texas Tech Health Science Center of El Paso who are both currently engaged in surgical academic practice. The population served in this community is predominantly of Hispanic with unique barriers that limit their access to health care, including a comparatively low socioeconomic and educational status as well as lack of health insurance. Close collaboration between the hospital social workers, the pharmacy, and the patient navigator provided important assistance with resources available to ensure the successful implementation of this QI project.

Planning the Intervention

The ACE Star Model of Knowledge Transformation (see Figure 1) was utilized to guide the evidence-based implementation of the proposed change in practice. The goal of this process is knowledge transformation, which is defined as “the conversion of research findings from primary research results, through a series of stages and forms, to impact health outcomes by the use of evidence-based care” (White et al., 2021). The five-pointed star in figure 1 depicts the five stages of knowledge transformation including knowledge discovery, evidence summary,

translation into practice, integration into practice, and evaluation. Transforming health care while implementing new research can permit patients to achieve better outcomes. In this study, knowledge discovery began with a ten-day reflective practice that focused on the need for improvement in the care of patients diagnosed with vascular disorders. PAD was identified as a common disease process throughout the 10-day practice reflection. Focus, Analyze, Develop, and Execute (FADE) (see Figure 2) is a quality performance model that emphasizes the need for high-quality solutions, performance, and patient satisfaction (Nursing Papers Market, 2021). The FADE QI model was used to identify this practice issue and improve alternatives to its management.

Figure 1

ACE Star Model of Knowledge Transformation

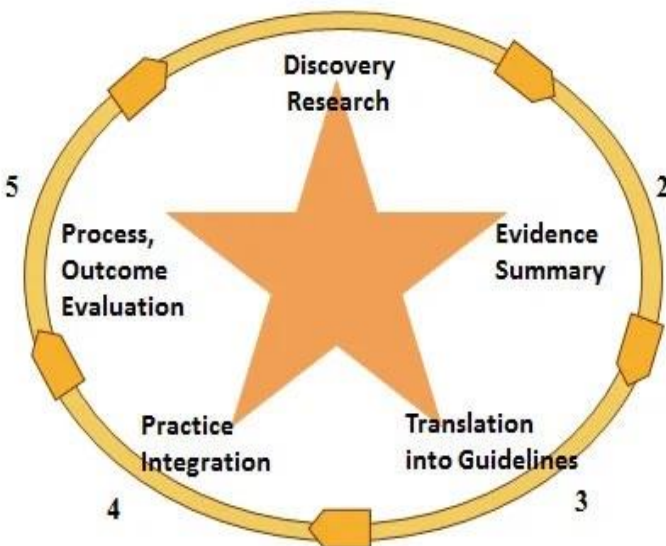
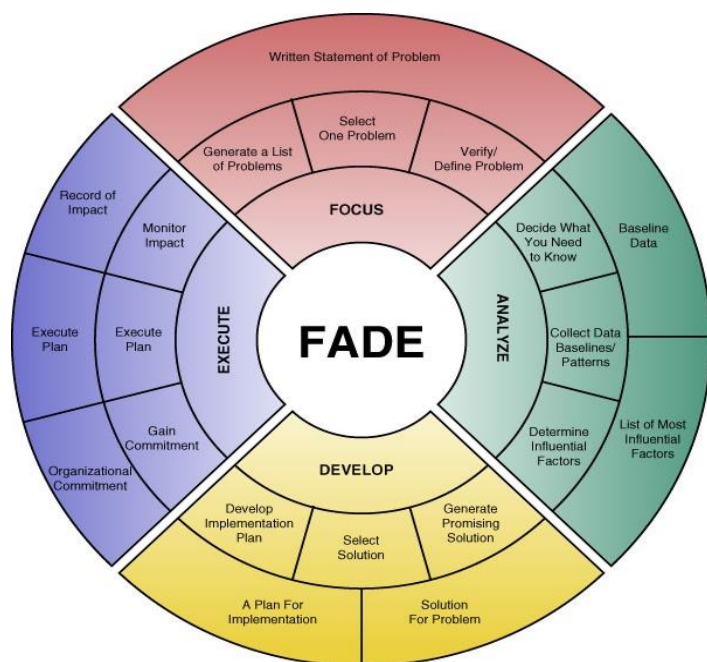


Figure 2*FADE Model*

An extensive literature search was completed that targeted Pubmed, MEDLINE, CINAHL, and the Cochrane Library databases. The following search terms were included: anticoagulation, antiplatelet revascularization, and PAD. As part of the evidence summary, information gathered in this review led us to consider new modalities for medical management. Likewise, the reports highlighting anticoagulation helped us to develop this QI project. The newly identified evidence- based data were presented to the vascular surgeons to obtain their clinical expertise and input which led to the development of clinical guidelines for this study. Practice integration was implemented with the best data available and provider expertise available with the goal of providing superior patient care. The proposed PICOT question was discussed with the vascular surgeons who agreed on the implementation of this change and permitted its integration into practice. Before completing the study, the process outcome and

evaluation were reviewed after the scheduled follow-up visit to determine the impact of this change on patient outcomes.

The proposed PICOT question focused on:

P: Adults (ages 50 to 81 years) with PAD requiring endovascular intervention.

I: Prescribe ASA (81 mg *per os* [PO] daily) and rivaroxaban (2.5 mg PO BID) post-revascularization.

C: Prescribe ASA (81 mg PO daily) and clopidogrel (75 mg PO daily) post-revascularization.

O: Reduce the number of limb ischemic vascular events to <6 events in PAD patients after peripheral revascularization.

T: 30 days

Study of Interventions

Treatment of adult patients with symptoms or a history of PAD was evaluated over eight weeks. Different treatment plans were formulated based on the extent of the disease and special attention was paid to those who were offered revascularization procedures. The patients were then screened for eligibility based on the specified inclusion and exclusion criteria for the implementation of daily ASA along with low-dose rivaroxaban twice daily. Patients were also provided with education on lifestyle modifications, exercise programs, medical management, treatment options, and expected outcomes including potential risks in their native language.

Methods Evaluated

Patients meeting the criteria for treatment with rivaroxaban and ASA based on the results of peripheral angiograms underwent ABI testing which was used as a baseline measure before treatment. Patients were re-evaluated after lower extremity revascularization with a repeat ABI

test. At follow-up, patients were asked to report present symptoms. Patients were also asked to describe their quality of life since the intervention with a particular focus on how PAD symptoms interfered with their ability to complete their activities of daily life. All data collected were documented in the patients' electronic health records.

Analysis

The effectiveness of the QI project was evaluated using both, qualitative and quantitative data. The ABI test provided a quantitative assessment of the vasculature both pre- and post-revascularization. Qualitative data were collected based on subjective information provided by the patient during visits with the provider.

Ethical Issues

The QI project was supported by the faculty at UMC Vascular and Endovascular Department. Patients' confidentiality was maintained by the Health Insurance Portability and Accountability Act (HIPAA) and the institutional policies. Before the initiation of the QI project, the University of Texas at El Paso Institutional Review Board reviewed and approved this study as a QI project and designated it as a non-research study. All available treatments were discussed with the patients. The patients were provided with the opportunity to decide on a specific treatment course after extensive education and discussion of potential adverse events, expected outcomes, and cost.

Results

Ten patients at our facility underwent LER during the eight-week duration of this project. An LER procedure was performed in patients with symptomatic PAD with claudication, rest pain, or ischemic ulceration, evidence of occlusive disease on imaging, and an abnormal result on an ABI test (Debus et al., 2021). The patients (six male and four female) ranged in age from

27 to 87 years. Two Hispanic males ages 64 and 66 years met the inclusion criteria for the implementation of the aforementioned medication regimen. One participant had a past medical history of hypertension and the second participant had no significant medical history. Eight patients were excluded from the QI project from various reasons. Among those deemed ineligible, one female was excluded because of poorly- controlled blood glucose levels. Another female was excluded due to a history of recent trauma. The other six patients were not included as they were deemed high risk for bleeding and were receiving full-dose anticoagulation for other reasons. One patient failed to meet the inclusion criteria because of a low GFR.

After Revascularization, the two patients who met inclusion criteria were prescribed 81mg of ASA daily and 2.5 mg of rivaroxaban twice a day. Patients were educated on potential adverse events, including bleeding. Patients were discharged from the hospital after the endovascular intervention with a follow-up visit scheduled with a healthcare provider for a review of clinical outcomes and diagnostic imaging. Both patients were asked to complete an ABI test at the local vascular clinic which was reviewed during the follow-up visit.

Both patients treated with rivaroxaban and ASA reported significant improvement in symptoms with the resolution of claudication and rest pain. No tissue loss or necrosis was documented. The ABI examination also revealed significant improvement in the lower extremities with near-normal patterns compared to the results from their respective ABI test performed before LER. No adverse events or acute episodes of major bleeding were reported. Neither patient required readmission to the hospital after revascularization.

Discussion

Summary

The development of MALE in individuals with lower extremity PAD frequently leads to a poor prognosis, thus highlighting the need for change. This QI project focused on evaluating the efficacy of rivaroxaban added to antiplatelet therapy with ASA as a means to reduce major cardiovascular and limb ischemic vascular outcomes in a high-risk population of PAD patients who underwent peripheral revascularization. The two patients who agreed to receive treatment demonstrated improved symptoms as well as significant improvement in ABI obtained after the intervention. As described in the literature, treatment of PAD patients who underwent LER with rivaroxaban (2.5 mg BID) plus ASA led to a significantly lower incidence of ALI, major amputation for vascular causes, myocardial infarction, ischemic stroke, and/or death from cardiovascular causes than was observed in response to ASA alone (Bauersachs et al., 2021). Furthermore, the implementation of evidence-based practice via this QI project led to a notable reduction in the incidence of MALE and the related complications. This drug combination should be considered as an important therapy for patients with PAD.

Safety Outcomes

The results from this QI project supported data obtained from the literature review. As reported by Sogaard et al., (2022), peripheral artery revascularization is associated with an immediate high risk of post-procedural re-thrombosis and an elevated risk of major CV and limb events that persists long after the intervention despite the administration of antiplatelet and statin therapy. Similarly, Bauersachs et al., (2021), reported that the primary efficacy outcome was its impact on a composite of ALI, major amputation for vascular causes, myocardial infarction, ischemic stroke, and/or death from cardiovascular causes. The primary composite efficacy results were assessed on an intention-to-treat basis within four weeks of revascularization. Thirty days after revascularization, none of the patients required further vascular interventions,

and neither of our target patients required readmission to the hospital. Of note, special emphasis should be placed on patient education with a focus on the potential risk of major bleeding when taking rivaroxaban and ASA.

Limitations

Limitations noted in this QI project that should be considered included the small number of participants who were eligible treatment. The outcomes from these participants were not compared to those who received another treatment option after LER, and the initiation of anticoagulation was not studied among those patients who underwent lower-extremity bypass surgery. While the incidence of the principal safety outcome of thrombolysis in myocardial infarction (TIMI) major bleeding risk score was not significantly higher among those treated with rivaroxaban plus ASA than with ASA alone, rivaroxaban plus ASA was associated with a significantly higher incidence of the secondary safety outcome of International Society on Thrombosis and Hemostasis (ISTH) major bleeding (Bauersachs et al., 2021). Finally, a lack of knowledge regarding disease progression among patients with PAD often leads to a poor prognosis. Early education on the disease process, including recognition of symptoms, risk factors, and prevention methods may require significant attention when designing future studies.

Conclusion

PAD has an impact on an estimated 230 million adults worldwide and at least 9.5 million adults older than 40 years in the U.S. today (Dittman et al., 2022). PAD is a progressive atherosclerotic disorder that can be asymptomatic, but often results in profound functional limitation and acute limb-threatening ischemia leading to amputation (Krantz et al., 2021). Among individuals with PAD, the development of a MALE is associated with a poor prognosis. Optimal medical management after the primary intervention can improve functional capacity and

decrease mortality (Dittman et al., 2022). Medical management with rivaroxaban (2.5 mg twice a day) together with ASA significantly reduce the development of MALE and other complications. This drug combination should be considered as an important therapy in patients with PAD who have undergone lower extremity revascularization.

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