with body mass index ($\rho = 0.32$, $p = 0.008$), waist circumference ($\rho = 0.31$, $p = 0.010$), and fasting serum glucose ($\rho = 0.24$, $p = 0.046$). CAP and MRI-PDFF were significantly correlated at BL ($\rho = 0.29$, $p = 0.016$) and W12 ($\rho = 0.32$, $p = 0.009$). However, absolute ($\rho = 0.22$, $p = 0.094$) and relative changes ($\rho = 0.21$, $p = 0.096$) in CAP and MRI-PDFF between BL and W12 were not significantly correlated. In subjects treated with GS-0976 20 mg daily, a 28.9% median relative reduction in MRI-PDFF was observed between BL and W12 ($p = 0.002$ vs. placebo); a 13.0% reduction in the 5 mg group was not statistically different from placebo (Figure). Relative reductions in CAP were smaller and did not differ between treatment groups (Figure). Relative reductions $\geq 30\%$ in MRI-PDFF in the GS-0976 20 mg, GS-0976 5 mg, and placebo groups were observed in 48%, 23%, and 15% of subjects ($p = 0.004$ vs. GS-0976 20 mg; $p = 0.43$ vs. GS-0976 5 mg), respectively. Relative CAP reductions $\geq 30\%$ were observed in 10%, 0%, and 7.7% of subjects, respectively (both $p < 0.05$ vs. placebo). The median relative change in CAP in 23 MRI-PDFF responders was $-7.5\%$ (IQR $-14.8$, 1.8) compared with $-3.0\%$ ($-10.8$, 9.9) among non-38 responders ($p = 0.23$).

Conclusion: Among NASH subjects in this multi-center trial of GS-0976, measures of hepatic steatosis quantified by CAP and MRI-PDFF were moderately correlated. However, changes in these parameters were not correlated and CAP was less responsive to change than MRI-PDFF. Further validation of CAP is necessary before it can be considered a valid endpoint for use in clinical trials of interventions for NASH.

FRI-449
An non-invasive biomarker of hepatic inflammation based on magnetic resonance imaging

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Magnetic resonance imaging
FRI-449
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Background and Aims: Inflammation and ballooning are pathological hallmarks of non-alcoholic steatohepatitis (NASH), but their detection and the diagnosis of NASH relies on an invasive liver biopsy. The non-invasive detection of inflammation and ballooning would therefore be a significant step in diagnosing, monitoring and treating NASH. In this preliminary study, we report on a magnetic resonance imaging (MRI) approach for identifying patients with mild to severe grades of inflammation and ballooning.

Method: The participants for this research were drawn from two independent studies. The participants in the first study were from Australia (n = 39) and comprised 10 healthy controls with normal body mass index (18.4–24.9) and 29 patients with biopsy-confirmed NAFLD. The participants in the second study were from Malaysia (n = 51) and comprised patients with biopsy-confirmed NAFLD. An identical gradient echo MRI protocol was acquired for both cohorts and a non-invasive imaging biomarker of inflammation (NIIBI) was developed from the images via post-processing. From the histopathologists’ grading of the biopsies, an inflammation score (IS) was generated from the sum of the lobular inflammation and ballooning components of the NAFLD activity score (NAS), with the healthy controls assigned an IS of 0. The data from two cohorts were then pooled before dividing participants with no inflammation (IS 0) from those with some inflammation (IS 1–5). The mean difference between the groups was assessed using the Student’s t-test. Area under the ROC curve (AUROC) analysis was used to assess the
diagnostic potential of the MRI biomarker for predicting inflammation.

Results: There were 28 participants with an IS of 0 (12 female, 16 male) and 62 participants with an IS between 1 and 4 (36 female, 27 male). No participant had an IS score of 5. The mean (standard deviation) NIIBI value was 0.25 (0.23) for the IS 0 group and 0.72 (0.36) for the IS 1–4 group (Figure 1). The difference between the mean NIIBI values of the two groups was statistically significant ($p < 0.0001$). The AUROC for distinguishing no inflammation from some inflammation was 0.87 (95% CI 0.80–0.95) and the sensitivity and specificity was 81% (95% CI 69% to 90%) and 79% (95% CI 59% to 92%) at an NIIBI cut-off value of 0.43.

Figure 1 Scatter plot of NIIBI values for the two groups of subjects. The lines through the data are the mean and the standard error on the mean.

Conclusion: A new, rapidly acquired MRI-based parameter has been developed for detecting inflammation and ballooning in the liver. This new measurement tool has the potential to assist in the identification of patients with NASH and to help pre-screen patients for recruitment into NASH clinical trials.

FRI-450
Temporal assessment of the non-invasive fibrosis scores FIB-4 and Non-Alcoholic Fatty Liver Disease Fibrosis Score (NFS) in a retrospective cohort study among patients with Non-Alcoholic Fatty Liver Disease (NAFLD)


Background: FIB-4 and NFS scoring systems have been validated to identify advanced liver fibrosis in patients with NAFLD. However, there are no longitudinal studies that support their usefulness in monitoring this disease.

Aims: To assess the diagnostic performance of both scoring systems in comparison to the liver biopsy (LB) in our setting and to analyze their temporal evolution.

Method: We included those patients who had baseline and follow-up visits at our specialized medical consultation for NAFLD from 1995 through 2016. Data on patient demographics, anthropometrics and metabolic risks, blood test results and fibrosis degree on LB were registered. NFS and FIB-4, their receiver operating curve (ROC) and their area under the curve (AUC) (95% CI) were calculated. Sensitivity (S), Specificity (Sp), Positive Predictive Value (PPV), and Negative Predictive Value (NPV) for the cut-off points (CP) suggested in the