

# Characterization of MR derived biomarkers of liver health in a European cohort with metabolic syndrome and NAFLD in comparison to healthy controls: Preliminary analysis of an ongoing prospective trial (RADICAL 1)

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## Introduction

- Multiparametric (mp) MRI can be used to non-invasively assess liver tissue<sup>1</sup>, utilizing precise biomarkers (such as proton density fat fraction (PDFF) and iron-corrected T1 (cT1) of steatosis and fibro-inflammation respectively<sup>2</sup>) to stratify patients within the non-alcoholic fatty liver disease (NAFLD) spectrum.
- This study compared the distributions of cT1 and PDFF in patients with suspected NAFLD and/or Metabolic Syndrome (MetS) with the aim of identifying the number of patients who could avoid unnecessary biopsy.

## Patients and Methods

- Of the 270 patients with suspected NAFLD and/or MetS recruited into RADICAL 1\*, 135 patients were randomized to undergo mpMRI with LiverMultiScan.
- 100 healthy controls from the UK Biobank3 study (defined by BMI <25 and PDFF<5%) were included in the analysis.
- Patients were separated into groups using combinations of BMI, PDFF, and cT1.
- Patients with low cT1 (< 800ms) and low PDFF (< 5%) were considered at low risk of NAFLD and having unnecessary biopsies. Patients with high cT1 and/or high PDFF were considered at a higher risk of having NAFLD.
- 17% of patients were classified at randomization as suspected MetS, 56% as suspected NAFLD, and 27% as suspected NAFLD+MetS.
- Evaluating differences in cT1 and PDFF utilizing pairwise ANOVA and Tukey's test for post-hoc analysis.

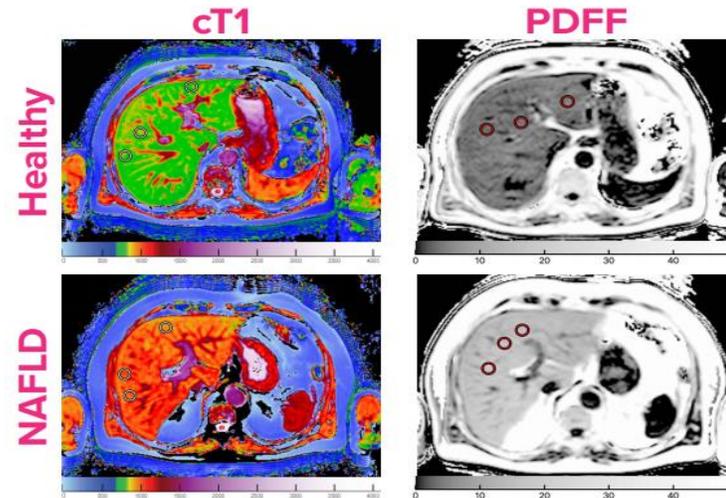
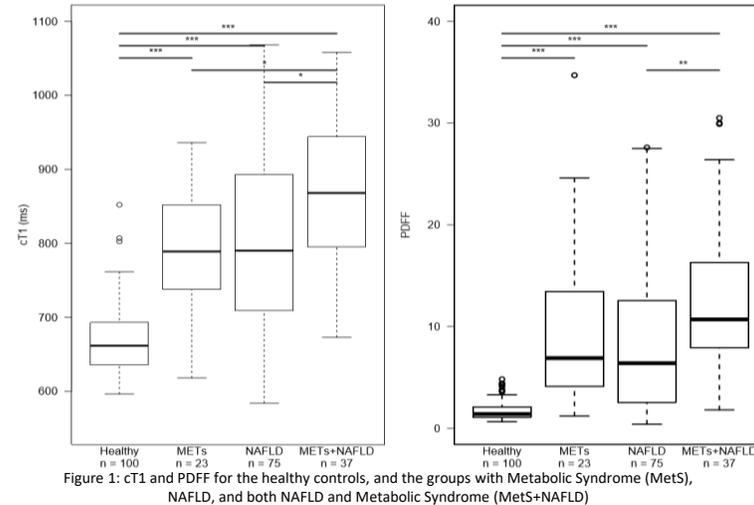


Figure 2: LiverMultiScan report results for a healthy control (top) and a NASH patient (bottom) showing differences in fibro-inflammation (cT1) and hepatic fat (PDFF)

## Results

- Proportion with PDFF>5% in each of the groups were 0% (healthy), 65% (MetS), 60% (NAFLD) and 95% (NAFLD+MetS); while the proportion of those with cT1<800ms and PDFF<5% (no evidence of liver disease) were 100% (healthy), 35% (MetS), 30% (NAFLD) and 3% (NAFLD+MetS).
- Compared to healthy controls, cT1 was significantly higher in MetS, NAFLD and NAFLD+MetS cohorts ( $p<0.0001$ ). Also, PDFF was significantly higher in the MetS, NAFLD and NAFLD+MetS cohorts ( $p<0.0001$ ) when compared to healthy controls (Figure 1).
- Suspected NAFLD+MetS patients had a significantly higher cT1 than those in the MetS and NAFLD cohort ( $p=0.0019$  and  $p=0.002$  respectively for both respectively), however, this group had significantly higher PDFF only against the NAFLD cohort ( $p=0.0008$ ) only (Figure 1).

## Conclusion

- Patients with suspected NAFLD and/or MetS had elevated cT1 and PDFF.
- 23.7% (32/135) classed as low risk and would not require a biopsy.
- Highlights opportunity for pathway optimization.

## References

- Banerjee R et al., Multiparametric magnetic resonance for the non-invasive diagnosis of liver disease. J Hepatol2014; 40: 69-77
- Pavlidis et al., Multiparametric magnetic resonance imaging predicts clinical outcomes in patients with chronic liver disease. J Hepatol2016; 64: 308-315

\* RADICAL 1 is a large prospective health economic study, evaluating the cost effectiveness of LiverMultiScan. N = 1072 across 13 sites in the EU and UK.