

15. Bioelectrical Impedance Analysis (BIA) Procedure

15.1 Introduction

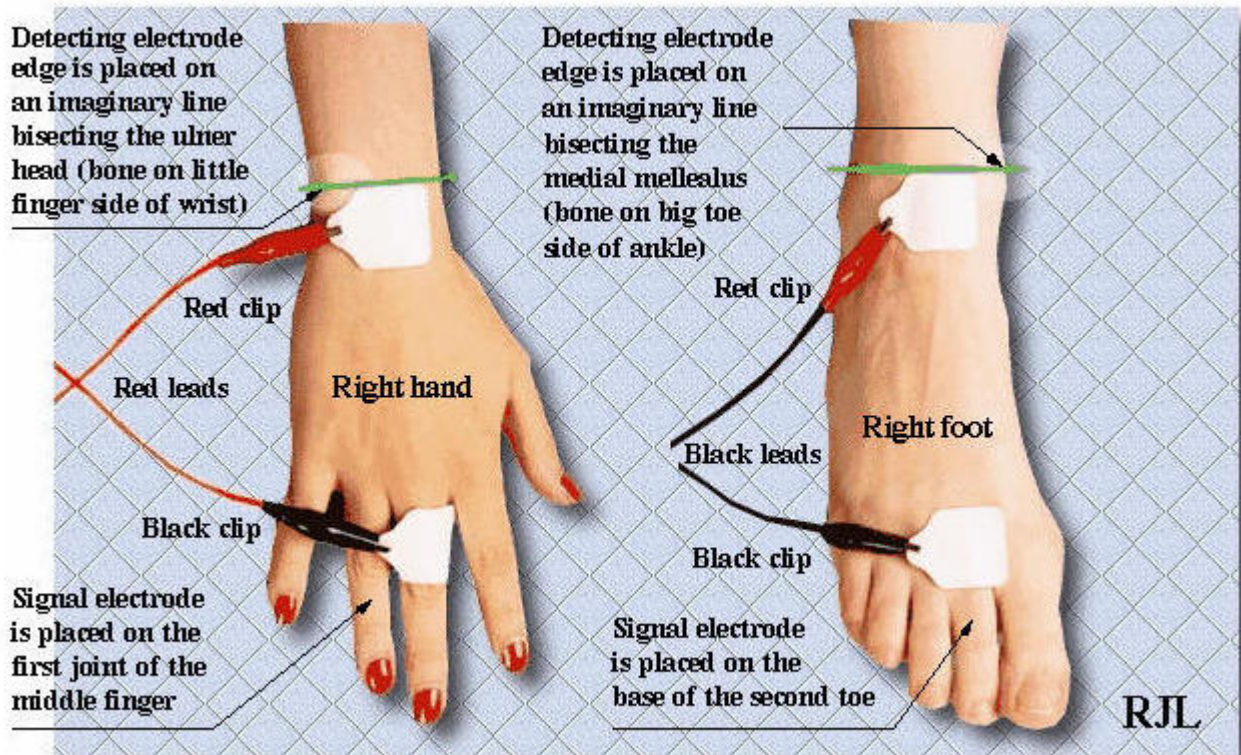
Accurate estimation of body composition and hydration plays an important role in the care of the end stage renal disease patient for a correct prescription of dialysis including ultrafiltration volume. There is interest in non-invasive, simple, and inexpensive techniques capable of estimating fluid content in different body compartments in order to determine the optimum hydration. Bioelectrical impedance analysis (BIA) which is used in nutritional analysis and intervention is considered such a technique.

Single frequency bioelectric impedance assessments will be performed at baseline and at the F-1, F-4, and F-12 visits. All measurements will be conducted in the recumbent position, and will be performed immediately prior to a mid-week HD treatment (i.e., Wednesday or Thursday).

15.2 Subject Preparation

- The subject should not have exercised or taken a sauna within 8 hours of the study.
- The subject should refrain from alcohol intake for 12 hours prior to the study.
- The subject's height and weight should be accurately measured and recorded.
- The subject should lie quietly during the entire test.
- The subject should not be wet from sweat or urine.
- The subject should not have a fever or be in shock.
- The study and testing procedure should be explained to the subject.
- The exam area should be comfortable and free of drafts and portable electric heaters.
- The exam table surface must be non-conductive and large enough for the subject to lie supine with the arms 30 degrees from the body and legs not in contact with each other.
- The BIA – Quantum II analyzer should have a new 9 volt battery.
- The analyzer calibration and patient cables should be checked regularly.
- Record results on Form 242
- **The subject should be asked whether he or she has an implantable defibrillator or pacemaker. Patients with these devices at baseline will be excluded from FHN due to safety issues with the cardiac MRI. However, it is possible that an implantable defibrillator or pacemaker might have been placed AFTER baseline evaluation. Subjects with an implantable defibrillator or pacemaker should not undergo the BIA procedure.**

Electrodes Placement on the Hand and Foot BIA TESTING PROCEDURE



15.3 Testing Procedure

- For subjects who have an arteriovenous fistula or graft in the upper extremity, the BIA procedure should be performed on the side opposite to the vascular access.
- For subjects with a catheter access, the BIA procedure should be performed on the right side.
- For subjects with a missing limb, the BIA procedure should be performed on the side opposite to the missing limb. If the subject is missing the designated digit (finger or toe), the lateral digit may be used to guide electrode placement.
- For subjects with missing limbs bilaterally, the BIA procedure should not be performed.
- The subject should remove his or her shoe and sock (generally the study is completed on the right side of the body). The same body side (left or right) should be used for follow-up testing.
- The subject should lie supine with the arms 30 degrees from the body and legs not touching (take care that upper thighs are not touching)
Remove any jewelry on the electrode side and from around the neck.

- The electrode sites may be cleaned with alcohol, particularly if the skin is dry or covered with lotion. If electrodes do not stick despite use of alcohol, use NU prep as directed.
- Attach the electrodes and patient cables as shown in the illustration.
- Turn the analyzer on and make sure the subject refrains from moving. When the measurements have stabilized, record the displayed Resistance (R) and Reactance (Xc) with the subject's name, age, gender, height and weight.
- Remove and dispose of the electrodes. Be careful not injure the subject's skin or contaminate the operator.
- The entire testing time is less than 5 minutes - the BIA analyzer is on for less than one minute.

15.4 Operator Proficiency:

- Two consecutive measurements made on a single, stable subject should result in values within one percent.
- Please note: R does not lock onto an exact number because of muscle contractions in the heart and will fluctuate within 1-3 ohms). The recorded value for R should be the most representative number. If the number varies widely, check electrode placement, jewelry, make sure that no electrical equipment is on the chair and that the upper thighs are not touching.

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Participant ID: _____

Participant Initials: _____

Clinical Center: _____

Site: _____

Visit Number: _____

CRF Date: ____ / ____ / ____

RC ID: _____

PHYSICAL ASSESSMENT

B. Ankle Brachial Index:

12. Right AB Index: _____

13. Left AB Index: _____

Calculation of Right Ankle Brachial (AB) Index [higher value of ankle systolic / higher value of brachial systolic]

Higher value in item # 7 or item #8 divided by value in item #6 or item 9.

Calculation of Left Ankle Brachial (AB) Index:

Higher value in item #10 or item #11 divided by value in item #8 or item 9.

BIOELECTRIC IMPEDANCE ASSESSMENT:

Assessment at Baseline Visit, 24 Month and 48 Month Visits.

14. Body position:

₁ Supine (preferred) ₂ Seated

Body position checked (in item #1) at Baseline Visit #3 must be used for subsequent testing.

15. Side measured:

₁ Right
₂ Left

Side measured (in item #2) at Baseline Visit #3 must be used for subsequent testing.

16. Measured Resistance (R):

_____ (ohms)

17. Measured Reactance (Xc):

_____ (ohms)

18. Technician ID:

₁ _____ (Tech. ID for Anthropometry, ABI, BIA)

OR ₂ _____ (Tech. ID for Anthropometry)

_____ (Tech. ID for ABI)

_____ (Tech. ID for BIA)