Importance of performance assurance in shock wave therapeutic devices

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Extracorporeal shock wave therapy (ESWT) is adopted as an innovative treatment in chronic musculoskeletal pain management as well as cardiovascular diseases, and its clinical efficacy is dose dependent. Although its unified definition is not available yet, the shock wave dose would be a quantity derived from combination of acoustic exposure parameters weighted on their therapeutic effects. Energy flux density (efd) is used as the most popular acoustic exposure parameter in ESWT and is expected to be a critical measuring parameter in shock wave dosimetry. In order to deliver a prescribed shock wave exposure in clinical practice, we have to ensure that the acoustic outputs ESWT devices produce is the same as the output settings doctors prescibe. Our survey shows that there are extremely large differences in the acoustic outputs from the domestic ESWT devices approved by MFDS for virtually the same clinical indications. For instance, the focal efd varies from 0.0035 to 35 mJ/mm2 in the focused ESWT devices, while it was different by up to 75 times among ballistic ESWT devices at their maximum output settings. The large variablity may be due to incomplete or unclear criteria on the acoustic exposure to a target clinical indication for clinical approval as well as authorized laboratories for testing the shock wave exposure not readily available. In order to assure the therapeutic efficacy & safety, the ranges of the acoustic exposure optimized to each clinical indication should be provided. Since the shock wave production employed in ESWT suffers from inevitable variability and the acoustic output deteriorates with the duration of operating time, the post-approval surveillance currently focused on adverse effects needs to be revised to include performance assurance in clinical ESWT devices.