Accuracy Of Cardiovascular Risk Stratification By Canadian Primary Care Physicians: Preliminary Results From The Primary Care Audit Of Global Risk Management (PARADIGM) Study

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BACKGROUND

Optimal clinical management requires proper CV risk stratification. Guidelines recommend the use of validated tools (eg, Framingham Risk Score (FRS)) but such tools are not widely adopted by primary care physicians (PCP). The PARADIGM study prospectively evaluated the methods and accuracy of CV risk stratification used by PCP in Canada.

PARADIGM OBJECTIVES

Primary objective

To evaluate primary care physician behaviour towards global cardiovascular risk prediction in healthy individuals

Secondary objectives

To evaluate the prevalence of classic and novel markers of risk
To evaluate the feasibility of bedside carotid atherosclerosis assessment, and its correlation to biochemical risk markers and Framingham Risk Score (FRS)
To disseminate best practices and new knowledge to key stakeholders in the primary prevention of cardiovascular disease

STUDY SETTING AND ENROLMENT

Primary care physician investigators from 105 sites prospectively enrolled 3015 healthy middle-aged adults undergoing cardiovascular risk assessment.

Inclusion Criteria

Men 24y, women ≥ 50y
Absence of known high FRS
Non-diabetic
Absence of lipid lowering treatment (current or past)
No previous history of atherosclerosis (angina, TIA, myocardial infarction, stroke, peripheral arterial disease)
Willingness to give informed consent

STUDY ALGORITHM

Visit 1

Obtain Informed consent
Collect demographics and CV risk factors
Document concomitant medications
Perform physical and laboratory measures

Visit 2 (within 60 days of Visit 1)

Review results
Determination of risk level and need for lipid lowering therapy
FRS completed and faxed to CCRN

Central Site

FRS calculated centrally

DATA MANAGEMENT

Centrally calculated Framingham risk scores were estimated using the sex-specific equations provided in D’Agostino et al. Circulation (2008), and sex-specific equations provided in D’Agostino et al. Circulation (2008) modified based on a) Male and b) Female for high risk populations. CRF completed and faxed to CCRN.

RESULTS

Table 1. Baseline Laboratory Results

| Medication Class | Median (SD) | n (%)
|------------------|-------------|-------|
| Total Cholesterol | 5.8 (1.8) | 217 (39)
| LDL Cholesterol | 3.3 (0.8) | 339 (51)
| HDL Cholesterol | 1.4 (0.4) | 54 (18)
| Triglycerides | 1.8 (0.4) | 142 (49)
| hsCRP (mg/L) | 5.6 (3.5) | 97 (31)
| Fasting Blood Glucose | 5.4 (3.1) | 97 (31)
| A1C (%) | 5.7 (0.5) | 97 (31)
| Creatinine | 0.08 (0.02) | 0.31 (0.13)
| Urine MACR (mg/mmol) | 1.5 (0.9) | 97 (31)

Table 2. Clinical Characteristics and Cardiovascular Medications at Baseline

<table>
<thead>
<tr>
<th>Variable</th>
<th>Median (SD) or %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs)</td>
<td>56.3 (8.4)</td>
</tr>
<tr>
<td>Male</td>
<td>56.8</td>
</tr>
<tr>
<td>European origin</td>
<td>69.6</td>
</tr>
<tr>
<td>Hypertension</td>
<td>20.6</td>
</tr>
<tr>
<td>Family Hx CVD</td>
<td>34.7</td>
</tr>
<tr>
<td>Systolic BP (mm Hg)</td>
<td>126.5 (14.0)</td>
</tr>
<tr>
<td>Diastolic BP (mm Hg)</td>
<td>75.9 (10.1)</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>27.5 (5.3)</td>
</tr>
<tr>
<td>Waist Circumference (cm)</td>
<td>94.3 (15.6)</td>
</tr>
<tr>
<td>Non-optimal lifestyle behaviours</td>
<td>65.1</td>
</tr>
</tbody>
</table>

Table 3. Agreement of Actual Agreement by Risk Category

<table>
<thead>
<tr>
<th>Risk Category</th>
<th>Agreement Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>57.9%</td>
</tr>
<tr>
<td>Intermediate</td>
<td>40.9%</td>
</tr>
<tr>
<td>High</td>
<td>9.2%</td>
</tr>
</tbody>
</table>

Table 4. Summary of Actual Agreement by Risk Category

<table>
<thead>
<tr>
<th>Site Risk Level</th>
<th>Agreement Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>65.7%</td>
</tr>
<tr>
<td>Intermediate</td>
<td>50.4%</td>
</tr>
<tr>
<td>High</td>
<td>34.2%</td>
</tr>
</tbody>
</table>

CONCLUSIONS

The PARADIGM study found that in middle-aged Canadians felt to be at low to intermediate CV risk:

- 1/3 have hypertension and 1/3 are current or former smokers
- 1/2 to 1/4 report a significant family history of CVD
- The majority are overweight or obese
- 55% feel they are doing the best they can through lifestyle intervention alone
- Mean LDL is 3.6 mmol/l and mean hsCRP is 2.6 mg/dl

In this group of investigators, 34% report using the FRS to determine CV risk

Overall level of agreement between physician and central risk determination was only fair

Agreement was moderate for sites using FRS, and only slight for sites using other methods of risk stratification

Using centrally calculated FRS as the gold standard, physicians accurately identified:

- 65.7% of low risk patients
- 50.4% of intermediate risk patients
- 34.2% of high risk patients

Two thirds of high risk patients were classified at lower risk levels

IMPLICATIONS

Risk stratification, the cornerstone of CV risk reduction in primary prevention, is suboptimally done by physicians and leads to considerable misclassification of individuals into lower or higher risk categories.

A large number of high risk patients were misclassified into lower risk groups suggesting that widespread educational initiatives are urgently required.

The noted discrepancies in reported FRS utilization and correlation between central and site risk categorization may be at play in any country using calculated risk as the determinant of an indication for statin therapy and intensity of lipid lowering.

CONFLICTS OF INTEREST

The authors report no conflicts of interest to disclose.

ACKNOWLEDGEMENTS

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REFERENCES

D’Agostino, R., et al. (2008). Circulation, 117(6), 743-53. Risk scores were categorized as Low (<10%), Intermediate (10-20%) and High (>20%). Concordance between the centrally calculated risk category and the physician risk assessment were evaluated using the kappa statistic and 95% confidence interval and estimated percent agreement (Low/Low, Intermediate/Intermediate, High/High). Chi-square tests were used to compare percent agreement and kappa statistics.

Figure 1. Recruitment Profiles

a) By Total Enrolment
b) By Province
c) By Ethnic Origin

Figure 2. Investigator Methods of CV Risk Determination

Figure 3. A) Investigator vs Central Risk Stratification and B) Overall Agreement Rates for Risk Stratification

Figure 4. Summary of Actual Agreement by Risk Category

Table 3. Baseline Laboratory Results

Table 4. Summary of Actual Agreement by Risk Category

Table 5. Agreement of Actual Agreement by Risk Category

Table 6. Summary of Actual Agreement by Risk Category