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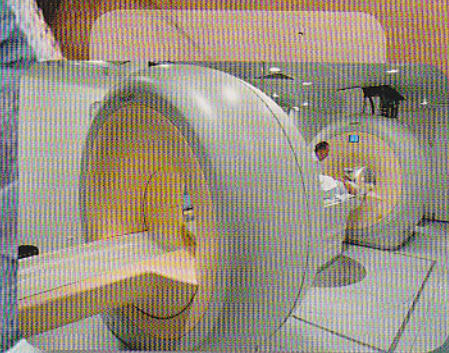
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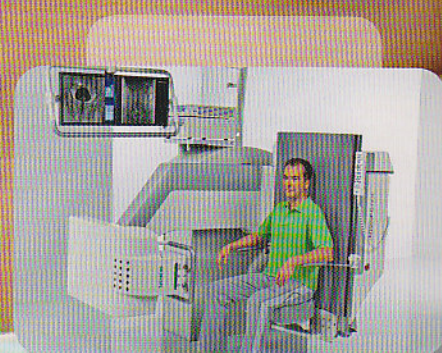
- Validation of blood pressure monitors
- Continuous StO_2 monitoring in goal-oriented ICU resuscitation
- Novel radiolabelled probes for imaging tumour angiogenesis
- Internal radionuclide dosimetry



Ultrasound imaging
with elastography
Page 32



Combined PET-MRI
Page 33



Urology work station
Page 34

ESH-IP for the validation of blood pressure monitors: a success story and its future

The validation of blood pressure monitors is an important prerequisite for the accurate measurement of blood pressure. In the last decade the European Society of Hypertension International Protocol (ESH-IP) has expanded the device validation procedure worldwide by three to four-fold compared to the period before its original publication in 2002 and is now the preferred validation protocol. In keeping with improvements in device technology, the International Protocol was revised, in 2010 and imposes stricter requirements for device accuracy.

by Dr G.S. Stergiou, Dr N Karpelias, Dr N Atkins and Dr E. O'Brien

Blood pressure measurement and protocols for device validation

Blood pressure measurement is widely used across the healthcare system, by clinicians of almost all specialties, nurses, medical assistants and even patients themselves. People with high blood pressure generally have their blood pressure measured in the office or clinic and because of the phenomenon of "white coat hypertension", such measurements are often falsely elevated, so 24-hour ambulatory blood pressure monitoring and/or self-monitoring by patients at home is often recommended [1]. In all cases, the accuracy of the blood pressure monitor is therefore an important prerequisite for the reliable assessment of the level of blood pressure so as to enable the accurate diagnosis of high blood pressure and to enable reliable decision making and long-term drug treatment [1].

In 1987 the US Association for the Advancement of Medical Instrumentation (AAMI) published the first protocol for formal validation of all blood pressure monitors against the mercury standard [2]. This was followed in 1990 by the British Hypertension Society (BHS) protocol [3] and revised versions of these protocols were published in 1993. In 2002, the European Society of Hypertension Working Group on Blood Pressure Monitoring published the International Protocol (ESH-IP) for the validation of blood pressure monitors [4]. The ESH-IP was developed on the evidence of a large number of validation studies performed using the AAMI and BHS protocols. The purpose of developing the ESH-IP protocol was to simplify the validation procedure and reduce the sample size required without losing the evaluation accuracy of the previous more complicated, cumbersome and costly protocols. In the rapidly expanding market

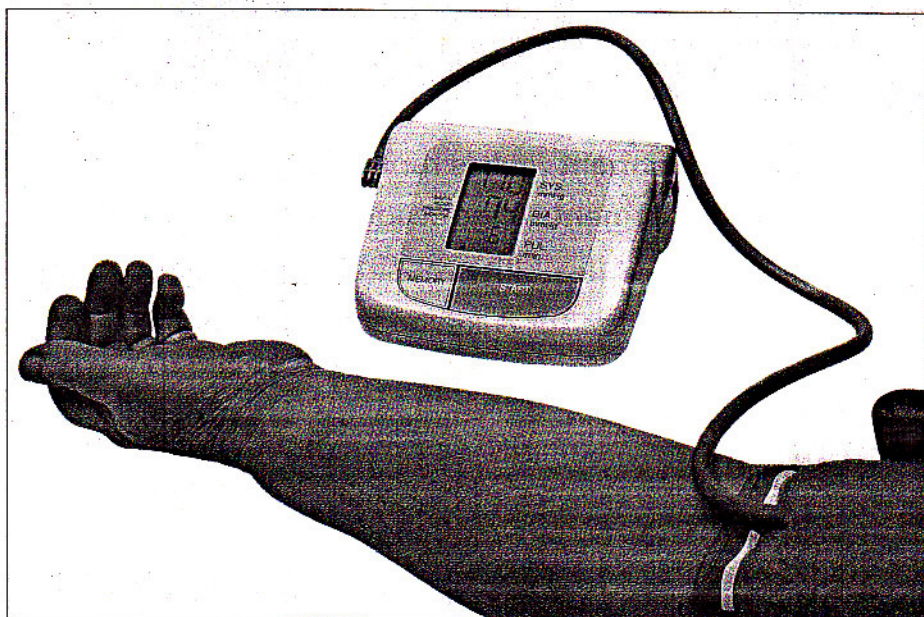
of blood pressure monitors for home, ambulatory and office measurements, it was anticipated that such a simplified protocol would facilitate greater use of the validation procedure by more centers throughout the world, thereby facilitating independent validation of greater numbers of devices.

Application of the ESH-IP for device validation (2002-2009)

A systematic review of the use of the ESH-IP for validating blood pressure measuring devices was recently performed [5]. The review covered the number of reported validation studies

(compared to the use of other protocols), the main study results, the performance in following the protocol's requirements and criteria, the problems in data reporting, the issues within the protocol that might need modification or clarification, and the impact of applying more stringent validation criteria. This analysis, which relies on data from 104 validation studies conducted using the protocol between 2002 (ESH-IP publication) and 2009, forms the basis for the recommendations in the revised ESH-IP [5].

According to the systematic review, within 8 years after the publication of the ESH-IP there were 48 studies reported using the BHS protocol, 38 using the AAMI and 104 using the ESH-IP [5]. In particular, between January 2007 and June 2009, 29 studies have been reported using the BHS and/or the AAMI protocols compared to 67 using the ESH-IP [5]. Thus, it appears that the ESH-IP has succeeded in expanding the validation procedure worldwide by three to four-fold compared to the period before its publication [5] and now is the preferred validation protocol. A total of 26 different research groups performed ESH-IP studies and evaluated devices from 32 different manufacturers [5].



Whether a blood pressure monitor is designed for use by a healthcare professional or by the patient himself, it is vital that the monitor be validated. The European Society of Hypertension International Protocol (ESH-IP) is now the most widely used protocol for BP monitor validation. The 2010 revision to the protocol tightens the validation criteria

ESH-IP validations have been conducted in 18 countries, the vast majority of them in Europe (70%), with some in the USA, in China and elsewhere [5]. Of these studies, 80% validated oscillometric devices, 80% upper arm devices (the rest being wrist devices); 65% of devices were designed for self-home monitoring, 20% were professional devices for office/clinic use and 15% were for ambulatory blood pressure measurement [5].

Interestingly, the proportion of the reported validation studies that fulfilled the ESH-IP criteria is impressively high (85%) [5]. This success might reflect improved accuracy of devices due to advancement in technology. However, other reasons are possible, such as a publication bias whereby negative studies are not published, and that the ESH-IP criteria are too easy to fulfil and need to be made more stringent.

There were also problems in conducting and reporting some of the ESH-IP validation studies that make the interpretation of the results rather questionable. A total of 21 different types of violations of the ESH-IP were detected, appearing 33 times and involving 23 studies [5]. Twenty per cent of the violations were regarded as major (affecting the protocol integrity, requirements and stringency of criteria), whereas the rest were minor with negligible impact [5]. Some of the studies did not provide a complete report of recruited and excluded subjects and others did not report the cuff sizes used, particularly for observer measurements. These findings suggest that a more standardized report of the validation study results is necessary.

With the aim of determining which of the ESH-IP validation criteria were easily passed by the currently available accurate devices and which were only marginally passed, several 'arbitrarily chosen' changes in all the validation criteria of the protocol were tested [5]. The impact of applying these arbitrary criteria on the evaluation of devices that had passed the ESH-IP in published validation studies was also investigated and helped to decide on which criteria to tighten in the revision of the ESH-IP.

ESH-IP revision 2010

On the basis of these analyses a revised version of the protocol was published in February 2010 [6]. There are several changes in the revised protocol, regarding participants' age, blood pressure limits for inclusion, distribution of observer blood pressure measurements and validation results reporting [6]. However, the most challenging change is the tightening of the validation criteria for the pass level. It has been estimated that about one third of validations that passed the ESH-IP 2002 will not satisfy the criteria of the revised ESH-2010 (Stergiou G, *et al.* unpublished data 2010). Thus, the

application of the revised ESH-IP is expected to more than double the validation fail rate.

Indeed it appears that time has come to increase the level of minimal accuracy requirements for device approval. First, 85% of the devices tested so far using the ESH-IP have been successful [5], implying an improvement in current technology of blood pressure monitors (although as mentioned above a publication bias cannot be excluded). Second, a recent analysis of successful ESH-IP validation studies showed a trend towards an improvement in accuracy of the electronic devices in the period between 2002-2010, as assessed by their performance in passing several validation criteria (Stergiou G, *et al.* unpublished data 2010).

Conclusions

Eight years after its publication, the ESH-IP has proven to be successful in achieving its goals. The large number of published studies, devices tested, and investigators involved indicate that the protocol has succeeded in expanding the validation procedure worldwide by three to four-fold compared with the period before its initial publication. However, there is a need to tighten the accuracy criteria so as to encourage the manufacture of better devices and there is also a need to improve the validation methodology by standardizing the reporting of validation studies. These issues have been successfully addressed in the 2010 revision of the ESH-IP.

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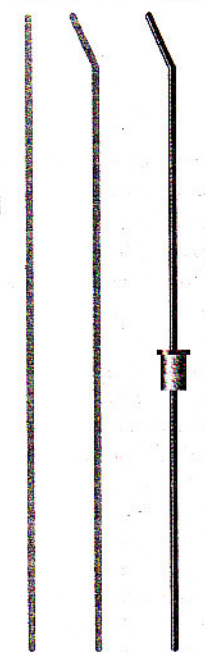
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