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 convicible 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

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. We've reported here a reproducibility study of 39 subjects who encompass a wide age range, both sexes, and both normal and abnormal risk factors.

3 Methods

Our study used one Colin AT 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 Data Preparation

5 Results, ABI
Figure 2: All right ABI measurements in study
Individual ABI measurements

Standard Deviation = 0.0291
95 Pct Confidence = 0.0594

Figure 3: Right ABIs for patients without heart disease
Figure 4: Left ABIs for patients with diagnosed heart disease
Individual ABI measurements

mean ABI

Standard Deviation = 0.0198
95 Pct Confidence = 0.0405

Left ABIs, with diabetes

Figure 5: Left ABIs for patients with diabetes
Right ABIs, no diabetes

Mean RABI = 0.0354
95 Pct Confidence = 0.0723

Figure 6: Right ABIs for patients without diabetes