Utilization of Cardiovascular Therapy Among At-Risk Individuals - Are AHA/ACC Treatment Guidelines Translated to Practice?

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BACKGROUND

- Approximately 1 million Americans die annually from myocardial infarction and other forms of CHD[1]
- AHA/ACC Guidelines for Secondary Prevention for Patients with Coronary and Other Atherosclerotic Vascular Disease recommend the following pharmaco-therapies[2]
  - ACE inhibitors for all patients with CV disease and those with hypertension, diabetes, or chronic kidney disease, unless contraindicated
  - ARBs for those intolerant of ACE inhibitors and those with heart failure or MI
  - Beta-blockers for those who have MI or acute coronary syndrome
  - Antiplatelet or anticoagulants for those who have acute coronary syndrome or PCI or MI, and aspirin for all patients unless contraindicated
  - Lipid-lowering drug therapy if LDL-C ≥100 mg/dL
- AHA 2004 guidelines for CV disease prevention in women recommend aspirin use for moderate- and high-risk individuals[3]
- NCEP ATP III guidelines recommend statin therapy for individuals at high and moderate CHD risk if their LDL-C is not at target goal[4]
- Evidence is limited on whether individuals at risk for CHD and their physicians are adopting the AHA/ACC guidelines for individuals with or at risk for CV disease

OBJECTIVE

- Evaluate the utilization of different CV therapies among individuals with T2DM, MI, and/or stroke, and those at risk for CHD, to assess whether prescribing guidelines were being followed

METHODS

Study Design

- Study to Help Improve Early evaluation and management of risk factors Leading to Diabetes (SHIELD), a population-based survey conducted to better understand the risk for the development of diabetes, as well as disease burden
  - Based upon a screening questionnaire mailed to 200,000 nationally representative households, responses for 211,097 adults from 127,420 households (64% response rate) were obtained
  - A 64-item survey was sent to 22,001 selected individuals derived from the screening respondents. Since 2004, sequential SHIELD surveys have captured self-reported information on health status, attitudes and behaviors, anthropometry, and medication use from this representative sample of the US population
- Cross-sectional analysis of use of CV drug therapies among SHIELD respondents

Study Population

- Respondents were 18 years of age or older
- Five respondent groups were included in the analyses: 1) T2DM, 2) CV event, 3) High CHD risk, 4) Moderate CHD risk, and 5) Low CHD risk
- T2DM was defined as having been "told by a doctor, nurse, or other healthcare professional that you have type 2 diabetes"
- CV event was defined as self-report of heart attack/heart disease, stroke, heart-bypass surgery, or angioplasty at baseline

Study Population (continued)

- CHD risk was defined based on NCEP ATP III risk categories[4]:

1. **High CHD Risk:** self-reported diagnosis of heart disease/heart attack, narrow or blocked arteries/carotid artery disease, stroke or diabetes
2. **Moderate CHD Risk:** respondents reporting ≥2 of the following risk factors:
   a. Men >45 years, women >55 years
   b. Reported diagnosis of low HDL-C
   c. Reported diagnosis of high blood pressure
   d. Current smoking status
   e. Family history of heart disease, narrow or blocked arteries, stroke, or diabetes
3. **Low CHD Risk:** respondents with 0-1 of the above risk factors

Therapy Assessment

- Respondents reported the name of each medication currently prescribed to them. They were instructed to refer to their medication labels for accurate reporting
- Lipid-lowering medications included statins, fibric acid derivatives, bile acid sequestrants, cholesterol absorption inhibitors, and combination therapy. Statin therapy included both monotherapy and combination therapy
- Antiplatelet and anticoagulant agents included clopidogrel, ticlopidine, cilostazol, dipyridamole, warfarin, and low molecular-weight heparins
- For aspirin use, respondents who indicated that they took aspirin every day "most of the time" or "always" were considered daily users (versus those reporting "sometimes or occasionally" or "not currently"). Aspirin was examined separately from the prescription antiplatelet and anticoagulant agents
- Antihypertensive medications included ACE inhibitors, ARBs, and beta-blockers

Statistical Analysis

- Bivariate analyses included t-tests and chi-square tests for assessing differences among groups
- Logistic regression analyses assessed the likelihood of statin treatment among risk groups, adjusting for age, gender, and geographic region
- Statistical significance was set a priori at p<0.05

RESULTS

- There were 3937 T2DM, 3777 CV event, 7510 High CHD risk, 4823 Moderate CHD risk, and 5307 Low CHD risk respondents included in the analysis

Table 1. Demographic characteristics of SHIELD respondents by risk group

Characteristics	T2DM (n=3937)	CV Event (n=3777)	High CHD Risk (n=7510)	Moderate CHD risk (n=4823)	Low CHD risk (n=5307)
Age, years, mean	60.4	65.1	60.4	57.2	43.5*
Women, %	58	51	56	60	70*
Race, % whites	85*	87	86	88	88
Education, % with some college or higher	64	62	64	68	75*
Income, % ≥$40,000/year	47	44	47	56	64*
Geographic region, %					
Northeast	20	20	19	19	19
North Central	24	24	24	25	25
South Atlantic	21	20	20	20	18
South Central	17	19	18	16	16
Mountain	6	5	6	6	7
Pacific	12	12	13	13	14

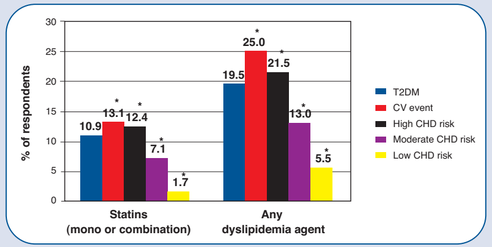
*p value <0.0001

RESULTS

- There was a significantly higher proportion of respondents who were younger, women, had higher education and income among low CHD risk respondents than in the other groups (p<0.0001)

DYSLIPIDEMIA THERAPY UTILIZATION

Figure 1. Proportion of SHIELD respondents currently taking dyslipidemia medications



*p<0.05 compared with T2DM

- Statin therapy and any dyslipidemia therapy utilization was very low in each group, ≤25% of respondents
- Use of dyslipidemia therapy is very low even among respondents with prior CV events
- Significantly more respondents in the CV event and High CHD risk groups were receiving dyslipidemia therapy than T2DM respondents (p=0.02)
- Significantly more T2DM respondents were receiving dyslipidemia therapy than Moderate and Low CHD risk groups (p<0.001)

Table 2. Multivariate logistic regression of impact of risk group on statin therapy utilization (yes/no), adjusting for age, gender, and geographic region

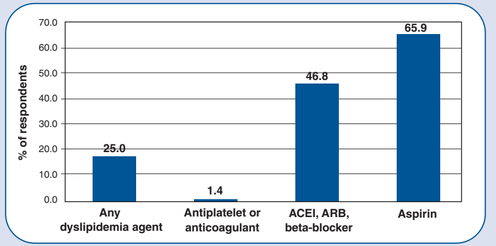
Model Parameters*	Odds ratio (95% CI)	p value
High CHD risk vs. T2DM	2.10 (1.71–2.59)	<0.0001
Moderate CHD risk vs. T2DM	0.72 (0.61–0.86)	<0.0001
Low CHD risk vs. T2DM	0.21 (0.16–0.27)	<0.0001
CV Event vs. T2DM	1.25 (1.06–1.46)	0.006

*model adjusted for age (p<0.0001), gender (p=0.25), and geographic region (p<0.01)

- Moderate and Low CHD risk groups were significantly less likely to receive statin therapy than T2DM respondents, after adjusting for age, gender, and geographic region (p<0.0001)
  - 28% less likely for Moderate CHD risk group
  - 79% less likely for Low CHD risk group
- High CHD risk and CV event groups were significantly more likely to receive statin therapy than T2DM respondents, after adjusting for age, gender, and geographic region (p<0.01)
  - Twice as likely to receive statin therapy for High CHD risk group
  - 25% more likely for the CV event group

THERAPY UTILIZATION IN CV EVENT GROUP

Figure 2. Proportion of respondents with a CV event currently taking CV medications



- A small proportion of CV event respondents were taking drug therapies recommended in guidelines
- Even though these respondents had had a MI or stroke, only 1.4% were taking antiplatelet or anticoagulant therapy
- Less than 50% of CV event respondents were receiving antihypertensive or dyslipidemia therapy

LIMITATIONS

- Respondents were not asked the reason they were taking aspirin daily; thus, their aspirin use may be related to other chronic conditions like arthritis or headaches
- Information on when the CV event occurred prior to the survey was not assessed; thus, individuals with events years ago may have received antiplatelet or anticoagulant therapy around the time of their event but stopped
- The true clinical indication for each therapy class could not be assessed since blood pressure and cholesterol levels were not captured in the SHIELD survey
- Household panels, like the SHIELD study, tend to under-represent the very wealthy and very poor segments of the population and do not include military or institutionalized individuals

SUMMARY

- AHA/ACC guidelines recommend lipid-lowering therapy for primary and secondary prevention of CV disease, yet 75% of respondents with a history of MI or stroke and 80% of T2DM respondents were not receiving therapy for dyslipidemia
- This gap in dyslipidemia therapy also exists for High and Moderate CHD risk respondents who, by definition, have CHD (high risk) or hypertension and other risk factors (moderate risk)
- More than 50% of the respondents with a CV event did not receive antiplatelet, anticoagulant, or antihypertensive therapy, as recommended in guidelines
- Daily aspirin use was not adopted by all respondents with a CV event; 34% of these respondents were not taking aspirin as a preventive measure

CONCLUSIONS

- Based upon the study findings, the AHA/ACC treatment guidelines were not translated to practice for most respondents in each risk group
- There remains opportunity for significant improvement in raising awareness and motivating at-risk individuals to adopt preventive measures for reducing CV disease
- Novel education programs may be required to increase the adoption of therapy guidelines among clinicians and their patients for all risk groups

Abbreviations

ACEI	Angiotensin-converting enzyme Inhibitor
ACC	American College of Cardiology
AHA	American Heart Association
ARB	Angiotensin II receptor blocker
CHD	Coronary heart disease
CV	Cardiovascular
LDL-C	Low-density lipoprotein cholesterol
MI	Myocardial infarction
NCEP ATP III	National Cholesterol Education Program Adult Treatment Panel III
PCI	Percutaneous coronary intervention
SHIELD	Study to Help Improve Early evaluation and management of risk factors Leading to Diabetes
T2DM	Type 2 diabetes mellitus

References

1. AHA. Heart Disease and Stroke Statistics - 2007 Update. Dallas, TX
2. Smith SC, et al. *Circulation* 2006; 113:2363-2372
3. Mosca L. *Arterioscl Thromb Vasc Biol* 2004; 24:394-396
4. National Cholesterol Education Program ATP III *JAMA* 2001; 285:2486-2497

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