Hip Imaging Protocol (HIP): the comparison of muscle ultrasound-derived parameters with CT imaging-derived parameters in primary total hip arthroplasty patients

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Purpose of the Study

Objectives: To compare muscle thickness/volume/area and intramuscular adipose tissue (IMAT) content acquired from CT scan with parameters acquired from muscle US.

Background & Significance

Reduction in health status through a multitude of disease states, e.g. sepsis, results in alteration of muscle size and composition. CT of the psoas muscle at the level of lumbar vertebrae L3 has been used as a method to standardize measurements of muscle composition. One clear disadvantage of using CT is the exposure of the individual patient to ionizing radiation, thereby limiting its utility, particularly if serial measurements result in repeated CT scans. Several studies in ICU patients have demonstrated changes in muscle composition. These patients received multiple CT scans as part of their clinical evaluation of abdominal contents. In this population, the comparison between CT psoas muscle parameters and muscle US parameters of rectus muscle scans was made. The limitation, however, was that there is no direct comparison, only psoas muscle compared with rectus muscle. The opportunities to obtain CT scans of the rectus muscle are limited. The clinical population of hip patients presenting for hip arthroplasty presents an opportunity to provide direct comparison i.e. CT versus muscle US of the same muscle.

Ultrasound to assess muscle histology and morphology during disease is relatively inexpensive, non-invasive and sensitive to changes over time when compared to the other assessments like muscle biopsy, CT or NMR/MRI. Ultrasound imaging is based on the fundamental principle that ultrasound waves are reflected by tissue in the path of the ultrasound beam. Differences in acoustic impedance between tissues determine the amount of sound reflected. The amount of sound reflected is determined by the product of tissue density and acoustic velocity. Healthy muscle is predominantly hypoechoic, with only scattered small hyperechoic regions; resulting in a so-called “starry night” appearance. Muscle wasting results in an increase in intramuscular adipose tissue (IMAT) infiltration, fibrosis, myonecrosis and even effusion surrounding the fascicles. A muscle with a high amount of IMAT and fibrosis has a predominantly hyperechoic appearance, with only minor hypoechoic regions. Equations to quantify muscle echo Intensity into percent intramuscular fat on the rectus femoris muscle was introduced by Young et al. by comparing T1-weighted MRI to ultrasound images of the rectus femoris muscle.

There is a need for valid, reliable and point of care assessment of skeletal muscle quality. The aim of this study is to establish that muscle US can provide accurate measurements of muscle parameters.

Design & Procedures

In a supine position, the tight muscles (rectus femoris, vastus lateralis) are assessed once by the use of ultrasound. The midpoint between the anterior iliac spine and the upper lateral epicondyle of the femur is used to place the ultrasound transducer. The measurements are performed on both legs, with the

patient in supine position, with legs extended and relaxed and toes pointing to the ceiling. The ultrasound transducer is placed perpendicularly and transversely to the long axis of the thigh with excessive use of contact gel and minimum pressure to avoid muscle compression.

Selection of Subjects

Dr Samuel Wellman, Attending Orthopedic Surgeon, will identify all patients with the clinical diagnosis of osteoarthritis of the hip who are eligible for the surgical procedure of primary total hip arthroplasty.

Inclusion criteria:
Diagnosis of osteoarthritis of the hip
Scheduled for unilateral primary total hip arthroplasty
Age greater than 18

Exclusion criteria:
inability to provide self-consent
Disease process affecting hip joint other than osteoarthritis
Scheduled for bilateral surgical procedure
Total hip revision

Subject Recruitment and Compensation

Dr Samuel Wellman, Attending Orthopedic Surgeon, will identify all patients in Orthopedic Clinic with the clinical diagnosis of osteoarthritis of the hip who are eligible for the surgical procedure of primary total hip arthroplasty. Dr Wellman will introduce the study protocol to the patient. All patients will have an HIP CT scan performed as part of the standard clinical evaluation prior to surgery. In this study the MSK POCUS will be performed as close to the time of the HIP CT as possible, either in the Orthopedic Clinic or in the Radiology Department at the time of the HIP CT.

Subject’s Capacity to Give Legally Effective Consent

All subjects will have the capacity to give their own consent to participate in the study. This will be determined by the patients' ability to give their own consent for the planned surgical procedure. Any patient deemed by the surgical team as unable to give their own surgical consent will be subsequently considered ineligible for the research study. The period of inclusion in the study will be of short duration that further reassessment will not be required.

Risk/Benefit Assessment

MSK POCUS is considered to be less than minimal risk. Vulnerable populations will be excluded.

The MSK POCUS is to be performed only for research purposes and will not alter the clinical course of the patient. If the patient chooses not to participate there is no alternative.

There is no direct benefit to the subject as the data will be collected solely for research purposes.

Body composition imaging is useful as part of the nutritional assessment of patients, particularly in high risk groups such as intensive care unit (ICU) patients. Measurement of the psoas muscle at L3 by abdominal CT is considered to be the best way to determine key parameters such as muscle thickness, volume & cross-sectional area. Abdominal CT exposes the patient to radiation and therefore, potential risk of injury. Abdominal CT is performed for clinical indications other than nutritional assessment, yet it provides the opportunity to measure the key muscle parameters. In addition, CT has limited ability to provide longitudinal assessment as repeated abdominal CT are performed infrequently. If MSK POCUS can provide similar measurements of muscle parameters, then this would provide a very useful clinical tool for longitudinal clinical assessment of nutritional status. In addition, MSK POCUS could be used in all patient populations, many of whom would otherwise not receive abdominal CT, yet in whom nutritional status would be valuable.

Data Analysis & Statistical Considerations

We will evaluate the patients only once to assess the IMAT derived by ultrasound and CT. Descriptive statistics will be used in the analysis as this study is observational and not a therapeutic intervention study.

Descriptive analyses will be carried out to summarize patient characteristics. Continuous variables will be reported as mean (range), mean (SD) or median and inter-quartile range (IQR), depending on distribution, and categorical variables as frequency (%). In order to assess the sensitivity of results to covariates, a further ‘adjusted’ effect will be calculated using linear regression. Since this is an observational study, sample size calculations were not employed, we expected to need 50 patients.

Data & Safety Monitoring

MSK POCUS will be performed using FDA approved US equipment. Ultrasound is considered to be less than minimal risk.