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From mercury sphygmomanometer to electric device on blood pressure measurement: correspondence of Minamata Convention on Mercury

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INTRODUCTION

The United Nations Minamata Convention on Mercury was ratified in 2013, and will come into effect on 2020.[1] The Convention forbid to manufacture, import and export devices using mercury, including mercury sphygmomanometer. On behalf of the Japanese Society of Hypertension, we overview the current situation of mercury sphygmomanometer relating to Minamata Convention on Mercury, and propose perspectives of blood pressure measurement and evaluation.

MINAMATA CONVENTION ON MERCURY

Mercury is a persistent and bioaccumulative toxic substance.[1,2] Many tons of mercury supplied for the manufacture of mercury device, for example, sphygmomanometers, and distributed throughout the world to hospitals and other health facilities will eventually find its way back into the environment through evaporation, sewage or in solid waste, most seriously damaging the marine environment and thus affecting the food chain.[2] To protect human health and the environment from such adverse effects of mercury, agreement of the Minamata Convention on Mercury was reached on 2013.[1] As sphygmomanometers are treated as a nonelectronic device, manufacture, import and export of them shall not be allowed after 2020. Sphygmomanometer contains 50 to 140 g metal mercury inside the column and bulb,[3] and is the second largest mercury-use device next to lamps among entire equipment in Japan,[4,5] whereas reduction of mercury volume encapsulated in fluorescent lamps have been promoted by replacing to light-emitting diode (LED) lamps.[5] It should be noted that the production of mercury thermometer was discontinued in Japan before 2010. The Minamata Convention raises the issue of the current usage of mercury sphygmomanometer, and alternatives of blood pressure measurement devices and their validation process after phasing out of mercury sphygmomanometer.

Mercury medical equipment is also becoming a rarity in other developed countries. In the United States, 13 states representing 30% of the US population have passed laws banning mercury-containing thermometers and sphygmomanometers.[6] In Scandinavian countries and the Netherlands, the use of mercury was no longer permitted after 2002.[7] In other European countries, sphygmomanometer and other kinds of mercury-containing measuring devices intended for industrial and professional uses shall not be placed in the market after 10 April 10.[8] However, the prohibition by the European Commission[8] has several exceptions for mercury-containing sphygmomanometers that can be used in sequence. For instance, in epidemiological studies that are ongoing at the time of 10 October 2012 or as reference standards in clinical validation studies of mercury-free blood pressure measurement devices, mercury sphygmomanometers are still allowed to be used.[8]

CURRENT USE OF MERCURY SPHYGMOMANOMETER IN CLINICAL PRACTICE IN JAPAN

The 2014 Japanese Society of Hypertension Guidelines recommended that clinic blood pressure is measured by the auscultation method using a mercury sphygmomanometer, although the use of a validated automatic device is also permitted.[9] The Guidelines introduced the so-called hybrid sphygmomanometer with an electronic analog column as an alternative of a mercury sphygmomanometer.[9] According to the surveillance among 4163 outpatient clinics by Tokyo Medical Association in 2011, 79.0% of the clinics had used mercury sphygmomanometer in clinical practice, the average number of stocked devices was 3.4 and a total of 522 devices were at backyard as dead storage among 265 clinics that do not currently use the devices.[10]

COLLECTION AND DISPOSE OF MERCURY SPHYGMOMANOMETER

An advanced trash incinerator is automatically stopped when the mercury vapor exceed the reference value. Because such cases happened several times because of illegal disposal of mercury sphygmomanometer, the Tokyo Medical Association started collecting mercury devices, mainly sphygmomanometer, from Tokyo city area regularly for noncommercial purposes in 2012.[10] The Japan Medical Association followed this action, and is currently trying to expand this service nationwide.[11] Governmental agencies have been revising the regulation in relation to mercury disposal to prevent the burden on the environment.[5] There is, however, a concern on emerging mercury pollution as recycling of metal mercury is disappearing because of a rapid demand decrease. With the Japan Medical Association,[11] we call on governmental organizations to start up specific financial support for collection and disposal of mercury devices appropriately.[12]

MYTH OF MERCURY ON BLOOD PRESSURE MEASUREMENT

Currently, blood pressure measurement by mercury sphygmomanometer is sometimes misunderstood as 'in the arm-cuff device,

mercury column bar reflects brachial artery pressure directly'. Actually, metallic mercury in the sphygmomanometer is pushed up into the column directly by air pressure within arm cuff, and not by artery pressure. Regardless of Korotkoff sound or cuff oscillometric technique, brachial artery is occluded by arm-cuff pressure, and changes in the biological information such as sound or oscillation are observed to measure or estimate systolic and diastolic blood pressure level. An accurately indication of the within arm-cuff pressure is therefore mandatory for blood pressure measurement device, whereas metallic mercury is a mere traditional medium—the heaviest liquid at room temperature.

We emphasize the inevitable disadvantages of mercury device that tend to be overlooked: (1) a low purity mercury provides wrong level, (2) an error will be emerged and expanded because of evaporation of mercury, (3) the on-time response to arm-cuff pressure during measurement will be degraded by dirt inside the column and (4) liquid mercury can be separated in the column by a violent use.[13,14] Although mercury sphygmomanometers should be maintained and calibrated regularly to ensure the accuracy of the measurement, such technically simply checks are rarely performed in the primary care setting.[13,14]

RECOMMENDED DEVICES FOR BLOOD PRESSURE MEASUREMENT

Arm-cuff device

Although various blood pressure measurement devices are available and recently innovated devices are likely to yield simple measurement, blood pressure should be measured by an arm-cuff device operated under standard measurement procedures, for example, at the upper arm of the nondominant hand with the measuring arm cuff at heart level.[15] The finger-cuff blood pressure is physiologically different from brachial blood pressure, and vasospasm under cold temperature and hydrostatic pressure differences are inevitable for the finger measurement.[15] Similar approach by a handy gadget had been proposed in the 1990s[16] based on the assumption that the pulse wave velocity was strongly correlated with blood pressure, although recent publications have denied such high correlations.[17,18]

Wrist-cuff devices are more portable and easier to handle compared with upper arm device, although we face difficulty in correction of the hydrostatic pressure.[15] For instance, a 5-cm difference from the right atrium of the heart causes 3.5 mm Hg difference of the blood pressure level, and this can provide wrong implications in clinical practice. Furthermore, the radial and ulnar arteries are surrounded by the radial bone, ulnar bone and long tendons at the wrist. Even a sufficient excess of cuff pressure over arterial pressure does not necessarily occlude these arteries adequately,[19] and measurements are also influenced by flexion and hyperextension of the wrist.[19] The currently available wrist-cuff device is therefore inappropriate as a tool for clinical decision making.

Aneroid sphygmomanometer

Aneroid sphygmomanometers in the narrow sense, in which cuff pressures are represented as the degree of metal flexures, are still common in many countries, in particular developing countries because of their inexpensiveness and long history for clinical use. In some developed countries, these comparably cheap aneroid devices are treated as a disposable tool, resulting in the reduction of maintenance cost. Aneroid devices are, however, not recommended as they are more prone to inaccuracy than other devices because of less resistance against a mechanical impact as degradation in precision, and aneroid manometers as well as mercury sphygmomanometers require observers' skill that can also become inaccurate with use.[20,21]

Electric sphygmomanometer

Semiconductor pressure sensor for industrial use can realize accurate blood pressure measurement nowadays. The lightweight and tough semiconductor shows good response for pressure change. Validation of such semiconductor pressure sensor is subject to legal regulation, Measurement Act,[22] and implementing agencies can undertake the validation process. Accuracy assurance of the semiconductor pressure sensor reaches $<0.01\%$ even as a consumer product. Regardless of home, ambulatory or clinic settings, electric semiconductor sensor is therefore widely used in the automated blood pressure devices. These automated devices require less training, avoid observer bias, can capture pulse rate simultaneously and, if equipped with an automated memory for home monitoring use, have the potential to prevent patients from misreporting their blood pressure measurements.[21] Furthermore, electric sensors are usually stable over time and much more likely not to work at all than to give a erroneous reading.[23] Automated blood pressure monitors are therefore unlikely to show the 'drift' over time that leads to inaccuracies of mercury or aneroid devices.[23]

The semiconductor pressure sensor is also embedded in the so-called hybrid sphygmomanometers, for example, A&D UM-101 (A&D Company, Tokyo, Japan)[24] and Nissei DM-3000 (Japan Precision Instruments, Shibukawa, Japan),[25,26] in which real-time bar graph corresponding to the inner arm-cuff air pressure is displayed on the portrait liquid crystal display (LCD) screen as an imitation of liquid mercury column. Observers can listen to the Korotkoff sounds by the stethoscope to determine blood pressure level according to the displayed bar graph, whereas pulse rate is detected by the oscillometric principle. The replacement of the mercury sphygmomanometer by validated professional oscillometric device resulted into different treatment decisions in $\sim 5\%$ of the cases.[27] From the above and considering environmental pollution of mercury, we have little rationale to continue using mercury sphygmomanometer in clinical practice, and electric manometers including hybrid sphygmomanometer are reliable alternative to the mercury sphygmomanometer.[23]

STANDARDS FOR BLOOD PRESSURE MEASUREMENT DEVICES

Manufacturers have to follow domestic standard in each country, for example, Association for the Advancement of Medical Instrumentation (AAMI)[28,29] in the United States, European Committee for Standardization (CEN)[30] that brings together the National Standardization Bodies of 33 European countries, and Japanese Industrial Standards (JIS) in Japan.[31] Furthermore, governmental approval such as Food and Drug Administration (FDA)[32] in the United States is obligatory for blood pressure measurement devices as a marketed medical tool. In Japan, Pharmaceutical and Medical Devices Agency (PMDA) bears the responsibility that evaluates the quality, efficacy and safety of medical devices based on current scientific and technological standards,[33] and all automated blood pressure measurement devices are authenticated by PMDA before being marketed. Meanwhile, blood pressure can be measured under diverse settings, and such government agencies do not necessarily require independent validation of accuracy. Thus, clinical evaluations of the device independent of manufacturers have been published in peer-reviewed journals according to the European Society of Hypertension (ESH) International Protocol revision 2010 (ESH-IP 2010)[34] and its predecessors.[35,36] Recently, AAMI and American National Standards Institute (ANSI) revised the

ANSI/AAMI standard[29] to adopt International Organization for Standardization (ISO) standards (ANSI/AAMI/ISO 81060-2:2013).[37] The ISO specifies the requirements and methods for the clinical evaluation of automated blood pressure devices, intermittent non-invasive automated estimation of the arterial blood pressure by utilizing a cuff.[37]

Meanwhile, the authors of the ESH-IP 2010 showed their concerns on mercury sphygmomanometers as 'because of the increasing ban on the use of mercury-containing sphygmomanometers, there is a need for an equivalent standard device that does not contain mercury.'[34] Although mercury sphygmomanometer is still required as reference standard for validation of blood pressure measuring devices in the ESH-IP 2010,[34] it will be revised in the near future to follow the Minamata Convention on Mercury. For potent purchasers of blood pressure devices who do not have access to many of these publications, the Working Group of the ESH had launched the specific website 'dabl educational trust'[38] in which scientific papers regarding validation study for marketed blood pressure measurement devices are introduced. Recently, the advanced website 'Medaval'[39] was constructed to introduce a comprehensive resource for medical device information, not limited to sphygmomanometers. Along with these scientific activities, we are willing to provide up-to-date information for fulfilling our responsibility as the world's largest producing country of blood pressure monitoring devices.

BLOOD PRESSURE MEASUREMENT FOR LONGITUDINAL SURVEY

Stroke mortality will be reduced by 8.9% in men and 5.8% in women when average blood pressure level among Japanese population decreases by 4 mm Hg.[9] Such reduction has to be measured accurately, although a systematic error between two different blood pressure monitors can be more than 4 mm Hg even when both had passed the clinical validation protocol.[15,34] For the epidemiological, longitudinal study and surveillance, to eliminate such an error between an old and new device is essential for reliable blood pressure level among population. The above-mentioned approach by the European Commission[8] to allow the exception of mercury use for ongoing epidemiological studies may be one interim solution, although we cannot overlook the known problems when using mercury devices. Hybrid sphygmomanometers[24–26] for epidemiological settings are therefore most practical approach with the assumption that these devices are appropriately validated to the specific population in each study.

PERSPECTIVES

Although there is room for argument on the discontinued process, mercury devices shall be eventually banned in clinical practice in the near future, and the incoming of the demise of mercury sphygmomanometer accelerates the widespread use of blood pressure measurement devices embedding semiconductor pressure sensor. We will intensify our efforts to follow and further to head the Minamata Convention on Mercury regarding blood pressure measurement.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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