



The budget impact of introducing multiparametric MRI as a monitoring tool to identify non-responders undergoing resmetirom treatment for MASH

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BACKGROUND

- Over 7 million American adults are estimated to have high-risk metabolic dysfunction-associated steatohepatitis (MASH).
- With the recent approval of a MASH therapy, resmetirom, eligible patients should be appropriately prescribed and monitored.
- Identification of non-responders may lead to a reduction in costs and improvement in patients care. Regular monitoring may also encourage medication (Rx) adherence.

RESEARCH QUESTION

What is the budget impact of introducing multiparametric MRI (cT1) to monitor treatment response to resmetirom treatment in MASH patients?

METHODS

- A budget impact model was developed to estimate the costs associated with introducing cT1 to screen, diagnose and monitor patients compared to Vibration Controlled Transient Elastography (VCTE), liver biopsy and no monitoring (NM).
- MASH regression was defined as fibrosis regression (fibrosis decrease ≥ 1 + no worsening in NAFLD activity score (NAS)) OR NAS improvement (NAS decrease ≥ 2 + no worsening in fibrosis).
- The analysis considers a hypothetical population of 5,000 patients with suspected MASH (fibrosis > 2) and assessed for resmetirom treatment.
- No monitoring assumed a confirmatory diagnosis with VCTE at initial screening and no follow up tests throughout the 2-year time horizon.
- Initial screening and diagnosis parameters were taken from literature¹⁻⁵ and monitoring parameters were taken from literature and costing sources¹⁻⁷.
- The model adopted a payer perspective, and costs were 2024 US Dollars (\$).

WHAT IS CORRECTED T1 (cT1)?

- cT1 is an MRI derived biomarker that correlates with liver histology and changes in cT1 correspond to a meaningful change in histology⁷.
- cT1 quantifies the level of disease activity in the liver and predicts the likely future course of disease.

REFERENCES

1. National Institute of Diabetes and Digestive and Kidney Disease, 2. Andersson et al 2022, 3. Salehi et al 2013, 4. www.MDSave.com, 5. Ratzu et al 2005, 6. Harrison et al 2024, 7. Alkhouri et al 2024, 8. Thomaides-Brears et al 2021

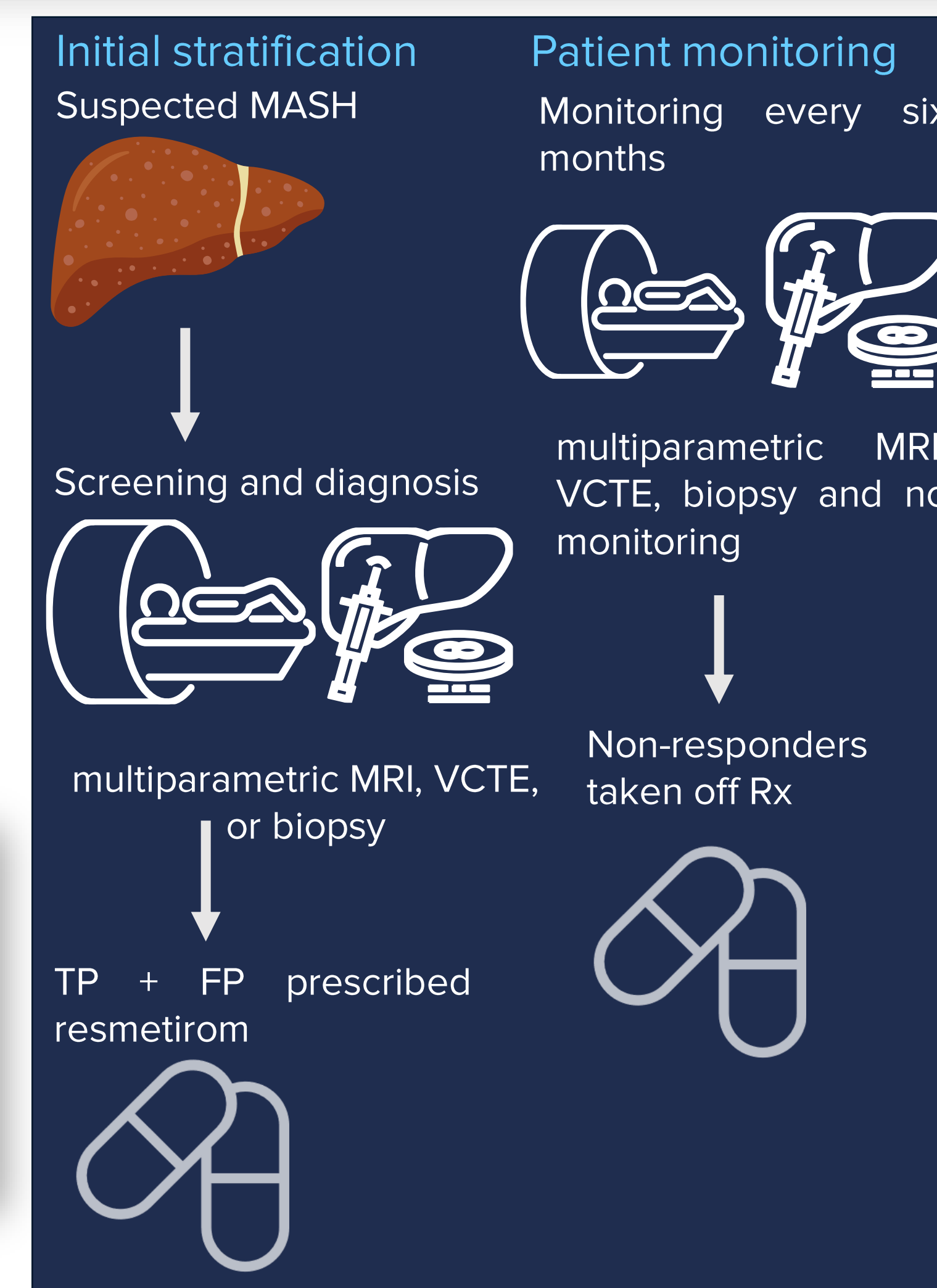
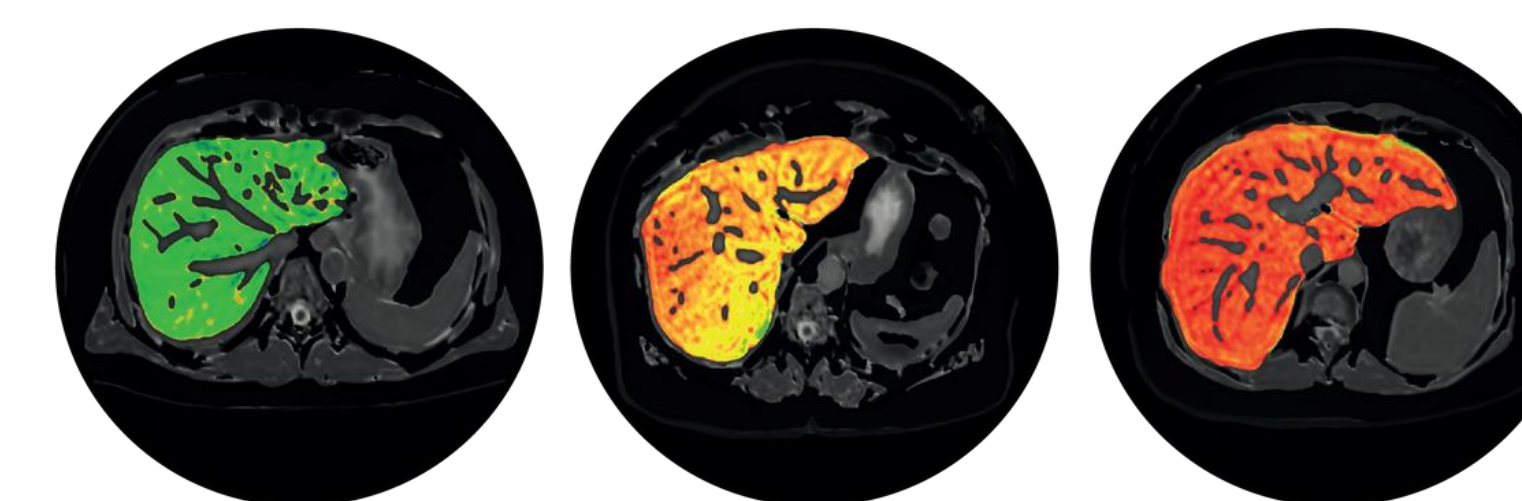


Table 1: Diagnostic tool accuracy data for initial stratification

Intervention	Sensitivity	Specificity
cT1	0.59	0.81
VCTE	0.67	0.28
Biopsy	0.69	0.92
No monitoring	0.67	0.28

Table 2: Diagnostic tool accuracy data for monitoring

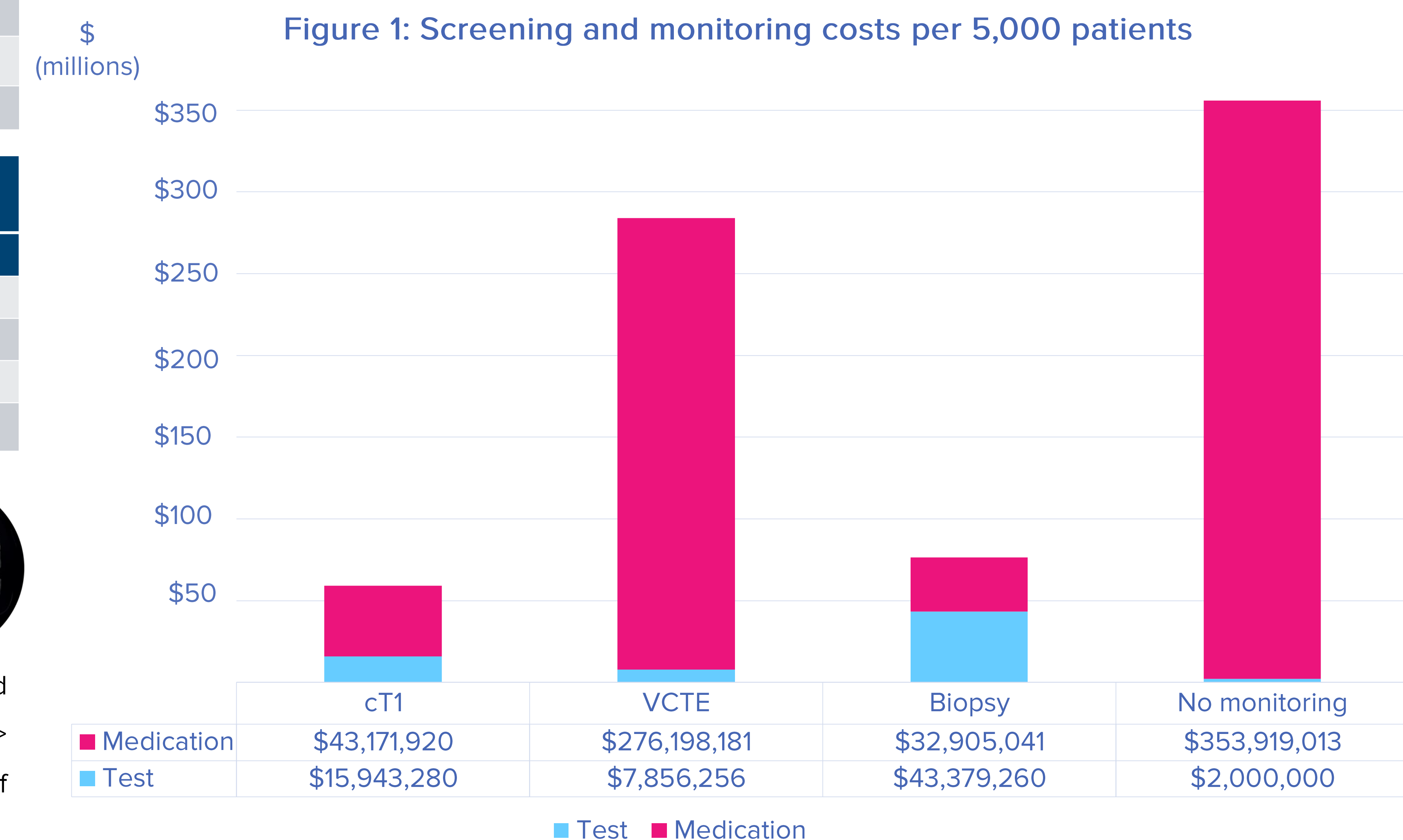
Intervention	Sensitivity	Specificity
cT1	0.52	0.76
VCTE	0.67	0.28
Biopsy	0.69	0.92
NM	0	0



A cT1 value of 800ms has been calculated as the upper limit of normal and cT1 > 800ms indicate the likely presence of disease activity.

RESULTS

- cT1 identified 1,080 patients eligible for treatment and identified 410 non-responders accurately.
- Introducing cT1 to for initial screening and diagnosis of 5,000 and monitoring to identify non-responders was the least costly intervention (\$59,115,200) compared to VCTE (\$284,054,437), biopsy (\$76,284,301) and no monitoring (\$355,919,013) (Figure 1).
- The minimum cost saving was \$17,169,101.
- These findings were also consistent in a scenario considering the following definition of disease regression: fibrosis regression (fibrosis decrease ≥ 1 + no worsening in NAFLD activity score (NAS)) which had a lower treatment response rate (24%).
- This analysis did not consider the number of technical failures associated with VCTE, or the potential impact of biopsy complication or death⁸.
- Although comparator tests may have been cheaper, driving forces such as poor specificity led to inaccurate monitoring and therefore increased medication expenditure.



CONCLUSION

- Introducing multiparametric MRI as a noninvasive approach to assign and monitor treatment in MASH may lead to a cost savings of \$17,169,101 for 5,000 patients, reducing Rx expenditure.
- This ensures that the right patient receives the right treatment for the right amount of time.

