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AUTOMATED AI-BASED QUANTITATIVE FIBROSIS STAGING TO SUPPORT IDENTIFICATION OF MASH PATIENTS ELIGIBLE FOR APPROVED THERAPIES

Y. CHOUDHURY[1], D. TAN[1], S. LEK[1], D. ABDURRACHIM[2], A. ABU BAKAR ALI[2], N. ALKHOURI[3,4]

1. HistoIndex Pte. Ltd., Singapore
2. Quantitative Biosciences, MSD, Singapore
3. Summit Clinical Research, San Antonio, TX, USA
4. Clinical Research Institute of Ohio, Westlake, OH, USA

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INTRODUCTION

Approved pharmacotherapies are available for the treatment of adults with metabolic dysfunction-associated steatohepatitis (MASH) and F2–F3 fibrosis[1,2]. However, selection algorithms based on non-invasive tests (NITs) often fail to accurately identify the treatment-eligible population defined by histological criteria for fibrosis. Furthermore, the NIT-based criteria identify a large target population (up to 8.3 million U.S. adults)[3], placing a financial burden on the healthcare system. This may be alleviated by adopting direct liver biopsy evaluation in select cases.

AIM

For direct fibrosis assessment in MASH liver biopsies, this study aimed to evaluate FibroSIGHT™ Plus, a fully automated artificial intelligence (AI)-based fibrosis scoring tool, based on second harmonic generation (SHG) imaging of liver biopsies and image analysis[4]. The performance of FibroSIGHT™ Plus was compared with fibrosis staging by community pathologists using standard methods.

METHODS

- A total of 75 MASH liver biopsies from a retrospective cohort from Mount Sinai were selected across a range of fibrosis stages (F0–F4) and their Masson's trichrome-stained images were reviewed by three expert hepatopathologists. The median score for each biopsy was used to assign a reference NASH Clinical Research Network (NASH-CRN) fibrosis stage[5] as ground truth.
- Three community pathologists also reviewed the same images and assigned fibrosis stages to each case, independently.
- An adjacent unstained section from each biopsy underwent stain-free SHG imaging and analysis with FibroSIGHT™ Plus to generate continuous qFibrosis® values and qFibrosis® stage assignments. qFibrosis® scores are aligned to the NASH-CRN fibrosis staging system[6].
- Concordance of community pathologists' staging and qFibrosis® staging with the reference stages was assessed.
- Exact agreement among all three readers was calculated for each pathologist group; qFibrosis® values were correlated with the reference stage (Spearman).

RESULTS

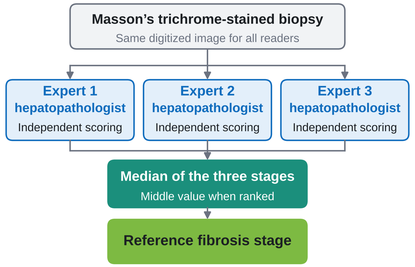

Figure 1. Establishment of the reference fibrosis stage. Each digitized Masson's trichrome-stained liver biopsy image was independently scored for fibrosis stage by three expert hepatopathologists, who were blinded to one another's assessments. The median of the three scores was taken as the reference fibrosis stage for that biopsy.

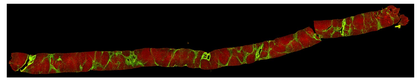

Figure 2. Representative SHG image of a liver biopsy (collagen, green; tissue, red). qFibrosis® continuous values are calculated automatically from SHG images, and qFibrosis® stages are derived.

Table 1. Baseline characteristics of the 75 MASH liver biopsies.

Characteristic	Total (n = 75)
Age, years, mean (SD)	58.52 (16.51)
Sex, n (%)	
Male	26 (34.67)
Female	49 (65.33)
T2DM, n (%)	
Yes	31 (41.33)
No	44 (58.67)
Reference stage, n (%)	
F0	8 (10.67)
F1	13 (17.33)
F2	15 (20.00)
F3	23 (30.67)
F4	16 (21.33)
F2–F3 (treatment-eligible)	**38 (50.67)**

F, fibrosis stage; NASH-CRN, NASH Clinical Research Network; SD, standard deviation; T2DM, type 2 diabetes mellitus. Reference stage = median of three expert hepatopathologists.

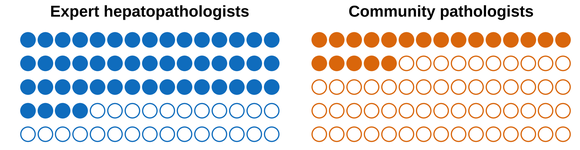

Figure 3. Exact fibrosis stage agreement among the three expert hepatopathologists and the three community pathologists (n = 75 cases). Each dot represents one case; filled dots indicate exact agreement among all three readers.

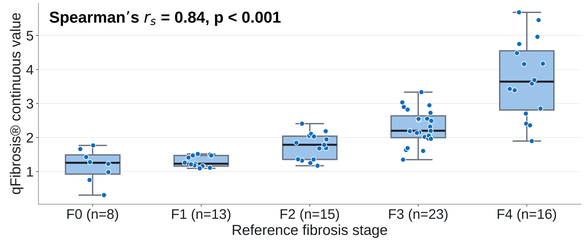

Figure 4. Correlation of qFibrosis® continuous values with reference fibrosis stage. Box = median and interquartile range; dots = individual cases.

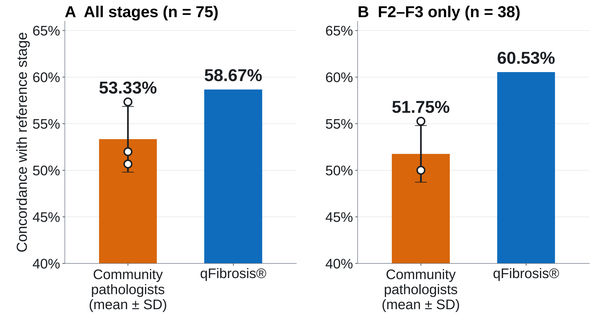

Figure 5. Concordance with reference fibrosis stage: (A) all stages (n = 75); (B) F2–F3 treatment-eligible cases (n = 38). Bars for community pathologists show the mean ± SD of the three readers; circles are individual readers. The y-axis starts at 40%.

Key findings

- Expert hepatopathologists agreed on the exact stage in 65.33% of cases vs. 26.67% for community pathologists.
- qFibrosis® continuous scores correlated well with reference stage (Spearman's r_s = 0.84, p < 0.001).
- qFibrosis® stage concordance was numerically higher than the mean concordance of the three community pathologists overall (58.67% vs. 53.33%) and in F2-F3 cases (60.53% vs. 51.75%).

CONCLUSIONS

- Community pathologists showed notable discrepancy in fibrosis staging, with low inter-reader agreement compared with expert hepatopathologists.
- qFibrosis® continuous values correlated well with the reference fibrosis stage.
- qFibrosis® stage showed numerically higher concordance with the reference stage than community pathologists, particularly in the treatment-eligible (F2-F3) population.
- FibroSIGHT™ Plus may provide more consistent fibrosis staging from direct biopsy evaluation to support treatment selection, particularly in resource-constrained settings with large MASH populations.

Abbreviations: AI, artificial intelligence; F, fibrosis stage; MASH, metabolic dysfunction-associated steatohepatitis; NASH-CRN, NASH Clinical Research Network; NIT, non-invasive test; SHG, second harmonic generation; SD, standard deviation; T2DM, type 2 diabetes mellitus.

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DISCLOSURES

Y.C., D.T., S.L. are employees of HistoIndex Pte. Ltd. D.A. and A.A.B.A. are employees of MSD (Quantitative Biosciences, Singapore). N.A. has received research funding from and/or served as a consultant for pharmaceutical and biomarker companies, including Madrigal and Novo Nordisk. Full disclosures are available in the AASLD meeting disclosure listing.

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CONTACT INFORMATION

Yukti Choudhury
HistoIndex Pte. Ltd., Singapore
Email: yukti.choudhury@histoindex.com