Reviewer's report

Title: Diagnostic accuracy of resting systolic toe pressure for diagnosis of peripheral arterial disease in people with and without diabetes: a cross sectional case control study

Version: 0 Date: 24 Sep 2017

Reviewer: Shan Bergin

Reviewer's report:

Thank-you for the opportunity to review this well conducted and beautifully written paper. My only concern with publication of the manuscript as is, is that the usefulness of TP as a diagnostic tool is perhaps overstated based on reported results and there are some findings and limitations that I feel are not given the attention they deserve in the paper. The reason for this concern is the potential for readers particularly more inexperienced ones to overestimate the usefulness of TP as a stand alone tool for diagnosis which is likely to result in overuse and over reliance on this as an indicator for PAD. I would ask the authors to consider revising some of the language used in the paper and to place more emphasis on some of the findings and limitations of the study.

Please see feedback below, I hope the authors find this useful:

1. In the abstract the conclusion is stated as "TPs are clinically useful for non-invasive vascular assessment of the lower limb....." however in the body of the paper the authors state that TP's are a "fair test" for use in clinical practice....."however should not be used as a standalone test due to the small probability of PAD being present with a negative test." This appears a bit contradictory and as mentioned above I believe the statement in the abstract overstates the usefulness of TPs based on the study findings. Abstract conclusions and statements/findings need to be consistent and should be an accurate representation of all findings.

2. Further to the above what do the authors mean by a "fair test" - is this based on the findings and accepted definitions of sensitivity and specificity? Again I think the authors need to be more clear about how useful/accurate/reliable the TPs are in detecting PAD based on their findings.

3. In Line 63 the statement is that there is "growing evidence" that ABI is problematic at times - I think this is well established and widely known now - the inference in this paper is that it is yet to be proven/accepted?

4. In Line 71 /72 the authors state that TP "may also be used as a standalone assessment of lower limb vascular function and for calculation of the ...TBI..." Can the authors provide a reference supporting the use of the TP as a stand alone assessment? In Line 79 it then
states that "despite the evidence of predictive capacity of TP for wound healing there has been little investigation of the diagnostic accuracy of this test for the identification of PAD" These statements appear contradictory.

5. Can the authors clarify why demographic information such as smoking status and history of foot complications was collected - there isn't any reference to any of this in the findings and I'm left wondering how it is relevant to this study? Similarly why data on intermittent claudication was collected - was this used to assign a severity rating to PAD?

6. The authors rely heavily on the reporting of sensitivity however in identifying reliability and usefulness of diagnostic tools specificity is equally important - the authors should include specificity results for all findings especially in the tabulated results. Reporting sensitivity alone can sometimes be misleading (I'm not saying that is the intention here) and as a reader always makes me wonder why it has been left out?

6. In terms of the criteria used for grading of stenosis - are these according to best practice guidelines/definitions etc - are they widely accepted values or were these determined for the purposes of this study only?

7. There needs to be greater discussion regarding the finding that TP is more useful in the presence of 'both distal and proximal disease' and the implication of this finding in the diabetes population who present overwhelmingly with distal disease alone. The ability of TP to detect PAD when distal disease alone was detected on CDU is much less than for other anatomical presentations (sensitivity 68.85 and 61.73)?

8. The mean TPs for both groups were quite high (normal is considered anywhere from 70-110mmHg as a rule) even in the presence of significant stenosis - so how relevant is the TP clinically in the absence of clinical signs such as ischaemic pain, non-healing wounds etc?? I think this is one of the most useful clinical utilities of TP so should be emphasised more - preventative care for modifiable risk factors (briefly mentioned as CVD risk factors but I owuld expand on and beyond this).

9. Can the authors comment on why the greatest sensitivity was found in mild to moderate as opposed to more severe disease - what are the implications of this?

10. Given that MAC is reported as more common in diabetes populations (and the reason we don't use ABI alone) can the authors comment on the low numbers with MAC reported in this diabetes group compared to the non diabetes group?
11. Similar to above can the authors comment on the lower numbers in the diabetes group who are reported to present with distal disease alone - this appears contrary to what we know about diabetes related PAD. Does this and point 10 above have any implications for the findings in the diabetes group as they appear to be somewhat atypical?

12. Can the authors comment in greater detail on the low sensitivity for TP in the diabetes group when a stenosis of >75mmHg was detected on CDU?

13. I would like to see it more clearly and consistently stated that based on these findings TP can be useful as an adjunctive test for PAD however it should not be used alone. I know this is stated at one point in the paper but I think overwhelmingly the paper reads as promoting the use of TP as a reliable stand alone test for PAD and I am not convinced the findings support that.

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