RISK-STRATIFICATION OF PATIENTS WITH NON-ALCOHOLIC FATTY LIVER DISEASE (NAFLD) IN PRIMARY CARE: LESSONS FROM THE CALGARY NAFLD PATHWAY

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BACKGROUND

- The Calgary non-alcoholic fatty liver disease (NAFLD) pathway (CNP) is the largest primary care-based NAFLD pathway in North America.
- We aimed to evaluate the performance of different risk-stratification modalities among CNP patients according to their baseline liver enzymes and metabolic syndrome risk factors.

METHODS

- The CNP uses validated shearwave elastography (SWE) assessment as the primary tool of risk-stratification for patients with a history of fatty liver or 'at-risk' of metabolic syndrome since March 2017.
- In the CNP, 'at-risk' of advanced fibrosis patients with SWE ≥ 8.0 kPa or inconclusive results are referred to hepatology. Since only an ALT assessment was mandatory at baseline, some patients did not have all baseline serum fibrosis-4 variables (FIB-4).
- We compared the performance of both SWE ≥ 7.0 and 8.0 kPa, and FIB-4 ≥ 1.3, according to sex, age, rural residence, body mass index (≥35), normal ALT (25 U/L for women and 30 U/L for men), and presence of Type 2 diabetes mellitus (DM) between March 2017 and December 2022.

RESULTS

- A total of 12,122 patients completed SWE assessment with a confirmed NAFLD diagnosis in the CNP between March 2017 and June 2022.
- Baseline FIB-4 was available in 8,590 patients (70.9%). Among those patients with available FIB-4, 2,643 (33.8%) had FIB-4 ≥ 1.3, 402 (4.8%) had an inconclusive SWE, 1,042 (11.9%) SWE ≥ 7.0 kPa, and 762 (8.9%) SWE≥ 8.0 kPa.

RESULTS

- The performance of different modalities among different cohorts is presented in **Table 1**.
- Patients with normal baseline ALT levels had FIB-4 ≥ 1.3 (p=0.61) and SWE ≥ 8.0 kPa (p=0.09) similar to patients with elevated ALT, **Table 2**.
- While SWE ≥ 7.0 and 8.0 kPa and transient elastography ≥ 8kPa were significantly higher among patients with a BMI ≥ 40, these patients had lower advanced fibrosis confirmed by liver biopsy (n=259 patients) compared to patients with BMI <40 (p<0.001). **Table 3**.

Table 1: Performance of FIB-4 and SWE in different subgroups of the Calgary NAFLD Pathway

Modality cut-off	Whole cohort N=8,590	Female N=4,538, (52.9%)	Age ≥ 50 yrs N=5,284 (61.5%)	BMI ≥ 35 N= 2,085 (30.2%)	DM N=2,922 (34.2%)
FIB-4 ≥ 1.3	2,643 (33.8%)	1,289 (28.4%)	2,350 (44.5%)	579 (27.8%)	1,081 (37.0%)
SWE ≥ 7.0 kPa	1,042 (11.9%)	540 (11.9%)	781 (14.8%)	387 (18.6%)	554 (19.0%)
SWE ≥ 8.0 kPa	762 (8.9%)	404 (9.0%)	596 (11.4%)	287 (13.9%)	448 (15.5%)

Table 2: Performance of FIB-4 and SWE according to elevated ALT

Characteristic	NAFLD Patients with normal ALT N=2,585 (30.1%)	NAFLD Patients with elevated ALT N=6,005 (70.3%)	P Value
FIB-4	0.99 (0.69- 1.42)	0.96 (0.66-1.44)	0.049
FIB-4 cut-off 1.30	30.4%	30.9%	0.610
FIB-4 cut-off 1.45	23.6%	24.7%	0.273
SWE	4.5 (3.7-5.8)	4.8 (4.0-6.0)	<0.001
SWE ≥7.0 kPa	10.6%	12.5%	0.017
SWE ≥8.0 kPa	**8.1%**	**9.3%**	0.090

ALT of 30 U/L for men and 25 U/L for women were considered the upper limit of normal.

- Patients with DM had significantly higher rates of FIB-4 ≥1.3 and SWE ≥ 7.0 and 8.0 kPa compared to patients without DM, **Table 1**.

Table 3: Comparison of Transient Elastography (TE) and fibrosis stages by liver biopsy according to morbid obesity class III (BMI ≥40)

	Class III obesity in adults (BMI ≥40) N= 137 (52.9%)	Normal, overweight, Class I, and II obesity (BMI<40) N=122 (47.1%)	P value
Age yrs.	55 (45-61)	61 (53-67)	<0.001
Male sex	59 (43.1%)	53 (43.5%)	0.95
Transient elastography (TE)			
Valid measurements	124 (90.5%)	122 (91.8%)	0.94
LSM by TE	13.7 (10.0-18.8)	14.7 (10.3-20.1)	0.29
Fibrosis stages			
0	**19 (13.9%)**	10 (8.2%)	
1	**31 (22.6%)**	11 (9.0%)	
2	33 (24.9%)	29 (23.8)	<0.001
3	40 (29.2%)	**28 (23.0%)**	
4	14 (10.2%)	**44 (36.1%)**	

Data are presented as numbers (%) or median (interquartile range)

CONCLUSIONS

- Models of care to risk-stratify NAFLD patients are needed
- Challenges with risk-stratification in patients with morbid obesity
- Patients with normal liver enzymes are at-risk of fibrosis similar to patients with elevated liver enzymes
- Risk of fibrosis is higher among patients with DM

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