Maastricht University

Smoking topography and the assessment of exposure to cigarette smoke compounds

Citation for published version (APA):

Pauwels, C. G. G. M. (2021). *Smoking topography and the assessment of exposure to cigarette smoke compounds*. [Doctoral Thesis, Maastricht University]. Maastricht University. https://doi.org/10.26481/dis.20211004cp

Document status and date:
Published: 01/01/2021

DOI:
10.26481/dis.20211004cp

Document Version:
Publisher's PDF, also known as Version of record

Please check the document version of this publication:

• A submitted manuscript is the version of the article upon submission and before peer-review. There can be important differences between the submitted version and the official published version of record. People interested in the research are advised to contact the author for the final version of the publication, or visit the DOI to the publisher's website.
• The final author version and the galley proof are versions of the publication after peer review.
• The final published version features the final layout of the paper including the volume, issue and page numbers.

Link to publication

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Impact paragraph

Smoking is still a worldwide problem that should be taken seriously as can also be deduced from the World Health Organization (WHO) Framework Convention on Tobacco Control (FCTC). The WHO FCTC is a legal framework that entered into force in 2005 as a response on the global tobacco epidemic. While all consumer products, and especially food and nutraceuticals are tested and rated for their potentially safe use, it is known for decades that tobacco products are unsafe but allowed. Moreover, while there is all-round legislation for product safety, the unsafe tobacco products are not regulated.

This thesis subject is in agreement with Article 9 and 10 of the WHO FCTC that includes regulations of the content and disclosures of tobacco products whereby it is unclear whether lowering smoke components has a health beneficial effect. A tobacco product may be harm reducing if it lowers total tobacco related mortality and morbidity (i.e. on population level) even though the use of that product may involve continued exposure to tobacco related chemicals. Toxicity to some extent is an inherent aspect of the tobacco product, but less harmful products can still benefit the general smokers' health.

For example, in the Netherlands yearly 20.000 smokers die because of smoking.[1] If this number could be halved, this would be a huge health benefit. To reach a less harmful product, the WHO Study Group on Tobacco Product Regulation (TobReg) proposed mandated lowering of harmful chemicals, or toxicants, in cigarette smoke. Such a strategy for regulation is based on product performance measures with the goal to reduce toxicant levels in mainstream cigarette smoke measured under standardized conditions. This is a challenge for which scientific data based on toxicological testing are needed. Currently, smoking machine tests under 'standardized conditions' are the golden standard to obtain such data although this approach is often criticized. No single protocol is able to give a good prediction for every smoker, with every brand, but the current International Standardization Organization (ISO) 3308 protocol definitely fails to link the actual risks for human smokers from a scientific and biologically relevant perspective. With this thesis, we aimed to improve this link and thereby decrease the gap in current knowledge about smoking topography and the assessment of exposure to cigarette smoke compounds.

Impact on fundamental and applied science

Human studies often show substantially elevated concentrations of (biomarkers of) toxicants in smokers' blood compared to those in the blood of non-smokers, indicating an increased health risk. The influence of human smoking behavior on

blood concentration of smoke toxicants, in combination with the yields of the used products, is scarcely investigated yet. Instead of comparing non-smokers to smokers, we investigated how the actual exposure doses depend on individual variations in smoking topography. In our studies, we aimed to reflect actual human exposure to smoke toxicants, providing insights into the relevance of using machine-smoking data in risk assessment and product regulation.

In this thesis, we show that smokers have a personal smoking profile that is fairly stable but varies greatly between smokers. This indicates that personal exposure (and therefore risk) vary greatly. Additionally, we show that smokers have a more intense smoking profile than even the Health Canada Intense (HCI) protocol. If this is taken into account, the calculations of Fowles and Dybing will yield reasonable results with epidemiological data. Ergo, the order of compounds as presented by Fowles and Dybing stay intact. Reduction of toxicant yields in smoke will therefore most likely be associated with less risk of developing smoking related diseases and thus lower total tobacco related mortality and morbidity.

In addition to the regular cigarette Marlboro red, we specifically focused on highly ventilated cigarettes of which it is assumed that these cigarettes are less harmful. The nicotine exposure of these cigarettes is very low, even below the threshold of initiating or sustaining nicotine addiction (daily dose of less than ~5mg). In contrast to the established theory, hardly any compensation is found for the highly ventilated cigarettes.

We showed that smoke compounds relate to each other, and that a limited set of smoke components is therefore sufficient for risk estimation. Hence, the data presented in this thesis could be used to improve the current measurement methods for toxicant exposure levels and thus consequently contribute to harm reducing measures with respect to tobacco smoking. The data presented for the different cigarette brands according to different smoking regimes can be used by risk assessors as input for their models. In addition, the puffing topography data can be used to generate more reliably model human exposure. The information from Chapter 2, 4 and 5 may lead to more reliable risk assessment models in which health effects are related to tobacco smoking. The papers that cited our articles (Chapter 2 and 4) are using our data as such.

The results in this thesis are especially relevant for other scientific researchers working in this field, because the list with human studies and the detailed data

of puffing parameters presented in Chapter 4 give insight in worldwide puffing topography; this is especially informative because it is specified per brand smoked. Furthermore, our own puffing topography study included a thorough investigation of the CReSSmicro™ device. The data have led to insight about the use of this device to measure smoking topography for fellow researchers and future studies. We have shown where the anomalies in the raw data possibly come from and how to deal with or prevent them.

Impact on regulation

In Chapter 2, we compared the ISO and Health Canada Intense (HCI) method for 11 cigarette brands commercially available in The Netherlands. Our data revealed that two to three times more TNCO was measured when using HCI compared to ISO. This was caused, among other things, by the fact that the measured smoke is mixed with air that enters via the ventilation holes in the filter of the cigarette during machine smoking of the ISO 3308 method. This means that the current measurement method used in the EU (e.g. ISO 3308) is underestimating actual exposure levels of smokers to the harmful chemicals in cigarette smoke. Tobacco manufacturers manipulated the method by adapting their cigarette design by adding filter ventilation holes. This urges for a different measurement method for detecting toxicant levels in mainstream cigarette smoke, as for instance the HCI method in which the ventilation holes are taped and thus closed.

In October 2017, the State Secretary sent a letter to Brussels wherein he argued for a different measurement method than the prescribed ISO 3308 method to measure tar, nicotine and carbon monoxide (TNCO) in the European Tobacco Products Directive (EU-TPD). This letter was (partly) based on data from this thesis (Chapter 2). Subsequently to the letter of the State Secretary, the RIVM was asked to measure 100 Dutch brands using the HCI method and the obtained results supported our outcome that is published in Chapter 2. Despite the recommendation from different parties such as the Dutch government, to include an independent measurement method, such as the WHO TobLabNet SOP 01, this is not implemented yet in the EU-TPD. This is unfortunate because countries cannot implement these SOPs in national legislation as they have to adhere to the EU legislation.

Because we used smoking machine settings with and without taping the cigarettes, the data for the different brands are also demonstrating the effect of a design feature such as filter ventilation on smoke toxicants (and the exposure of the smoker). This information adds to the idea of limiting the allowed cigarette design features such

as a maximum filter ventilation percentage or no filter at all.

In conclusion, HCI results in cigarette smoke emission that is too low to represent human smoking. In order to give a more accurate reflection of human smoking behavior, cigarettes should be machine smoked with a more realistic puffing regime that has a higher puff frequency and a higher puff volume, and with and without filter ventilation blocking. In addition, two regimes can be used to prevent that possible design features manipulate one type of regime and thus the smoke toxicant measurements.

Reference

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