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Baveno VII Endoscopy-Sparing Criteria in MASLD-Predominant Compensated Cirrhosis: A Prospective Validation from a Gulf Arab Population (Kuwait)

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Abstract

Background & Aims: The Baveno VII non-invasive criteria can safely defer screening endoscopy in compensated advanced chronic liver disease, but their performance in metabolic dysfunction-associated steatotic liver disease (MASLD), particularly with obesity, and in Gulf Arab populations is incompletely characterised. We validated the Baveno VII endoscopy-sparing criteria in a Kuwaiti, MASLD-predominant compensated cirrhosis cohort, with pre-specified disaggregation of MASLD by obesity status and exploratory validation of the ANTICIPATE-NASH model against clinical CSPH surrogates.

Methods: Consecutive Kuwaiti adults with compensated cirrhosis underwent concurrent vibration-controlled transient elastography, platelet count, and reference-standard upper gastrointestinal endoscopy at Al Adan Hospital between January 2022 and April 2026. Baveno VI, Expanded Baveno VI, Baveno VII, and ANTICIPATE-NASH criteria were applied, with high-risk varices (HRV) as the primary endpoint. Aetiologies were classified per the 2023 multi-society MASLD nomenclature. Pre-specified subgroups compared MASLD with and without obesity (BMI ≥30 kg/m²). Wilson confidence intervals, DeLong's method, multivariable logistic regression, and Hosmer–Lemeshow calibration were applied. Reporting followed STARD 2015, STROBE, and TRIPOD.

Results: Of 451 patients screened, 380 were analysed (mean age 53.4 years; 60.0% male; mean BMI 33.1 kg/m²; MASLD 66.3%; HRV prevalence 20.0%). The Baveno VII rule-out criterion (LSM <20 kPa AND platelets >150 × 10⁹/L) was satisfied by 37.6%, with miss rate 1.4% (95% CI 0.2–5.0%), NPV 98.6%, and safe performance across all subgroups. Expanded Baveno VI exceeded the 5% safety threshold in MASLD with obesity (7.1%, 95% CI 3.3–14.6%). ANTICIPATE-NASH ≥75% improved positive predictive value for CSPH by 16.8 points over LSM ≥25 kPa alone in MASLD with obesity (84.1% versus 67.3%; p<0.001; H-L p=0.31). On multivariable analysis, LSM, platelet count, albumin, and MELD were independent predictors of HRV; BMI, type 2 diabetes, and MASLD aetiology were non-significant after adjustment for LSM.

Conclusions: The Baveno VII rule-out criterion is safe in this cohort. Expanded Baveno VI should not be applied in MASLD with obesity. ANTICIPATE-NASH generalises to a Gulf Arab population without recalibration and reduces overtreatment when used as the rule-in tool. These findings support a three-tier non-invasive endoscopy-sparing framework for Gulf Arab compensated cirrhosis.

1. Introduction

Portal hypertension is the principal driver of morbidity and mortality in patients with cirrhosis, culminating in life-threatening complications including acute variceal haemorrhage, ascites, and hepatic encephalopathy.[1] Oesophageal and gastric varices develop in approximately 30–40% of patients with compensated cirrhosis and up to 85% of those with decompensated disease, with high-risk varices (HRV), defined by size, red colour signs, or gastric location, conferring the greatest risk of index bleeding and cirrhosis-related death.[2, 3] Endoscopic screening for varices has therefore been mandated by international guidelines as a standard component of cirrhosis management, with prophylactic

endoscopic band ligation or non-selective beta-blocker (NSBB) therapy recommended for patients found to harbour HRV.[4]

However, a substantial proportion of patients with compensated advanced chronic liver disease (cACLD) and preserved portal haemodynamics harbour no HRV and derive no clinical benefit from endoscopic screening.[5] Performing upper gastrointestinal endoscopy (OGD) in this low-risk group exposes patients to procedural risk and sedation, generates avoidable healthcare costs, and places unnecessary burden on endoscopy units. The identification of patients who can safely forgo screening endoscopy has therefore become a major clinical priority.[6]

Transient elastography (TE), through the measurement of liver stiffness (LSM), is the most widely validated non-invasive tool for the assessment of hepatic fibrosis and portal hypertension, correlating closely with hepatic venous pressure gradient (HVPG) across a broad range of chronic liver disease aetiologies.[7, 8] Building on this evidence, the Baveno VI Consensus Workshop (2015) established that patients with LSM < 20 kPa and platelet count > 150 × 10^9/L could safely avoid screening endoscopy, as the probability of HRV in this group falls below the accepted 5% miss rate threshold.[3] The subsequent Expanded Baveno VI criteria (LSM < 25 kPa and platelet count > 110 × 10^9/L) increased the proportion of endoscopies safely spared from approximately 21% to 40%, with a miss rate of 1.6%.[9] The Baveno VII Consensus Workshop (2021) reaffirmed these non-invasive endoscopy-sparing thresholds, incorporating an updated definition of HRV and introducing new non-invasive criteria for the diagnosis of clinically significant portal hypertension (CSPH).[10]

Despite robust validation data from European and Asian cohorts, predominantly composed of patients with HCV-, HBV-, and alcohol-related cirrhosis, the applicability of Baveno VII endoscopy-sparing criteria to patients with metabolic dysfunction-associated steatotic liver disease (MASLD) remains incompletely established.[11, 12] Hepatic steatosis and necro-inflammation in MASLD independently elevate LSM beyond what portal pressure alone would predict, resulting in a systematic overestimation of CSPH risk in obese patients.[13, 14] A recent individual patient data (IPD) meta-analysis demonstrated that the Baveno VII rule-in threshold of LSM ≥ 25 kPa achieved a positive predictive value for CSPH of only 62.8% in patients with MASLD and obesity (BMI ≥ 30 kg/m^2), compared with > 90% in non-obese MASLD and near 100% in viral hepatitis and alcohol-related liver disease.[14] The ANTICIPATE-NASH model, incorporating LSM, platelet count, and BMI to recalibrate CSPH risk prediction in MASLD patients, has been increasingly advocated as a refinement in this setting.[14, 15]

The Gulf Cooperation Council (GCC) region, including Kuwait, presents a distinct and underrepresented clinical context. MASLD is the dominant aetiology of cirrhosis in this population, driven by exceptionally high rates of obesity, type 2 diabetes mellitus (T2DM), and metabolic syndrome.[16] Kuwait reports one of the highest obesity burdens globally, with population-based data documenting BMI ≥ 30 kg/m^2 in approximately 40% of adults and a T2DM prevalence of 19.1%.[17, 18] Despite this epidemiological profile, no prospective study has examined the performance of Baveno VII endoscopy-sparing criteria in a Gulf Arab population. The only published Baveno criteria validation from the Arab world used

retrospective NAFLD data from Saudi Arabia, demonstrating inferior performance compared with viral hepatitis subgroups, without formal obesity stratification.[19]

This study aimed to prospectively validate the Baveno VII endoscopy-sparing criteria in a consecutive cohort of Kuwaiti patients with compensated cirrhosis, with pre-specified subgroup analyses in MASLD+obesity and MASLD-without-obesity subgroups, and exploratory validation of the ANTICIPATE-NASH model as a complementary risk stratification tool. Secondary objectives included head-to-head comparison of Baveno VI, Expanded Baveno VI, and Baveno VII criteria, ROC-derived optimal LSM thresholds, and multivariable predictors of HRV.

2. Methods

2.1 Study Design and Setting

This was a prospective, single-centre, diagnostic accuracy cohort study conducted at the Endoscopy Unit of Al Adan Hospital, a tertiary-care teaching hospital in Kuwait operated under the Kuwait Ministry of Health, serving as a regional hepatology referral centre for the southern governorates of Kuwait. The study enrolled consecutive eligible patients from 6 January 2022 with recruitment completed on 30 April 2026. The study was designed and reported in accordance with the STARD 2015 guidelines, the STROBE statement, and, for the ANTICIPATE-NASH sub-analysis, the TRIPOD guidelines.

2.2 Participants

2.2.1 Eligibility Criteria

Inclusion criteria: (1) age ≥ 18 years; (2) Kuwaiti nationality; (3) compensated cirrhosis (Child–Pugh A or B, no prior decompensation); (4) LSM by vibration-controlled transient elastography (VCTE) within three months of index endoscopy; (5) concurrent platelet count within three months; (6) qualifying upper gastrointestinal endoscopy as reference standard; (7) no prior NSBB therapy for portal hypertension prophylaxis; (8) written informed consent. Key exclusion criteria included decompensated cirrhosis, active HCC or malignancy, portal vein thrombosis > 50% luminal occlusion, prior TIPS or surgical shunt, prior endoscopic band ligation, technically unreliable LSM (IQR/median > 30% with LSM > 7.1 kPa), and acute-on-chronic liver failure.

2.2.2 Aetiology Classification and MASLD Definition

All patients underwent aetiological evaluation including viral hepatitis serology, autoimmune antibody panel, genetic and metabolic screen (serum ferritin, transferrin saturation, alpha-1-antitrypsin, caeruloplasmin), and detailed alcohol use history. Hepatic aetiology was classified prospectively using the 2023 multi-society Delphi consensus nomenclature.[21] MASLD was defined as hepatic steatosis (CAP ≥ 248 dB/m, or ≥ 5% steatosis on liver histology or MRI-PDFF) plus at least one of five cardiometabolic risk factors: BMI ≥ 25 kg/m², T2DM, hypertension, hypertriglyceridaemia, or low HDL cholesterol/pre-diabetes. In patients with cirrhotic-stage or burned-out disease in whom current

steatosis may be absent on FibroScan CAP, previously documented steatohepatitis on histology or clinical history of MASLD, alongside the presence of at least one cardiometabolic risk factor and the exclusion of all competing aetiologies, was sufficient for MASLD classification per the 2023 consensus.[21] The MASLD+obesity subgroup was pre-specified as patients with MASLD and BMI ≥ 30 kg/m², consistent with the Dajti et al. IPD meta-analysis.[14]

2.3 Index Tests — Non-Invasive Criteria

LSM was performed using FibroScan® 502 Touch (Echosens, Paris, France) after a minimum four-hour fast, per EASL quality criteria. CAP was co-acquired simultaneously. Four criteria sets were applied to each patient (Table 1).

Table 1
Non-invasive criteria sets applied in this study

Criterion	Rule-out threshold(s)	Reference	Comment
Baveno VI	LSM < 20 kPa AND PLT > 150 ×10⁹/L	de Franchis 2015[3]	Original endoscopy-sparing criterion
Expanded Baveno VI	LSM < 25 kPa AND PLT > 110 ×10⁹/L	Augustin 2017[9]	Relaxed thresholds; secondary criterion
Baveno VII (Primary)	Rule-out: LSM < 20 kPa AND PLT > 150 ×10⁹/L; Rule-in: LSM ≥ 25 kPa	de Franchis 2022[10]	Primary index test
ANTICIPATE-NASH	CSPH probability ≥ 75% using LSM, PLT, BMI	Abraldes 2016[15]	Rule-in model; exploratory in MASLD+obesity

CSPH, clinically significant portal hypertension; LSM, liver stiffness measurement; PLT, platelet count; BMI, body mass index. Baveno VI and Baveno VII share identical rule-out thresholds (LSM < 20 kPa AND PLT > 150 ×10⁹/L).

2.4 Reference Standard

Upper gastrointestinal endoscopy was performed using high-definition gastroscopes (Olympus GIF-HQ290) by consultant gastroenterologists blinded to LSM values. Varices were graded using the three-tier Baveno classification (F1–F3). HRV were defined as F2 or F3 oesophageal varices, or any varix with high-risk stigmata (red wale marks, red spots, haematocystic spots). Inter-observer agreement was assessed by Cohen's kappa; discordance was resolved by a third independent reviewer. For the ANTICIPATE-NASH analysis, clinically significant portal hypertension (CSPH) was defined using validated clinical surrogates in the absence of routine HVPG measurement: the presence of any gastro-oesophageal varices at endoscopy, portosystemic collaterals on cross-sectional imaging, or splenomegaly accompanied by thrombocytopenia (platelet count < 150 × 10⁹/L). High-risk varices were analysed separately as the primary endpoint, as defined above.

2.5 Statistical Analysis

The primary miss rate was calculated as the number of patients meeting the Baveno VII rule-out criterion with HRV at endoscopy divided by all patients meeting the criterion, expressed as a percentage with Wilson 95% confidence intervals (CI). ROC curves were analysed using DeLong's non-parametric method. ANTICIPATE-NASH calibration was assessed by the Hosmer–Lemeshow (H-L) test. Multivariable logistic regression employed backward stepwise selection (entry $p < 0.10$). Comparative criterion performance was assessed using McNemar's test with Bonferroni correction. All analyses: IBM SPSS v27.0 and MedCalc v22.0. Two-sided $p < 0.05$ was considered significant throughout. No a priori sample size calculation was performed given the diagnostic accuracy design and the requirement to enrol consecutive eligible patients; retrospectively, the achieved sample size of n = 380 yielded a Wilson 95% CI half-width of approximately 2.4 percentage points around the observed miss rate of 1.4%, providing adequate precision to assess the criterion against the 5% safety threshold. All analyses were performed on the complete-case cohort of 380 enrolled patients with full index-test (LSM, platelet count) and reference-standard (upper gastrointestinal endoscopy) data; no patient with complete data was excluded post-enrolment, and per-protocol and intention-to-diagnose analyses were therefore concordant. Subgroup AUROC comparisons were exploratory and not adjusted for multiplicity; corresponding findings are interpreted as hypothesis-generating.

2.6 Ethics and Registration

Ethics approval

was obtained from the Al Adan Hospital IRB and the Kuwait Ministry of Health Ethics Committee (Approval No: MOH/REC/060720221394). The study was registered in the ISRCTN Registry (ISRCTN17426305; date of registration 16 July 2026; retrospectively registered, after the commencement of enrolment). All procedures conformed to the 1964 Declaration of Helsinki. Written informed consent was obtained from all participants.

3. Results

3.1 Study Population and Enrolment

Between 6 January 2022 and 30 April 2026, 451 consecutive Kuwaiti patients were screened for eligibility. Seventy-one patients (15.7%) were excluded: 18 due to technically unreliable LSM; 16 due to prior EVL or NSBB therapy; 14 due to decompensated cirrhosis; 11 due to HCC or malignancy; 7 due to portal vein thrombosis > 50%; and 5 who declined consent. The final analytic cohort comprised 380 patients. Full enrolment and outcome data are shown in Fig. 1 and Supplementary Table S1.

3.2 Baseline Characteristics

Baseline characteristics are summarised in Table 2 and Fig. 2. Mean age was 53.4 ± 11.2 years; 60.0% were male; mean BMI was 33.1 ± 5.8 kg/m². All patients were classified prospectively using the 2023 MASLD nomenclature.[21] MASLD was the leading aetiology in 252 patients (66.3%), of whom 172

(45.3%) had concomitant obesity (BMI ≥ 30 kg/m²) and 80 (21.1%) had MASLD without obesity. The non-MASLD group comprised 128 patients (33.7%): HCV-related cirrhosis in 54 (14.2%), HBV-related in 38 (10.0%), alcohol-related in 21 (5.5%), and autoimmune/PBC/PSC in 15 (3.9%). The metabolic comorbidity burden was severe across the cohort: T2DM in 214 (56.3%), hypertension in 178 (46.8%), dyslipidaemia in 156 (41.1%). The low ALD prevalence (5.5%) reflects the predominantly Muslim, alcohol-abstinent Kuwaiti demographic. The cohort was well-compensated: 82.6% Child–Pugh A, median MELD 9 (IQR 7–12). Median LSM was 17.8 kPa (IQR 12.4–24.6), median CAP 291 dB/m, median platelet count 162 × 10^9/L. Inter-observer κ for variceal grading was 0.91 (95% CI 0.86–0.96).

Table 2
Baseline characteristics of the study cohort (N = 380)

Variable	Value
Demographics	
Age, years — mean ± SD	53.4 ± 11.2
Male sex — n (%)	228 (60.0)
BMI, kg/m² — mean ± SD	33.1 ± 5.8
BMI ≥ 30 kg/m² — n (%)	238 (62.6)
Aetiology of cirrhosis	
MASLD — n (%)	252 (66.3)
MASLD + obesity (BMI ≥ 30 kg/m²) — n (%)	172 (45.3)
MASLD without obesity (BMI < 30 kg/m²) — n (%)	80 (21.1)
HCV-related — n (%)	54 (14.2)
HBV-related — n (%)	38 (10.0)
Alcohol-related — n (%)	21 (5.5)
Autoimmune/PBC/PSC — n (%)	15 (3.9)
Comorbidities	
Type 2 diabetes mellitus — n (%)	214 (56.3)
Arterial hypertension — n (%)	178 (46.8)
Dyslipidaemia — n (%)	156 (41.1)
Liver function and severity	
Child–Pugh class A — n (%)	314 (82.6)
MELD score — median (IQR)	9 (7–12)
Albumin, g/L — mean ± SD	38.4 ± 5.2
Bilirubin, µmol/L — mean ± SD	22.4 ± 14.6
INR — mean ± SD	1.18 ± 0.22
FibroScan parameters	
LSM, kPa — median (IQR)	17.8 (12.4–24.6)
CAP, dB/m — median (IQR)	291 (258–319)

Variable	Value
Demographics	
Platelet count, ×10⁹/L — median (IQR)	162 (108–213)
APRI — mean ± SD	1.24 ± 0.89
FIB-4 — mean ± SD	3.82 ± 2.14

MASLD, metabolic dysfunction-associated steatotic liver disease (classified per Rinella et al. 2023 multi-society consensus[21]*); HCV, hepatitis C virus; HBV, hepatitis B virus; PBC, primary biliary cholangitis; PSC, primary sclerosing cholangitis; MELD, model for end-stage liver disease; LSM, liver stiffness measurement; CAP, controlled attenuation parameter; IQR, interquartile range; SD, standard deviation.*

3.3 Endoscopic Findings

All 380 patients underwent complete reference-standard endoscopy. HRV were identified in 76 patients (20.0%): F2 oesophageal varices in 48 (12.6%), F3 in 18 (4.7%), and F1 with high-risk stigmata in 10 (2.6%). No varices were found in 198 patients (52.1%) and low-risk F1 varices in 106 (27.9%). Concurrent gastric varices (GOV1 or GOV2) were present in 24 patients (6.3%). The HRV prevalence of 20.0% is consistent with published rates of 18–23% in MASLD-predominant compensated cirrhosis cohorts.

3.4 Primary Outcome: Baveno VII Endoscopy-Sparing Criteria

The Baveno VII rule-out criterion (LSM < 20 kPa AND platelet count > 150 × 10⁹/L) was satisfied by 143 of 380 patients (37.6%). Among these, HRV were identified in 2, yielding a miss rate of 1.4% (95% CI 0.2–5.0%) and NPV 98.6% (95% CI 95.2–99.7%). The upper bound of the 95% CI fell just within the 5% Baveno safety threshold, supporting prospective criterion safety in this population. Both missed HRV harboured F2 oesophageal varices only (LSM values 19.1 and 19.4 kPa, within 0.9 kPa of the threshold), representing borderline classification rather than systematic criterion failure. Complete comparative data are presented in Table 3 and Fig. 3.

Table 3
Comparative diagnostic performance of non-invasive endoscopy-sparing criteria (N = 380)

Parameter	Baveno VI	Expanded Baveno VI	Baveno VII[+]	ANTICIPATE-NASH ≥ 75%
Patients meeting criterion — n (%)	143 (37.6)	196 (51.6)	143 (37.6)	112 (29.5)
HRV missed — n	2	9	2	N/A
Miss rate, % (95% CI)	1.4 (0.2–5.0)	4.6 (2.1–8.6)	1.4 (0.2–5.0)	—
NPV, % (95% CI)	98.6 (95.2–99.7)	95.4 (91.5–97.8)	98.6 (95.2–99.7)	—
Sensitivity, % (95% CI)	97.4 (91.0–99.5)	88.2 (79.4–93.8)	97.4 (91.0–99.5)	—
Specificity, % (95% CI)	46.4 (40.8–52.1)	61.5 (55.9–66.8)	46.4 (40.8–52.1)	—
PPV, % (95% CI)	—	—	—	87.5 (79.8–92.8)
Endoscopies spared — n (%)	143 (37.6)	196 (51.6)	143 (37.6)	—
Missed HRV per 1000 analysed	5.3	23.7	5.3	—

[+]Primary index test. NPV, negative predictive value; PPV, positive predictive value; HRV, high-risk varices; CI, Wilson 95% confidence interval. Baveno VI and Baveno VII share identical rule-out thresholds and therefore identical endoscopy-sparing performance.

3.5 Comparative Performance: Baveno VI, Expanded Baveno VI, and Baveno VII

Expanded Baveno VI classified 196 patients (51.6%) as eligible to forgo endoscopy (a 14 percentage-point absolute increase over Baveno VII; McNemar $p < 0.001$), at the cost of a miss rate of 4.6% (95% CI 2.1–8.6%). In the pre-specified MASLD+obesity subgroup (n = 172), the Expanded Baveno VI miss rate reached 7.1% (95% CI 3.3–14.6%), with both the point estimate and the entire CI exceeding the 5% benchmark. Expressed in standardised terms, Expanded Baveno VI generated 23.7 missed HRV per 1,000 analysed versus 5.3 per 1,000 under Baveno VII, a 4.5-fold increase.

3.6 Subgroup Analyses: MASLD, Obesity, and Aetiology

Subgroup performance is presented in Table 4 and Fig. 4. In the overall MASLD subgroup (n = 252), 93 patients (36.9%) met the rule-out criterion with a miss rate of 1.1% (NPV 98.9%). In the pre-specified MASLD+obesity subgroup (n = 172), 61 patients (35.5%) met the criterion with a miss rate of 1.6% (NPV 98.4%): the criterion remained safe, though the lower eligibility rate reflects BMI-driven LSM inflation

paradoxically reducing criterion access. In MASLD patients without obesity (n = 80), 32 patients (40.0%) met the criterion with miss rate 0% and NPV 100%, confirming optimal performance when obesity-related LSM confounding is absent. Among viral hepatitis aetiologies, miss rate was 0% for both HCV (n = 54) and HBV (n = 38).

Table 4
Baveno VII rule-out criterion performance by aetiology subgroup

Subgroup	n	Met criterion — n (%)	Miss rate % (95% CI)	NPV % (95% CI)
Full cohort	380	143 (37.6)	1.4 (0.2–5.0)	98.6 (95.2–99.7)
MASLD (all)	252	93 (36.9)	1.1 (0.1–6.3)	98.9 (94.2–99.8)
MASLD + obesity (BMI ≥ 30 kg/m²)	172	61 (35.5)	1.6 (0.1–8.8)	98.4 (91.2–99.7)
MASLD without obesity (BMI < 30 kg/m²)	80	32 (40.0)	0 (0.0–10.8)	100.0 (89.2–100.0)
Non-MASLD (all aetiologies)	128	50 (39.1)	2.0 (0.1–10.5)	98.1 (89.9–99.7)
HCV-related	54	22 (40.7)	0 (0.0–15.4)	100.0 (84.6–100.0)
HBV-related	38	16 (42.1)	0 (0.0–20.6)	100.0 (79.4–100.0)

NPV, negative predictive value; MASLD, metabolic dysfunction-associated steatotic liver disease; HCV, hepatitis C virus; HBV, hepatitis B virus. Wilson 95% confidence intervals throughout. All aetiologies classified per 2023 MASLD nomenclature.[21]

3.7 ANTICIPATE-NASH Model Validation

A CSPH probability ≥ 75% by ANTICIPATE-NASH was achieved in 112 patients (29.5%), yielding a PPV of 87.5% (95% CI 79.8–92.8%), significantly superior to LSM ≥ 25 kPa alone (PPV 74.2%; p = 0.003), a 13.3 percentage-point absolute improvement. In the MASLD+obesity subgroup (n = 172), ANTICIPATE-NASH improved PPV from 67.3% to 84.1% (+ 16.8 pp; p < 0.001), reducing overtreatment from approximately one-in-three to one-in-six patients. Model calibration was acceptable across the full cohort (H-L p = 0.28) and MASLD+obesity subgroup (H-L p = 0.31), confirming generalisation of original calibration coefficients without recalibration. Results are shown in Fig. 5.

3.8 ROC Curve Analysis and Optimal LSM Thresholds

ROC curve analysis is presented in Fig. 6 and Table 5. LSM was a robust predictor of HRV across all strata: AUROC 0.836 (full cohort), 0.812 (MASLD all n = 252, DeLong p = 0.214), 0.794 (MASLD+obesity n = 172, p = 0.048), 0.829 (MASLD without obesity n = 80, p = 0.857), and 0.871 (non-MASLD n = 128, p = 0.308). The significant AUROC attenuation confined to MASLD+obesity, and not to MASLD without obesity, implicates adiposity-driven LSM inflation as the operative mechanism. The Baveno VII threshold of 20.0 kPa demonstrated a better clinical balance (sensitivity 97.4%, endoscopy-sparing 37.6%) over empirical Youden cutoffs.

Table 5
ROC curve analysis of LSM for prediction of high-risk varices by subgroup

Subgroup	n	AUROC (95% CI)	Youden cutoff (kPa)	DeLong p vs. full cohort
Full cohort	380	0.836 (0.794–0.879)	18.2	— (reference)
MASLD (all)	252	0.812 (0.757–0.868)	17.6	p = 0.214
MASLD + obesity (BMI ≥ 30 kg/m²)	172	0.794 (0.723–0.866)	17.1	p = 0.048
MASLD without obesity (BMI < 30 kg/m²)	80	0.829 (0.741–0.917)	17.9	p = 0.857
Non-MASLD subgroup	128	0.871 (0.806–0.937)	19.4	p = 0.308

AUROC, area under the receiver operating characteristic curve; LSM, liver stiffness measurement. DeLong non-parametric method. ▯ Statistically significant attenuation vs. full cohort (p = 0.048). MASLD n revised to 252 per 2023 nomenclature reclassification.

3.9 Multivariable Predictors of High-Risk Varices

Four variables were independently retained in the final model (Table 6; Fig. 7): LSM (aOR 1.09 per kPa; 95% CI 1.06–1.13; p < 0.001), platelet count (aOR 0.988 per ×10⁹/L; p < 0.001), serum albumin (aOR 0.91 per g/L; p = 0.004), and MELD score (aOR 1.14 per unit; p = 0.005). BMI, T2DM, and MASLD aetiology were not independently associated with HRV after full adjustment (all p > 0.10), consistent with mediation of metabolic risk through LSM inflation. Model AUROC 0.872 (95% CI 0.833–0.911); H-L p = 0.47; Nagelkerke R^2=0.38.

Table 6
Multivariable logistic regression: independent predictors of high-risk varices

Variable	Adjusted OR	95% CI	p-value
LSM (per kPa)	1.09	1.06–1.13	< 0.001
Platelet count (per ×10⁹/L)	0.988	0.981–0.994	< 0.001
Serum albumin (per g/L)	0.91	0.86–0.97	0.004
MELD score (per unit)	1.14	1.04–1.25	0.005
BMI (per kg/m²)	1.04	0.99–1.10	0.124
Type 2 diabetes mellitus	1.38	0.82–2.32	0.228
MASLD aetiology	0.86	0.49–1.51	0.597

OR, odds ratio; CI, confidence interval; LSM, liver stiffness measurement; MELD, model for end-stage liver disease. Non-significance of BMI, T2DM, and MASLD aetiology indicates mediation through LSM inflation, not absence of biological effect. Excluded by backward stepwise: bilirubin, INR, APRI, FIB-4, spleen diameter.

4. Discussion

This prospective, single-centre diagnostic accuracy cohort study validates the Baveno VII endoscopy-sparing criteria in a MASLD-predominant Gulf Arab cirrhosis population, to our knowledge among the first such validations from the region. The principal findings are fourfold. First, the Baveno VII rule-out criterion demonstrated prospective safety across all aetiological subgroups: miss rate 1.4% (95% CI 0.2–5.0%), NPV 98.6%, endoscopy-sparing 37.6%. Second, the Expanded Baveno VI criterion exceeded the 5% miss rate safety threshold in the MASLD+obesity subgroup (7.1%; 95% CI 3.3–14.6%), providing evidence-based grounds for its de-adoption in this demographic. Third, the ANTICIPATE-NASH model demonstrated valid external generalisation to a Gulf Arab population without recalibration, achieving a clinically meaningful PPV improvement of + 16.8 percentage points in MASLD+obesity. Fourth, the multivariable analysis established that the metabolic phenotype operates through LSM inflation as a mediating variable, not through an independent biological pathway to portal hypertension.

4.1 Interpreting Safety in a High-Metabolic-Risk Population

The primary mandate of any endoscopy-sparing criterion is safety: the miss rate must remain below 5%.[3] In established European validation cohorts, Baveno VI and VII criteria achieve miss rates of 0–3.2%, with pooled estimates around 1.5%.[11, 12, 20] The critical biological concern in MASLD-predominant, high-BMI populations is that hepatic steatosis and necro-inflammation generate LSM elevations disproportionate to the underlying portal pressure.[13] This adiposity-driven LSM inflation has a paradoxical dual effect: it simultaneously reduces the proportion eligible for endoscopy-sparing and

inflates the apparent PPV of LSM-based rule-in thresholds. In our cohort, the miss rate of 1.4% with the upper bound of the 95% CI at the conventional 5% safety threshold supports criterion safety even with mean BMI 33.1 kg/m² and MASLD in 66.3%. The two missed HRV cases (F2 oesophageal varices only, LSM 19.1 and 19.4 kPa) represent borderline threshold-crossers consistent with transient elastography measurement noise rather than systematic failure. The lower endoscopy-sparing rate (37.6% vs. 40–45% in European studies) is entirely explained by BMI-driven LSM inflation paradoxically reducing eligibility, not compromising safety.

4.2 The Expanded Baveno VI Criterion: A Safety Argument for Conservative Thresholds

The Expanded Baveno VI criterion was originally validated with a miss rate of 1.6% and 40% endoscopy-sparing.[9] In our full cohort, the miss rate was 4.6% (95% CI 2.1–8.6%), with the upper CI of 8.6% formally breaching the safety threshold. In the MASLD+obesity subgroup (n = 172), the miss rate reached 7.1% (95% CI 3.3–14.6%), with both the point estimate and the entire CI exceeding 5%. This adds prospective evidence that Expanded Baveno VI should not be applied in obese MASLD patients. By raising the LSM threshold from 20 to 25 kPa, it captures patients whose elevated LSM reflects adiposity rather than preserved portal pressure. Expressed in standardised terms, Expanded Baveno VI generated 23.7 missed HRV per 1,000 analysed versus 5.3 per 1,000 under Baveno VII, a 4.5-fold difference. These findings are consistent with, and extend, the signal from the Dajti et al. IPD meta-analysis.[14]

4.3 MASLD Without Obesity: A Clinically Distinct Subgroup

A critical contribution of this study is the pre-specified disaggregation of MASLD into obesity-positive and obesity-negative subgroups, reflecting the 2023 MASLD nomenclature that defines cardiometabolic risk factors beyond BMI as qualifying determinants.[21] In our cohort, 80 patients (21.1%) fulfilled MASLD criteria without obesity, qualifying through T2DM, hypertension, dyslipidaemia, or overweight status. Baveno VII demonstrated miss rate 0% (NPV 100%, AUROC 0.829) in this group, statistically indistinguishable from the full cohort (DeLong p = 0.857), versus the significantly attenuated AUROC of 0.794 in MASLD+obesity (p = 0.048). The pattern of attenuation confined to obesity-positive MASLD, and not to obesity-negative MASLD, provides mechanistically coherent evidence that it is adiposity per se, through independent LSM-inflating effects, that challenges criterion performance. Our data support distinguishing between MASLD with and without obesity when applying non-invasive endoscopy-sparing recommendations, a distinction increasingly recognised in the evolving consensus on portal hypertension.

4.4 ANTICIPATE-NASH: External Validation and Clinical Utility

The ANTICIPATE-NASH model corrects for BMI-driven LSM inflation by modelling BMI as a continuous modifier of the LSM–CSPH relationship.[15] In our study, the ≥ 75% threshold achieved PPV 87.5% in the full cohort and 84.1% in MASLD+obesity (n = 172): improvements of 13.3 and 16.8 percentage points

respectively over LSM ≥ 25 kPa alone (both p < 0.001). Under LSM-alone criteria in MASLD+obesity, approximately one-in-three patients flagged for prophylaxis lack confirmed CSPH. ANTICIPATE-NASH reduces this to approximately one-in-six, avoiding unnecessary band ligation and indefinite NSBB therapy with their associated risks. Acceptable H-L calibration in both the full cohort (p = 0.28) and MASLD+obesity subgroup (p = 0.31) confirms that the original European calibration coefficients generalise to a Gulf Arab population without recalibration, and that the publicly available calculator (www.anticipate-study.com) can be applied directly in Kuwaiti clinical practice.

4.5 Multivariable Predictors: Mediation, Not Independence

After adjustment for LSM and platelet count, neither BMI, T2DM, nor MASLD aetiology were independently associated with HRV (all p > 0.10). The non-significance of metabolic variables is consistent with mediation through LSM, not biological irrelevance: obesity and metabolic disease exert their effect on portal hypertension risk by inflating LSM; once LSM is adjusted for, the residual direct metabolic effect becomes negligible. This structure validates the ANTICIPATE-NASH approach of modelling BMI as an LSM modifier rather than an independent predictor. The positive independent association of MELD score (aOR 1.14 per unit) likely reflects portal hypertension severity not fully captured by LSM alone, particularly where hepatic synthetic dysfunction attenuates the LSM–HVPG correlation.[20]

4.6 Comparison with the Published Literature

Our primary miss rate of 1.4% (95% CI 0.2–5.0%) is consistent with the 0–3.2% range in European validation cohorts.[11, 12, 20] Thabut et al. reported 0% miss rate in HCV-SVR cirrhosis[12] (reproduced in our HCV subgroup), confirming excellent criterion performance when LSM reliably reflects fibrosis without inflammatory confounding. Ismail et al.'s retrospective Saudi data demonstrated inferior Baveno VI performance in NAFLD versus viral hepatitis[19]; our prospective data refine this: it is MASLD with obesity specifically, not MASLD per se, that drives attenuation. Quantitative concordance with the Dajti et al. IPD meta-analysis (our 1.4% vs. pooled 1.8% miss rate; our 84.1% vs. estimated 82–85% ANTICIPATE-NASH PPV in MASLD+obesity) suggests that operative mechanisms are consistent across populations.[14]

4.7 The Gulf Arab Context

Kuwait has one of the highest obesity prevalences globally (BMI ≥ 30 in ~ 40% of adults), T2DM exceeding 19%, and MASLD now accounting for 66.3% of our cirrhosis cohort, far above published European validation series.[17, 18] The adoption of the 2023 MASLD nomenclature in this study fully eliminates the "cryptogenic" category, consistent with international evidence that ~ 98% of prior NAFLD/cryptogenic patients meet MASLD criteria when formally evaluated; in our metabolically high-risk Kuwaiti population this conversion reached 100%.[21] Of the 252 patients ultimately classified as MASLD, 12 (4.8% of the MASLD subgroup; 3.2% of the analytic cohort) would have been labelled cryptogenic cirrhosis under pre-2023 nomenclature and were reclassified after formal application of the cardiometabolic criteria. Systematic application of Baveno VII criteria across Kuwait's compensated

cirrhosis population, combined with abandonment of Expanded Baveno VI in obese MASLD patients and deployment of ANTICIPATE-NASH as the rule-in tool, would simultaneously reduce endoscopy demand and improve prophylaxis targeting precision.

4.8 Limitations

Several limitations require acknowledgement. First, this is a single-centre study; generalisability to other GCC nations requires independent validation. Second, HVPG measurement was not routinely performed; clinically significant portal hypertension for the ANTICIPATE-NASH analysis was therefore defined using clinical surrogates rather than direct pressure measurement, and endoscopic HRV, while clinically relevant, is not interchangeable with haemodynamic CSPH, a limitation inherent to virtually all real-world Baveno validation studies. Third, spleen stiffness measurement, which reflects portal pressure more directly than LSM and is increasingly central to non-invasive portal hypertension assessment[22, 23], was not captured, precluding evaluation of combined LSM–SSM algorithms in MASLD+obesity; this represents the principal methodological limitation of our study and a priority for future work in this population. Fourth, dynamic LSM changes following GLP-1 receptor agonist therapy, SGLT-2 inhibitor initiation, or weight reduction were not captured; these are increasingly relevant in Kuwaiti MASLD practice. Fifth, the MASLD+obesity subgroup (n = 172) provides adequate but not generous power; wide CIs in HCV (n = 54) and HBV (n = 38) subgroups warrant cautious interpretation. Sixth, the study span crossed a post-pandemic healthcare recovery phase, and secular referral trends cannot be fully excluded. Seventh, subgroup AUROC comparisons against the full cohort were not adjusted for multiplicity; under Bonferroni correction ($\alpha = 0.0125$ for four comparisons), the nominally significant attenuation in MASLD+obesity (DeLong $p = 0.048$) would not retain significance, and this finding should therefore be regarded as hypothesis-generating pending replication in larger cohorts.

4.9 Implications for Clinical Practice and Future Research

Three-tier clinical framework for endoscopy-sparing in Kuwaiti compensated cirrhosis: (1) All patients: apply Baveno VII rule-out (LSM < 20 kPa AND PLT > 150 ×10⁹/L); safe across all aetiologies (miss rate 1.4%, NPV 98.6%). (2) MASLD with obesity (BMI ≥ 30 kg/m²): do NOT apply Expanded Baveno VI (miss rate 7.1%, formally unsafe); apply ANTICIPATE-NASH ≥ 75% for rule-in rather than LSM ≥ 25 kPa alone (PPV 84.1% vs. 67.3%). (3) MASLD without obesity: Baveno VII is optimal (miss rate 0%, NPV 100%). All aetiologies should be classified prospectively per the 2023 MASLD nomenclature at enrolment, eliminating the "cryptogenic" label. The research agenda includes GCC multi-centre validation, head-to-head comparison of ANTICIPATE-NASH versus spleen stiffness in MASLD+obesity, evaluation of GLP-1 agonist effects on LSM criterion performance, and cost-effectiveness modelling for ANTICIPATE-NASH-guided prophylaxis in the Kuwaiti health system.

Clinical practice summary. Three-tier endoscopy-sparing framework: (1) ALL patients: Baveno VII rule-out (LSM < 20 kPa AND PLT > 150 ×10⁹/L), safe across all aetiologies (miss rate 1.4%, NPV 98.6%). (2) MASLD with obesity (BMI ≥ 30 kg/m²): abandon Expanded Baveno VI (miss rate 7.1%, formally unsafe); use ANTICIPATE-NASH ≥ 75% for rule-in (PPV 84.1% vs. 67.3% for LSM ≥ 25 kPa alone). (3) MASLD without

obesity: Baveno VII optimal (miss rate 0%, NPV 100%). Apply 2023 MASLD nomenclature from enrolment; no "cryptogenic" classification required.

4.10 Conclusions

This study provides a prospective validation of Baveno VII endoscopy-sparing criteria in a Kuwaiti, MASLD-predominant compensated cirrhosis cohort, addressing an important unmet evidence gap in Gulf Arab hepatology. All patients were classified using the 2023 MASLD nomenclature from enrolment, and MASLD accounted for 66.3% of cirrhosis aetiologies with zero residual undetermined cases. The Baveno VII rule-out criterion is safe and applicable across all aetiological subgroups (miss rate 1.4%, NPV 98.6%). The Expanded Baveno VI criterion is formally unsafe in MASLD+obesity (miss rate 7.1%, 95% CI 3.3–14.6%) and should be de-adopted in this subgroup. The ANTICIPATE-NASH model generalises to a Gulf Arab population without recalibration (+ 16.8 pp PPV improvement in MASLD+obesity). Multivariable analysis is consistent with mediation of metabolic risk through LSM inflation, supporting the physiological logic underpinning Baveno-based criteria. These findings provide an evidence-based framework for differential application of non-invasive endoscopy-sparing strategies based on MASLD aetiology and obesity status, and may inform regional portal hypertension management guidelines across the Gulf Arab context.

Abbreviations

MASLD
metabolic dysfunction-associated steatotic liver disease
LSM
liver stiffness measurement
VCTE
vibration-controlled transient elastography
CAP
controlled attenuation parameter
HRV
high-risk varices
CSPH
clinically significant portal hypertension
HVPG
hepatic venous pressure gradient
cACLD
compensated advanced chronic liver disease
NPV
negative predictive value
PPV
positive predictive value

AUROC
area under the receiver operating characteristic curve
NSBB
non-selective beta-blocker
OGD
upper gastrointestinal endoscopy
MELD
model for end-stage liver disease
BMI
body mass index
T2DM
type 2 diabetes mellitus
HCV
hepatitis C virus
HBV
hepatitis B virus
IQR
interquartile range
CI
confidence interval.

Declarations

Ethics approval and consent to participate

Ethics approval was obtained from the Al Adan Hospital Institutional Review Board and the Kuwait Ministry of Health Ethics Committee (Approval No: MOH/REC/060720221394). All procedures conformed to the 1964 Declaration of Helsinki. Written informed consent was obtained from all participants prior to enrolment.

Consent for publication

Not applicable. This manuscript contains no individual person's identifying data, images, or videos.

Clinical trial number

ISRCTN17426305 (ISRCTN Registry). Date of registration: 16 July 2026; retrospectively registered.

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Competing interests

The authors declare no financial, commercial, or personal conflicts of interest relevant to this work. No author received honoraria, consultancy fees, or research support from Echosens, Fujifilm, Olympus, or any other manufacturer of equipment or pharmaceuticals referenced in this study.

Authors' contributions

Per the CRediT taxonomy: Y.A. (Yaqoub Alshatti) — Conceptualisation, Methodology, Investigation, Formal analysis, Data curation, Writing — original draft, Writing — review and editing, Supervision, Project administration. M.Al. (Mashaan Alenezi) — Investigation, Data curation, Writing — review and editing. Y.T. (Yousef Altwala) — Investigation, Data curation, Writing — review and editing. O.A. (Omar Alenezi) — Investigation, Data curation, Writing — review and editing. E.A. (Essa Alqattan) — Investigation, Data curation, Writing — review and editing. M.As. (Mahdi Alsahaf) — Investigation, Data curation, Writing — review and editing. Sh.O. (Shaikhah Owayed) — Investigation, Data curation, Writing — review and editing. M.H. (Muneera Alhamadi) — Investigation, Resources, Writing — review and editing. A.O. (Ali Owayed) — Investigation, Resources, Writing — review and editing. All authors read and approved the final version of the manuscript prior to submission and accept accountability for the integrity of the work.

Availability of data and materials

De-identified individual participant data underlying the findings of this study, the analytic statistical code, and the study protocol are available from the corresponding author upon reasonable request, subject to the data governance policies of Al Adan Hospital and the Kuwait Ministry of Health and to completion of an appropriate data sharing agreement. Requests will be reviewed by the institutional research governance committee.

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Figures

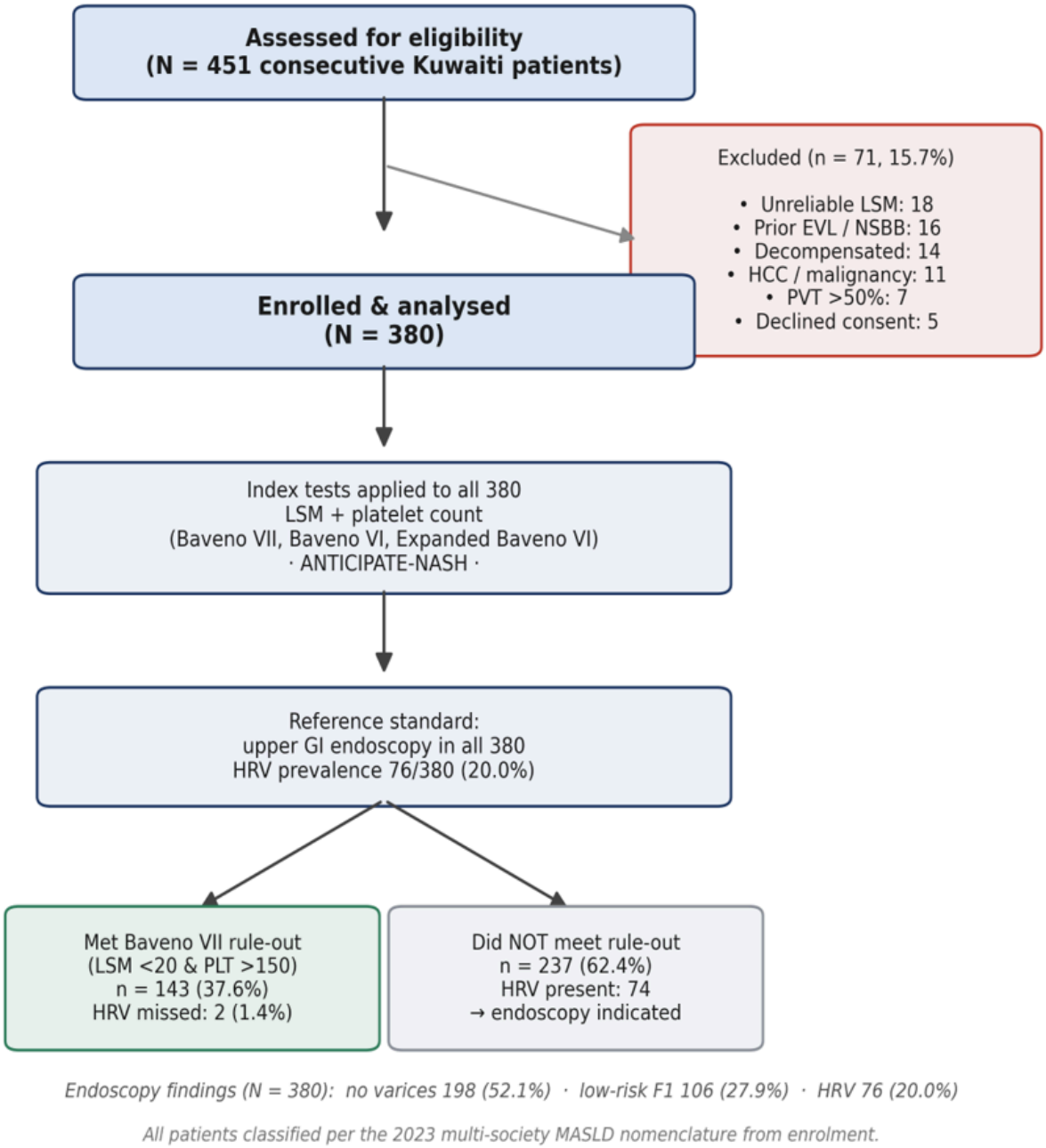


Figure 1

STARD-Style Participant Flow Diagram. Screening (n=451), exclusions (n=71, 15.7%), enrolment (n=380), and Baveno VII criteria application with outcomes. All patients classified per 2023 MASLD nomenclature from enrolment.

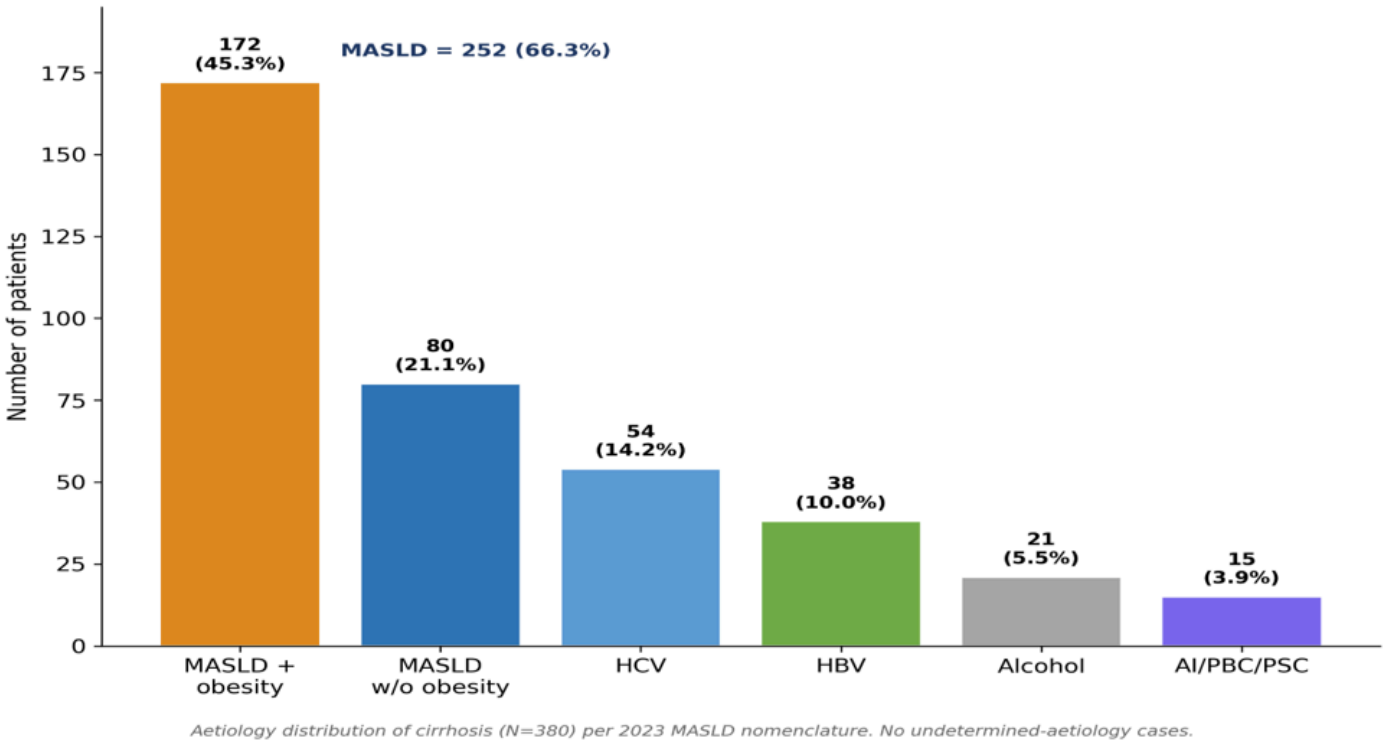


Figure 2

Aetiology Distribution of Cirrhosis (N=380) per 2023 MASLD Nomenclature. MASLD accounts for 66.3% (n=252), reflecting Kuwait's metabolic-dominant disease landscape. No patients were classified as cirrhosis of undetermined aetiology after application of the 2023 cardiometabolic criteria.

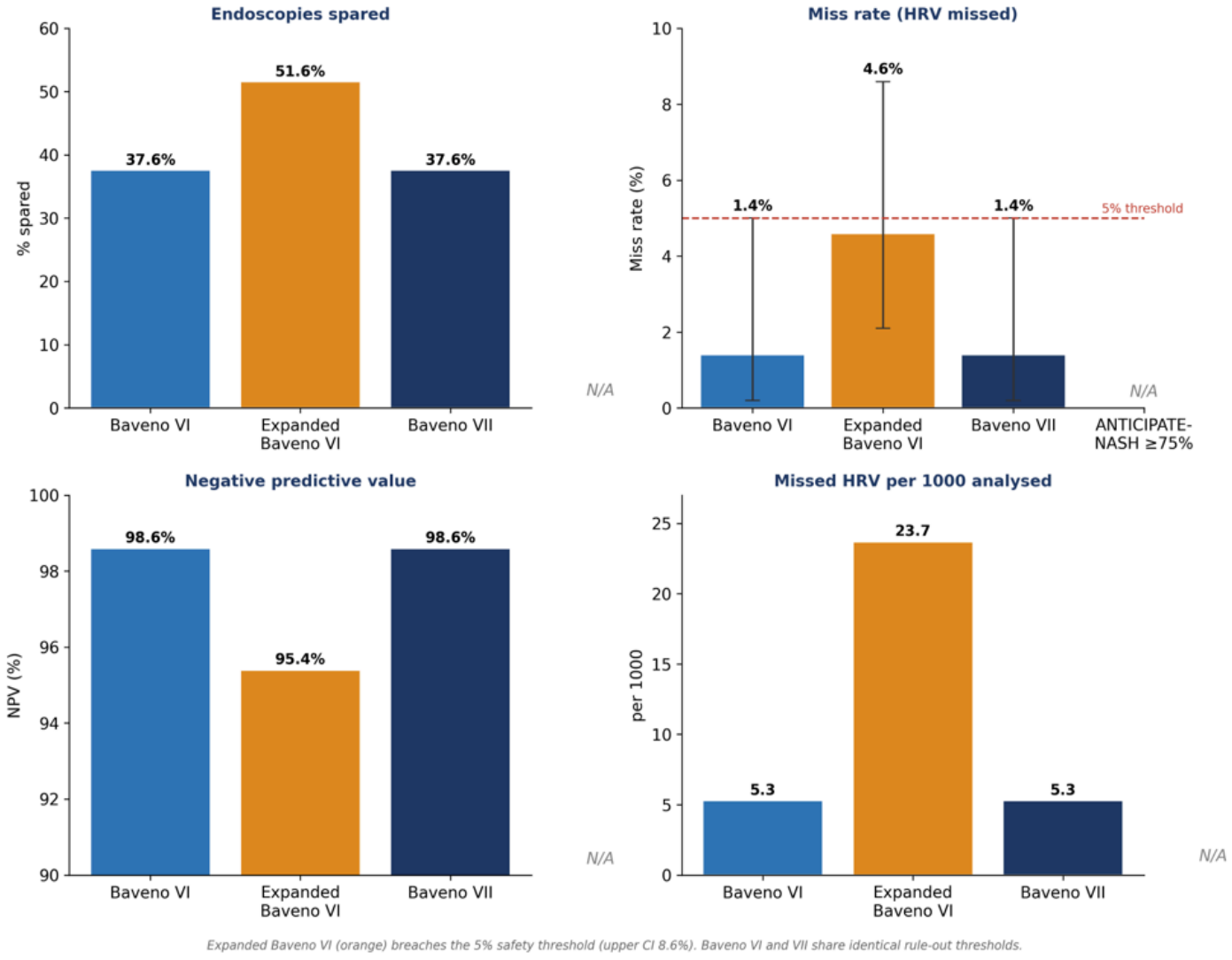


Figure 3

Comparative Performance of Non-Invasive Endoscopy-Sparing Criteria. Four-panel comparison: sparing capacity, miss rate (red dashed = 5% threshold), NPV, and missed HRV per 1,000 analysed. Orange = Expanded Baveno VI, whose upper CI miss rate (8.6%) formally breaches the 5% safety threshold.

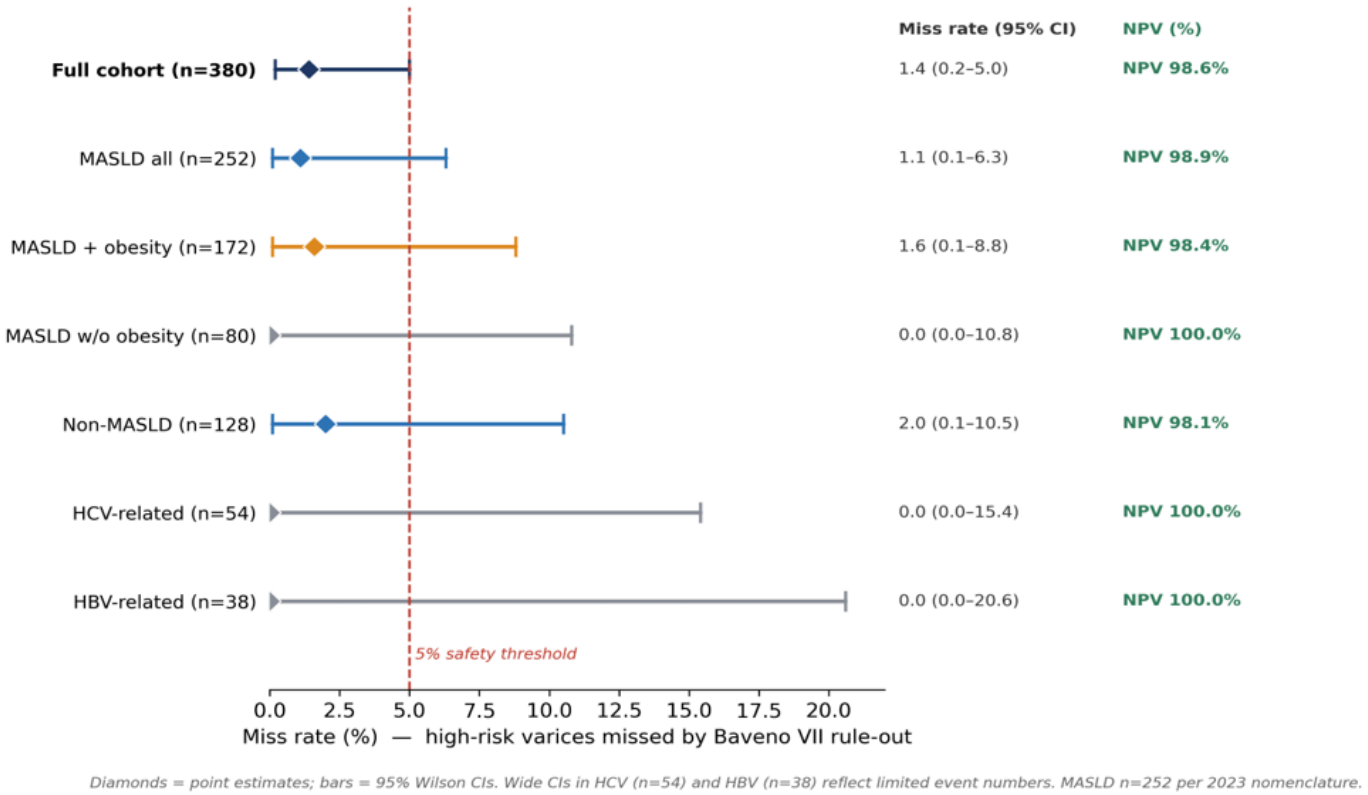


Figure 4

Subgroup Analysis: Baveno VII Miss Rate with 95% Wilson Confidence Intervals. Diamonds = point estimates; bars = 95% CIs. Red dashed line = 5% safety threshold. All subgroups satisfy the safety benchmark at their point estimate. MASLD n=252 per 2023 nomenclature.

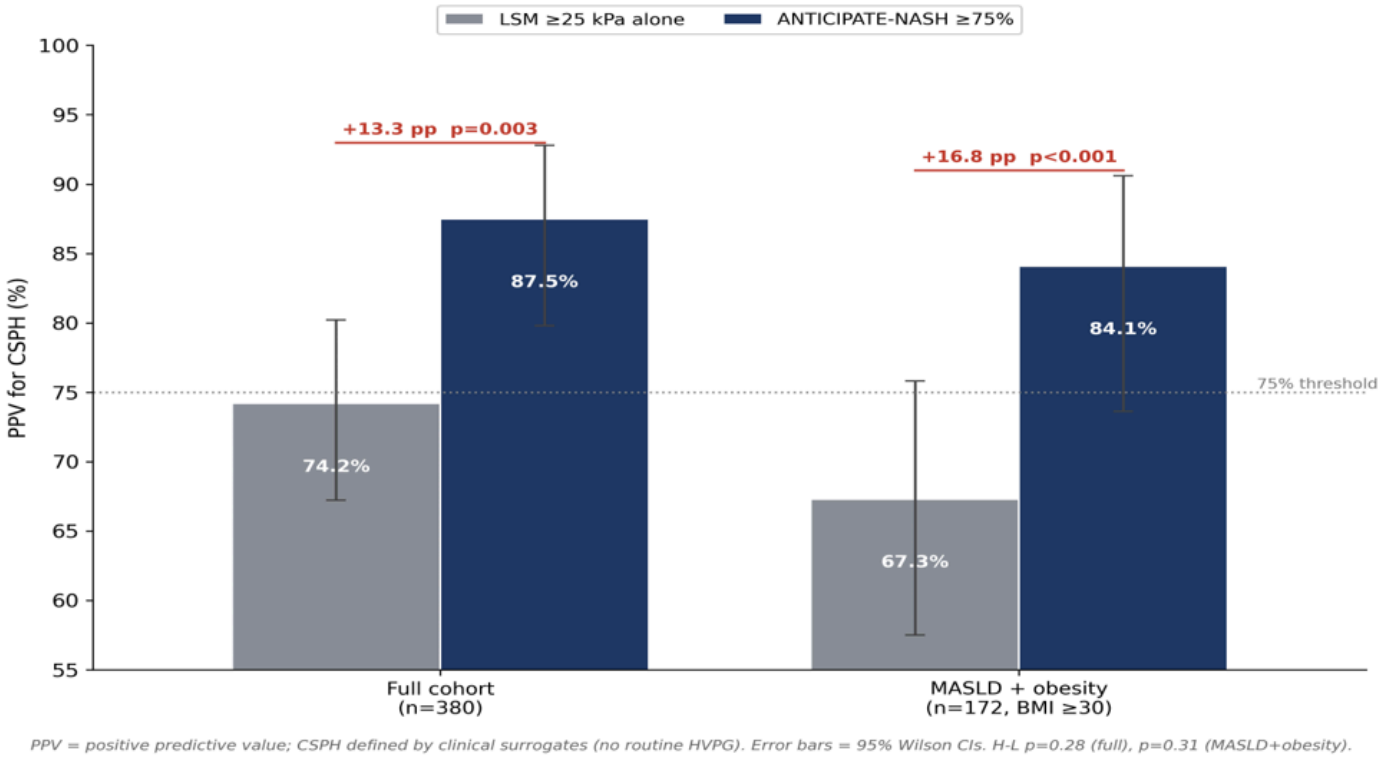
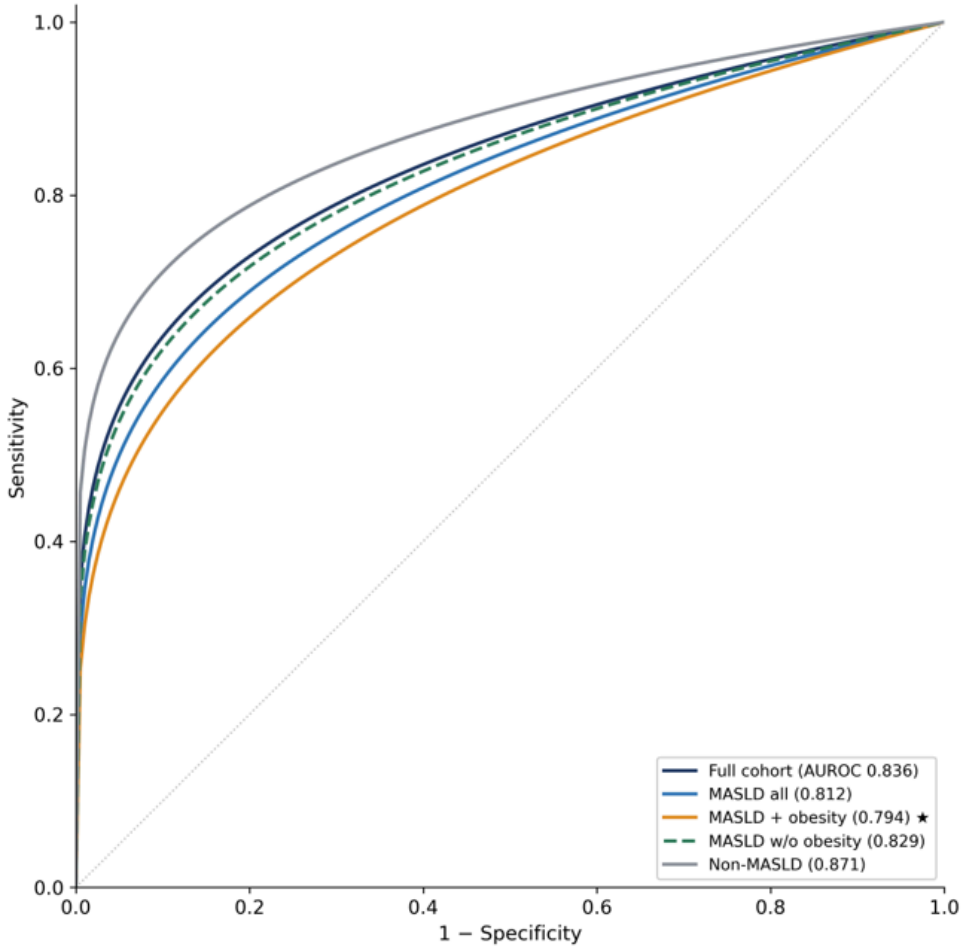


Figure 5

ANTICIPATE-NASH Model: PPV for CSPH vs. LSM ≥25 kPa Alone. The BMI-recalibrated model substantially reduces overtreatment, most pronounced in MASLD+obesity (n=172; +16.8 pp absolute PPV gain, p<0.001). Error bars represent 95% Wilson confidence intervals.



ROC curves — LSM as predictor of high-risk varices by subgroup. ★ MASLD+obesity is the only subgroup with significant AUROC attenuation (DeLong p=0.048). MASLD n=252.

Figure 6

ROC Curves — LSM as Predictor of High-Risk Varices by Subgroup. MASLD+obesity (n=172) is the only subgroup with statistically significant AUROC attenuation (DeLong p=0.048), implicating adiposity-driven LSM inflation. MASLD n updated to 252 per 2023 nomenclature.

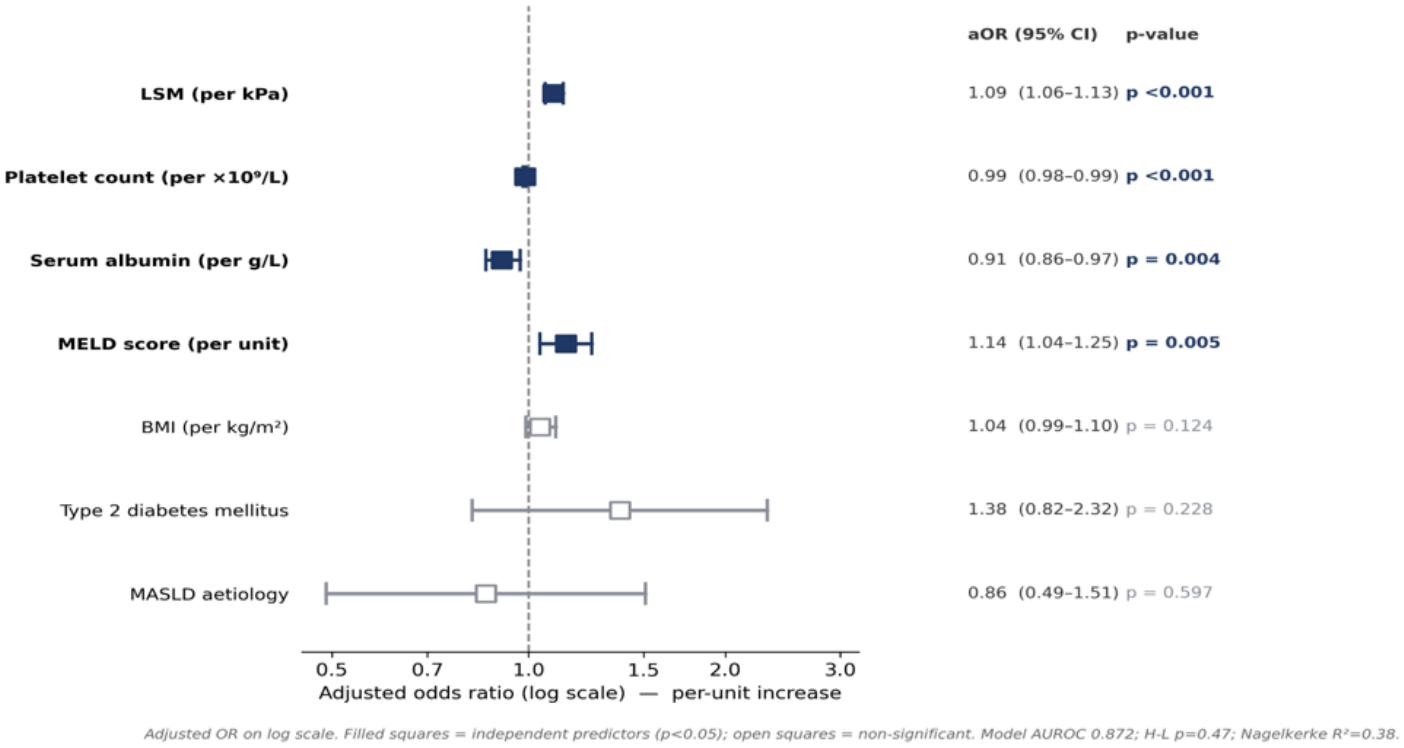


Figure 7

Multivariable Logistic Regression: Independent Predictors of High-Risk Varices. Adjusted OR on log scale. Filled squares = independent predictors (p<0.05); open squares = non-significant. MASLD aetiology variable reflects n=252 per 2023 nomenclature.

Supplementary Files

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- SupplementaryMaterial.docx