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Indiaâ??s Home BP Monitoring market faces accuracy gap: Only 15% of devices clinically validated

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A study of 357 blood pressure monitoring devices available across India found that only 55 were clinically validated, highlighting a major challenge for the growing home blood pressure monitoring market. Experts call for wider access to validated devices and greater patient awareness to strengthen hypertension management



India's home blood pressure monitoring (HBPM) market faces a significant challenge in ensuring device accuracy, with only 15 per cent of the 357 blood pressure monitoring devices available in the country found to be clinically validated. The findings highlight the need for stronger quality assurance, improved consumer awareness and wider adoption of validated monitoring devices as India seeks to strengthen hypertension detection and management.

Presenting the findings during an academic session at Sri Chamundeshwari Medical College, Hospital & Research Institute (SCMCH&RI), Karnataka, Dr Noriko Matsushita, Senior Manager, Global Medical Affairs, Omron Healthcare Singapore Pte. Ltd. (Asia-Pacific Regional Office), and Visiting Assistant Professor (Honorary), Sardar Patel Institute of Medical Education and Health Science, highlighted the growing importance of home blood pressure monitoring in preventive healthcare.

The research involved an assessment of blood pressure monitoring devices available through online platforms and retail pharmacies across 16 Indian states. Of the 357 devices identified, only 55 were found to be clinically validated, indicating that the majority of devices available in the market lacked confirmed clinical validation.

“Total 357 devices are available in India, across India. Then only 55 devices are clinically validated. So we need to say only 15 per cent of the devices are clinically validated,” said Dr Noriko Matsushita.

She emphasised that consumers and healthcare professionals should prioritise clinical validation rather than choosing devices based solely on price or brand reputation. The recommended option is an automatic upper-arm cuff monitor that has undergone clinical validation to establish its measurement accuracy against accepted reference methods.

“Even cheap or expensive, doesn't matter. Clinical validated device is most important for the accuracy,” she said.

Home monitoring critical to hypertension management

Dr Noriko Matsushita highlighted the limitations of relying exclusively on blood pressure readings taken during hospital or clinic visits. While office blood pressure measurement is performed by trained healthcare professionals, it captures a patient's blood pressure only at a particular point in time. Home monitoring, in contrast, enables patients to measure their blood pressure regularly, including in the morning and evening, providing a more comprehensive picture of blood pressure variations.

Blood pressure fluctuates throughout the day and can be influenced by several factors, including stress, salt consumption, seasonal changes and the time of measurement. These variations can complicate hypertension diagnosis and treatment decisions when clinicians depend only on occasional clinic readings.

She explained the importance of identifying two conditions: white-coat hypertension, in which blood pressure is elevated in a clinical setting but remains normal at home, and masked hypertension, in which clinic readings appear normal despite elevated blood pressure at home. Masked hypertension is particularly concerning because patients may remain undiagnosed or may not receive appropriate treatment.

The importance of combining clinic and home readings was evident in a clinical study involving nearly 1,600 hypertension patients across India, including Karnataka. According to the findings presented, 78 per cent of patients appeared to have controlled blood pressure based on clinic measurements. However, when both clinic and home blood pressure readings were considered, the proportion with controlled blood pressure declined to 56 per cent.

“This gap is 21.8 per cent,” she said, highlighting the difference between clinic-based assessment and actual blood pressure control at home.

The study also found that only 44.4 per cent of the hypertension patients surveyed had a blood pressure monitoring device at home. This points to another gap in India's hypertension management ecosystem: access to home monitoring remains limited even among people already receiving treatment.

Device validation and patient education

Addressing the challenges faced by consumers in selecting appropriate devices, she referred to India's home blood pressure monitoring guidelines, which recommend validated automatic upper-arm cuff devices. With a wide range of products available through pharmacies and e-commerce platforms such as Amazon and Flipkart, patients often find it difficult to distinguish clinically validated devices from those whose accuracy has not been established.

She advised healthcare professionals to educate patients about checking product packaging for clinical validation information and selecting devices that meet established accuracy requirements.

Clinical validation involves comparing the performance of an automatic blood pressure monitor against an accepted reference measurement method under standardised testing protocols. Such studies assess accuracy across different population groups and measurement conditions.

The findings point to an opportunity for India's medical device industry to expand the availability of clinically validated blood pressure monitors while strengthening patient and healthcare professional awareness. For manufacturers, improving access to validated devices and making reliable information about device accuracy readily available could become important differentiators in an expanding home healthcare market.

As hypertension continues to pose a major public health challenge, the next phase of India's home blood pressure monitoring market will depend not simply on increasing device ownership but on ensuring that patients have access to accurate monitors and are educated on their correct use.

Narayan Kulkarni

(narayan.kulkarni@mmactiv.com)