Reviewer’s report

Title: Peripheral Artery Disease and Exertional Leg Symptoms in Diabetes Patients in Ghana.

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Reviewer: Sreek Vemulpallli

Reviewer’s report:

The authors have conducted a cross-sectional case-control study whereby all patients in the study underwent the Edinburgh Claudication Questionnaire as well as ankle brachial index testing. The authors conclude that: there is a high burden of PAD in T2DM patient in Ghana. The use of intermittent claudication to screen for PAD was not in agreement with ABI diagnosed PAD. Future studies should investigate the cost-effectiveness of ABI as a diagnostic tool and treatment target of PAD. I have several questions about the design and discussion of the study.

Population: The selection of the control cohort is not completely clear to me. Were controls selected as every third patient to visit "the clinic?" Was any matching undertaken in selecting the controls?

A Consort diagram would also be helpful - how many patients were approached for the study (both diabetics and controls), and how many were actually consented?

Study period (over what years did this study take place? Were the controls recruited simultaneously to the PAD patients?)

Methods:

What were the covariates of adjustment in the multivariate model?

The authors state in the discussion: "In this study, however, low ABI was not associated with any macrovascular disease, which was assessed retrospectively from case notes and self-report." This assessment is not discussed in the results or methods section and therefore should be removed from the manuscript unless the authors can provide details about how follow-up was conducted, number of patients with follow-up, length of follow-up, etc…

Results and Discussion:

The paper is initially setup as a comparison between those with and without diabetes (patients were recruited from the diabetes clinic and non-diabetic controls were recruited). However, we are never given a table of baseline characteristics between those with and without diabetes. In general, I find a number of comparisons being made in this manuscript - diabetics vs. non diabetics, claudication vs. no claudication, hypertensive diabetics vs. non-hypertensive diabetics, etc… and am having difficulty following the main point of the manuscript.
Additionally, the authors present data in the discussion that is not given in the results section: The findings of this study showed that the prevalence of falsely elevated ABI (ABI > 1.3) is 6%, more in diabetes patients (5.1% vs. 0.9%, p < 0.001) than non-diabetes participants.

Discussion:

The authors make a comment that because both high and low ABIs have been associated with coronary heart disease, stroke, and cardiovascular mortality, that the ABI must be important in CVD risk prediction. However, it is not the association between the ABI and outcomes that accounts for the ABIs potential place in risk assessment but the additive value or net reclassification afforded by the ABI. The authors' statement should be modified to take this into account or deleted.

One of the authors' main discussion point that the Edinburg Claudicaiton Questionnaire is not sensitive for PAD when compared to ABI screening is not surprising given that it is well known that the vast majority of patients with PAD are either asymptomatic or have atypical symptoms (which may not be picked up with the ECQ).

The baseline characteristics of those with and without intermittent claudication are quite different from those reported in most studies presently available in the literature. Classic claudication symptoms are generally found more often in males than females and PAD (even if the overall burden of PAD is greater in females) is generally found more often in smokers, however, the authors found classic claudicaiton symptoms more frequently in females and PAD (as diagnosed by ABI) was not associated with smoking. These findings need to be addressed more completely in the discussion.

Minor comments:

p. 4 lines 46/47 - the definition of a "normal" ABI is wrong as written: (normal (0.9 ≥ ABI > 1.3))

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Unable to assess

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.
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