Reviewer's report

Title: The reliability of toe systolic pressure and the toe brachial index in patients with diabetes

Version: 1 Date: 22 July 2010

Reviewer: Anna Spencer

Reviewer's report:

Major Compulsory Revisions

This study was so inadequate in study design that the reliability was always going to be questionable.

1. Firstly, the study was completely undermined by the amount of experience and training of the testers that participated in this reliability study. Reference was made to the “clinical experience” of the raters ranging from limited to 1 year and 6 months. What the authors did not make clear was whether the measurement was routinely performed during this time. The sixty minute training session one week prior to commencement also seemed inadequate given that the researchers have chosen the manual method of blood pressure measurement over automatic. It seems that attempts to reduce the human element has been inadequately and therefore the true reliability of the technology has not been isolated.

2. Sample Size. Interestingly the previous ICC studies listed in Table 1 range from 50-60 participants. In this study a sample size of 30 has been chosen. I understand that power studies are limited in relation to reliability. However, it seems that a larger sample size would have added greater weight to the result. Portney and Watkins (2001) are quoted as saying that “when very small samples are used (n<30), power is substantially reduced. Peat (2001) suggests that n > 50 is a more appropriate sample size for reliability studies.

It is notable that the authors chose to quote the appropriateness of the sample size from the journal of Wound Ostomy Continence Nurses Society. Sample size is listed as a limitation of the study but again the significance of this limitation is very large.

3. Time between sessions. The one week difference in repeating the tests seemed excessive. Is the test then of the consistency of the participants blood pressure or the reliability of the technology.

4. Environment. Is the room temperature of 20 degrees celcius appropriate for a vascular study when it would not be considered a normal room temperature.

Essentially all these limitations have been written about in the discussion section of the study. However, I feel that the study design has been so poor as to critically undermine the integrity of the study.
Minor Essential Revisions

1. Background – Last paragraph
The aim of the study needs to be able to stand alone, without the context of the surrounding text. “The aim of this study..using a manual method” – needs to be a more specific reference to the method ie use of a manual sphymomenometer and PPG.

Statistical Analysis Section. “Data from the right side only” – should include some reference to the patient as it reads like only data from the right side of SPSS was used.

Conclusion
The conclusion, like the aim, should stand alone without interpretation. “Despite the reasonable ICC results, the range of error was broad.” What error exactly? Can this conclusion be drawn given that the study design was so flawed.

Level of interest: Reject as not of sufficient priority to merit publishing in this journal

Quality of written English: Needs some language corrections before being published

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:
I declare that I have no competing interests.