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PRESS RELEASE

NEW PUBLICATION ASKS - "IS IMPEDIMED BIS TECHNOLOGY THE NEW GOLD STANDARD MEASURE FOR AIDING IN THE CLINICAL ASSESSMENT OF LYMPHOEDEMA?"

A Clinical Review in the latest edition of the Journal of Lymphoedema¹ has proposed that bioimpedance spectroscopy (BIS) be adopted as a reference method for the clinical assessment of lymphoedema, noting that BIS is well positioned with respect to criteria commonly used to establish a reference method, such as specificity, accuracy, precision, repeatability, sensitivity and practicability.

The review follows numerous recent publications in the area of clinical assessment of lymphoedema^{2, 3, 4, 5, 6, and 7}, the majority of which used BIS as their assessment tool, providing a compelling argument for its use as an aid in early detection.

According to the review, "A convincing argument can be made that on theoretical grounds, analytical and technical accuracy and precision and practicality in use, impedance technology is the method of choice when compared to competing technologies. The case is well made for its adoption for the assessment of lymphoedema post-breast cancer treatment. It should be acknowledged that impedance ratios, in common with the other assessment modalities, should not be considered as providing the definitive diagnostic criterion. "

Associate Professor Leigh Ward, who authored the review said, "The continued use of outmoded methods such as calculating limb volumes from tape measurements does the patient at risk of developing lymphoedema a disservice. Such methods lack the sensitivity and specificity required of a diagnostic technology. The benefits of early detection for better patient management are clear. The marriage of BIS technology for early detection of lymphoedema with early intervention can only but lead to better patient outcomes."

ImpediMed CEO Greg Brown said, "This publication is further support for the use of BIS for aiding in the clinical assessment of lymphoedema. Awareness of pre-surgical assessment, education and ongoing surveillance is growing, and ImpediMed is well positioned to offer the first FDA cleared device to help aid in pre-emptive care with its L-Dex[®] devices. With the upcoming MEDCAC meeting we hope this Clinical Review adds support to an already established list of peer reviewed papers for the use of ImpediMed technology (BIS)."

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2. Ward, L.C., S. Czerniec, and S.L. Kilbreath, *Operational equivalence of bioimpedance indices and perometry for the assessment of unilateral arm lymphedema*. Lymphat Res Biol, 2009. 7(2): p. 81-5
3. Hayes, S., et al., Lymphedema secondary to breast cancer: how choice of measure influences diagnosis, prevalence, and identifiable risk factors. Lymphology, 2008. 41(1): p. 18-28
4. Stout-Gergich N, Washington F, Pfalzer L, Soballe P and McGarvey C , Preoperative assessment enables the early diagnosis and successful treatment of lymphedema., Cancer, Vol 112, pp 2809-2819, June 2008.
5. Hayes, S.C., et al., Lymphedema after breast cancer: incidence, risk factors, and effect on upper body function. J Clin Oncol, 2008. 26(21): p. 3536-42
6. Ward LC, Czerniec S, Kilbreath SL, Quantitative bioimpedance spectroscopy for the assessment of lymphedema. *Breast Cancer Res Treat* 2008 117(3): 541–7
7. Ward LC, Kilbreath SL, Cornish BH, Bioelectrical impedance analysis for early detection of lymphoedema. In: Weissleder H, Schuchhardt C, eds. *Lymphedema Diagnosis and Therapy*. 4th edn. Viavital Verlag GmbH Publ, Essen: 2008 ,Chap 15, 502–17

L-Dex[®] is a trademark of ImpediMed Limited.

“ L-Dex[®] values that lie outside the normal range may indicate the early signs of lymphoedema and values that have changed +10 L-Dex units from baseline may also indicate early lymphoedema. The L-Dex scale is a tool to assist in the clinical assessment of lymphoedema by a medical provider. The L-Dex scale is not intended to diagnose or predict lymphoedema of an extremity”.

About ImpediMed

ImpediMed Ltd. is the world leader in the development and distribution of medical devices employing Bioimpedance Spectroscopy (BIS) technologies for use in the non-invasive clinical assessment and monitoring of fluid status. ImpediMed's primary product range consists of a number of medical devices that aid surgeons, oncologists, therapists and radiation oncologists in the clinical assessment of patients for the potential onset of secondary lymphoedema. Pre-operative clinical assessment in breast cancer survivors, before the onset of symptoms, may prevent the condition from becoming a lifelong management issue and thus improve the quality of life of the cancer survivor. ImpediMed had the first medical device with an FDA clearance in the United States to aid health care professionals, clinically assess secondary lymphoedema of the arm in female breast cancer patients. For more information, visit. www.impedimed.com.