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ASX ANNOUNCEMENT

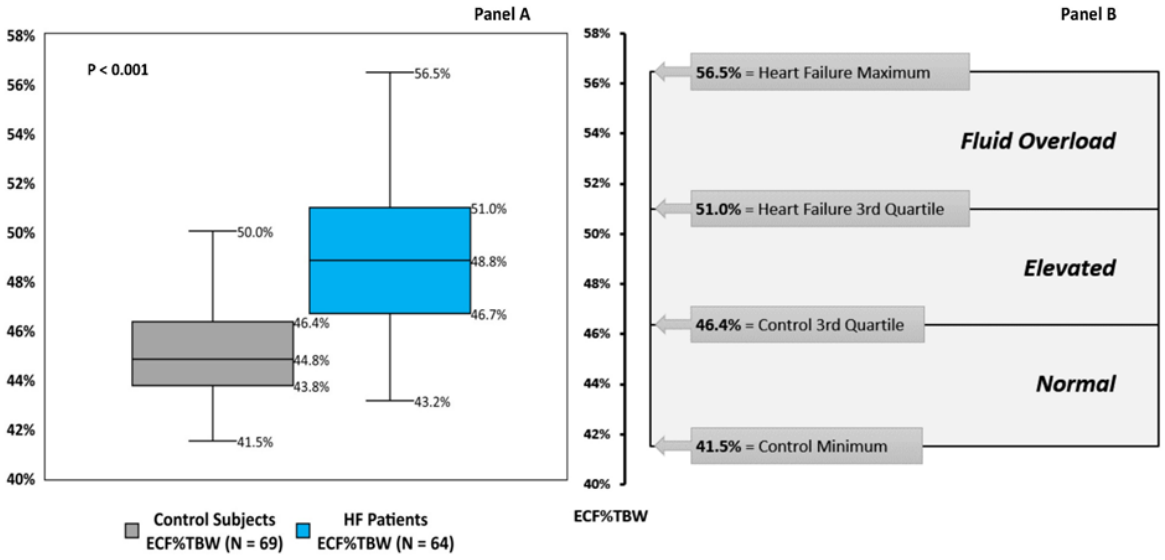
SOZO Clinical Utility in Heart Failure Published

Brisbane, Australia – ImpediMed Limited (ASX.IPD), a medical technology company that uses bioimpedance spectroscopy (BIS) technology to generate powerful data to maximise patient health is pleased to announce that the full peer-reviewed manuscript demonstrating the clinical utility of ImpediMed's SOZO device in monitoring heart failure patients has been published in Frontiers in Cardiovascular Medicine.

The publication, titled Clinical Utility of Fluid Volume Assessment in Heart Failure Patients Using Bioimpedance Spectroscopy, describes the BIS-derived HF-Dex™ values, Extracellular Fluid expressed as a percentage of Total Body Water (ECF%TBW), in a clinically relevant way that can be used by physicians to aid in clinical risk stratification and fluid volume monitoring of heart failure patients.

The following results were noted:

1. ECF%TBW was significantly higher for the Heart Failure population as compared to the Control population (49.2 ± 3.2% versus 45.2 ± 2.1% respectively: p<0.001)
2. Interquartile ranges did not overlap (46.7 to 51% versus 43.8 to 46.4%, respectively: p<0.001).
3. BIS measurements correlated with inferior vena cava size (correlation -0.73, p<0.0001).
4. No healthy subject's ECF%TBW exceeded the 51% threshold for fluid overload.



The paper made the following conclusions:

1. BIS-measured ECF%TBW values were significantly higher in Heart Failure patients as compared to adults without Heart Failure.
2. Three strata of ECF%TBW (normal, elevated and fluid overload) were described that may aid in clinical risk stratification and fluid volume monitoring of Heart Failure patients.
3. As more data is accumulated, the results suggest that BIS measurements may provide a unique additional tool to aid in clinical decision making.

Additionally, the paper outlined the four clinical settings in which SOZO can be used to track fluid volume changes in heart failure patients:

1. Emergency departments (EDs) and urgent care centers,
2. Risk stratifying HF patients at the time of hospital discharge based on the extent of residual congestion,
3. Longitudinal management in clinic and skilled nursing facilities, and
4. Assessing at-risk HF populations for health care managers and chief medical officers.

“While BIS technology has been validated for fluid monitoring, the lack of established reference ranges in heart failure has limited its effectiveness for workflow implementation. The current study illustrates the use of a HF-Dex scale differentiating normal from abnormal extracellular fluid. Identifying subclinical fluid overload would be valuable in risk factor stratification for heart failure patients in the acute and chronic settings,” stated Dr. Andrew Accardi, Emergency Medicine Physician at Scripps Health in San Diego California and first author of the manuscript.

“The use of HF-Dex in BIS shows promise to monitor and follow volume status in heart failure. While the current technology has been in use for lymphoedema, the present study illustrates the potential utility as a tool to aid in clinical decision making for heart failure patients,” Dr. Tom Heywood, Medical Director, Advanced Heart Failure and Mechanical Circulatory Support Program at Scripps Health and senior author of the manuscript.

“We are very pleased with the progress made in Heart Failure through this study and our continued collaboration with Scripps Health. This study is a critical step in obtaining real world evidence for our HF-Dex application. It demonstrates that SOZO can track patient fluid levels and that established normative range data can be useful in risk stratifying patients,” stated Richard Carreon, Managing Director and CEO of ImpediMed.

Frontiers in Cardiovascular Medicine publishes peer-reviewed research articles across cardiovascular medicine. Led by an outstanding Editorial Board of international experts, this multidisciplinary open-access journal provides a unique forum that helps scientists and clinicians to disseminate novel discoveries and technologies widely, advance scientific knowledge rapidly, and propose new paradigms and theories. The Journal covers all aspects of cardiovascular medicine with an emphasis on studies that challenge the status quo of treatments and practices in cardiovascular care or facilitate the translation of scientific advances into the clinic as new therapies or diagnostic tools.

A link to the manuscript can be found here:

http://journal.frontiersin.org/article/10.3389/fcvm.2021.636718/full?&utm_source=Email_to_authors_&utm_medium=Email&utm_content=T1_11.5e1_author&utm_campaign=Email_publication&field=&journalName=Frontiers_in_Cardiovascular_Medicine&id=636718

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About ImpediMed
Founded and headquartered in Brisbane, Australia with US and European operations, ImpediMed is a medical technology company that uses bioimpedance spectroscopy (BIS) technology to generate powerful data to maximise patient health.

ImpediMed produces a family of FDA cleared and CE Marked medical devices, including SOZO® for multiple indications including heart failure, lymphoedema, and protein calorie malnutrition sold in select markets globally.

For more information, visit www.impedimed.com.

About SOZO Digital Health Platform
SOZO, the world's most advanced, noninvasive bioimpedance spectroscopy (BIS) device, delivers a precise snapshot of fluid status and tissue composition in less than 30 seconds. Using ImpediMed's BIS technology, SOZO captures a vast array of data over a wide spectrum of frequencies from 3 kHz to 1000 kHz, which can be used in multiple applications. Results are available immediately online for easy data access and sharing across an entire healthcare system. The FDA-cleared, CE-marked and ARTG-listed digital health platform aids in the early detection of secondary lymphedema, provides fluid status for patients living with heart failure, and can be used to monitor and maintain overall health – all on a single device.

For more information, visit: https://www.impedimed.com/products/sozo/.

About SOZO Fluid Analysis for Heart Failure
The SOZO fluid analysis for heart failure provides an objective measure of fluid overload in heart failure patients. It utilises ImpediMed's HF-Dex™ heart failure index which is a measure of extracellular fluid as a percent of total body water. HF-Dex is presented together with BIS-derived reference ranges for normal fluid volumes, elevated fluid volumes, and fluid overload, which is defined as HF-Dex greater than 51%. When used as part of a clinical assessment of heart failure, SOZO helps differentiate between fluid and tissue-related weight changes to track response to medication changes and to provide a marker for readmission when HF-Dex is higher than 51%.

For more information, visit: https://www.impedimed.com/healthcare/heart-failure/.

Forward-Looking Statements
This announcement contains or may contain forward-looking statements that are based on management's beliefs, assumptions and expectations and on information currently available to management.

All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including without limitation our expectations with respect to our ability to expand sales and market acceptance in the US and Australia including our estimates of potential revenues, costs, profitability and financial performance; our ability to develop and commercialise new products including our ability to obtain reimbursement for our products; our expectations with respect to our clinical trials, including enrolment in or completion of our clinical trials and our associated regulatory submissions and approvals; our expectations with respect to the integrity or capabilities of our intellectual property position.

Management believes that these forward-looking statements are reasonable as and when made. You should not place undue reliance on forward-looking statements because they speak only as of the date when made. ImpediMed does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. ImpediMed may not actually achieve the plans, projections or expectations disclosed in forward-looking statements. Actual results, developments or events could differ materially from those disclosed in the forward-looking statements.