ENDOVASCULAR

CRITICAL LIMB ISCHEMIA

CRT-200.02

Therapeutic Window of Clopidogrel and Ticagrelor in Patients with Critical Limb Ischemia

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BACKGROUND Critical limb ischemia (CLI) is associated with increased risk of amputations, cardiovascular events and mortality. Antiplatelet therapy is a crucial component of CLI treatment. High on-treatment platelet reactivity (HPR), defined by a platelet reactivity unit (PRU) score above 208 on the VerifyNow P2Y12 Assay, is associated with increased risk of ischemic events. Low on-treatment platelet reactivity (LPR), defined by a PRU score below 85, is associated with increased risk of bleeding events. The goal of the current study is to investigate a therapeutic range (TR) of clopidogrel and ticagrelor defined by PRU scores between 85 and 208.

METHODS In a retrospective analysis, data from the "Switch To Ticagrelor in Critical Limb Ischemia Anti-Platelet Study 'STT-CLIPS'" study was used to assess the therapeutic window of 48 CLI patients. Data included four measurements of platelet reactivity using the VerifyNow P2Y12 Assay: baseline (before daily dose) and steady state (6 hours after daily dose) while taking clopidogrel 75 mg daily for at least two weeks, and two weeks after switching to ticagrelor 90 mg twice daily.

RESULTS At baseline, 47.9% of patients on clopidogel were within TR (37.5% HPR, 14.6% LPR) compared to 10.2% on ticagrelor (2.1% HPR, 87.5% LPR; $p < 0.001$). At steady state, 43.8% of patients on clopidogel were within TR (31.3% HPR, 25.0% LPR) compared to 10.2% on ticagrelor (2.1% HPR, 87.5% LPR; $p < 0.01$). HPR was more common on clopidogrel compared to ticagrelor at baseline (37.5% vs. 2.1%; $p < 0.0001$) and at steady state (31.3% vs. 2.1%; $p < 0.001$). LPR was more common in ticagrelor compared to clopidogrel at baseline (87.5% vs. 14.6%, $p < 0.0001$) and at steady state (87.5% vs. 25%, $p < 0.0001$).

CONCLUSION With only 42.9% of patients on clopidogrel (at steady state) being in the therapeutic range of platelet inhibition, there is a reasonable concern for either bleeding or ischemic complications. Though ticagrelor has been proposed as an antiplatelet alternative in patients with CLI, this study observes an excess of platelet inhibition, warranting concern for bleeding complications.

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Frailty in Patients With Critical Limb Ischemia

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BACKGROUND Critical limb ischemia (CLI) is an advanced stage of peripheral arterial disease in which insufficient blood flow to an affected extremity results in ischemia, frailty, and adverse outcomes. Frailty is increasingly used to preoperatively risk-stratify patients and has become an important prognostic marker for mortality in cardiovascular (CV) patients. The aim of this study was to assess the utility of the Vascular Quality Initiative (VQI) and modified Frailty Index (mFI) frailty scales in patients with CLI by correlating frailty indices to adverse in-hospital events.

METHODS This study retrospectively examined frailty in 494 patients with CLI who presented to LAC+USC (January 2012-June 2017). Patients were analyzed on 15 criteria unique to the VQI and mFI scales and separated into 10 and 11 categories respectively. The frailty index was calculated by scoring 1 point for a positive category, summing up the positive value categories and dividing by 10, yielding a ratio between 0 and 1. The index was classified as a VQI-derived frailty index ≥ 0.3 = "frail", FI ≤ 0.08 = "non-frail" and 0.08<FI ≥ 0.3 = pre-frail. The mFI scale was performed in the same manner and patients were separated: mFI ≤ 0.08 = "non-frail", those with mFI ≥ 0.25 = "frail", 0.08$\leq$ mFI$\geq$0.25 = "pre-frail". Once these patients were separated, the indices were correlated to rates of death, amputation, and CV endpoints using Chi Square, ANOVA and Student t-tests.

RESULTS Using the mFI, planned amputations occurred in 19.5% of frail versus 2.5% of pre-frail patients ($p = 0.008$). Frailty status calculated with the VQI index correlated with death and planned amputation: frail patients experienced 23% planned amputations versus 4% in non-frail and 16% in pre-frail ($p = 0.025$). Death only occurred in frail patients ($p = 0.034$). Unplanned amputation showed no correlation in either index.

CONCLUSION The VQI frailty index is more efficacious in amputation and mortality risk stratification than the mFI. The VQI may be used as a screening tool to identify patients who are at high risk for amputation and death. It is a tool that can assist with informed decision-making in patients with CLI.

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Outcomes of Split Thickness Skin Grafting for Foot and Ankle Wounds in Patients With Peripheral Arterial Disease

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BACKGROUND Tissue ischemia resulting from arterial insufficiency is a major contributing factor to lower extremity wound healing in patients with peripheral arterial diseases (PAD). Rapid wound closure provides a barrier to further infection and limb loss. Split thickness skin grafting (STSG) is relatively common and easy to perform, but outcomes data are scant in the post-endovascular intervention population. In this study, we evaluated factors predictive for complete wound healing following endovascular intervention for PAD.

METHODS We retrospectively reviewed all patients with PAD and wounds of the foot and ankle who underwent STSG between January 2014 and December 2016 at MedStar Georgetown University Hospital. Lower extremity revascularizations, percent take rate of STSG, and amputation rate were of particular interest. Wounds with 100% take rate were defined as fully healed.

RESULTS Thirty-five patients with 48 wounds underwent STSG. There were 21 males and 14 females with a mean age of 64 years. Revascularization was performed in 24 patients (33 limbs) for non-healing wounds and abnormal pedal pulses before STSG. The most common endovascular intervention was balloon angioplasty for tibial lesions. A total of 9 patients had endovascular intervention for SFA and popliteal chronic total occlusion. The presence of a patent pedal arch showed improved wound healing at one month ($p<0.05$). Initial wound surface area at presentation (20.3cm^2 vs. 41.8cm^2) was also significant for complete healing at one month ($p<0.05$). However, at 90 days of follow-up, the initial wound size lost significance. Additionally, at 90 days of follow-up 18 wounds were fully healed, five required revision, 15 were unhealed, and 9 did not return for follow up. Ultimately, a total of 6 limbs had major amputations at an average of 502 days. During this period, 23 wounds eventually healed and the remaining had some degree of breakdown that required both conservative treatment or reoperations for limb salvage and wound closure.

CONCLUSION These results show the importance of a patent pedal arch to the healing potential of the foot and ankle wound with STSG and limb salvage efforts in this high-risk patient population.

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High On-treatment Platelet Reactivity to Aspirin and Clopidogrel Increases the Risk of Cardiovascular Events in Patients with Critical Limb Ischemia

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BACKGROUND Critical limb ischemia (CLI) is associated with increased risk of adverse cardiovascular and limb events. This study aims to determine if high on-treatment platelet reactivity (HPR) to aspirin (HPRA) and/or clopidogrel (HPRC) is associated with increased risk of adverse cardiovascular or limb events.