An Education Program for Risk Factor Management After an Acute Coronary Syndrome: A Randomized Clinical Trial

BACKGROUND:
- Lifestyle improvements after an acute coronary syndrome (ACS) reduce cardiovascular risk but are difficult to achieve
- Cardiovascular risk factors such as poor diet, smoking, physical inactivity, high body mass index (BMI), large waist circumference, and regular alcohol consumption are modifiable
- Collaborative models that enhance communication among care providers can improve the quality of care and outcomes for patients

OBJECTIVE:
- To determine whether a nurse-led or dietician-led cardiovascular risk factor education program would improve risk factor reduction over the long term after an ACS

METHODS:
- **Design:** 2-arm, parallel-group, multicenter, randomized clinical trial; Duration: 12 months
- **Inclusion criteria:** ≥18 years of age, hospitalized in a cardiac intensive care unit (ICU) for an ACS (unstable angina, ST-segment elevation MI, or non-segment elevation MI), and had at least 1 of the following education-modifiable risk factors: current smoking (for ≥12 months), sedentary lifestyle (<3 hours of physical activity per week), or overweight or obesity (BMI ≥25 for overweight and ≥30 for obesity). Patients also had to be willing and able to attend regular visits at an outpatient program
- **Exclusion criteria:** Not discussed.
- **Primary outcome measure:** Composite that involved correction of at least 1 of the following 3 cardiovascular risk factors between baseline and month 12:
  - Smoking cessation (complete cessation for smokers; with nonsmokers at baseline and month 12 considered successes and nonsmokers at study inclusion who started smoking [or relapsed] during the 12 months considered failures)
  - Overweight or obesity (≥24% reduction in waist circumference or ≥5% reduction in weight, with patients having a BMI of <25 at baseline and at 12 months considered successes and patients who became overweight during the study considered failures)
  - Physical activity (≥3 hours/week)
- **Secondary outcome measures:**
  - Correction of all 3 CV risk factors
  - Correction of each individual CV risk factor
  - Correction of other risk factors, including HTN (BP <140/90 mm Hg), diabetes mellitus (HbA1c <6.5%), and dyslipidemia (LDL <100 mg/dL)
  - Physical and mental summary scores of the 12-item Short Form Health Survey for quality of life (continuous variables on a scale of 0 to 100, with higher scores indicating higher quality of life)
  - Number of correct answers on a patient knowledge questionnaire comprising 19 questions
  - Patient satisfaction on a numeric scale rate 0 to 10, with higher scores indicating higher levels of satisfaction
RESULTS:

- A total of 502 patients were enrolled in the study. There were 22 patients lost to follow-up and 36 patients who were lost due to follow-up refusal. The data was handled using an intent-to-treat method.
- **Primary outcome measure***: The 2 treatment groups did not differ in the primary composite endpoint (correction of at least smoking, physical inactivity, overweight, or obesity) with an adjusted relative risk of 1.11 (95% CI, 0.90-1.37).
- **Secondary outcome measures**:

<table>
<thead>
<tr>
<th>Outcome</th>
<th>No</th>
<th>Study (n=251)</th>
<th>Control (n=251)</th>
<th>Adjusted Relative Risk (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Correction of ≥1 CV risk factor*</td>
<td>502</td>
<td>130 (51.8%)</td>
<td>125 (49.8%)</td>
<td>1.11 (0.90-1.37)</td>
<td>0.34</td>
</tr>
<tr>
<td>Correction of all CV risk factors</td>
<td>502</td>
<td>68 (27.1%)</td>
<td>55 (21.9%)</td>
<td>1.22 (0.89-1.66)</td>
<td>0.21</td>
</tr>
<tr>
<td>Nonsmokers or smoking cessation</td>
<td>502</td>
<td>184 (73.3%)</td>
<td>176 (70.1%)</td>
<td>0.99 (0.87-1.13)</td>
<td>0.89</td>
</tr>
<tr>
<td>≥4% reduction in waist circumference or ≥5% reduction in weight</td>
<td>502</td>
<td>119 (47.44%)</td>
<td>111 (44.2%)</td>
<td>1.07 (0.84-1.36)</td>
<td>0.59</td>
</tr>
<tr>
<td>Physical activity ≥3 hrs per week</td>
<td>502</td>
<td>193 (76.9%)</td>
<td>183 (72.9%)</td>
<td>1.05 (0.92-1.21)</td>
<td>0.47</td>
</tr>
<tr>
<td>Blood pressure &lt;140/90 mm Hg</td>
<td>502</td>
<td>186 (74.1%)</td>
<td>180 (71.7%)</td>
<td>1.03 (0.89-1.19)</td>
<td>0.71</td>
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<tr>
<td>LDL &lt;100 mg/dL</td>
<td>502</td>
<td>181 (72.1%)</td>
<td>160 (63.7%)</td>
<td>1.10 (0.94-1.29)</td>
<td>0.24</td>
</tr>
<tr>
<td>HbA1c &lt;7% among patients with DM only</td>
<td>129</td>
<td>40 (60.6%)</td>
<td>24 (38.1%)</td>
<td>1.73 (0.94-3.21)</td>
<td>0.10</td>
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<tr>
<td></td>
<td></td>
<td>n=66</td>
<td>n = 63</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12-item Short Form Health Survey (Physical)</td>
<td>502</td>
<td>47.5 (9.3)</td>
<td>47.3 (9.4)</td>
<td>0.39 (-1.38 to 2.15)</td>
<td>0.44</td>
</tr>
<tr>
<td>12-item Short Form Health Survey (Mental)</td>
<td>502</td>
<td>47.5 (11.2)</td>
<td>47.6 (11.2)</td>
<td>-0.92 (-3.27 to 1.43)</td>
<td>0.43</td>
</tr>
<tr>
<td>Patient knowledge questionnaire, score range 0-19</td>
<td>502</td>
<td>14.8 (2.4)</td>
<td>15.2 (2.3)</td>
<td>-0.20 (-0.63 to 0.24)</td>
<td>0.37</td>
</tr>
</tbody>
</table>

- **Author’s conclusion**: A nurse- and dietician-led education program aimed at reducing cardiovascular risk factors in patients post-ACS resulted in no additional reduction in risk factors compared with conventional care.

STRENGTHS:

- Long study duration (12 months)
- Similar characteristics at baseline
- Low potential for conflict(s) of interest resulting in bias
- Broad inclusion criteria

LIMITATIONS:

- Unblinded
- Decreasing compliance over 12-month study period
- Lack of consistency in the control group
- Diet and physical activity were self-reported
• Nurse providing smoking cessation consultation could not prescribe nicotine replacement therapies, and it is unclear what patients used
• No description of specific dietary recommendations
• Unclear how biological and clinical variables were measured if the patient had a follow-up via telephone

CONCLUSION:
• Although the study showed that cardiovascular risk factors were not significantly reduced in the study group, there is still value in the use of a multidisciplinary team to educate patients with chronic conditions.
  • Because there were so many patients who completed a follow-up visit via telephone, the study investigators may not have been able to accurately measure their clinical and biological variables. There may have been a difference between the two groups, but it is difficult to show results if the patients did not attend the follow-up visits.
• Future research:
  • Education and lifestyle interventions have the potential to reduce cardiovascular risk factors, but it may be more beneficial to involve all members of the healthcare team to produce a more significant change. A trial should be done involving more disciplines to determine the effect this would have on risk factor reduction.


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