FerriScan®
MRI Measurement of Liver Iron Concentration

FerriScan® R2-MRI **Fact Sheet – Sickle Cell Disease and Iron Overload**

Sickle Cell Disease (SCD) and Iron Overload

Sickle cell disease patients who receive regular or intermittent blood transfusions are at risk of iron overload. Once a threshold LIC is exceeded, iron can begin to accumulate in the heart and other organs[7]. Patients with elevated LIC are at greater risk of future cardiac complications and premature death[8,9].

7% of sickle cell patients' deaths are directly attributable to iron overload[3]. The accurate assessment and monitoring of body iron is therefore crucial.

FerriScan has been established in Sickle Cell Centres of Excellence throughout the world as the most accurate MRI-based method for measurement of liver iron, eliminating the need for liver biopsy.

FerriScan is recommended in treatment guidelines for the annual measurement of liver iron concentration, including:

- The 2008 Nursing Practice Guidelines: Care of the Patient with Sickle Cell Disease and Iron Overload recommends an accurate quantification of LIC at the beginning of chelation therapy and regularly thereafter. FerriScan is endorsed as a suitable test.
- The 2008 Standards for the Clinical Care of Adults with Sickle Cell Disease in the UK recommends all transfused patients have regular monitoring of LIC using MRI.
- The UK Sickle Cell Society recommends FerriScan for measuring LIC in sickle cell disease patients receiving blood transfusions.

The liver is the body's primary site of iron storage and is closely correlated to total body iron stores[4]. An accurate estimate of these iron levels is therefore vital to both the diagnosis and management of patients with iron overload.

FerriScan applies its unique patented software and analysis process to R2-MRI images, providing a highly accurate measurement of Liver Iron Concentration[1].

FerriScan provides the clinician with accurate, reliable information on which to base patient management decisions on commencement of chelation therapy, adjustments to dosage and changing the mode of chelator delivery.

Testing of serum ferritin levels can provide a useful adjunct to FerriScan analysis as it indicates how iron levels are trending over time. However, the correlation between serum ferritin and LIC is not close enough for it to be used as a basis for the accurate determination of treatment options[2].

Why use FerriScan in Patients with Sickle Cell Disease?

- FerriScan is the only regulatory cleared (FDA, CE, TGA) method for the quantification of LIC. FerriScan has international regulatory clearance (USA, Europe, Australia);
- FerriScan is non-invasive and can provide information about the distribution of iron within the liver;
- FerriScan has high sensitivity and specificity for measuring LIC;
- FerriScan can measure LIC over the entire range encountered in clinical practice[3];
- Results are accurate, reliable and reproducible over time and between MRI centres and models of scanner;
- FerriScan results are clinically validated to be unaffected by inflammation, fibrosis or cirrhosis;
- FerriScan requires no breath-hold and may therefore be used for paediatric patients.

Advantages of FerriScan over serum ferritin

- Other factors present in patients with iron overload such as infection, inflammation, fever, cancer or liver damage may result in significant elevation of serum ferritin (SF) concentrations in the absence of iron overload;
- In the absence of inflammation or liver disease, high serum ferritin concentrations indicate iron overload, but are not a quantitative measure;
- SF is an imprecise and potentially misleading parameter on which to base clinical management decision in patients with sickle cell disease[3];
- SF has significant limitations in assessment of iron burden in children with SCD, and liver iron assessment therefore is necessary for optimal management[5].

Advantages of FerriScan over other MRI-based methods (including liver T2* methods)

- FerriScan has been used to non-invasively measure LICs in over 49,000 patients;
- FerriScan has been calibrated against liver biopsy to measure LICs from 0.3 to 42.7 mg Fe/g dry tissue in a trial of 105 subjects with hereditary haemochromatosis and thalassemia disorders using 5 different MRI scanners. This range is larger than is achievable using any other published MRI-based method. For example, published T2* methods measured LICs up to 236, 27.67 and 32.98 mg/g dry tissue, respectively, whereas SIR methods only measured LICs up to 20.99 mg Fe/g dw;
- FerriScan has been validated on GE, Philips and Siemens scanners;
- FerriScan has regulatory clearance from the FDA, TGA, and European CE mark;
- FerriScan has been independently validated by third parties;
- FerriScan is the method of choice for measuring LIC in clinical trials of iron chelators;
- Data analysis is performed at a central location which is quality assured and certified. This enables comparisons to be made over time and between MRI centres.

Advantages of FerriScan over other MRI-based methods (including liver T2* methods)

- Non-invasive;
- Painless;
- No risk of bleeding or infection;
- Provides information about the distribution of iron in the liver;
- FerriScan measures iron in a volume of liver that is thousands of times greater than liver biopsy;
- The size of the biopsy specimen only represents 1/50,000th of the total mass of the liver; therefore, the location where the biopsy is taken from will affect the result, and may not be representative of the entire liver;
- Results are available within two business days.

References

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