Potential Effects of a Menthol Ban on Smoking Behavior in Menthol Cigarette Smokers

Michael Kotlyar, PharmD
Associate Professor
Department of Experimental and Clinical Pharmacology,
College of Pharmacy
University of Minnesota
October 8, 2021
Disclosures

• No conflicts of interest

• Grant Funding: ClearWay MN and the National Institutes of Health
Background

- Following the passage of the Family Smoking Prevention and Tobacco Control Act (FSPTCA), the FDA banned fruit or candy flavored cigarettes but menthol was excluded from this ban.

- The Tobacco Products Scientific Advisory Committee (TPSAC) in their report recommended that “removal of menthol cigarettes from the marketplace would benefit public health in the United States”
  - in part because smoking cessation is more difficult for those smoking menthol vs. non-menthol cigarettes, particularly in African Americans
  - Report produced by the FDA evaluating the public health effects of menthol in cigarettes reached similar conclusions (FDA 2013)

- Recently, the FDA taken the initial steps necessary to enact a national ban on menthol characterizing flavor in combustible cigarettes and cigars in the United States.
What do menthol cigarette smokers say they would do if menthol was banned?

<table>
<thead>
<tr>
<th>Study</th>
<th>n</th>
<th>Intention if menthol cigarettes banned</th>
</tr>
</thead>
<tbody>
<tr>
<td>D’Silva et al 2015</td>
<td>1,158</td>
<td>46% would quit smoking; 27% switch to non-menthol cigarettes</td>
</tr>
<tr>
<td>Hartman et al 2011</td>
<td>2,887</td>
<td>39% would quit smoking and not switch to alternative product</td>
</tr>
<tr>
<td>O’Connor et al 2012</td>
<td>170</td>
<td>35% report intention to quit smoking</td>
</tr>
<tr>
<td>Pacek et al 2019</td>
<td>126</td>
<td>25% would plan to quit smoking</td>
</tr>
<tr>
<td>Pearson et al 2012</td>
<td>465</td>
<td>39% would try to quit smoking; 13% switch to non-menthol cigarettes; 25% would switch and try to quit</td>
</tr>
<tr>
<td>Rose et al 2019</td>
<td>806</td>
<td>24% would quit smoking; 32% switch to non-menthol cigarettes</td>
</tr>
<tr>
<td>Wackowski et al 2014</td>
<td>619</td>
<td>64% would quit smoking; 18% switch to non-menthol cigarettes</td>
</tr>
<tr>
<td>Wackowski et al 2015</td>
<td>187</td>
<td>28% would try to quit smoking; 46% switch to non-menthol cigarettes</td>
</tr>
</tbody>
</table>

Cadham et al. BMC Public Health 2020;20:1055
Assessing Response to Hypothetical Ban on Menthol Cigarettes

- African American smokers of menthol cigarettes were asked to abstain from menthol cigarettes for a four week period

- No specific instructions given regarding how to cope with the inability to smoke menthol cigarettes

- Visits occurred at baseline, week 1, week 2 and week 4

- At final visit, participants were asked their level of support for a menthol ban

Results

- 32 participants completed the study
  - 17 Men; 15 women
  - Average age = 46.4 (range 27 – 61)
  - Average cigs per day at screening = 13.5

- Three smokers attempted to quit
  - One smoker quit for 4 weeks
  - Two others decreased to 1 to 2 cigarettes per day

- Those who smoked switched to non-menthol cigarettes

- Number of cigarettes smoked decreased from 11.9 cigs per day at baseline to 9.8 cigs per day at week 4 (p<0.001)

Results / Conclusions

- At the conclusion of the study, participants indicated that quitting menthol cigarettes was difficult (average score = 7.2) but that they were supportive of banning menthol (average score = 7.1)

Conclusions

- During a simulated ban on menthol cigarettes, most smokers switch to non-menthol cigarettes

- Smoking patterns do not suggest increased harm as a result of the switch to non-menthol cigarettes (e.g. number of cigarettes smoked decreased, exhaled CO decreased, motivation to quit increased)

Effects of Menthol Smokers Switching to Non-Menthol Cigarettes

• 29 non-treatment seeking menthol cigarette smokers switched from usual brand to non-menthol cigarettes for 2 weeks (one week of menthol and two weeks of non-menthol cigarettes provided to participants)

<table>
<thead>
<tr>
<th>Measure</th>
<th>Baseline</th>
<th>End of Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cigarettes per day</td>
<td>12.2 ± 5.6</td>
<td>10.0 ± 5.0*</td>
</tr>
<tr>
<td>Urinary Cotinine (ng/ml)</td>
<td>1786 ± 1160</td>
<td>1440 ± 1007*</td>
</tr>
<tr>
<td>Exhaled CO (ppm)</td>
<td>32.0 ± (20.3)</td>
<td>28.2 ± (19.4)</td>
</tr>
<tr>
<td>motivation to quit smoking</td>
<td>3.3 (2.4)</td>
<td>5.4 (2.5)*</td>
</tr>
<tr>
<td>confidence in ability to quit smoking</td>
<td>4.2 (2.9)</td>
<td>5.5 (2.7)*</td>
</tr>
<tr>
<td>Craving (from Wisconsin Smoking Withdrawal Scale)</td>
<td>3.3 (0.6)</td>
<td>2.8 (0.8)*</td>
</tr>
<tr>
<td>Nicotine Dependence</td>
<td>45.0 (10.7)</td>
<td>36.8 (10.9)*</td>
</tr>
</tbody>
</table>

• Results generally consistent with previous study
  – Fewer cigarettes smoked per day
  – Increase in motivation to quit smoking

Bold et al. Tobacco Control 2020;29:624-630.
Does Switching to non-menthol cigarettes facilitate cessation?

• Smoking cessation is more difficult for those smoking menthol vs. non-menthol cigarettes, particularly in African Americans (TPSAC 2011, Villanti et al 2017, Smith et al 2020)

• Several studies suggest that if menthol cigarettes are not available, many smokers of menthol cigarettes switch to non-menthol cigarettes

• Is switching to non-menthol cigarettes prior to a cessation attempt results is an effective initial step to cessation?
  • Recent study evaluating data from PATH found that switching from menthol (vs maintaining menthol use) was associated with a 58% increased the probability of 30+ day abstinence and 97% increase the the probability of 12-month abstinence (Leas et al 2021)
Does Switching to non-menthol cigarettes facilitate cessation?

• Randomized study of African American menthol smokers
• Randomized to 4 weeks of their usual brand cigarettes or non-menthol cigarettes before a quit attempt (cigarettes provided to participants)
  • Referred to quit line for assistance with their quit attempt (to approximate the natural environment)
• Participants were generally healthy menthol cigarette smokers (≥ 5 cigarettes per day for a period longer than 1 year) who expressed an interest in quitting smoking (rate themselves ≥ 7 on a 10 point scale assessing motivation to quit smoking)
• Outcomes include
  • Time to lapse (time to 1st cigarette smoked from quit date)
  • Time to relapse (number of days from quit attempt until the 1st of 7 consecutive smoking days)
  • Number of cigarettes smoked
  • Motivation to quit (pre-quit visits)
  • Support for menthol cigarette ban

Pre-Cessation Results

• 122 participants completed baseline visit (60 in menthol group, 62 in non-menthol group)
  • 107 (54 menthol; 53 non-menthol) completed 4 week pre-cessation period
  • Mean (SD) age: 47 (10) vs. 45 (11)

• Pre-Cessation Results
  • Fewer cigarettes smoked per day in non-menthol group (mean ratio: 0.86; 95% confidence interval [CI]: 0.76, 0.98; p = .02)
  • Perceived effectiveness of their skills for quitting smoking higher in the non-menthol group
  • Withdrawal symptom severity lower in non-menthol group
  • Support for ban on menthol in cigarettes similar between group

Pre-Cessation Results

<table>
<thead>
<tr>
<th>Measure</th>
<th>Menthol Group</th>
<th>Non-menthol Group</th>
<th>Non-menthol vs. menthol</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline Week 4</td>
<td>Baseline Week 4</td>
<td>Mean (95% CI)</td>
</tr>
<tr>
<td>Exhaled CO (ppm)</td>
<td>15.3 (8.1)</td>
<td>14.2 (7.9)</td>
<td>15.3 (7.8)</td>
</tr>
<tr>
<td>Withdrawal (from MNWS)</td>
<td>7.0 (6.3)</td>
<td>6.4 (6.0)</td>
<td>6.7 (6.0)</td>
</tr>
<tr>
<td>QSU total score</td>
<td>133 (32.4)</td>
<td>109 (30.3)</td>
<td>129 (38.7)</td>
</tr>
<tr>
<td>Motivation to quit</td>
<td>7.8 (2.2)</td>
<td>8.3 (2.0)</td>
<td>8.0 (2.3)</td>
</tr>
<tr>
<td>Confidence in ability to quit</td>
<td>6.5 (2.5)</td>
<td>7.5 (2.2)</td>
<td>7.2 (2.3)</td>
</tr>
<tr>
<td>Effectiveness of quitting skills</td>
<td>6.2 (2.3)</td>
<td>7.1 (2.7)</td>
<td>6.4 (2.6)</td>
</tr>
<tr>
<td>Effort put toward quitting</td>
<td>9.0 (1.9)</td>
<td>8.9 (1.9)</td>
<td>8.8 (2.1)</td>
</tr>
<tr>
<td>Support for menthol ban</td>
<td>5.5 (3.4)</td>
<td>5.9 (3.3)</td>
<td>5.7 (3.4)</td>
</tr>
</tbody>
</table>

Cessation Results

• 95 (45 menthol, 50 non-menthol) completed 12 week post-cessation visit
• Hazard Ratio for time to lapse was 0.82 (non-menthol vs menthol) (95% CI 0.55 to 1.22; p=0.33)
  – Median time to lapse in the non-menthol group was 2.55 days versus 1.07 days in the menthol group (p=0.08, post hoc test)
• Hazard Ratio for time to relapse was 0.67 (non-menthol vs menthol) (95% CI 0.42 to 1.06; p=0.09)
  – Difference primarily due to lower rates of early relapse in the non-menthol group
  – 21% of the non-menthol group relapsed within the first day versus 40% of the menthol group (p=0.05, post hoc test)
Conclusions

• Results of pre-cessation phase of the study similar to previous studies in which smokers switched to non-menthol cigarettes
  • Number of cigarettes smoked decreased modestly
  • Few differences between groups in most measures, however perceived effectiveness of quitting skills was modestly higher in those switching to non-menthol cigarettes (vs. continuing to smoke menthol)
  • Support for a menthol ban did not decrease during study participation

• Switching to non-menthol cigarettes may have positive effects on short-term cessation measures largely by decreasing the proportion of relapses occurring within the first day of quitting
  • More intensive interventions may be necessary to sustain early abstinence

Overall Conclusions

• Following a ban of menthol characterizing flavor, many menthol smokers would likely switch to non-menthol cigarettes
  • Those who switch do not change their smoking behavior in a way that is likely to be more hazardous, with some indicators suggesting that there may be some benefit (e.g., decreased smoking, increases in measures of motivation to quit)

• Switching to non-menthol cigarettes may be an effective first step to short-term cessation but effects are small – more research is needed regarding how to sustain any early success achieved

• Data from longitudinal studies and from localities that have banned menthol will help inform effects of menthol bans (Chung-Hall et al 2021; Chaiton et al 2020)

• More research needed on effects of either including or excluding menthol bans for other tobacco products (e.g., e-cigarettes) on overall tobacco use patterns
  • Some data suggests that decreasing access to flavored e-cigarettes may increase combustible cigarette use (Denlinger-Apte et al 2021; Buckell et al 2019)
Acknowledgements

- Dorothy Hatsukami
- Ryan Shanley
- Kolawole Okuyemi
- Sheena Dufresne
- Gretchen Corcoran
- Anne Mills
- Kayla Robel

- Work presented from Dr. Kotlyar’s lab was funded by grants # RC-2013-0001 and RC-2014-0010 from ClearWay Minnesota and by awards # UL1TR000114 and UL1TR002494 from the National Center for Advancing Translational Sciences of the National Institutes of Health. The content is solely the responsibility of the authors and does not necessarily represent the official views of the funding agencies.