Reproducibility of ankle/Brachial Index (ABI) Measurements using the Colin VP 1000/2000 device

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1 Introduction

The last two decades have seen remarkable progress in the treatment of risk factors for atherosclerosis. Not only have effective drugs for treating hyperlipidemia and hypertension been developed, but their effects on the progression of atherosclerosis have been carefully documented.

To be specific, adequate treatment of hypercholesterolemia has been shown to cause regression in size of both coronary (,) and carotid plaques. Not surprisingly, normalization of plasma lipids also reduces cardiovascular events and overall deaths (45 PLAC I, ACAPS, VA HIT) of note that is one of the trials cited, VA HIT involved treatment of patients with low high density lipoproteins (HDL) and showed that raising HDL lowered atherosclerotic event risk while the other trials involved low-density lipoprotein (LDL) lowering. Earlier studies with niacin, which both lowers LDL and raised HDL, showed an impressive long lasting effect on both morbidity and mortality.

All but one of the above-cited studies had one thing in common - they all involved costly end points, either years of follow up or invasive angiography. That study PLAC II had as an end point measurement of the thickness of the wall of the common carotid artery at its bifurcation ( ), increased thickening meant the presence of plaque and the decrease seen with LDL lowering treatment was suggestive of plaque regression, which was confused by the reduction of cardiovascular events and deaths in its risks study PLAC I. The cost of PLAC I which used the techniques of B-mode ultrasound imagery cost a tiny fraction of the larger end-point study and gave a statistically significant result in one year and contrast to the ten year length of the much larger PLAC II trial.

Epidemiologists have been aware for some time of the value of non-invasive end-points for assessment atherosclerosis progression. Unfortunately, obtaining reproducible ultrasound measurements of carotid unusual medial thickness (IMT) the standard assay of plaque burden requires convincible skills on the part of the operator and reproducibility is significantly decreased by having more than one operator performing the studies.

The ankle brachial ratio, i.e. the systolic blood pressure at the ankle divided by that in the arm is widely used in epidemiological studies as a surrogate for overall plaque burden (,,).

2 The Ankle Brachial Index (ABI)

The test requires only an arm and a leg pressure cuff. The results from both arms and both legs may be measured for better reproducibility. Despite the relative simplicity of the test, it has not been widely accepted in clinical practice. Reasons for this are not obvious but probably include the time consumed and the variability introduced by individual measurements of blood pressure in both arms and both legs. In addition, sphygmomanometer calf blood pressure management in diabetics are often erroneous, unobtainable because diabetic arteries are much stiffer and resistant to compression than are non-diabetic vessels. Together, their drawbacks have limited the use of the ABI for assessment of individual plaque burdens and progression of disease.

Recently, a self-contained instrument for simultaneous measurement of blood pressure and all four extremities and for arterial pulse wave velocity (PWV) has been introduced in to the United States. PWV is a direct function of arterial stiffness and allows immediate recognition of artifactually high blood pressure. Weve reported here a reproducibility study of 62 subjects who encompass a wide age range, both sexes, and both normal and abnormal risk factors. This study utilzes data collected for two as yet unpublished studies of ABI.

As computed by the Colin VP machine, ABI equals ankle systolic blood pressure divided by the larger of the left and right brachial systolic blood pressures. As the machine measures both ankles, it reports a left and a right ABI.

3 Methods

The study used one Colin VP machine, two operators, and 39 subjects. The subjects were recruited randomly from among our patient population. They range in age from ??? to ??? years; with 28 males, 11 females; 21 with diagnosed heart disease; and 7 with diabetes. . Each subject was measured three times in one session by a single operator

In the session, the operator placed the four Colin blood pressure cuffs on the patients arms and ankles, and then positioned the carotid sensor, with any repositioning necessary for the machine to verify the carotid sensor. Then an automatic measurement sequence was initiated, lasting about one minute. The carotid sensor was then removed while the machine printed results. For the next measurement, the carotid sensor was positioned again and another automatic measurement sequence initiated, followed by carotid sensor removal. This process was repeated for a total of three measurements, after which the blood pressure cuffs were removed. Immediately after the first session was completed, the second operator repeated the cuffing and carotid sensor placement for three more measurements. Thus each operator made three measurements per session in two back-to-back sessions for a total of six measurements.

4 Results, ABI

Figure 1 plots all the data used in the study. There are three pairs of left and right measurements for each subject, so each left–right pair is represented by a point in a 2D plot, with x coordinate equal to right ABI, and y coordinate equal to left ABI. the three points for each subject are linked by lines to make a triangle. Small triangles indicate measurements with small variation, and large triangles large variation. The general diagonal trend of the data indicates the correlation of left and right ABI.

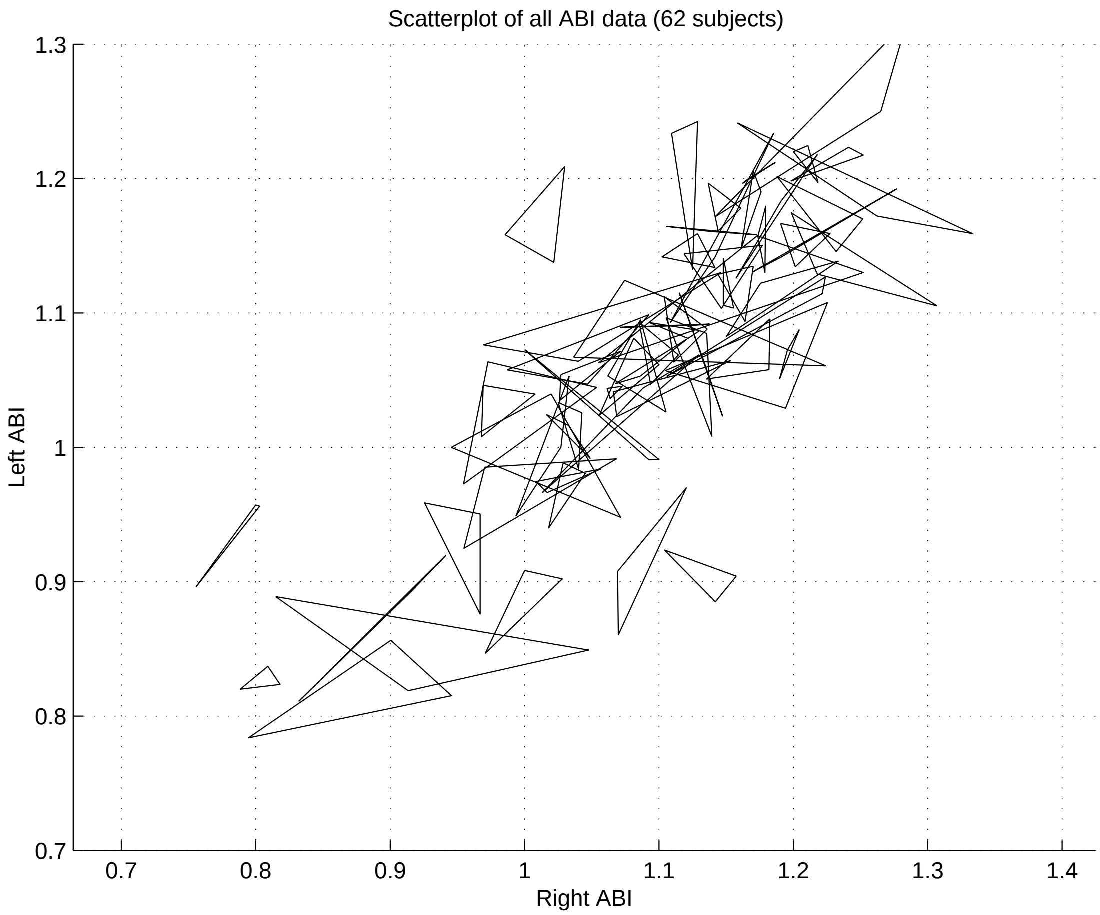

Figure 1: Scatterplot of all ABI measurements in study. Each triangle indicates a single subject's three left and right measurements.

Figure 2 shows how, for each patient, the individual measurements vary from the mean of the three measurements. Note that there is no significant trend of greater variation with either larger or smaller mean ABI. The uniformity of variation with respect to mean ABI allows us to combine subjects' variation to compute an overall standard deviation for the group of subjects. Note that the right ABI has greater variation than the left.

Figure 3 splits the data from 2 by sex. Note that the difference in variation between left and right appears in both groups. Although the variation is slightly smaller in women, the difference is not statistically significant. The results are summarized in table 1.

As noted above, a curious feature of the data is the difference in variation between left and right ABIs. It raises the question: is this result due to one or two outlier right ABIs, or is it a trend apparent in numerous measurements? In an effort to answer this question, histograms

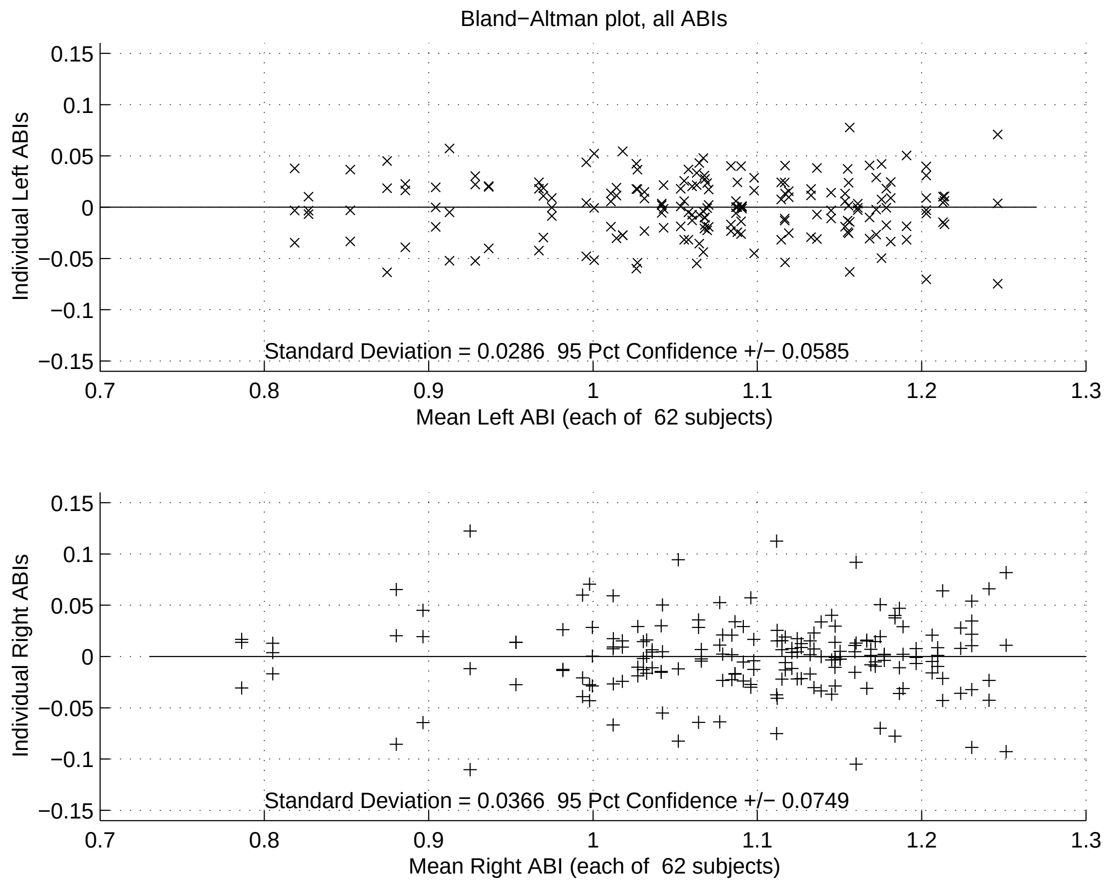

Figure 2: Bland-Altman plot of all ABIs. Here each patient's mean ABI has been subtracted from the three measurements, with a marker for each single measurement.

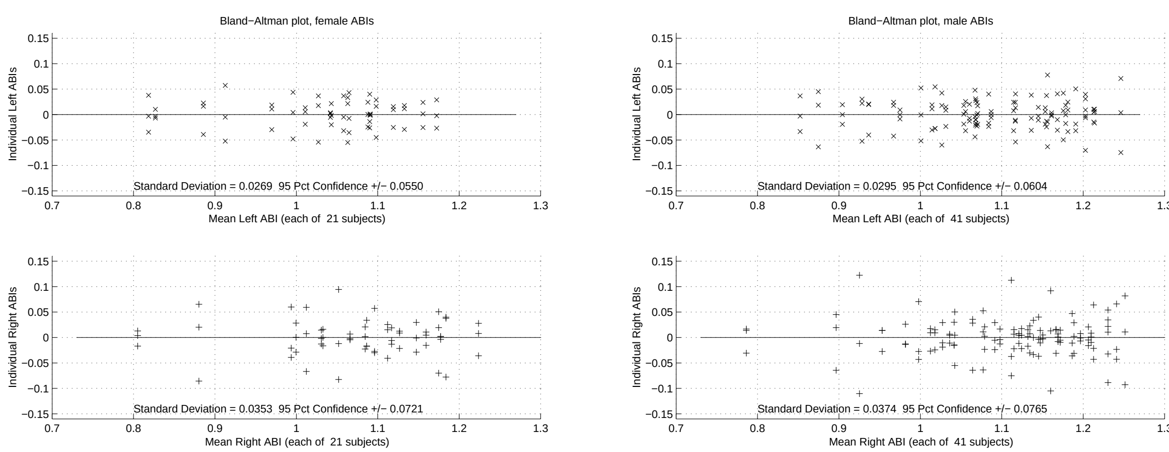

Figure 3: Bland-Altman plots separated for female and male subjects.

Group	Left σ	Right σ	Left .95 CI	Right .95 CI
All subjects	.0286	.0366	.0585	.0749
Female	.0269	.0353	.0550	.0721
Male	.0295	.0374	.0604	.0765

Table 1: Table of variations computed.

of left and right ABI differences from each subject's mean were plotted in figure 4. As can be seen, this difference in variation is not due to a small number of outliers. the right ABI has a longer thicker tail than the left.

5 Discussion

One useful datum to obtain from this study is the 95 percent confidence interval of an ABI measurement made by the Colin VP machine. Because the differences between male and female ABI are not statistically significant, we conclude that the variation computed for all subjects is the best estimate. Because the difference between the left and right measurements is statistically significant, we must present separate left and right best estimates. Therefore plus or minus .059 (left) and plus or minus .075 (right) is our best estimate of the 95 percent confidence interval for the Colin AT ABI measurements.

Another useful datum would be how much of the observed variation is due to actual changes in the patients physical state, and how much is due to "noise" in the Colin AT machine. Unfortunately, these two sources of variation cannot be separated in this study.

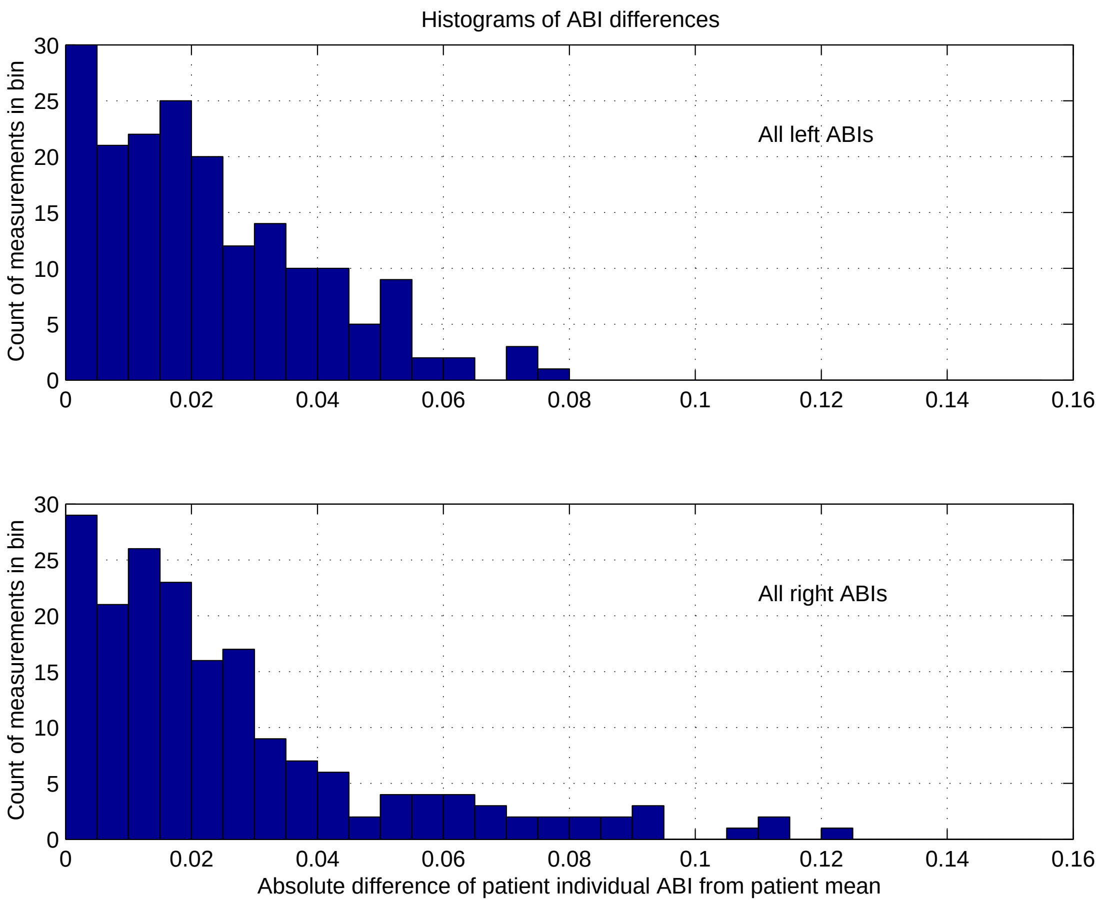

Figure 4: Histogram of absolute difference from each patient's mean.