



Volume: 37, Article ID: e2015027, 6 pages

http://dx.doi.org/10.4178/epih/e2015027

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Joint Statement of the Ad-hoc Committee of the Korean Society for Preventive Medicine and the Korean Society of Epidemiology on Tobacco Lawsuits on the causal link between tobacco smoking and lung cancer

Ad-hoc Committee of the Korean Society for Preventive Medicine and the Korean Society of Epidemiology on Tobacco Lawsuits

PROCESS AND BACKGROUND

The National Health Insurance Service (NHIS) has filed a damage suit against tobacco producers KT&G, Philip Morris Korea, and BAT Korea (hereafter referred to as "Tobacco Lawsuit"). In the course of the ongoing lawsuit, heated debates are underway regarding the causal relationship between tobacco smoking and lung cancer. The affected individuals of this class action are those with one of three lung cancer types (small cell lung cancer, squamous cell lung cancer, and squamous cell laryngeal cancer), having a smoking history of 20 pack-years or more, and having smoked for 30 years or more.

Given the nature of tobacco smoking as an very important risk factor threatening public health, the Korean Society for Preventive Medicine (CEO: Won-Chul Lee) and the Korean Society of Epidemiology (President: Bo Youl Choi), whose core values lie in disease prevention and health promotion, have paid particular attention to the Tobacco Lawsuit, especially to the raised debates about the causal relationship between smoking and lung cancer.

Under the current circumstances, in which the plaintiff (NHIS) and the defendants (tobacco companies) repeatedly mention the value and role of epidemiologic studies in evaluating the causal connection between environmental risk factors and lung cancer in their respective briefs submitted to the court, the Korean Society for Preventive Medicine and the Korean Society of Epidemiology, whose key discipline is epidemiology, have

This article is also being simultaneously published in Journal of Preventive Medicine and Public Health by the Korean Society for Preventive Medicine.

This article is available from: http://e-epih.org/ © 2015, Korean Society of Epidemiology come to have deep concerns and feel the urgent need for a position statement regarding this issue.

To address this issue, the Korean Society for Preventive Medicine and the Korean Society of Epidemiology agreed to jointly constitute an "Ad-hoc Committee of Korean Society for Preventive Medicine and the Korean Society of Epidemiology on Tobacco Lawsuits" (hereafter referred to as "ad-hoc Committee"), whereupon the ad-hoc Committee was constituted with area experts (cf. the annexed list of the ad-hoc Committee members).

After two seminars, continuing discussions by email, drafting a raw version of the statement with comments from ad-hoc Committee members, and coming to an agreement on the language and content, the ad-hoc Committee has drafted a joint statement. After obtaining approvals from the Korean Society for Preventive Medicine and the Korean Society of Epidemiology as well as their respective boards, the ad-hoc Committee publishes this Joint Statement on behalf of both societies.

FOCAL POINT OF THE "CAUSAL LINK BETWEEN SMOKING AND OCCURRENCE OF LUNG CANCER"

In the aforementioned tobacco lawsuit, debates have been held about the role of epidemiology in disease causality in the briefs based on an incorrect understanding of the value and role of epidemiological studies. As epidemiology constitutes the scientific basis of the Korean Society for Preventive Medicine and the Korean Society of Epidemiology, we regard it as the academic and social duty of both societies and the ad-hoc Committee to provide a correct understanding of the role of epidemiology in disease causality.

After reviewing the briefs submitted by the plaintiff (NHIS) and defendants (tobacco companies), the ad-hoc Committee viewed the following three perspectives of the "causal link be-

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tween smoking and lung cancer" to be addressed.

- (1) Distinction between specific and non-specific diseases and causal inference.
- (2) Relative risk and attributable fraction of smoking for the cancer types involved.
- (3) Application of epidemiological study results in a population to individual causation.

Along with these perspectives, the ad-hoc Committee wishes to make an additional point about the role of epidemiological studies in identifying disease causation.

THE DICHOTOMY OF SPECIFIC AND NON-SPECIFIC DISEASES IS DEVOID OF A SCIENTIFIC FOUNDATION

Since the introduction of the concept of specific and non-specific diseases during the case of the "Vietnam veterans" class action lawsuit as "Agent Orange victims" (hereafter referred to as "Agent Orange Lawsuit"), the Supreme Court of the Republic of Korea has continued to use this concept in tobacco lawsuits and exhaust gas lawsuits. The brief of the tobacco companies has emphasized, "lung cancer is a non-specific disease."

In the Supreme Court ruling on the Agent Orange Lawsuit, a specific disease is defined as "a disease caused by a specific etiology in which pathogenic cause and effect are clearly traceable" and a non-specific disease as "a disease with complex etiologies and mechanisms that develops in complex interactions between genetic factors, such as heredity and predisposition, and non-genetic factors, such as alcohol drinking, smoking, age, dietary habits, and occupational and environmental factors" (Supreme Court Ruling 2014-04-10. Sentencing 2011C22092 Decision). The criteria for a specific disease pointed out in the Supreme Court Ruling of the Agent Orange Lawsuit are as follows: (1) "stemming from one etiology" and (2) a clear correspondence between pathological cause and effect.

Regarding this, the opinion of the ad-hoc Committee is as follows

First, the terms "specific disease" and "non-specific disease" are not used in the epidemiologic field dealing with disease causation. These terms have no entries in the Dictionary of Epidemiology [1] edited by the International Epidemiologic Association; Modern Epidemiology [2], a textbook of epidemiology; or Gordis' Epidemiology [3]. Second, these terms are not familiar, even to epidemiologists. While specificity is mentioned as one of the considerations that may be considered in disease causation, dichotomizing diseases into specific and non-specific diseases is not acceptable in the epidemiological discipline that deals with disease causation.

Nevertheless, if a specific disease were to be defined as a disease having necessary and sufficient conditions stemming from

a single cause, such a specific disease cannot exist. Even in case of an infectious disease, while it is considered to develop owing to a specific bacterial or viral species as a direct cause, a number of other factors are also involved in disease occurrence. This also applies to tuberculosis and cholera, which are mentioned in the brief submitted by KT&G (2015-01-15, p. 24) as examples of specific diseases. Mycobacterium tuberculosis (Mtb) is a necessary condition for tuberculosis (TB), because without Mtb, there would be no TB. However, although a high proportion of the Korean population are Mtb carriers, only a very low percentage of them are TB patients. In other words, Mtb is not a sufficient condition for TB in that TB occurs only under specific conditions, such as malnutrition, hygienic problems, immunodeficiency disorders, or use of immunosuppressant drugs. In addition, in the case of cholera, only some of those infected with Vibrio cholerae show the typical symptoms of cholera accompanied by acute watery diarrhea. Furthermore, most of the leading chronic diseases in Korea, including lung cancer, are not diseases with a single etiology. They occur by complex interactions between various risk factors through various mechanisms. Nonetheless, even though they are not considered "specific diseases," their causal connection to environmental risk factors cannot be denied. As an example, it is not correct to categorically deny the causal link between occupational radiation exposure and cancers among those occupationally engaged in radiological exposures and thus not recognize these cancers as occupational diseases simply because cancer does not meet the definition of a specific disease. The practice of dichotomizing diseases into specific and non-specific diseases in assessing the effects of risk factors is based on a false understanding of disease causation; it is therefore improper to use it as a basis for assessing the causal link in the Tobacco Lawsuit.

The "clear correspondence between cause and effect" presented as the second criterion for a specific disease is conceptually close to specificity, which is one of Hill's considerations for causation. For example, if risk factor A is not related to other diseases, but is related to disease B, a specificity can be determined to exist between risk factor A and disease B. Additionally, if risk factor A has a low relative risk in relation to other diseases, but has a very high relative risk in relation to disease B, a specificity can be determined to exist between risk factor A and disease B. Under this logic, the affected group in the Tobacco Lawsuit, i.e., patients with three types of lung cancer who have a smoking history of 20 pack-years or more and who have smoked for 30 years or more may be regarded as having a high level of "specificity" for lung cancer.

In sum, it is not acceptable to dichotomize a disease as being either specific or non-specific. Moreover, if specificity can be determined in terms of magnitude of the causal relationship between a specific etiology (cause) and a disease (effect), the level of specificity between smoking and the cancer types involved in the current Tobacco Lawsuit can be said to be very high.

THE ATTRIBUTABLE FRACTION OF SMOKING TO THE CANCERTYPES INVOLVED INTHETOBACCO LAWSUIT RANGES FROM 81.5% TO 95.4%

Both the plaintiff and the defendants of the Tobacco Lawsuit have mentioned the relative risk and attributable fraction (also used as attributable risk) in the relationship between smoking and lung cancer. In particular, the tobacco companies emphasize that the data related to relative risk and attributable fraction in Korea are lower compared to foreign data. For example, in the brief submitted in January 2015 (Philip Morris Korea, 2015-01-14, Brief p. 9), based on the data reported in BMC Cancer in 2014 [4], Philip Morris Korea presents that "the population attributable fraction is 53.3% for cigarette smoking."

Various epidemiological data are presented in the ongoing Tobacco Lawsuit. The parties have presented the population attributable fraction, and the relative risk for lung cancer in the entire smokers; however, these data cannot be recognized as epidemiological indicators worth consideration in the current litigation. In this regard, the ad-hoc Committee presents the following views.

First, the affected group of this class action are patients with small cell lung cancer, squamous cell lung cancer, and squamous cell laryngeal cancer, who have a smoking history of 20 pack-years or more and a smoking period of 30 years or more. Therefore, the scientific foundation for the arguments advanced in the Tobacco Lawsuit should be focused on the relative risk and attributable fraction of these affected individuals.

Second, the population attributable fraction mentioned in the Tobacco Lawsuit is an indicator that assesses the causal contribution of smoking in the entire population, including non-smokers. Given that the Tobacco Lawsuit involves only lung cancer patients with a smoking history, the population attributable fraction is not an adequate indicator for the Tobacco Lawsuit, and the arguments about the causal relationship between smoking and lung cancer should be based on the attributable fraction among the exposed group (smokers).

Third, the results of the studies conducted in Korea in relation to the cancer types included in the Tobacco Lawsuit are as follows. In a Korean study published in 2005 [5], the relative risks of smokers for the development of small cell lung cancer and squamous cell lung cancer with respect to non-smokers were estimated at 21.7-fold and 11.7-fold, respectively. According to a 2004 study on laryngeal cancer [6], the relative risk of smokers for the development of laryngeal cancer with respect to non-smokers was estimated at 5.4-fold. The attributable fractions of

smokers calculated based on the relative risks (=[RR-1]/RR) sof small cell lung cancer, squamous cell lung cancer, and laryngeal cancer (RR of 21.7-, 11.7-, and 5.4-fold, respectively) were 95.4%, 91.5%, and 81.5%, respectively. These results demonstrate much higher attributable fractions compared to the attributable fractions (53% to 70%) calculated on the basis of the relative risks of smoking for overall lung cancer without cytohistological consideration (RR, 2.5 to 5.0).

In sum, in consideration of the cancer types involved in the Tobacco Lawsuit, the attributable fraction of the exposure group (smokers), not the population attributable fraction, is the appropriate indicator of the causal contribution of smoking to lung cancer. Based on the results of domestic research, the relative risks and attributable fractions for the cancer types involved in the Tobacco Lawsuit are much greater than those mentioned so far by defendants in the arguments advanced in the Tobacco Lawsuit.

THE EPIDEMIOLOGICAL RESEARCH RESULTS SHOULD BE CONSIDERED THE MOST IMPORTANT FACTOR IN ASSESSING INDIVIDUAL CAUSAL CONNECTIONS BETWEEN SMOKING AND LUNG CANCER

Tobacco companies have put forward arguments that information regarding the causal link between smoking and lung cancer is based on studies in populations (general causality) and cannot be used for assessing individual causal links (individual causality). Regarding this, the views of the ad-hoc Committee are as follows.

First, the medical society accepts the causal link between smoking and lung cancer as a scientifically proven fact. The rationale for this recognition stems from a variety of studies, not just follow-up studies with population groups. Cohort studies have played an important role in quantifying the extent of damages caused by smoking. On a related note, animal experiments, observation studies with individual patients, and chemical assays have greatly contributed to determining the mechanisms by which smoking induces lung cancer [7]. Such individual observations and experiments have yielded well-established factual findings, such as the occurrence of tumors when "tobacco juice" was smeared on animals' skin; smoking-induced pulmonary ciliostasis, in which smoking impeded the activity of the upper bronchial cilia and thus triggered the trapping of hazardous substances in the lungs; and evidence of the presence of carcinogenic substances such as benzopyrene in tobacco smoke. The body of knowledge about the causal link between smoking and lung cancer has thus been formed through population studies, animal experiments, observations of individual patients, and laboratory studies.

Second, the argument that epidemiological evidence cannot be used as information proving the individual causal relationships because they are "in principle, statistics on population groups" contains a serious argumentative gap. In modern clinical medicine, clinical trials with population groups are recognized as the best approach to assess the efficacy of a therapy. If statistics obtained from a population group cannot be applied to individual cases, the inevitable conclusion is that the body of knowledge established through a multitude of clinical trials should not be applied at all in clinical settings in diagnosing patients and selecting therapies. This is obviously an erroneous conclusion that stems from a faulty premise. The general causality verified in a population group is expressed as the sum total of individual causality of the members constituting that population group. Risk factors and causal relationships to a disease can be determined more accurately through epidemiological studies with the affected population group than through individual observations of the members of that group. Therefore, the approach using population groups is not a limitation of epidemiological study; rather, it is a strength that can overcome the limitations of assessing individual cases.

Third, the argument that epidemiological evidence cannot be used as information proving the individual causality because they are population-based statistics contains a serious error in logic. If epidemiological evidence cannot be applied to individuals and the statistical proofs obtained from population group do not have any explanatory power on individual cases, it would indicate that those who have ceased smoking on the basis of the epidemiological evidence have made an irrational decision. Furthermore, if the epidemiological evidence is not applicable among individuals, advice and therapies for tobacco cessation by many physicians in the clinical setting (e.g., "Quit Smoking Clinic") can also be labeled as useless activities. The claim that the statistical results obtained from population groups cannot be applied to individual cases is tantamount to accusing all those who quit and attempt to quit smoking and physicians who recommend smoking cessation of irrational decision-making, which is not socially and practically acceptable. That smoking is a causal factor for lung cancer is widely established general knowledge, which is also clearly described as a warning on cigarette packs. It is the responsibility of the field of preventive medicine to explore ways and means to prevent disease and promote the health of individuals by applying knowledge about etiologies and causal mechanisms of diseases. It is the duty of all and an important activity of those concerned to spread such knowledge, to warn youth against the dangers of smoking to prevent them from starting smoking, and to guide smokers toward cessation: all of this is based on applying the knowledge obtained from population groups to individuals.

Fourth, it is essential to use the concept of probability of cau-

sation in relation to the application of the attributable fractions verified in the data from population studies at the individual level. According to the Dictionary of Epidemiology, probability of causation for a given case is the probability that exposure played a role in disease occurrence [1]. This concept is considered important in establishing legal standards, because it concerns the probability for the case in which a randomly selected patient had developed a given disease from exposure to the factor being investigated [2]. The concept of probability of causation is an important concept presented in epidemiology textbooks. However, it has not been reflected so far in the Tobacco Lawsuit and prior tobacco lawsuits in Korea. Instead, a problematic and erroneous claim has been put forward that the attributable fractions derived from studies with population groups cannot be applied to individual cases, thus revealing a serious problem. The concept of probability of causation is intuitively applied in practical decision-making. For example, an individual who has smoked for 10 years is diagnosed with lung cancer, and his/her physician says that it cannot be verified whether the lung cancer was triggered by smoking because populationbased knowledge cannot be applied to an individual, thus implying that smoking can be continued. In this scenario, the physician has certainly failed to do his/her duty as an expert who must consider scientific evidence in a balanced way and make the best possible rational recommendations. In reality, the probability that smoking caused the lung cancer of this patient is very high, and continuing smoking will assuredly exacerbate the course of the disease, which is also understood based on the probability of causation.

Fifth, the information on attributable fractions obtained from epidemiological studies with population groups needs to be considered in the court to assess the probability of causation of lung cancer in the individual patients. The presence of a particular relationship between attributable fractions and the probability of causation has been proven, with the probability of causation being equal to or greater than the attributable fraction [1,2]. In other words, even in a case where the attributable fraction is low, the probability of causation can be very high. For example, the Dictionary of Epidemiology demonstrates that a case with an attributable fraction of 20% can exhibit a probability of causation of 100% [1]. Because probability of causation can be accurately estimated on the basis of a biological mechanism, even in a case where the attributable fraction is very low, its probability of causation can be 100% in the presence of an obvious biological mechanism [8]. In the case of the affected group in the Tobacco Lawsuit, i.e., patients with small cell lung cancer, squamous cell lung cancer, or squamous cell laryngeal cancer who have a smoking history of 20 pack-years or more and have smoked for 30 years or more, they have attributable fractions ranging from 80% to 90% or more. Consequently, if the general causality between smoking and lung cancer is recognized, and the individual patient can be considered to have randomly been selected from the lung cancer patients, the probability of causation of smoking being the cause of the lung cancer of this patient is 80% to 90% or more. It is necessary to assess the probability of causation of individual lung cancer patients using these considerations. Using the concept of probability of causation, a recent study estimated that over 90% of the lung cancer cases in Quebec, Canada are legally attributable to smoking [9].

In sum, the claim that the statistically established causal relationship in population cannot be applied to individual cases is logically and practically problematic. The information on the causal link between smoking and lung cancer can be applied to individual cases with the concept of probability of causation.

THE ROLE OF EPIDEMIOLOGY IN ASSESSING CAUSALITY

In the course of the Tobacco Lawsuit, many different arguments have been put forward regarding the role of epidemiology in determining the causality of a disease. Some of the arguments are not admissible from the viewpoint of experts in the field of epidemiology. The discipline of epidemiology is the academic foundation of the Korean Society for Preventive Medicine and the Korean Society of Epidemiology. As such, it is judged to be of vital importance to provide a correct understanding and increase awareness of the role of epidemiology to the press and general public watching the Tobacco Lawsuit.

The ad-hoc Committee wishes to express deep concerns about the following contents described in the briefs submitted by the parties concerned.

"Epidemiology is a discipline investigating population groups and thus cannot be used as a tool for determining the etiology of the given disease in individual cases. Therefore, even though an epidemiological study quantitatively detected a cause-effect relationship in a particular group, a conclusion drawn does not provide a suitable basis for the application to the individuals belonging to that group. This may be pointed out as an inherent limitation of epidemiology itself" (KT&G, 2015-01-15, brief p. 10).

"Epidemiology is a discipline investigating the correlation between particular factors and a given disease, and the results of epidemiological studies are, in principle, statistics limited to the population group being investigated" (BAT Korea, 2014-12-26, brief p. 12).

In particular, KT&G (brief 2015-01-15) assigned a separate chapter titled "Limitations of Epidemiology" describing the limitations of epidemiology in relation to the arguments made in the course of the Tobacco Lawsuit.

In deriving the causality of a given disease, epidemiology reflects not only the research data derived from the studies with the corresponding population group, but also from animal experiments, observations of individual patients, and laboratory studies, comprehensively considering their contributions. Epidemiology derives the attributable fraction, which means the causal contribution of a particular risk factor to the incidence of the given disease, from the data of population group studies. Additionally, using the concept of probability of causation, it also provides information on the causal contribution to the disease in individual cases. Determining the conclusions drawn from epidemiological studies as statistics that "cannot be applied to individuals" or making claims on the "limitations of epidemiology" is depreciating the broad intellectual activities of epidemiologists to elucidate the causalities of diseases and denying the essential tasks of the preventive medicine.

It is suspected that the reason underlying such irrational claims criticizing the "limitations of epidemiology" and determining the results of epidemiological studies as mere "statistical relations," is the intent to prevent the results of epidemiological studies regarding the causal link between smoking and lung cancer from being taken as proof of causality in the court. The ad-hoc Committee regards such arguments as an important social issue that can seriously harm efforts of the whole society to prevent diseases and promote health that goes beyond the interest of particular groups.

CONCLUSION

In relation to the ongoing Tobacco Lawsuit, the Korean Society for Preventive Medicine and the Korean Society of Epidemiology constituted an ad-hoc Committee of the Korean Society for Preventive Medicine and the Korean Society of Epidemiology on Tobacco Lawsuits and presented the results of the joint ad-hoc Committee's discussions in the form of a joint statement as a position paper declaring their opinions. The decision and ensuing activity of the two societies arose from the ongoing debates about the causal link between tobacco smoking and lung cancer in the course of the Tobacco Lawsuit, thereby regarding it as the social duty of the two societies as experts in the disease causation to clarify their positions and publicize their opinions based on the latest scientific discussions. It was of particular importance to bring out the value of epidemiology as a discipline, given the related negative arguments put forward by the parties concerned in relation to the causality of the diseases involved in the Tobacco Lawsuit. It is hoped that this joint statement of the ad-hoc Committee will assist in initiating more clear and scientific debates in the course of the Tobacco Lawsuit.

Ad-hoc COMMITTEE OF THE KOREAN SOCIETY FOR PREVENTIVE MEDICINE AND THE KOREAN SOCIETY OF EPIDEMIOLOGY ONTOBACCO LAWSUITS

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CONFLICT OF INTEREST

The authors have no conflicts of interest to declare for this study.

SUPPLEMENTARY MATERIAL

Supplementary material is available at http://www.e-epih.org/.

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