Cholesterol 1,2,3™

Use of Skin Cholesterol to Monitor Response to Cholesterol-Lowering Therapy

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Due to their well-established benefit in preventing subsequent coronary artery disease cholesterol-lowering medications are becoming increasingly important in the management of individuals with elevated serum lipids. Monitoring response to such therapy is important in terms of achieving targeted lipid levels. Existing monitoring methods require a blood sample to determine LDL and HDL levels. Skin cholesterol (SC) has been reported to be elevated in individuals with atherosclerotic disease. We sought to evaluate SC to non-invasively monitor response to cholesterol-lowering medication. SC levels were determined by Cholesterol 1,2,3, as follows: (1) an applicator pad was applied to the palmar surface of the skin and a digitonin-peroxidase conjugate was added to a well in the pad with a dropper bottle, (2) after a 1-minute incubation the hand was rinsed briefly with tap water and blotted dry, (3) peroxidase substrate solution was then transferred to a microwell and absorbance at 450nm was determined. A negative control well in the pad remained colourless in a valid assay. The assay was standardized *in vitro* using cholesterol-coated microwells. *In vitro* testing showed that the detector was inhibited from binding to the microwells by soluble cholesterol and that this inhibition was concentration dependent. The detector had a linear range of 0.02 to 2.0mg/mL cholesterol *in vitro*. Intra-assay precision was 8.7-17.6% and interassay precision was 7.2%. In a prospective clinical study we determined SC levels in individuals newly being placed on cholesterol-lowering medications. At approximately three-month intervals thereafter, for a total of three visits, these individuals returned to the clinic and the SC levels were measured and serum lipids determined. Results from the first 10 patients with three visits showed that: (1) SC levels decreased in 10/13 (77%) situations where serum LDL decreased, (2) SC levels increased in 5/5 (100%) situations where serum LDL increased, (3) overall agreement between SC change and LDL change was 83.3% (15/18). Changes in SC were significantly correlated with changes in serum LDL (Pearson correlation 0.608, $P<0.001$). These data suggest that the non-invasive determination of skin cholesterol levels may have value in monitoring response to cholesterol-lowering medications.

Presented to the 51st Annual American Association of Clinical Chemistry Meeting, New Orleans, July 25-29, 1999.

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