Innovative Approaches to Lymphedema Management in Breast Cancer Patients: Early Detection and Remote Monitoring with a BIA Home-Use Device

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Abstract

Background: Breast cancer, a common occurrence in women is often associated with lymphedema. Patients undergoing surgery present a higher risk of suffering from this disease and often go untreated or are only referred to treatment or follow-up late. Depending on the stage of lymphedema, it may or may not be reversible. This fact emphasizes the importance of early detection.

Objective: The main goal of the study was to assess the feasibility of monitoring cancer patients' fluids using a BIA home device and be able to detect relevant changes, which could agree with the increased risk of developing lymphedema. This remote monitoring by a clinician has not been possible before and a comparable bioelectrical water analyzer device has never been available to patients in the comfort of their homes.

Methods: The study includes adult patients diagnosed with unilateral breast cancer who underwent lumpectomy and/or mastectomy, bilateral mastectomy, and/or reconstruction and were followed for 12 months. Clinic visits every 3 months with the standard of care treatment given by the clinician and daily fluid monitoring with a home-use bioelectrical impedance analyzer device were required for participation.

Results: Preliminary results are presented for eight cases who did not develop lymphedema but showed that daily monitoring with the home device is possible and it aided in the detection of fluid changes due to interventions like radiation or chemotherapy, which typically subside after treatment, versus a permanent fluid increase indicating lymphedema. The daily monitoring empowered patients to take charge of their health, with more than half expressing a desire to continue using the home device beyond the end of the study. A trend of decreased weight and fluids both in the affected (surgical side) and the unaffected arm was observed for all participants.

Conclusions: This case report highlights the necessity of everyday monitoring for breast cancer-related lymphedema (BCRL) patients, particularly for early detection and differentiation of symptoms, improved health, and ownership for cancer patients as well, which should benefit both patients and medical professionals. Clinical Trial: N/A

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Case Report

Innovative Approaches to Lymphedema Management: Early Detection and Remote Monitoring with a BIA Home-Use Device

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Abstract

Background: Breast cancer, a common occurrence in women is often associated with lymphedema. Patients undergoing surgery present a higher risk of suffering from this disease and often go untreated or are only referred to treatment or follow-up late. Depending on the stage of lymphedema, it may or may not be reversible. This fact emphasizes the importance of early detection.
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versus a permanent fluid increase indicating lymphedema. The daily monitoring empowered patients to take charge of their health, with more than half expressing a desire to continue using the home device beyond the end of the study. A trend of decreased weight and fluids both in the affected (surgical side) and the unaffected arm was observed for all participants.
Conclusions: This case report highlights the necessity of everyday monitoring for breast cancer-related lymphedema (BCRL) patients, particularly for early detection and differentiation of symptoms, improved health, and ownership for cancer patients as well, which should benefit both patients and medical professionals.

Keywords: Breast cancer, breast cancer-related lymphedema, lymphedema, early-stage detection, early detection, lymphedema management, bioimpedance analyzer (BIA), Home Body Water Analyzer, remote monitoring, physiotherapy.

Introduction

BCRL is the most common complication arising after breast cancer surgery and treatment, characterized by abnormal swelling post-surgery or even years after treatment [1]. This condition may be managed but not cured once it takes place [2]. Early surveillance allows both risk reduction through therapy interventions and reversal of the earliest ISL Stages 0-1. Statistics show that one in every five women suffers from BCRL, caused by surgery removing lymph fluid circulation and radiotherapy scarring lymph nodes, leading to an imbalance in lymphatic fluid. Early diagnosis and precise evaluation are necessary to minimize edema progression and prevent lymphatic drainage failure. Lymphedema, a chronic condition characterized by lymphatic fluid buildup, which causes swelling can be primary (hereditary or congenital) or secondary (due to trauma like surgery, radiation therapy, or infection). Early diagnosis and management through therapies (manual drainage), compression garments, exercise, and limb elevation help control symptoms and prevent complications [3,4]. Standard clinical practice involves circumferential or volumetric measurements, which occur as often as every month or every 3 or 6 months. Hence, subclinical (not visible) lymphedema, could be missed. Furthermore, despite the growing awareness and prevalence of BCRL, a significant deficit in the breast cancer treatment paradigm for early surveillance of lymphedema remains. Often patients are not referred to therapy proactively but rather reactively once symptoms are already apparent and progressed from Stage 0 to Stage 1 [3, 4, 5].
The InBody BWA ON device uses bioelectrical impedance analysis (BIA) to assess body composition, including hydration levels, fat, and muscle mass, segmentally, which may aid in lymphedema diagnosis. It is easy to use, fast, reproducible, and portable. Bioelectrical impedance devices send low amplitude alternating currents through the body and different frequencies to measure the resistance (i.e. impedance) to the flow of that current in the body water. This way the complete amount of water in the body (TBW – Total Body Water), the water outside the cells (ECW – Extracellular Water), and the water inside the cells (ICW – Intracellular Water) can be found. The ECW/TBW ratio serves as an indication of inflammation or edema (EI – Edema Index). Regular measurements with home-use devices like the BWA ON have not been available before, and they may enable early lymphedema detection and management, reducing healthcare and quality-of-life costs associated with BCRL diagnosed in later stages. Real-time measurements are shared with healthcare providers for customized consultations and prescriptions, evaluation of treatment effectiveness, as well as patient compliance, while also monitoring weight, muscle mass, and body fat percentage, helping prevent and manage lymphedema.

Methods

Subjects:

Eight adult female patients diagnosed with unilateral breast cancer who underwent surgery (resulting in lymph node removal) 1-12 months before study enrollment participated in the study. Participants presented in this initial report were tested at two recognized institutions, REHAB Hospital of the Pacific in Honolulu (Site 1) and Shirley Ryan Ability Lab in Chicago (Site 2). The study protocol was the same for all study sites and was approved by the local IRBs. All participants were consented before being allowed to participate in the study. Table 1 shows detailed demographics, surgery dates, and additional treatment required during the study as this could affect water levels without lymphedema onset.

Table 1. Participants detailed demographics.

ID	AGE (yrs)	Dominant Arm (A/L/R)*	Diagnosis Date	Surgery			SNLB or ALND	Radiation (Y/N)** (B/D)***	Chemo (Y/N) (B/D)
				Site	Date	Type			
BWA-100	66	A	01/24/23	L	01/30/23	lumpectomy	SNLB	Y-B	N
BWA-101	66	R	02/23/23	L	03/21/23	lumpectomy	SNLB	Y-D	N
BWA-102	64	R	02/07/23	L	03/30/23	lumpectomy	SNLB	Y-D	N
BWA-105	52	R	02/20/23	L	03/20/23	lumpectomy	SNLB	Y-D	N
BWA-110	54	R	02/14/23	L	03/10/23	lumpectomy	SNLB	Y-D	N
BWA-112	54	R	04/21/23	L	06/14/23	lumpectomy	SNLB	Y-D	Y-D
BWA-113	52	R	11/19/22	R	08/02/23	lumpectomy	SNLB	Y-D	Y-B
BWA-200	60	R	10/01/22	L	03/10/23	lumpectomy	ALND	Y-D	N

*(A/L/R) Ambidextrous, Left or Right dominance

**(Y/N) Yes/No

***(B/D) Before or During Study

Note: BWA-200 was the only participant to undergo prophylactic mastectomy and reconstruction

Procedure

Clinic visits (5) occurred in month 0 (enrollment) and at 3, 6, 9, and 12 months. Limb volume, bioelectrical impedance (BIA), is measured using a professional device (InBody 770; InBody Co. Ltd., Seoul, Korea, via InBody BWA) that has been used for research and in the clinic [6], range of motion, and QOL assessments (DASH and LLIS) were performed at each visit following the standard of care procedure. The clinician also examined the patient for any visible inflammation and asked if they were experiencing any discomfort. According to all the information, they determined the patient's lymphedema stage from 0 to 2 and recommended follow-up treatment if needed.

To allow each participant to test themselves at home a home-use BIA device, the BWA ON (InBody Co. Ltd., Seoul, Korea, via InBody BWA), was provided to them during their first clinic visit. The clinician helped with the device setup, assisted with the first measurement, and ensured the appropriate phone application (Apple or Google) was installed and working on the patient's phone. The patient was registered and data sharing with their clinic monitoring software was established before they left. Participants measured themselves daily, 30 minutes to an hour after waking up, and after 5 pm, before going to bed. Through the Apple or Google application, participants had access to their body composition (weight, skeletal muscle, fat, and visceral fat level) and their extracellular to total body water (ECW/TBW) ratio levels, and clinicians were able to see their progress remotely as well.

Figure 1. Bioelectrical body water analyzer for home use, BWA ON (InBody Co. Ltd., Seoul, Korea, via InBody BWA)

Figure 1 shows the home device used by participants at home. The black screen indicated when the device had connected to the phone app via Bluetooth and the patient could test. The phone app checked the electrode connections and started the test, showing its progress. Once the test was completed, patients were able to add details about exercise or any issues that may help explain detected changes in fluid levels or share if there was nothing new to report.

Figure 2. [A] Information displayed by the Clinicians software and the patient's Apple phone application [B] ECW/TBW ratio difference between the two arms is shown in graph mode, [C] segmental ECW/TBW ratio is provided (limbs and trunk separately) and other body composition outputs.

Figure 2 shows a screenshot of the information available to participants in the Apple app as well as what the clinicians may see in the computer application to monitor their patients day to day fluid levels.

Results

Previous studies have shown that the prevalence of lymphedema diagnosis among breast cancer surgery patients is expected to be around 21.4% [7], so with eight cases presented in this initial report, only one case of lymphedema (or none), may have developed.

A non-permanent change in water levels was detected in one participant undergoing chemotherapy treatment. Water levels went back to normal once the treatment was completed. This coincides with previous reports of chemotherapy causing temporary swelling [8].

Fluid movement during the day could affect fluid distribution, so this study looked at the ECW/TBW ratio difference between the two arms (affected minus unaffected) in the morning and evening measurements and the inter-limb (ILB) ECW/TBW ratio (affected arm/unaffected arm).

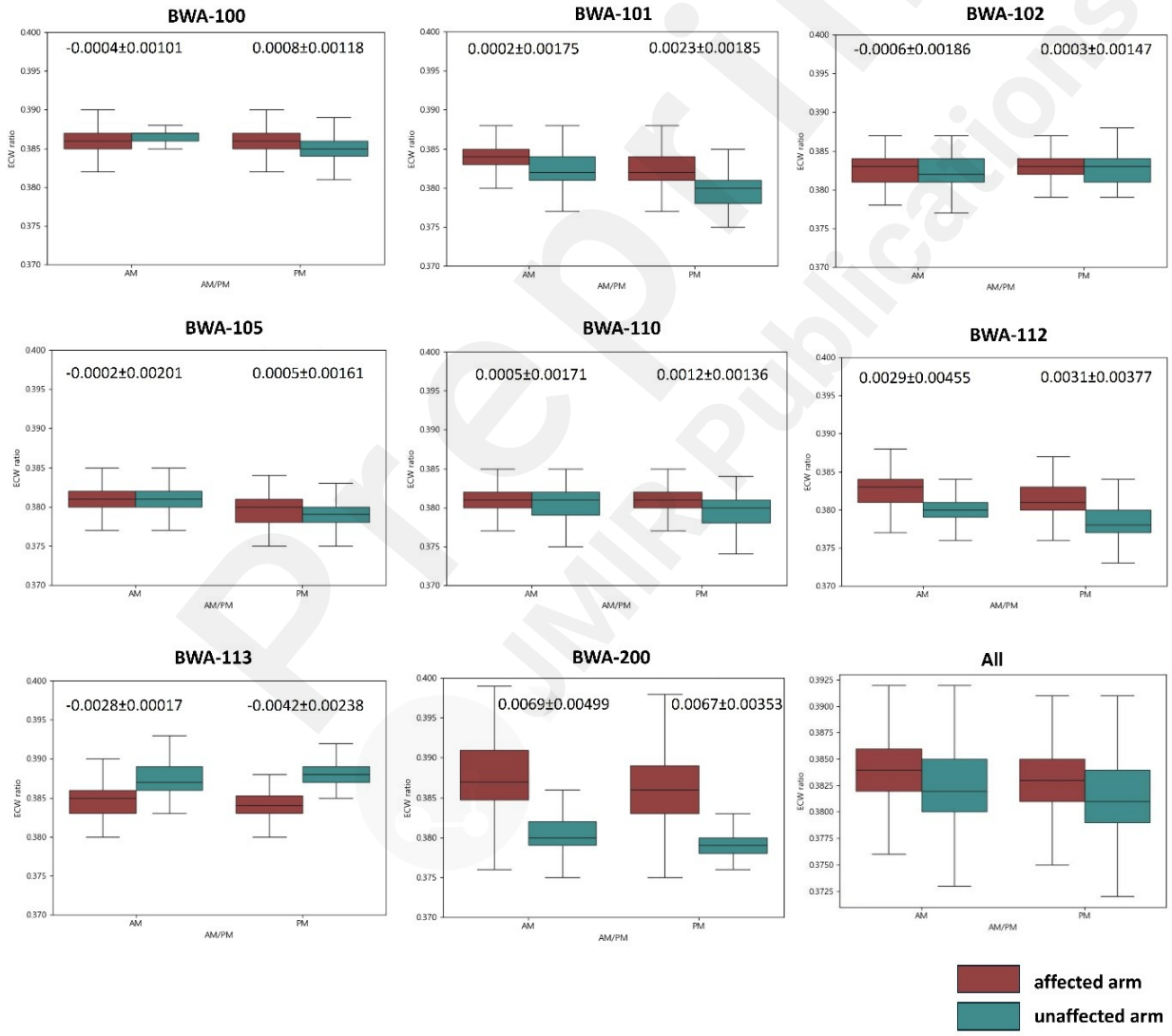

Figure 3. ECW/TBW ratio of affected (red) and unaffected (green) arms for the morning and evening. The average and standard deviation of the difference between them are shown above each time of the day measurement (*p<.03).

The daily measurements of ECW/TBW ratio for the affected arm (red) and unaffected arm (green) were grouped as morning (AM) and evening (PM) measurements in Figure 3, which shows the average and standard deviation of the difference in ECW/TBW ratio between the two arms for each participant at each time of the day. T-tests showed that for all participants except BWA-200, the difference between AM and PM measurements is significant (p<.03). In the future, to reduce the patient burden of taking two daily measurements, the treatment protocol by the healthcare provider should indicate at what time the patient should test themselves and maintain consistency to have the same reference to be able to detect significant fluid changes. For most participants, the (PM) difference is larger, which could be due to fluid movement and distribution during the day.

All participants except BWA-113 show a higher ECW/TBW ratio in the affected arm. BWA-113's diagnosis and surgery occurred in the dominant arm. Lymphedema literature has found different cutoffs for dominant and non-dominant arm's volume, and BIA impedance ratio [6], so this could help explain this result. BWA-100, BWA-102, and BWA-105 show minor differences between the two arms, while BWA-101, BWA-112, BWA-113, and BWA-200 show a larger difference both for AM and PM, and BWA-110 shows a large difference only for PM. BWA-200 shows the largest difference and no significant difference between AM and PM.

As seen in Figure 4, all participants have an inter-limb (ILB) value ($[ECW/TBW_{affected\ arm}]/[ECW/TBW_{unaffected\ arm}]$) larger than '1' at some point, meaning that the ECW/TBW ratio in the affected arm is larger than the unaffected arm. Ideally, the arms are balanced, and the value is '1'. Others have shown this value is related to lymphedema onset [9, 10, 11]. Occurrences of ILB larger than '1' were 75.95% for all eight participants. BWA-101, BWA-110, BWA-112, and BWA-200 show higher percentage (>80%) with BWA-112 being the highest. Treatments during the study (Table 1) could affect fluid levels so this average may not confirm lymphedema but may help determine if those changes are permanent or not. BWA-100, BWA-102, and BWA-113 occurrences are below average. Further analysis is needed to determine if they underwent less radiation/chemotherapy treatment.

Additionally, all participants showed a weight loss trend during the monitoring period, as well as a decrease in the ECW/TBW ratio in both the affected and unaffected arms. Weight gain can also increase the risk of lymphedema and cancer recurrence, and it is common in cancer survivors, so weight monitoring may be an additional benefit for these patients, which could improve their long-term outcomes.

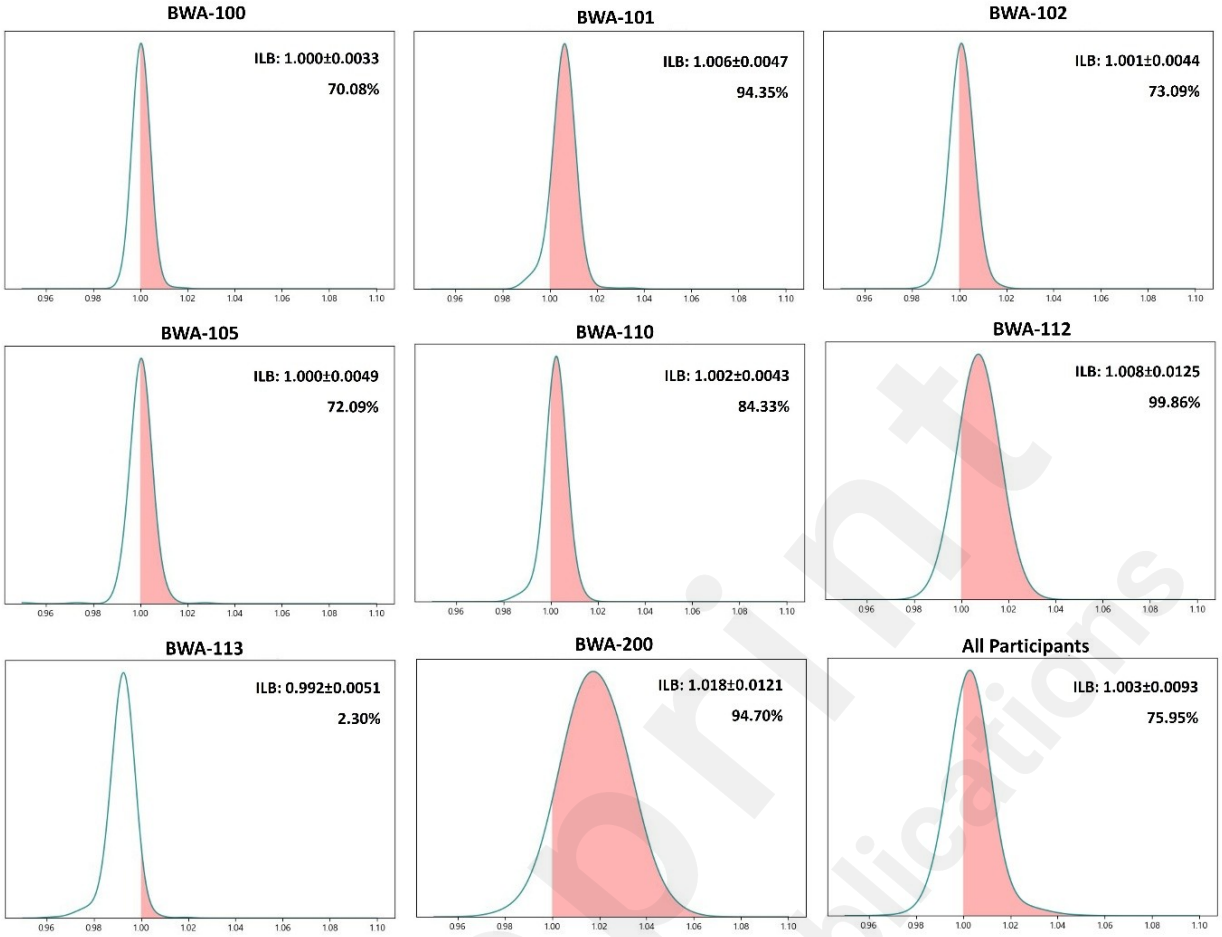

Figure 4. Distribution of the interlimb ratio (ILB) of the ECW/TBW ratio of the affected and unaffected limb larger than ‘1’ (orange). The average and standard deviation and the percentage of times the ratio is larger than 1 are shown.

Discussion

This study aimed to verify whether the BWA ON can aid in detecting BCRL at an early stage. Traditionally, patients visit the hospital every 3 to 6 months for lymphedema assessment. However, daily home monitoring could be meaningful as it could quickly alert patients and clinicians to fluid changes. Cases where treatment led to significant changes in ECW/TBW or considerable differences between the two arms were reported. Possible BCRL was reported, with patients reaching stage zero post-treatment by the end of the study. For BWA-200, monitoring, even without consistent daily tests, allowed the patient to check her body water when she had subjective symptoms, allowing her to manage them. A limitation of the study is the small number of participants at this point which does not allow further analysis as none of them developed

Conclusion

Lymphedema is a well-known disease that is difficult to improve after irreversible symptoms affect quality of life. The ECW/TBW ratio of the upper extremities, measured through BIA, could be an indicator of the development and severity of BCRL [11]. Preliminary data suggests that taking a step further with daily at-home BIA monitoring may aid early detection and prevention by empowering patients as well as clinicians.

Acknowledgments

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Conflicts of Interest

Authors acknowledge that Monica Padilla, PhD is an employee of a US company associated with the parent company InBody, Co. Ltd, where Yoomi Heo, MS is an employee. The parent company manufactures the BIA device used in the study.

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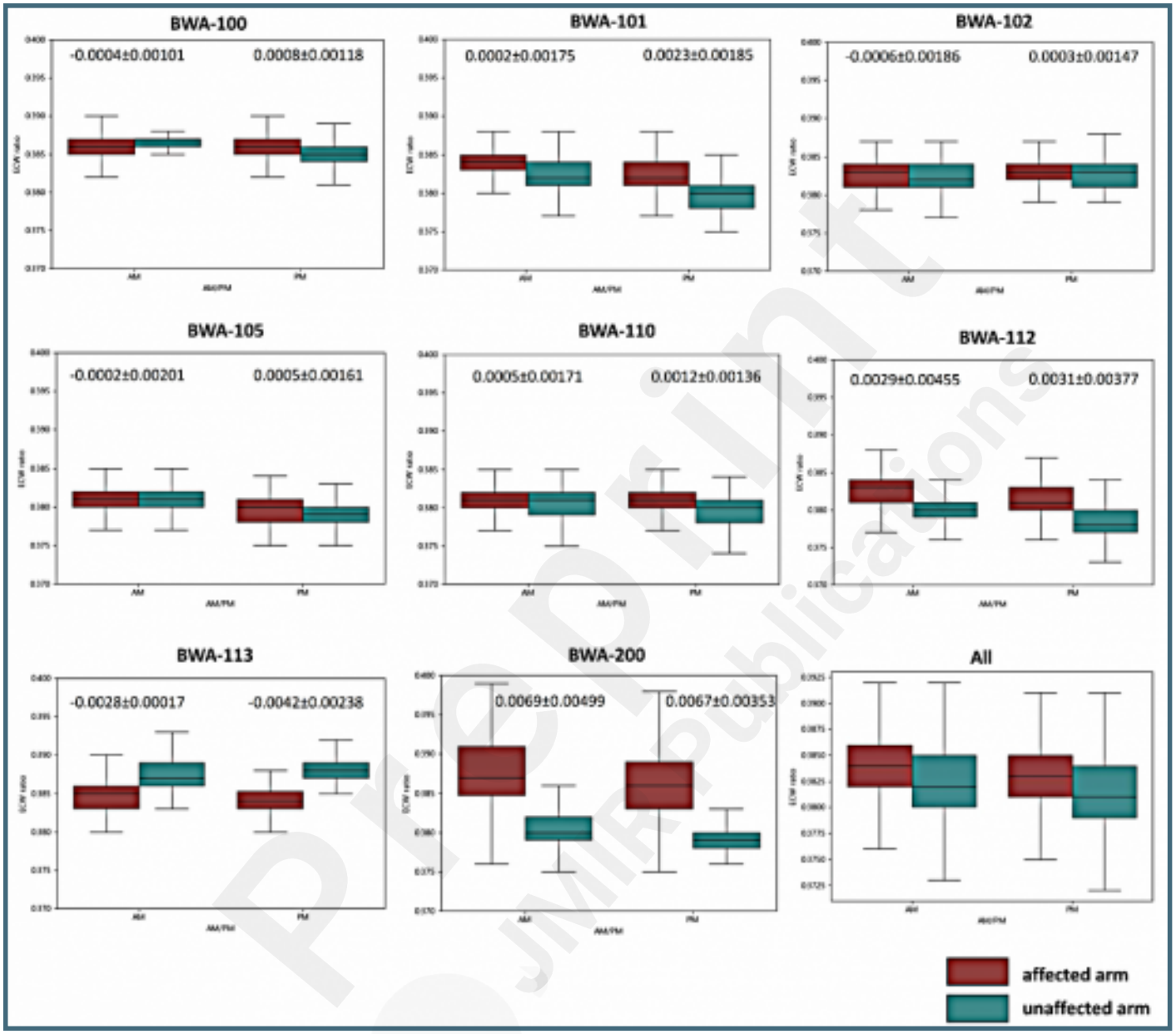
Supplementary Files

Figures

Bioelectrical body water analyzer for home use, BWA ON (InBody Co. Ltd., Seoul, Korea, via InBody BWA).

[A] Information displayed by the Clinicians software and the patient's Apple phone application [B] ECW/TBW ratio difference between the two arms is shown in graph mode, [C] segmental ECW/TBW ratio is provided (limbs and trunk separately) and other body composition outputs.



Distribution of the interlimb ratio (ILB) of the ECW/TBW ratio of the affected and unaffected limb larger than ‘1’ (orange). The average and standard deviation and the percentage of times the ratio is larger than 1 are shown.