JAPANESE EXPERIENCE WITH HEAT-NOT-BURN

Hiroya Kumamaru M.D.
SMOKING IS THE BIGGEST CAUSE OF DISEASE/DEATH IN JAPAN
SMOKING IS RELATED TO ABOUT 129000 DEATHS

Deaths Numbers caused by Non-infectious disease with Related Risk Factors

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>No. death (x1000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoking</td>
<td>103,900</td>
</tr>
<tr>
<td>Hypertension</td>
<td>34,100</td>
</tr>
<tr>
<td>Lack of Exercise</td>
<td>34,000</td>
</tr>
<tr>
<td>Diabetes</td>
<td>32,700*</td>
</tr>
<tr>
<td>Excessive Salt intake</td>
<td>30,600</td>
</tr>
<tr>
<td>Alcohol</td>
<td>23,900</td>
</tr>
<tr>
<td>Helicobacter Pyroli</td>
<td>23,000</td>
</tr>
<tr>
<td>High LDL-C</td>
<td>21,200</td>
</tr>
<tr>
<td>HCV infection</td>
<td>19,000</td>
</tr>
<tr>
<td>Low intake of ω-3 FFA</td>
<td>11,600</td>
</tr>
<tr>
<td>Obesity</td>
<td>8,900</td>
</tr>
<tr>
<td>HBV infection</td>
<td>2,600</td>
</tr>
<tr>
<td>Low intake of vegetables</td>
<td>1,100</td>
</tr>
<tr>
<td>Excessive Trans FFA intake</td>
<td>0</td>
</tr>
</tbody>
</table>

Subject: Death of 960000 in 2007
Result: smoking: 129000 deaths
Hypertension: 104000 deaths

厚生科学審議会地域保健健康増進栄養部会 他 健康日本21（第2次）の推進に関する参考資料 2012 より改変
SMOKING RATE IN JAPAN
SURVEY

【1989~2016】: MOHWL

National Health Nutrition Survey

2016
Smoking Rate=18.3%
(Male 30.2%, Female 8.2%)

※2001年以前は総数のデータが存在しません

http://www.mhlw.go.jp/bunya/kenkou/kenkou_eiyou_chousa.html 2017/10/10参照
2002年10月
千代田区で路上喫煙を禁じる条例
これを皮切りに全国へ広がる

2003年5月
受動喫煙防止をうたう
健康増進法の施行

2004年6月
日本も批准
WHOタバコ規制枠組み条約

2008年7月
タスポ全国導入完了

2008年8月
タバコの値上げ検討中
議員連盟が1箱1,000円を目指す

2009年3月
神奈川県
公共的施設における
受動喫煙防止条例成立

2009年4月
JR東日本の
首都圏エリアの
駅ホームが全面禁煙へ

2009年3月
47都道府県中
32都府県で
タクシー禁煙化

1) 全国ハイヤー・タクシー連合会：喫煙タクシーに係る各県協会の取組みについて：平成21年3月1日現在 http://www.taxi-japan.or.jp/images/article/21y3m1dkinen.pdf
SOCIAL ENVIRONMENT CHANGE AGAINST SMOKING

- 10/2002 **Walk-smoking** has been prohibited by ordinance of a district of Tokyo (Chiyoda/23 districts)
- 05/2003 **MOHLW** launched Health Promotion Act to prevent passive smoking
- 06/2004 Japan joined for **WHO Framework Convention on Tobacco Control Treaty**
- 04/2006 **Smoking Cessation Treatment** became re-inversed by health insurance
- 03/2009 in **32/47 prefectures**, decided **Taxis to be no smoking**!
- 04/2009 **Japan Railway (JR) East** decided to prohibit smoking in the **plataform of all the stations** in metropolitan area
- 10/2010 **Tobacco price increased** more than \100(>30%)/pack
### SMOKING CESSATION SUCCESS RATE, 2017

<table>
<thead>
<tr>
<th>Overall average</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Stop after 1st outpatient</td>
<td></td>
</tr>
<tr>
<td>Stop after 2nd outpatient</td>
<td></td>
</tr>
<tr>
<td>Stop after 3rd outpatient</td>
<td></td>
</tr>
<tr>
<td>Stop after 4th outpatient</td>
<td></td>
</tr>
<tr>
<td>Completed 5 outpatients</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Stop-Outpatients</th>
<th>Overall (n=1308)</th>
<th>1st</th>
<th>2nd</th>
<th>3rd</th>
<th>4th</th>
<th>Completed (n=390)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall average</td>
<td>27.3%</td>
<td>8.6%</td>
<td>24.5%</td>
<td>2.8%</td>
<td>36.3%</td>
<td></td>
</tr>
<tr>
<td>1st outpatient</td>
<td>4.7%</td>
<td>88.4%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2nd outpatient</td>
<td>13.0%</td>
<td>8.1%</td>
<td>26.9%</td>
<td>4.0%</td>
<td>48.0%</td>
<td></td>
</tr>
<tr>
<td>3rd outpatient</td>
<td>25.4%</td>
<td>6.0%</td>
<td>30.2%</td>
<td>3.0%</td>
<td>37.5%</td>
<td></td>
</tr>
<tr>
<td>4th outpatient</td>
<td>32.0%</td>
<td>8.7%</td>
<td>22.1%</td>
<td>3.0%</td>
<td>32.9%</td>
<td></td>
</tr>
</tbody>
</table>

Stop-Smoking Continued: Stopped a wk, failure, unknown, no answer, failure after SS coating end.

Central Social Insurance Medical Council, Ministry of Health’s Advisory Board

NEW TYPE OF TOBACCO PRODUCTS

• Since 2014, new types of tobacco products have been launched in Japan.

• As of June 2018, 3 new types of tobacco products are available in Japan nationwide.

• These are sometimes referred to as “heat-not-burn” tobacco.
THS 2.2 - Eliminating Combustion Reduces the Formation of Harmful Chemicals

Average reductions in the formation of harmful chemical levels measured in the THS 2.2 aerosol compared to the smoke from the 3R4F reference cigarette.

- WHO (9 chemicals): ≈ 95% reduction
- FDA (18 chemicals): > 90% reduction
- Health Canada (44 chemicals): ≈ 95% reduction
- PMI (58 chemicals): > 90% reduction
- Carcinogens (15 chemicals): > 95% reduction

* Aerosol collection with Health Canada’s Intense puffing regime (55 mL puff volume, 2 second puff duration, 30 second interval puff); Comparison on a per-stick basis. Reduction calculations exclude Nicotine, Glycerin and Total Particulate Matter.

3R4F Reference cigarette. THS 2.2 = Tobacco Heating System 2.2
The results indicated that smokers who switched completely from smoking cigarettes to using glo experienced similar reductions in exposure (to a number of smoke toxicants) as those who stopped smoking.\(^a\, ^b\)

These qualities do not necessarily mean that glo produces less adverse health effects than other tobacco products.

\(^a\) Gale et al (2017) BMC Public Health doi.org/10.1186/s12889-017-4678-9

Scientific data: **Vapor chemistry**

Approximately **99% reduction** in levels of measured constituents compared to cigarette smoke

Relative reduction rate to our representative cigarette (per puff)

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Source:

*Chemical and in vitro toxicological analysis of a vapor from a novel tobacco vapor device and capsule*
Takahashi, Y, Kanemaru, Y; Fukushima, T; Eguchi, K and Miller-Holt, J

*Presented at EuroTax 2016*
Comparison of Chemicals in Mainstream Smoke in Heat-not-burn Tobacco and Combustion Cigarettes

Kanae Bekki*, Yohei Inaba, Shigehisa Uchiyama and Naoki Kunugita

Department of Environmental Health, National Institute of Public Health. Minami, Wako-shi, Saitama 351-0197, Japan

Abstract: Because of the health effects of secondhand smoke, the Japanese government is trying to establish an effective law for total avoidance of secondhand smoke in indoor environments for tobacco-free Tokyo Olympic and Paralympic games 2020, as requested by the International Olympic Committee (IOC) and the World Health Organization (WHO). Meanwhile, Philip Morris International has begun selling a new heat-not-burn tobacco, iQOS,
Table 2. Concentrations of tar, nicotine, CO and TSNA in mainstream cigarette smoke and transfer rates of each component in iQOS (regular and menthol) and conventional combustion cigarettes (3R4F and 1R5F)

<table>
<thead>
<tr>
<th>Element</th>
<th>Mainstream cigarette smoke</th>
<th>Transfer rate (%)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>iQOS regular</td>
<td>iQOS menthol</td>
<td>3R4F</td>
</tr>
<tr>
<td>TPM (mg/cig)</td>
<td>44.0 ± 11.4</td>
<td>49.9 ± 8.6</td>
<td>36.9 ± 1.9</td>
</tr>
<tr>
<td>Water (mg/cig)</td>
<td>33.1 ± 10.2</td>
<td>35.3 ± 8.3</td>
<td>10.1 ± 0.9</td>
</tr>
<tr>
<td>Tar (mg/cig)</td>
<td>9.8 ± 3.0</td>
<td>13.4 ± 2.2</td>
<td>25.2 ± 1.5</td>
</tr>
<tr>
<td>Nicotine (mg/cig)</td>
<td>1.1 ± 0.1</td>
<td>1.2 ± 0.1</td>
<td>1.7 ± 0.1</td>
</tr>
<tr>
<td>CO (mg/cig)</td>
<td>0.44 ± 0.04</td>
<td>0.43 ± 0.04</td>
<td>33.0 ± 1.8</td>
</tr>
<tr>
<td>TSNA (ng/cig)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NNN</td>
<td>19.2 ± 2.1</td>
<td>24.9 ± 3.5</td>
<td>311.1 ± 24.3</td>
</tr>
<tr>
<td>NAT</td>
<td>34.0 ± 3.1</td>
<td>37.2 ± 3.9</td>
<td>246.4 ± 16.9</td>
</tr>
<tr>
<td>NAB</td>
<td>4.5 ± 0.5</td>
<td>5.5 ± 0.6</td>
<td>30.4 ± 2.0</td>
</tr>
<tr>
<td>NNK</td>
<td>12.3 ± 1.5</td>
<td>13.8 ± 2.6</td>
<td>250.4 ± 13.7</td>
</tr>
<tr>
<td>Total of TSNA</td>
<td>70.0 ± 7.2</td>
<td>81.4 ± 10.4</td>
<td>838.2 ± 53.7</td>
</tr>
</tbody>
</table>

Values are mean ± SD. TPM: total particulate matter, TSNA: tobacco specific nitrosamines, NNN: N-nitrosonornicotine, NAT: N'-nitrosanatabine, NAB: N-nitrosoanabasine, NNK: nicotine-derived nitrosamine ketone, CO: carbon monoxide
SALES VOLUME (CIGARETTES/HNB)

Source: Tobacco Institute of Japan IMS and PMJ Estimate/RRP includes competitive RRP IMS

TOBACCO/NICOTINE RELATED LEGISLATION IN JAPAN

**Tobacco Products**
- Tobacco Business/Tax
  - Tobacco Business Act
  - Tobacco Tax Act
- Indoor/Outdoor Smoking Restrictions
  - Health Promotion Act
    - Human Health
  - Industry Safety and Health Act
    - Labor Environment

**Nicotine Products**
- Cessation Aid / NRT
  - Currently none
- Pharmaceutical Affairs Act
SUMMARY

• After the NRT introduction which was not a big success, since 2014, 3 “heat-not-burn” products have been launched nationwide in Japan, and these have been penetrating in the smokers currently about 20%!

• Overall tobacco sales volume (cigarettes+HNB) is decreasing, while sales of heat-not-burn is increasing, indicating that switching from cigarettes to heat-not-burn products is happening very quickly.

• Why?
  • E-cigarettes are not launched because of regulatory authority issue
  • Social courtesy awareness (passive smoking, ash, risk of child burn, etc)
  • Health conscious of Japanese
  • Tokyo Olympic in 2020

• Heat-not-burn products can be an alternative by contributing harm-reduction of smoking, to those who cannot quit smoking, and yet, possibly could be a step toward cessation.