

Evaluation Of The Fatty Liver Index As A Diagnostic Predictor For Non-Alcoholic Fatty Liver Disease In Type 2 Diabetics

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ABSTRACT

The Fatty Liver Index (FLI) has demonstrated utility in diagnosing hepatic steatosis. However, in some middle-income settings such as Peru, its predictive performance has not been validated, nor have optimal cut-off points been established. This study evaluates the FLI as a diagnostic predictor for non-alcoholic fatty liver disease in patients with type 2 diabetes at a tertiary hospital in northern Peru. **Materials and Methods:** A prospective external validation study of the FLI model was conducted with 175 outpatients at Chimbote Regional Hospital, Peru, during November–December 2024. Using the data collected and the published model equation, the FLI score was calculated for each patient. The model's predictive performance was assessed through measures of calibration, discrimination, and classification. **Results:** Among the selected patients, 74.2% were diagnosed with metabolic dysfunction-associated fatty liver disease (MAFLD). The FLI model demonstrated good discriminative ability, with an area under the curve (AUC) of 0.89 (95% CI: 0.83-0.94) and a calibration slope of 1. In our population, an FLI score <30 had a negative likelihood ratio of 0.08, effectively ruling out MAFLD, whereas an FLI score ≥70 produced a positive likelihood ratio of 10.71, confirming the diagnosis. **Conclusions:** In our study, the FLI model showed excellent predictive performance for MAFLD. Its simplicity and low cost may make it a practical tool in low- and middle-income countries for identifying diabetic patients who require hepatic ultrasound.

KEYWORDS: Non-alcoholic Fatty Liver Disease; Diabetes Mellitus Type 2; Predictive Models; Fatty Liver Index

ABBREVIATIONS: BMI: body mass index; IC: intervalo de confianza; HbA1: glycosylated hemoglobinA1; SD: standard deviation; T2D: type 2 diabetes.

INTRODUCTION

Currently, metabolic dysfunction-associated fatty liver disease (MAFLD) has become a prevalent chronic illness of high clinical relevance due to its growing impact and close relationship with the global epidemic of metabolic disorders. Patients with type 2 diabetes (T2D) represent a high-risk group, with an estimated prevalence of MAFLD between 60% and 80% worldwide [1], 56.8% in South America [2], and 18% in Peru [3].

In this context, several non-invasive models have been developed to identify hepatic steatosis, such as the Fatty Liver Index (FLI) developed by Bedogni et al. [4] in the general Italian population, using ultrasonography as the diagnostic reference. Initially, 13 variables were evaluated, of which body mass index (BMI), waist circumference, triglycerides, and gamma-glutamyl transferase (GGT) collectively demonstrated the best predictive ability, achieving an area under the curve (AUC) of 0.84 (95% CI: 0.81-0.87). The result was expressed as a score between 0 and 100, referred to as the Fatty Liver Index (FLI), in which a score <30 allows the presence of fatty liver to be ruled out (negative likelihood ratio = 0.2), while a score ≥60 confirms its presence (positive likelihood ratio = 4.3).

The anthropometric and biochemical parameters used in the FLI model are low-cost, routinely available in outpatient care, and have demonstrated good predictive performance for hepatic steatosis in Asian and European studies [5-7]. However, the metabolic, racial, and clinical characteristics of these populations do not necessarily reflect those of the Peruvian population with T2D, in whom the performance of this model has not yet been evaluated, thereby justifying the need for our study.

Adults with T2D are at increased risk of developing MAFLD, due to the frequent coexistence of dyslipidemia, obesity, and insulin resistance [8].

The purpose of applying predictive models such as the FLI in this context is to enable early and non-invasive identification of patients at risk of MAFLD, facilitating timely stratification, such as referral for ultrasonography or adjustments in metabolic treatment. Its potential clinical utility lies in serving as a screening tool during the initial evaluation of patients with T2D.

The objective of this study was to evaluate the predictive ability of the non-invasive FLI model for the detection of MAFLD in patients with T2D attending outpatient consultations at a tertiary hospital in northern Peru.

METHODS

Study Design and Setting

An external validation study of a predictive model was conducted by prospectively collecting clinical and biochemical data from T2D patients attending the outpatient endocrinology clinic during November-December 2024 at Hospital Regional Eleazar Guzmán Barrón (HREGB), a tertiary care hospital located in the city of Chimbote, northern Peru.

Study Population

Patients with a prior diagnosis of type 2 diabetes mellitus, aged ≥ 25 years, and without a history of significant alcohol consumption (≥ 30 g/day in men and ≥ 20 g/day in women) were included. Exclusion criteria were a history of viral hepatitis (A, B, or D), chronic liver diseases, thyroid disorders, Cushing's syndrome, use of hepatotoxic medications within the previous six months, renal replacement therapy, hemodialysis, pregnancy, or breastfeeding.

Sample Size

The sample size was calculated following the recommendation of Peduzzi & Concato [9], which establishes a minimum of 10 events for each independent variable included in a logistic regression model. Since the FLI model uses five predictors, a minimum of 50 events of hepatic steatosis was required. Considering an expected prevalence of 60% of hepatic steatosis in patients with T2D [5], a minimum sample size of 84 patients was required.

Data Preparation

The data were entered into a password-protected Excel spreadsheet, with access restricted to the research team. The collected data were reviewed to ensure that each patient had complete information required for the study, and duplicate or incomplete records were removed.

Outcome

The predicted outcome (presence of hepatic steatosis) was determined categorically using abdominal ultrasonography as the reference standard. All examinations were performed by a single board-certified radiologist (CMP: 12061297, RNE: 039824) using a VINNO X2 ultrasound machine, serial number U0212HY010.

Predictor Variables

The multivariable predictive model FLI includes weight (kg), height (cm), waist circumference (cm), triglycerides (mg/dL), and gamma-glutamyl transferase (GGT, U/L). Anthropometric variables were obtained directly from the “Diabetes Follow-up Forms” [10], which were prospectively collected by nursing staff from the “Diabetes Epidemiological Surveillance” program, previously trained by the research team.

Study Procedures

Patients with T2D were identified through the Diabetes Epidemiological Surveillance Program at HREGB. After meeting the inclusion criteria and providing informed consent, they were prospectively evaluated by the research team. During the first contact, anthropometric measurements were performed following the standardized protocol of the Peruvian Ministry of Health [11]. Subsequently, within 72 hours, a fasting blood sample (≥ 8 hours) was collected for the determination of triglycerides (mg/dL) and gamma-glutamyl transferase (GGT, U/L). Samples were processed at the HREGB laboratory according to its “Biochemistry Procedures Manual” [12], using automated enzymatic methods with internal quality control.

The outcome was assessed following the protocol “Evaluation of Hepatic Steatosis by Ultrasonic Attenuation” [13]. The radiologist was blinded to clinical and biochemical data, and nursing and laboratory personnel were blinded to the ultrasound findings, in order to minimize review bias.

Statistical Analysis

To evaluate the predictive performance of the FLI model, a single dataset was used, which was exported to the R statistical software (version 4.4.1). For external validation, the FLI model was applied to each patient with T2D, represented in its original form [4] as:

$$FLI = \frac{e^{(0.953 \times \ln(\text{triglycerides}) + 0.139 \times BMI + 0.718 \times \ln(GGT) + 0.053 \times \text{waist circumference} - 15.745)}}{1 + e^{(0.953 \times \ln(\text{triglycerides}) + 0.139 \times BMI + 0.718 \times \ln(GGT) + 0.053 \times \text{waist circumference} - 15.745)}} \times 100$$

Model performance was evaluated using measures of calibration, discrimination, and classification.

Model calibration was assessed using the calibration slope, comparing predicted probabilities with observed outcomes within each probability decile. Calibration was considered good when the slope ranged from 0.9 to 1.1; acceptable, with slight under or overestimation, for slopes between 0.8 and 0.9 or between 1.1 and 1.2; and model recalibration was recommended if the slope was below 0.8 or above 1.2 [14].

The discriminative ability of the model was interpreted based on the area under the receiver operating characteristic curve (AUC): non-informative ($AUROC \leq 0.5$), poor discrimination ($0.5 < AUROC < 0.7$), and good discrimination ($AUROC \geq 0.7$) [15].

The stratification and classification ability of the FLI were assessed using likelihood ratios (LR). Values close to or greater than 10 confirmed the presence of disease [16], whereas values close to or below 0.1 provided evidence to rule it out. Additionally, the Youden index was calculated to identify the optimal cutoff points for ruling out and confirming MAFLD [4].

The expected prevalence of hepatic steatosis for the sample size calculation was 60%, which is considered an acceptable level to avoid extreme class imbalance. For this reason, no techniques were applied to correct for class imbalance.

To explore the fairness of model performance, stratified subgroup analyses were conducted. The model’s discriminative and classification abilities were evaluated according to sex, presence of comorbidities, and glycemic control status ($HbA1c \geq 7\%$, poor glycemic control). Statistical comparisons between AUC values were performed using DeLong’s test, with a p-value < 0.05 .

considered statistically significant. These analyses allowed us to identify potential variations in model performance across different subgroups.

Ethical Approval

The study protocol was approved by the Ethics Committee of the School of Human Medicine at Universidad Nacional del Santa and by the Ethics Committee of HREGB. The study was conducted in accordance with the principles of the Declaration of Helsinki [17] and the Council for International Organizations of Medical Sciences guidelines [18]. Informed consent was obtained from all participants.

RESULTS

Participant Flow

During the study period, 250 patients scheduled for outpatient endocrinology consultations were randomly selected. After applying the eligibility criteria, 232 met the requirements and provided informed consent; of these, 215 agreed to participate in the study. Blood samples were collected and processed the day after the first contact. Among them, 200 patients had complete laboratory results and were scheduled for abdominal ultrasound within a maximum of two days. The final study sample consisted of 175 patients (**Figure 1**).

Descriptive Characteristics of the Study Population

Normality analysis indicated a parametric distribution for BMI, while all other variables were non-parametric.

The mean BMI was 29.62 ± 4.73 kg/m², indicating a predominance of overweight/obesity. Median waist circumference was 100 cm (IQR: 94–104), reflecting a high prevalence of central obesity. Median GGT was 32 U/L (IQR: 20.5–46.5), generally within the normal range. Triglycerides had a median of 190 mg/dL (IQR: 121.5–248.5), suggesting a tendency toward hypertriglyceridemia. Of the 175 patients, 130 (74.2%) had hepatic steatosis diagnosed by ultrasonography, 125 (71.4%) were female, and 112 (64%) had no associated comorbidity.

Patients with hepatic steatosis showed significantly higher values of BMI, waist circumference, ALT, AST, GGT, triglycerides, capillary glucose, and HbA1c ($p < 0.05$). Although liver enzymes remained within reference ranges, they were at the upper limit in this group, and hypertriglyceridemia was also observed. Capillary glucose was elevated in both groups. Mean HbA1c was $<7\%$ in both groups, but higher in patients with steatosis. No significant differences were observed in age, duration of T2D, sex, or comorbidities ($p > 0.05$) (Table 1).

MAFLD was more frequent in women than in men, with 95 cases (76%) versus 35 cases (70%), respectively. When analyzed for the presence of comorbidity, 48 patients with comorbidities (76.1%) had MAFLD, while 82 patients without comorbidities (73.2%) had MAFLD. Considering glycemic control, 50 patients (84.7%) with HbA1c $>7\%$ and 80 patients (68.7%) with HbA1c $<7\%$ were diagnosed with MAFLD.

Model Evaluation

In our population, the calibration slope was 1.00 (95% CI: 0.73-1.31; $p < 0.001$) with an intercept of 0.000 (95% CI: -0.50 to 0.47) (Figure 3), demonstrating good calibration of the FLI model. The AUC was 0.89 (95% CI: 0.83-0.94) (Figure 2).

The stratification and classification ability of the model, considering an FLI score ranging from 0 to 100, showed that a cutoff point <30 (negative LR = 0.08) allows the presence of MAFLD to be ruled out, while an FLI ≥ 70 (positive LR = 10.71) would confirm the diagnosis. Intermediate FLI values (30-70) would require abdominal ultrasonography for diagnostic confirmation (Table 2).

Subgroup Analysis

In the sex-stratified analysis, the AUC was 0.87 (95% CI: 0.75-0.99) in men and 0.90 (95% CI: 0.83-0.96) in women ($p=0.73$). According to comorbidity status, the AUC was 0.94 (95% CI: 0.87-1.00) in patients with comorbidities and 0.86 (95% CI: 0.78-0.94) in those without ($p=0.13$). Finally, regarding glycemic control, AUCs were 0.86 (95% CI: 0.79-0.94) and 0.93 (95% CI: 0.86-1.00) in patients with good and poor glycemic control, respectively ($p=0.19$) (Table 3, Figure 4).

Cutoff values remained consistent and were not influenced by sex, comorbidity status, or glycemic control. Across all subgroups, intermediate FLI values (scores between 30 and 70) corresponded to an indeterminate zone (Table 3).

DISCUSSION

In our study, the FLI showed an AUC of 0.89 with adequate calibration. An FLI score <30 reliably excluded the presence of MAFLD, whereas a score ≥ 70 confirmed the diagnosis. When comparing our findings with the original study by Bedogni et al. [4], some differences were observed: in that study, the AUC was 0.84, and the cutoff points determined using Youden's index (FLI <30 to rule out and FLI ≥ 60 to confirm hepatic steatosis) showed more limited performance. In contrast, in our population, the FLI model demonstrated greater discriminative ability with adjusted cutoff points. This improved diagnostic performance may be attributed to differences in study populations, as the original study included a general population, whereas our analysis focused on patients with type 2 diabetes.

Similarly, the predictive ability of the FLI has been evaluated in different countries. For example, in the study by Okada et al. [5] conducted in Japan, the FLI showed acceptable diagnostic performance in the subgroup of patients with T2D (AUC = 0.83), with good calibration (slope = 0.94) and an optimal cutoff point of 31.1, achieving a sensitivity of 81.1% and specificity of 73.2%. In contrast, in our study, the model demonstrated a higher AUC and nearly perfect calibration. Moreover, the cutoff score of FLI <30 and ≥ 70 proved to be more useful and clinically applicable, as they allowed the exclusion or confirmation of MAFLD with high certainty, in contrast to the single threshold proposed by Okada et al.

On the other hand, the study by Chen et al. [6] conducted in China reported that FLI showed limited discriminative ability in the subgroup of patients with T2D (AUC = 0.74). The optimal cutoff was 88.23, with a sensitivity of 52.4% but a specificity of 82.7%. In this context, FLI performed better in confirming cases (high PPV: 82.1%) than for ruling them out (NPV: 53.5%). These findings differ from those obtained in our study, where FLI achieved a higher AUC with a better balance between sensitivity and specificity, and the adjusted cutoffs of FLI <30 and ≥ 70 demonstrated stronger clinical utility.

In China, Liu et al. [7] demonstrated that FLI is a strong predictor of MAFLD in patients T2D, with an AUC of 0.96. They reported an optimal cutoff value of 2.071, with a sensitivity of 90.9% and a specificity of 87.8%. Notably, this value corresponded to a transformed/standardized FLI rather than the original 0–100 scale proposed by Bedogni et al. [4]. While Liu's analysis reinforces the utility of FLI in Asian populations with diabetes, their proposed threshold is not directly applicable to our population. Our results confirm that, in our context, the original FLI model retains high performance, though with the need to adjust the upper cutoff for high risk of MAFLD, making it easier to apply and interpret in routine clinical practice.

In our study, the overall prevalence of MAFLD was 74%, being slightly more frequent in women; however, the difference by sex was marginal, and the presence of comorbidities had a limited effect. By contrast, patients with poor glycemic control showed a higher frequency of MAFLD. Our findings highlight that overweight, hypertriglyceridemia, and glycemic dysregulation are associated with MAFLD, underscoring the need for comprehensive management strategies that prioritize glycemic control and weight reduction to prevent progression of liver disease.

Finally, in the subgroup analysis of the discriminative ability of FLI, slightly higher AUC values were observed in women, in patients with comorbidities, and in those with poor glycemic control (HbA1c $\geq 7\%$). However, none of these differences reached statistical significance, suggesting an equitable predictive performance of the FLI model across the different subgroups analyzed.

Clinical Implications

The use of the FLI model with cutoffs validated in our population could improve early detection of MAFLD and reduce the demand for ultrasonography in patients with type 2 diabetes.

LIMITATIONS

Our study population consisted exclusively of patients with T2D, unlike the original study [4] conducted in the general population. This may affect comparisons, as patients with diabetes are at higher risk of developing MAFLD.

Excluding subjects with significant alcohol consumption reduced sample heterogeneity, likely contributing to improved model performance. This contrasts with the original cohort, which included a heterogeneous general population with and without alcohol consumption and a lower baseline metabolic burden. These findings highlight a critical point: while the FLI maintains optimal performance in both populations, its performance parameters and optimal cutoff points are not universal. Rather, they appear to be conditioned by the epidemiological and clinical profile of the population.

Although this is the first external validation study of the FLI model in a Peruvian cohort, its single-center design may limit the generalizability of the results to the broader population.

CONCLUSIONS

The non-invasive FLI model demonstrated good predictive ability for detecting MAFLD in outpatients with T2D at a tertiary hospital in northern Peru, supporting its potential implementation in our setting as a screening tool with adjusted cut-off points. An FLI score < 30 would rule out the presence of MAFLD, whereas a score ≥ 70 would confirm the presence of disease. Scores between 30 and 70 would identify patients requiring liver ultrasonography as a complementary diagnostic test.

The FLI model with adjusted cut-off points demonstrated consistent and comparable predictive ability across the different subgroups, with no significant differences by sex, presence of comorbidity, or glycemic control status, supporting its robustness as a screening tool applicable to the studied population.

RECOMMENDATIONS

Prospective multicenter studies with larger sample sizes are required to confirm the predictive ability of the FLI in middle-income countries such as Peru.

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Conflict of Interest: The authors declare that they have no financial or non-financial conflicts of interest.

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TABLES Y FIGURES

Table 1. Comparison of clinical, anthropometric, and biochemical variables according to the presence of hepatic steatosis (n = 175).

VARIABLE	WITH STEATOSIS HEPÁTIC	WITHOUT STEATOSIS HEPATIC	STATISTICAL TEST ^a	p-value ^b
FLI (score)	83	30	w= 65,8	0,000
BMI (kg/m ²)	30,81	26,17	t=-8,21	0,000
Diagnosis Duration (years)	12	10	t=-1,50	0,341
Age (years)	62	64	w = 3159	0,425
Waist circumference (cm)	102	94	w=1086	0,000
ALT (U/L)	32	17	w=1220	0,000
AST (U/L)	24,5	18	w=1699	0,000
GGT (U/L)	36	19	w=1189	0,000
Triglycerides (mg/dL)	210	105	w=943,5	0,000
Preprandial capillary glucose (mg/dL)	168,5	150	w=2065	0,003
HbA1c (%)	6,7	6,4	w=1744	0,000
Female sex	95 (54.3%)	30 (17.1%)	$\chi^2=0,67$	0,412
With comorbidity	48 (27.4%)	15 (8.6%)	$\chi^2=0,19$	0,665

a. The p-value for parametric quantitative variables was calculated using the Student's t-test (t); for non-parametric quantitative variables, the Wilcoxon test (W) was used; and for qualitative variables, the Chi-square test (χ^2) was applied.

b. Statistically significant difference at $p < 0.05$, indicating an association of the variable with hepatic steatosis.

Table 2. Risk stratification of the FLI model for the diagnosis of hepatic steatosis in patients with type 2 diabetes mellitus.

FLI Cutoff ^a	%	SEN (%)	SP(%)	LR+	LR-
≥10	174	99	0	1,00	Infinito
≥20	166	97	13	1,11	0,23
≥30	148	96	49	1,88	0,08

≥40	137	92	62	2,42	0,13
≥50	124	86	73	2,32	0,22
≥60	113	80	84	5,00	0,24
≥70	100	75	93	10,71	0,27
≥80	77	58	93	8,29	0,45
≥90	42	32	98	16,00	0,69
≥100	0	1	100	Infinito	0,99

a. The optimal cutoff point was calculated based on the highest Youden index.

Abbreviations: FLI = Fatty Liver Index; % = number of patients with FLI ≥ cutoff points; SEN = sensitivity; SP = specificity; LR+ = positive likelihood ratio; LR- = negative likelihood ratio.

Table 3. Risk Stratification by Subgroups of the FLI Model for the Diagnosis of Hepatic Steatosis in Patients with Type 2 Diabetes Mellitus

FLI Cutoff ^a	n(%)	SEN (%)	SP(%)	LR+	LR-	AUC (IC 95%)	p-value ^b
MALE SUBGROUP (n = 50)							
≥30	40 (80%)	97	60	2,42	0,05	0,87 (IC95%: 0,75-0,99)	0,737
≥70	27 (54%)	74	93	10,57	0,28		
FEMALE SUBGROUP (n = 125)							
≥30	108 (86,4%)	96	47	1,81	0,09	0,90 (IC95%: 0,83-0,96)	0,134
≥70	73 (58,4%)	75	93	10,71	0,27		
SUBGROUP WITH COMORBIDITY PRESENT (n = 63)							
≥30	54 (85,7%)	97	53	2,06	0,06	0,94 (IC95%: 0,87-1,00)	0,134
≥70	34 (53,9%)	71	99	71,00	0,29		
SUBGROUP WITHOUT COMORBIDITIES (n=112)							

≥30	94 (83.9%)	95	47	1,79	0,11	0,86 (IC95%: 0,78-0,94)
≥70	66 (58,9%)	77	90	7,70	0,26	

SUBGROUP WITH GOOD GLYCEMIC CONTROL (HbA1c <7%) (n = 116)

≥30	94 (81%)	95	50	1,90	0,10	0,86 (IC95%: 0,79-0,94)	
≥70	61 (52,59%)	73	92	9,13	0,29		0,189

SUBGROUP WITH POOR GLYCEMIC CONTROL (HbA1c ≥7%) (n = 59)

≥30	54 (91.5)	98	44	1,75	0,05	0,93 (IC95%: 0,86-1,00)
≥70	39 (66,1%)	78	99	78	0,22	

a. The optimal cutoff point was calculated based on the highest Youden index.

b. Statistically significant difference at $p < 0.05$

Abbreviations: n = participants; FLI = Fatty Liver Index; % = number of patients with FLI ≥ cutoff points; SEN = sensitivity; SP = specificity; LR+ = positive likelihood ratio; LR- = negative likelihood ratio.

Figure 1. Patient Selection Process

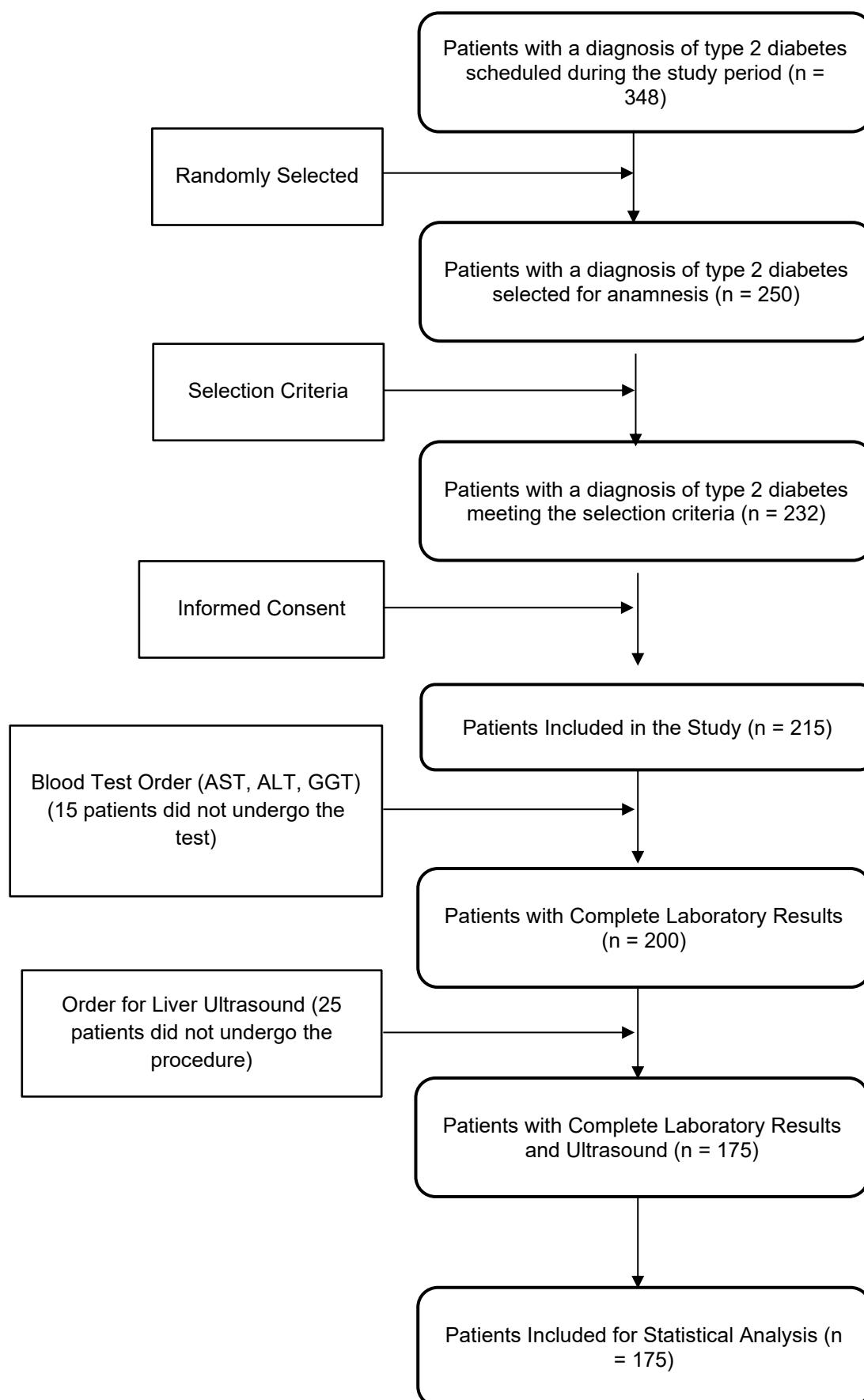


Figure 2. ROC Curve of the FLI Predictive Model for the Diagnosis of Hepatic Steatosis in Patients with Type 2 Diabetes Mellitus

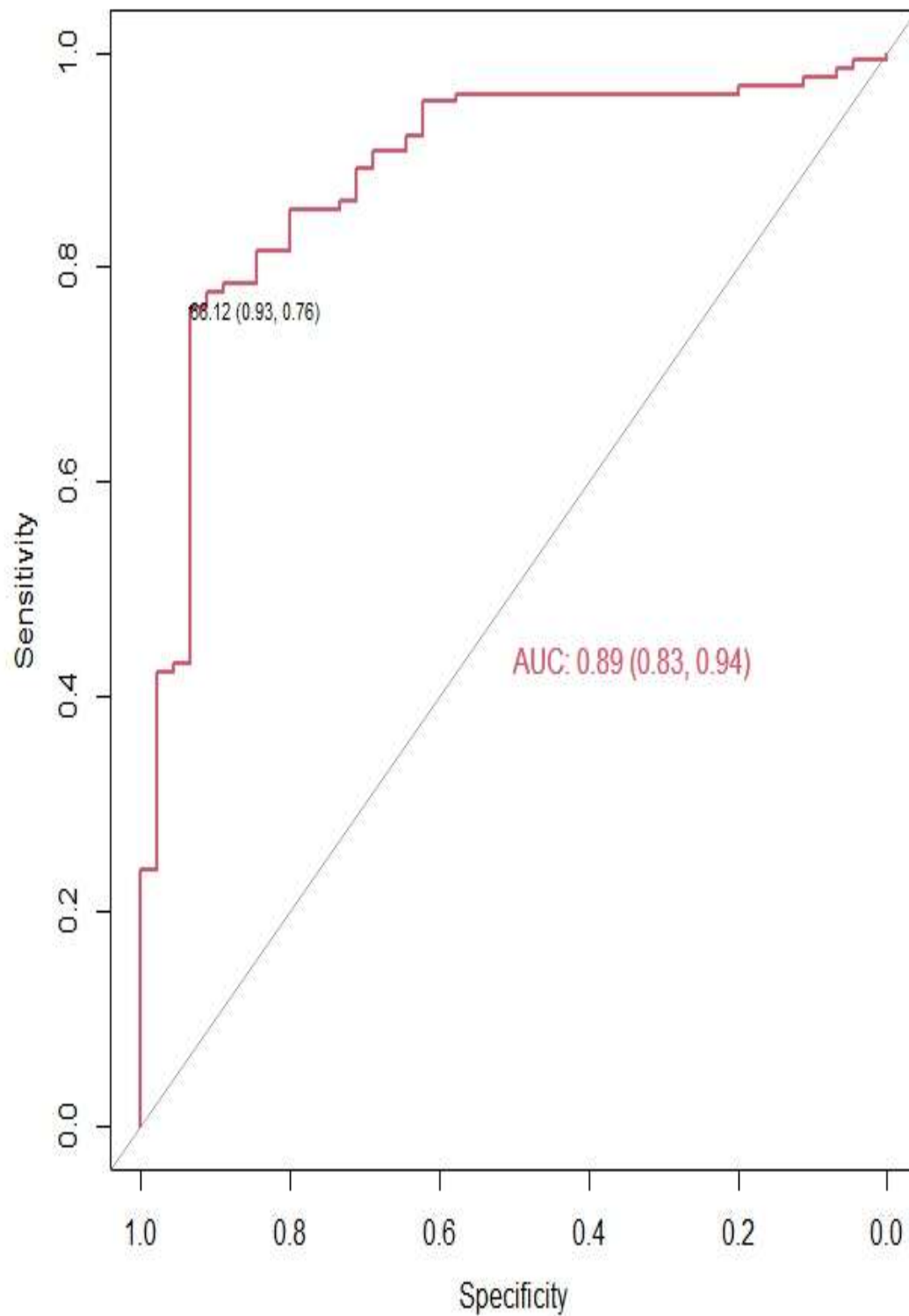


Figure 3. Calibration Curve of the FLI Model for the Diagnosis of Hepatic Steatosis in Patients with Type 2 Diabetes Mellitus

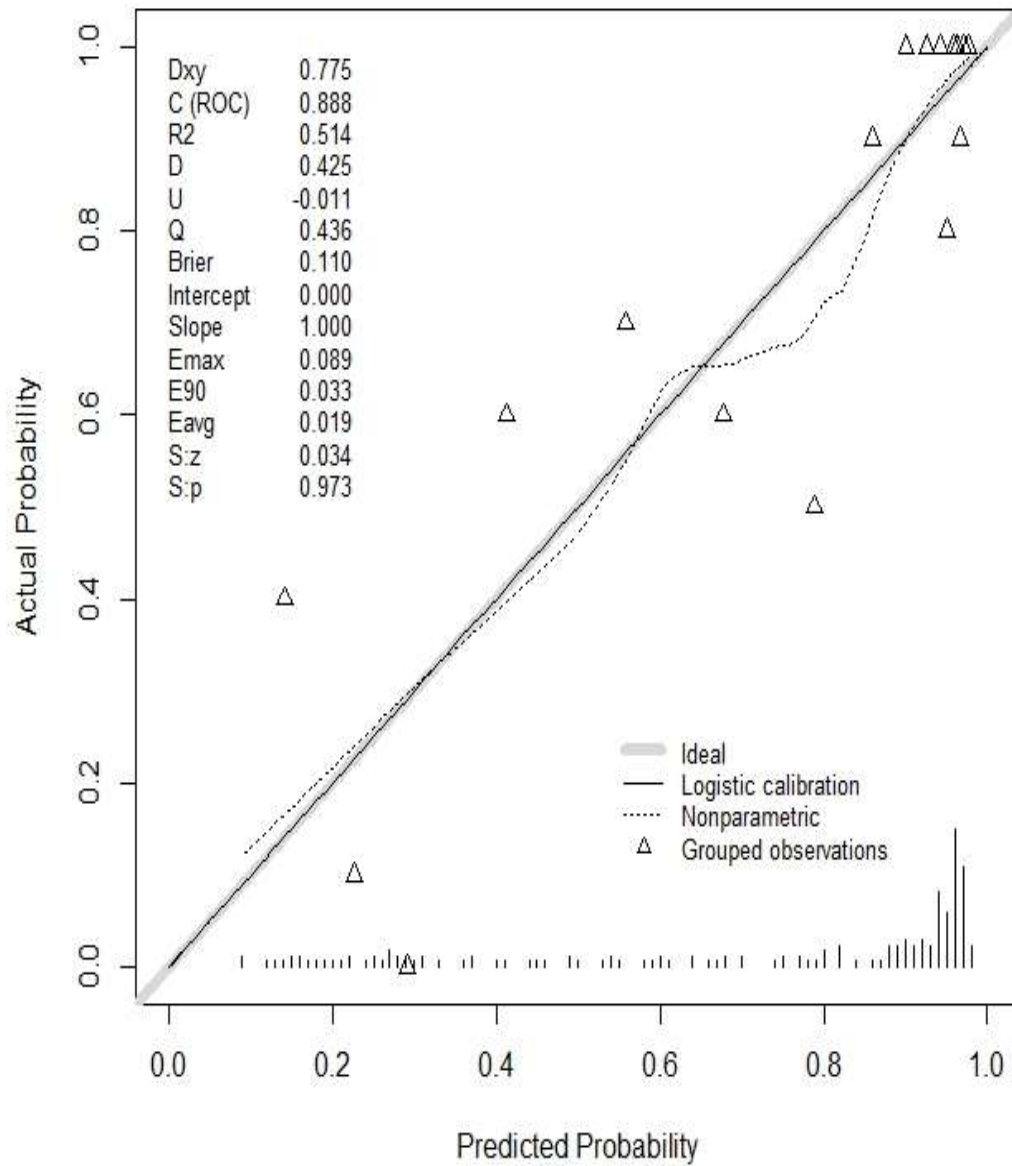
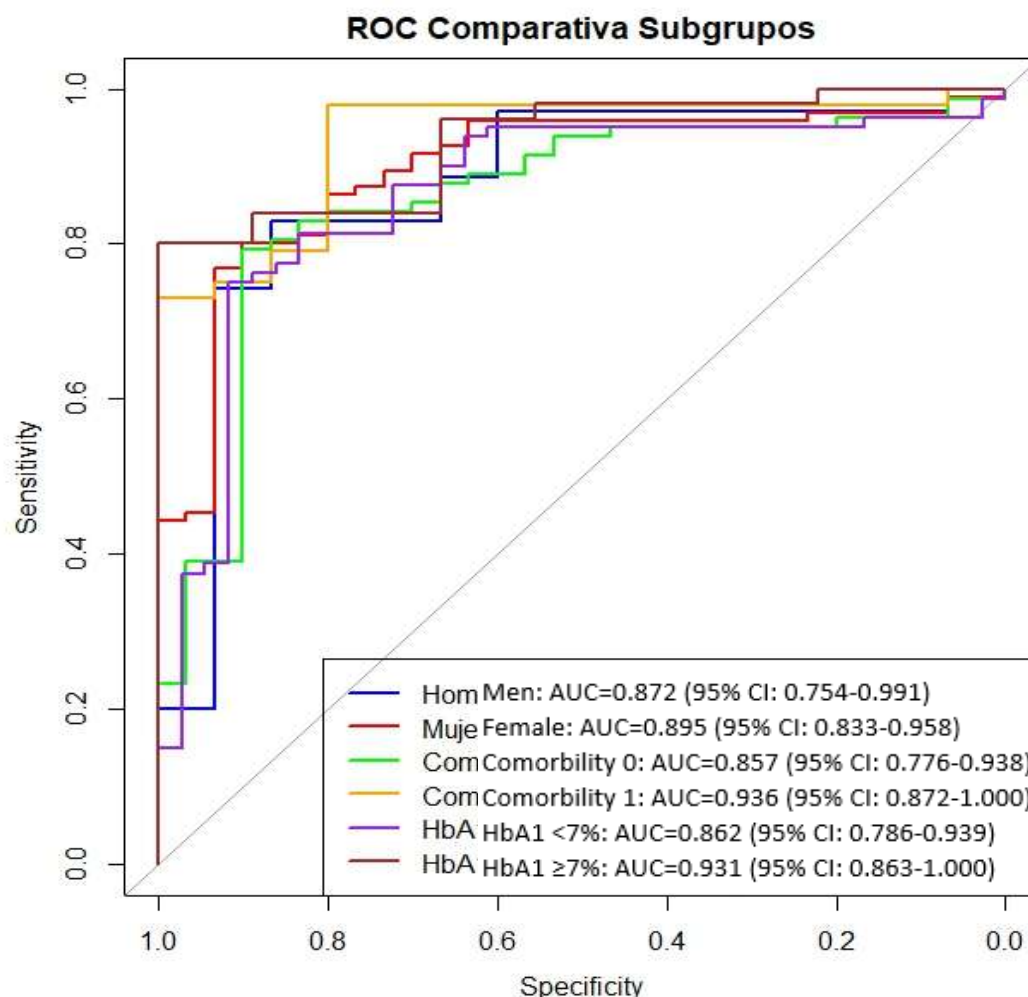


Figure 4: ROC Curves of the FLI Model for the Diagnosis of Hepatic Steatosis in Patients with Type 2 Diabetes Mellitus, According to Subgroup Analysis



Note: The analysis included subgroups by sex, presence (1) or absence (0) of comorbidities, and glycemic control (HbA1c <7% vs ≥7%). AUC values (95% CI) are presented for each subgroup.

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