Blood pressure measurement devices – issues of accuracy and quality monitoring

Interview with Dr. S. Mieke from the National Institute of Natural and Engineering Science (PTB), Germany. Conducted by Dr. Anja Kroke, Editor

Dr. S. Mieke: There are good and reliable alternatives to mercury manometers. Aneroid sphygmomanometers are equally valid in their performance compared to mercury devices given that they fulfill certain quality standards like the European or US-American standards for blood pressure measuring devices. However, the aneroid devices are susceptible to mechanical damage when dropped or banged. Their size allows them to be carried around and, therefore, they might be frequently subjected to damage. Special care has to be taken to make sure that the devices are working accurately.

What can a physician do to ensure the accuracy of a blood pressure measuring device?

Dr. Mieke: In addition to evaluation after the device is dropped, I recommend having a BP measuring device checked at least every 2 years. These checks should include the determination of measurement accuracy and air leakage of the device. In general, and especially after it is dropped, one needs to make sure that the zero position of the pointer has not changed. If the zero position is altered, the device should not be used until repaired.

WHL News

New Working Group “Hypertension in Diabetes” established in Prague, Czech Republic

Hypertension in diabetes is a widespread and important cardiovascular risk factor, especially for cardiovascular disease in type 2 diabetes and for nephropathy in both type 1 and type 2 diabetes. A few years ago, the European Association for the Study of Diabetes (EASD) initiated a Study Group “Hypertension in Diabetes” to increase awareness and research efforts from the perspective of diabetes specialists.

The contact person for this organization is its secretary, Dr. John Petrie, Glasgow, UK (e-mail: jrpls@clinmed.gla.ac.uk).

More recently, a similar approach was undertaken by the European Society of Hypertension (ESH) in establishing a similar Working Group “Hypertension in Diabetes”, that was officially started at a first meeting in Prague on June 28, 2002. The EASD Hypertension in Diabetes Study Group organized a well-attended symposium “Evidence-based Diabetology: the case for anti-hypertensive treatment” on Sep-

continued on page 2

Contents

| Blood pressure measurement devices – issues of accuracy and quality monitoring | 1 |
| Interview with Dr. Mieke |
| WHL News |
| New Hypertension in Diabetes Working Group |
| New Websites |
| People |
| Calendar | 4 |
Interview continued

A major improvement in blood pressure control among patients is the self measurement. Most of these devices are automated oscillometric devices. What does a patient have to consider when buying a BP measuring device?

Dr. Mieke: Automated oscillometric devices are especially suitable for patient self measurement. They are easy to operate and due to the automated deflation rate, sources of measurement error are reduced. However, due to the measurement principle, which involves detection of pulse wave oscillations and determination of corresponding BP values via certain algorithms—some limitations have to be taken into account. In patients with arrhythmia, for example, no reliable BP measurement with oscillometric devices is currently possible. Therefore, before buying a BP device, the patient should consult a physician to determine whether he or she has an arrhythmia. If the pulse is regular, an automated oscillometric device is suitable.

Are there alternatives to oscillometric devices in case they are not suitable?

Dr. Mieke: Yes, there are some semi-automated devices available that use a microphone in the cuff for the detection of the Korotkoff sounds and transform the sound into the blinking of a lamp. Systolic BP is determined when the lamp starts blinking and diastolic BP when it stops blinking. Therefore, the patient does not have to learn the auscultation of the Korotkoff sound.

What should be taken into consideration when choosing between upper arm or wrist devices?

Dr. Mieke: In principle, there are devices of equal quality on the market for both measuring sites. It has to be noted, however, that only the best of the wrist devices reach the quality of upper arm devices. In my view, one important issue makes upper arm devices superior to wrist devices. Considerable measurement error is introduced when the BP measurement is not taken at heart level. The hydrostatic pressure strongly influences blood pressure values; for example, a measurement taken on a hanging hand is not representative. To give you a concrete idea of this effect; a 5 cm distance change from the heart level results in a 4 mmHg BP value change.

Indepedent of the measurement principle, what else should the buyer look for in terms of device quality?

Dr. Mieke: A BP measuring device should have a label guaranteeing that it fulfills minimum standards. For example, in the European Union all BP devices on the market have to carry the CE mark indicating the fulfillment of certain quality criteria. In addition, national organizations like the British or the German Hypertension Society have developed additional benchmarks with which they endorse BP measuring devices. Finally, consumer organizations evaluate the quality of BP measuring devices which might help in the decision regarding which model to buy.

Once a BP measuring device has been bought and used, how can a patient make sure that the device is still working correctly?

Dr. Mieke: An important sign of inappropriate functioning of a BP measuring device is a sudden and large change in obtained BP values. If possible, the device should be taken to the manufacturers service station. Alternatively, one could compare the physician's measurement (auscultation method) with that obtained with the machine. This can be done either simultaneously (for upper arm devices as long as the deflation rate remains below ca. 3 mmHg/s) or sequentially with about 30 seconds waiting period between measurements. Ideally, three consecutive measurements should be performed and the difference between physician and automated device should not exceed 10 mmHg in both systolic and diastolic BP. Even if the device is working well a check should be performed every 5 years.

Do these rules apply to all regions of the world or are there further requirements for regions with a special climate?

Dr. Mieke: This is an important question. Like many other medical devices, BP measuring devices might suffer in humid climates. In particular, air leakage of the devices might be affected. Therefore, attention should be given to the deflation rate. According to WHO instructions for BP measurements, the deflation rate should be 2-3 mmHg/second for auscultatory measurements and oscillometric devices often have higher rates (about 5 mmHg/s). A significant increase in deflation rate could be a sign of malfunctioning. This can be easily checked by comparison with an identical, but unused device or by comparison with the manufacturer's specifications.

You have mentioned the European and US-American standards for blood pressure measuring devices. Does this mean that different quality criteria exist?

Dr. Mieke: Unfortunately, yes. To my knowledge, there are about six standards for the clinical testing of BP measuring devices that are
Interview continued

applied in different regions of the world as well as numerous national standards. Although these standards are similar to each other, they differ in certain aspects. It would be advantageous for manufacturers and consumers to have uniform performance standards. Therefore, we have taken the initiative to develop an ISO (International Standardization Organization) standard. This would ensure that equal criteria for evaluating BP devices would be applied worldwide.

How long will it take until this international norm has been developed?

Dr. Mieke: First drafts are planned to be circulated in 2003. The final version can be expected in 2005/2006 depending on the discussion.

What is specified in such a standard?

Dr. Mieke: Besides technical specifications, the validation procedure and the range of acceptable measurement differences in comparison to the reference measurement will be the main focus of the ISO working group. This includes, for example, the minimum number of test persons in a validation trial, their blood pressure, age, etc.

This sounds quite elaborate. Are such efforts really necessary?

Dr. Mieke: Yes, because measurement accuracy in BP measuring devices is a prerequisite for the detection and the control of hypertension. Unreliable or biased measurements might lead to unnecessary drug treatment or under-treatment. Given the severe health consequences of high blood pressure, every effort should be made to achieve effective prevention or treatment. The technical equipment is one aspect in this context, the correct application of the devices is another equally important issue.

Dr. Mieke, thank you very much for this valuable information.

Dr. S. Mieke is Head of the Section Measurement of Blood Pressure and Flow in Medicine at the National Institute of Natural and Engineering Science (PTB), Germany. e-mail: stephan.mieke@ptb.de

Anja Kroke
Editor

New Working Group established continued

tember 4, 2002, at the EASD meeting in Budapest, with participation by R. Cifkova, Czech Republic, C. Berne, Sweden, Moti Ravid, Israel, Jan E. Staessen, Belgium, and Peter Nilsson, Sweden as chairman.

The contact persons are Dr. Peter Nilsson, University Hospital, Malmö, Sweden and Dr. Renata Cifkova, Prague, Czech Republic.

A proposal has been made that these two related groups should have joint activities in order to bring specialists from the diabetes field and the hypertension field together for scientific discussions. The aim of these activities should ideally be to promote knowledge and clinical skills related to hypertension detection and control in diabetes, but also to promote an increased understanding of pathophysiology. During 2003, both the EASD and the ESH groups will organize a meeting, where a member from the other group will be invited to increase cooperation. The next meeting of the ESH Working Group will be held in association with the ESH meeting in Milan, Italy, in June 2003.

Anybody who is interested in joining either of the two groups is welcome to get in further contact, preferably by e-mail:

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New Websites

The Hypertension & Obesity Initiative is now available on the WHL website at www.mco.edu/whl. Contact can be made with the e-mail address: whlsec@mco.edu.

For more information about The United States Healthcare Directory, please visit the website www.national-directories.com or contact Barbara Caldwell (Caldwell@n-d.com).
People

Dr. Emma Schwedt was elected new President of the Uruguyan League against Arterial Hypertension, Cnel. Brandzen 1961 of. 307, C.P. 11200 Montevideo, Uruguay.
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In April 2002, Dr. Won-Ro Lee was elected president and Dr. Jong-Hoa Bae chairman of the Korean Society of Hypertension. The address is: Kyung Hee University Hospital, Seoul 130-702, Korea.
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Fax: (+82) 2-962-6638
E-mail: jhbae120@yahoo.com

Calendar

2nd Genova Meeting on Hypertension, Diabetes and Renal Diseases
February 28–March 1, 2003
Genova, Italy
Information: Ms. Barbara Rossi c/o Aristea
Fax: (+39) 010 553 1544
E-mail: rossi@ariste.com

13th Biennial Congress of the Southern African Hypertension Society
March 7–9, 2003
Johannesburg, South Africa
Information: SAHS,
Dr. Vicki Pinkney-Atkinson
PO Box 122, River Club,
South Africa 2149
Fax: (+27) 11 706 4915
E-mail: sahs@mweb.co.za

13th Congress of the European Society of Hypertension
June 13–17, 2003
Milan, Italy
Information: Dr. Guiseppe Mancia;
University of Milano-Bicocca, San Gerardo Hospital, Dept. of Clinical Medicine
Via Donizetti, 106
I-20052 Monza-Milan, Italy
E-mail: guiseppe.mancia@unimib.it
AIM Organizing Secretariat
E-mail: esh2003@aisc.it

18th Annual International Interdisciplinary Conference on Hypertension
June 22–25, 2003
Accra, Ghana
Information: ISHIB, 2045, Manchester Street,
NE, Atlanta, GA 30324-4110, USA
Fax: (+1) 404 875 6334
E-mail: ishib2003@ishib.org

3rd Asian-Pacific Congress of Hypertension
September 28–October 1, 2003
Information: Dr. Tek-Siong Chee
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The WHL is a division of the International Society of Hypertension (ISH), and is in official relations with the World Health Organization (WHO).
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