

NIS REPORT SYNOPSIS

Prevalence of Subclinical Atherosclerosis and its Associated Factors in Hyperlipidemic Korean Adults with Diabetes (ALTO study)

Study Site(s)

There were 362 patients at 6 centres in Korea.

Publications

None at the time of writing this report.

Study dates

First Subject In: 24 January 2011

Last Subject Last Visit: 4 May 2011

Medicinal products and concomitant medication

Not applicable (non-interventional treatment)

Objectives

- 1) To investigate the prevalence and distribution of subclinical atherosclerosis by measurement of intima media thickness (IMT) and atherogenic plaque in hyperlipidemic Korean subjects with diabetes.
- 2) To define the associated factors for subclinical atherosclerosis in hyperlipidemic Korean subjects with diabetes.

Study design

This was a multi-centre, cross-sectional study to investigate the prevalence of subclinical atherosclerosis measured by IMT and define its association factors. During visit to physician, demographic data including duration of diabetes and medication profiles were collected. Serum cardiometabolic profiles such as lipid, glucose, hsCRP, Apo B/A1 ratio and urine albumin to creatinine ratio were analysed at the central laboratory. The IMT of the carotid artery were measured with ultrasonographic examinations by one skilled technician.

Target subject population



Patients had a diagnosis of diabetes, as defined by ADA guideline, and hyperlipidemia, as defined by NCEP-ATP III

Study variable(s)

Primary outcome variable:

- Mean cIMT and its distribution of in hyperlipidemic Korean adults with diabetes

Secondary outcome variables:

- The presence and number of plaque in hyperlipidemic Korean adults with diabetes
- The associated factors for subclinical atherosclerosis in hyperlipidemic Korean adults with diabetes
 - Serum cardiometabolic profiles
 - Diabetic microvascular complication-retino/nephro/neuro
 - UKPDS/Framingham risk score

Statistical methods

Descriptive statistical analysis was performed to define mean, standard deviation, median values for cIMT in hyperlipidemic Korean adults with diabetes. Prevalence was calculated with χ^2 test using cut-off point based on literature search. Comparisons among groups were performed by one-way analysis of covariance (ANCOVA) after adjusting multiple factors. Multiple linear regression model was used to examine the association between cIMT values and demographics, serum cardiometabolic profiles. Otherwise relevant statistics were performed as the measures. This survey was the descriptive study without specific hypothesis. All statistical analysis was performed by using SAS

Subject population

A total of 362 patients were enrolled for participating in this study. Among them, 355 patients completed the study with a dropout of 7 patients (1.9%) from the study.

The patient demographics are summarized below in Table S1. The baseline characteristics of patients indicated that the mean age \pm SD was 57.0 ± 10.6 and mean age at menopause \pm SD was 50.7 ± 5.8 .

Table S1. Patient Demographics

Item	Category	Number of Patients
Age (years)	N	355
	Mean[SD]	57.0[10.6]

Table S1. Patient Demographics

Item	Category		Number of Patients
		N	355
Sex	Male	n(%)	179(50.4)
	Female	n(%)	176(49.6)
		N	176
Menopause	Yes	n(%)	138(78.4)
	No	n(%)	38(21.6)
Age at menopause (years)		N Mean[SD]	138 50.7[5.8]

Summary of results

The prevalence and distribution of subclinical atherosclerosis were analysed by the following five features of the atherosclerosis with the results respectively: (1) 65.0% in male and 65.9% in female patients by an increased IMT average or presence of atherogenic plaque, (2) 66.1% in male and 67.0% in female by an increased IMT Max or presence of atherogenic plaque, (3) 14.1% in male and 18.2% in female by an increased IMT average only, (4) 15.3% in male and 21.0% in female by an increased IMT Max only, and (5) 60.5% in male and 59.1% in female by presence of atherogenic plaque only. The differences in the prevalence for male and female patients by each feature were not statistically significant. (Table S2).

Table S2. Prevalence and Distribution of Subclinical Atherosclerosis*

Item		Total N=353	Male N=177	Female N=176	p-value (chi-square test)
IMT Average or atherogenic plaque	n(%)	231(65.4)	115(65.0)	116(65.9)	0.8531
IMT Max or atherogenic plaque	n(%)	235(66.6)	117(66.1)	118(67.0)	0.8509
IMT Average	n(%)	57(16.1)	25(14.1)	32(18.2)	0.3003
IMT Max	n(%)	64(18.1)	27(15.3)	37(21.0)	0.1596
Atherogenic plaque	n(%)	211(59.8)	107(60.5)	104(59.1)	0.7946

* Reference: Cho et al, the Korean Journal of Internal Medicine 64:275-283, 2003.

Factors associated with subclinical atherosclerosis were also defined as the secondary objectives of this study. Based on multivariate analysis, it was revealed statistically significant with age only in male and age and waist circumference in female patients for the feature (1); for the feature (2), statistical significance was seen with age only in male and age, duration of diabetes and waist circumference in



female patients; for the feature (3), statistical significance was shown with HDL-C and triglyceride in male and height in female patients; for the feature (4), it was seen that age and triglyceride were statistically significant factors in male and smoking, neuropathy and Apo A1 were in female patients; lastly, it was indicated statistically significant with age and albumin to creatinine ratio in male and age only in female patients for the feature (5).

For safety, adverse events were not collected specifically for this study because of the way it was designed as a non-interventional study without the study medication as per protocol. However, serious adverse events related to the study procedure had to be collected, and the causal relationship was assessed based the protocol.