Varices and Screening Endoscopy

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The Baveno VI Criteria

The first five Baveno consensus conferences recommended performing endoscopy on every patient with a diagnosis of cirrhosis. For the first time, Baveno VI conference introduced a ***two-step strategy*** for the screening of esophageal varices in patients with compensated advanced chronic liver disease (cACLD), establishing what became known as the Baveno VI criteria [1]. These resulted from the combination of a liver stiffness measurement by transient elastography (LSM by TE) of less than 20 kPa, together with a platelet count over 150×10^9/L. The risk of high-risk varices (HRV) when fulfilling both criteria was considered low enough to circumvent the performance of an endoscopy. In those patients outside Baveno VI criteria, an endoscopy should be performed. These criteria have been widely adopted in practice and recommended by subsequent guidelines for the management of a chronic liver disease [2]. Furthermore, since the Baveno VI conference, the criteria have undergone an unprecedented level of validation, with 28 fully published manuscripts up to March 2021 testing its performance.

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The basic tenet of the proposal at Baveno VI was that *"for high risk varices (HRV: medium-large varices or small with red signs) the acceptable risk of missing varices should be near 0 or 5% at the most")* [3]. This put the emphasis on not missing an opportunity of doing primary prophylaxis of bleeding (either with beta-blockers or variceal ligation), and considered much less harmful the performance of an unneeded endoscopy since the invasiveness of endoscopy is low. Indeed, setting that threshold at the 5% level means that we would accept to do an endoscopy with up to 95% chance of a false-positive result, and up to 5% chance of a false-negative result, or what would be equivalent to the value of not missing a case of HRV (a false negative) was 19 (95/5) times greater than the value of doing an unneeded endoscopy (false positive).

The subsequent ANTICIPATE study showed that the pointwise estimate of a combination of LSM by TE of 20 kPa and a platelet count of 150 × 10^9/L corresponds to the predicted risk of HRV of ~5% [4]. The Baveno VI criteria, therefore, set the maximum allowed risk of missing varices at the 5% mark (Fig. 10.1). Provided that the ANTICIPATE model is well calibrated, the negative predicted value (NPV) of the criteria would tend to be >95%, since all patients with negative criteria would have a theoretical risk of HRV below 5%. This seems very reasonable in a two-step strategy where, in the first step, a high NPV is favored.

The interpretation of the 5% threshold raised some questions [5], including whether this should correspond to a sensitivity of >95% for the criteria or a NPV

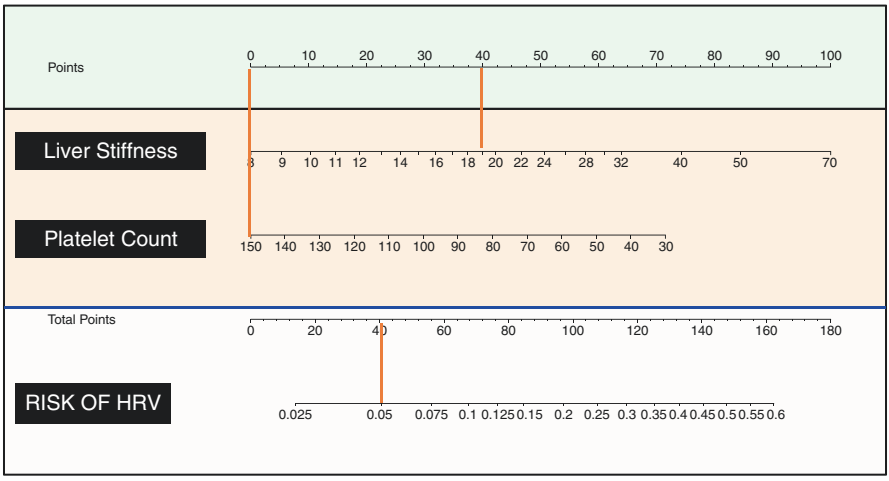

Fig. 10.1 ANTICIPATE nomogram for predicting HRV based on LSM by TE and platelet count. A LSM of just below 20 kPa, together with a platelet count of 150 × 10^9/L yields a probability of HRV of 5% [4]

of >95%. It is important to emphasize that sensitivity is a backward probability. For example, the sensitivity of the Baveno VI criteria would be the probability of having positive criteria provided the patient has HRV. Therefore, sensitivity never reflects a clinical question, but might be relevant in the early development of a diagnostic test, especially when the study is based on a case-control study. The NPV better reflects the clinical question addressed here: what would be the probability of not having HRV provided that the patient has values within the Baveno VI criteria.

Evolving recommendations for the management of compensated cirrhosis, based on the result of the PREDESCI study [6] might result in the use of beta-blockers in patients with clinically significant portal hypertension (CSPH), regardless of the presence of varices. This shift in paradigm, if widely adopted, will decrease the relevance of Baveno VI criteria for the assessment of varices, since patients already on beta-blockers do not require endoscopy. However, a relevant proportion of patients would have either contraindications or intolerance to beta-blockers, and these patients would require endoscopic assessment unless they are within the Baveno VI criteria.

Validation of Baveno VI Criteria

We performed a systematic search of fully published studies up to March 2021 assessing the performance of Baveno VI criteria. The search strategy is reported in detail in supplementary data 11.1. We identified 28 studies, of which the main characteristics are reported in Table 10.1.

We performed a univariate quantitative meta-analysis of proportions to pool NPVs since, as discussed above, this is the metric we consider the benchmark for validation of the performance of the criteria. The forest plot is shown in Fig. 10.2, with further methodological details in the figure legend. The pooled NPV was 0.99 (95% CI 0.99–1.00), with no significant heterogeneity. The proportion of saved endoscopies ranged from 8% to 60%. The interpretation of the proportion of saved endoscopies must be taken with caution, since they are highly dependent on the spectrum of diseases assessed in individual studies. Results of the meta-analysis of sensitivity are provided in supplementary data 11.2 (pooled sensitivity 0.99; 95% CI 0.98–0.99). We did not use bivariate models (which take into account the covariance of sensitivity and specificity) in our meta-analysis for two reasons. First, bivariate models require continuity correction, which adds a 0.5 to cells with a zero value. Since the number of zero cells was high (a number of studies had a sensitivity of 100% or an NPV of 100%), adding that 0.5 would artificially bring down sensitivity and NPV. Second, as detailed above, Baveno VI is meant to be used in the first step of the approach to diagnosing varices, so the main goal is a high NPV, and positive predictive value and specificity have much less relevance.

Table 10.1 Main characteristics of the included validation studies

Study	Inclusion criteria	Patients (*n*)	Age, Mean (yr.) (SD)	Male %	BMI, Mean (SD)	Child Pugh A, %. (Score, SD)	Time interval (month)	Etiology						Prevalence of HRV's, %	Prevalence of any varices, %
								Viral (all), %	HCV,%	HBV,%	Alcohol %	NAFLD/ NASH, %	Other, %		
Augustin et al., [7]	LSM ≥ 10. Compensated cirrhosis	925	59.4 (11.2)	55.4	27.1	95.7%	3–12 months	N/A	62.8	N/A	N/A	N/A	N/A	9.9	24.9
Bae et al., [8]	LSM ≥ 10 kPa Compensated cirrhosis	282	54.0[a] [6]	67.1	25.1 (3.7)	100.0	6 months	N/A	12.0	60.6	13.1	14.3	5.9	19.5	44.0
Bellan et al., [9]	Hep C cirrhosis LSM >6 kPa	160	65[a]	56.9	26[a]	90.5 [b]MELD 8	N/A	100.0	100.0	0	0	0	0	10.6	35.6
Cales et al., [10]	Cirrhosis	287	55.4 (10.7)	72.1	27.2 (5.6)	60.3% Score 6.7	3 months	25.8	N/A	N/A	64.5	5.6	4.2	17.4	44.2
Calvaruso et al., [5]	Hep C cirrhosis. LSM ≥ 12 kPa or Stage 4 fibrosis or evidence of GEV	1381	65.9	59.8	26.0	88.6	1 year	100.0	100.0	0	0	0	0	9.4	49.2
Colecchia et al., Prospective cohort [11]	LSM ≥ 10 kPa	115	58	67.8	26.4	86.9% [b]MELD 7.0	3 months	N/A	40.9	4.4	16.5	16.5	21.7	13	52.2
Colecchia et al, Retrospective cohort [11]	LSM ≥ 10 kPa	498	60 [10]	58.4	25.9	70.3% [b]MELD 8.0	3 months	N/A	85.1	5.9	7	N/a	N/A	20.1	50.6

Duan et al., Beijing cohort [12]	LSM ≥ 10 kPa Compensated cirrhosis	104	52[a]	54.8	23.2[a]	80.8%	3 months	34.6	0	34.6	10.6	N/A	50.0	18.3	51.9
Gaete et al., [13]	Compensated cirrhosis. Child-Pugh A	300	61	59.7	N/A	[b]MELD 8	6 months	N/A	10.7	0.7	4.3	67.3	17.0	18.0	N/A
Galizzi et al., 2021 [14]	NASH Compensated F3/4 fibrosis	21	61	19.0	31.4	100%	12 months	0	0	0	0	100.0	0	14.3	28.6
Jangouk et al., (US) [15]	LSM ≥ 10 kPa Compensated cirrhosis	161	62	99.4	29	92.4% [b]MELD 9	3 months	N/A	73.3	N/A	13.0	10.6	3.1	8.7	34.1
Jangouk et al., (IT) [15]	LSM ≥ 10 kPa Compensated cirrhosis	101	63	72.3	25	91.1% [5]	2 months	N/A	66.4	N/A	11.8	3.0	18.8	16.8	52.4
Kew et al., [16]	LSM ≥ 10 kPa	352	61	61.1	N/A	100%	12 months	42.3	16.8	25.6	8.8	32.1	16.8	15.9	N/A
Kotwal et al., Development cohort [17]	LSM ≥ 10 kPa Compensated cirrhosis	372	59.4	59.4	N/A	100%	12 months	92.2	87.1	5.1	32.0	11.0	0	9.1	27.2
Kotwal et al., Validation cohort [17]	LSM ≥ 10 kPa Compensated cirrhosis	200	61	49.0	N/A	100%	12 months	23.0	23.0	0	24.0	48.5	4.5	5.5	25.0
Lee et al., [18]	LSM ≥ 10 kPa Compensated cirrhosis	1218	56.0 (11.5)	63.9	N/A	76.6% [b]MELD 6.8 (1.1)	6 months	N/A	12.1	39.7	29.2	19.0	19.0	20.4	N/A
Matsui et al., [19]	cACLD	384	64.4	53.6	24.2	100% cACLD	12 months	45.8	39.3	6.5	9.4	38.8	6.0	2.9	14.8

(continued)

Table 10.1 (continued)

Study	Inclusion criteria	Patients (*n*)	Age, Mean (yr.) (SD)	Male %	BMI, Mean (SD)	Child Pugh A, %. (Score, SD)	Time interval (month)	Etiology						Prevalence of HRV's, %	Prevalence of any varices, %
								Viral (all), %	HCV,%	HBV,%	Alcohol %	NAFLD/ NASH, %	Other, %		
Maurice et al., [20]	LSM ≥ 10 kPa cACLD	310	58	67.4	N/A	89% MELD 7	12 months	N/A	54.5	7.7	12.9	13.5	11.3	4.8	23.2
Moctezuma-Velazquez et al., **PBC** group [21]	LSM ≥ 10 kPa PBC and PSC only	147	59.1 (11.5)	14.0	N/A	[b]MELD 8.2 (3.0)	12 months	0.0	0.0	0.0	0.0	0.0	100.0	14	33
Moctezuma-Velazquez et al., **PSC** group [21]	LSM ≥ 10 kPa PBC and PSC only	80	44.8 (16.9)	68.0	N/A	[b]MELD 9.6 (5.3)	12 months	0.0	0.0	0.0	0.0	0.0	100.0	12	36
Nawalerspanya et al., [22]	Age ≥ 18 yo Compensated cirrhosis	128	57.4 (11.3)	60.2	23.5 (2.1)	100%	6 months	N/A	37.5	32.8	4.7	5.5	19.5	7.8	N/A
Petta et al., [23]	Cirrhosis LSM >11.5 (M) LSM > 11.0 (XL)	790	62 [10]	55.0	32.6 (6.7)	100%	6 months	0.0	0.0	0.0	0.0	100.0	0.0	11.5	31.3
Protopapas et al., [24]	cACLD LSM >12.	107	63.7 (12.1)	60.7	N/A	5.7 (0.2)	6 months	45.8	N/A	N/A	24.2	N/A	31.8	20.6	47.7
Sharma et al., [25]	cACLD LSM ≥10 kPa	895	41.4	71.3	N/A	100% cACLD	3 months	55.3	19.1	36.2	19.1	21.9	3.1	29.5	56.0
Silva et al., [26]	LSM >12.5 Compensated cirrhosis	97	54.3 (11.2)	76.3	N/A	100%	12 months	0.0	78.4	3.1	8.2	N/A	10.3	14.4	44.3

Sousa et al., [27]	cACLD	104	57.0	69.2	N/A	N/A	12 months	0.0	79.8	3.8	11.5	N/A	4.8	8.6	25.0
Stanislas et al., [28]	cACLD LSM ≥ 11 kPa	60	48.8	75.0	22.4	66.7	N/A	100.0	0	100.0	0	0	0	26.7	40.0
Stefanescu et al., [29]	cACLD	185	59[a]	35.0	26.0[a]	MELD 9.2	6 months	66.9	59.6	7.3	30.4	N/A	2.7	23.2	N/A
Thabut et al., [30]	cACLD	891	53.9[a]	67.5	25.5[b]	100	1 year	0.0	81.0	16.6	N/A	N/A	N/A	8.1	24.7
Tosetti et al., [31]	cACLD LSM ≥ 10 kPa	442	60[a]	64.2	25.4[b]	100%	1 year	79.4	68.8	10.6	5.9	14.7	0	31.2	7.0
Wang et al., [32]	HBV cirrhosis	341	48[a]	82.4	23.4[a]	94.7%	<2 days	100.0	0	100.0	0	0	0	20.5	61.9
Wong et al., [33]	cACLD Compensated cirrhosis	267	58 [11]	72.3	24.8 (3.7)	100	2 weeks	0.0	7.7	77.7	N/A	7.3	7.3	13.9	N/A

[a] Median
[b] MELD score

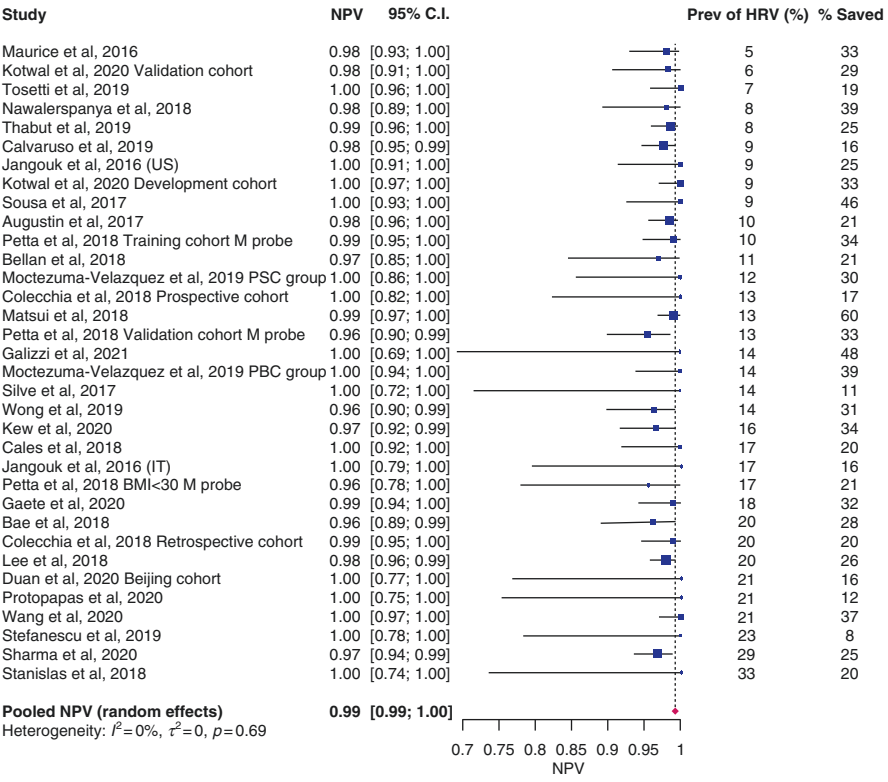

Fig. 10.2 Forest plot showing NPVs of the Baveno VI validation studies. Studies were ordered by prevalence. Prevalence and proportion of saved endoscopies are shown in the right columns. Meta-analysis was performed after double arcsine transformation of the proportions, pooled with random effects. *Note*: Calés et al. 2018 study data was extracted from the following systematic review, since more complete data was obtained from the authors [34]

Impact of Etiology on the Performance of Baveno VI Criteria

Even if there was no heterogeneity in the NPVs of Baveno VI across studies, to confirm that Baveno VI criteria perform well across etiologies, we conducted a subgroup meta-analysis. Only 12 of the 28 studies performed etiology-specific analysis. Figure 10.3 demonstrates the forest plot of the studies. There were no significant differences in NPVs according to etiology subgroups.

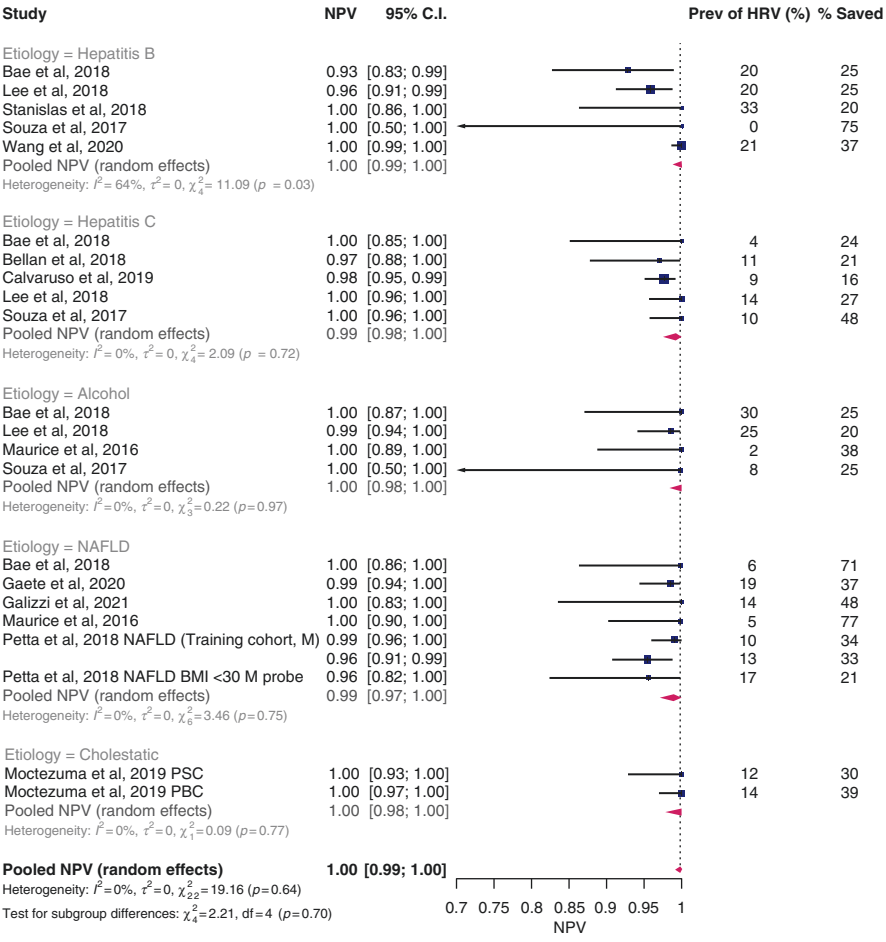

Fig. 10.3 Etiology-specific pooled negative predictive values of Baveno VI criteria

Can Baveno VI Criteria Be Expanded?

The Baveno VI criteria is undoubtedly a validated tool to select for low-risk cACLD patients who can safely avoid a surveillance gastroscopy. However, it has been suggested that the number of saved endoscopies is low. As stated above, this is an unsound metric to compare different studies since it largely depends on how early in the natural history of cACLD these criteria are applied.

In an attempt to increase the proportion of saved endoscopies, the Expanded Baveno VI criteria were proposed after the Baveno VI conference, in which the

LSM by TE threshold was increased to 25 kPa, and the platelet threshold decreased to 110×10^9/L [7]. A systematic search identified 16 studies assessing the expanded Baveno VI criteria, and results are shown in Fig. 10.4. Pooled NPV was 0.97 (95% CI 0.95–0.98). However, distinct from Baveno VI criteria, performance of Expanded Baveno VI showed significant heterogeneity ($p < 0.0001$). Results of the meta-analysis of sensitivities are provided in Supplementary data 11.3 (pooled sensitivity 0.90; 95% CI 0.87–0.93).

To address the sources of heterogeneity, we first evaluated whether etiology was associated with different performance of the expanded criteria. Eight studies showed etiology-specific data. Subgroup meta-analysis did not show any differences in performance across etiologies (Fig. 10.5).

We then evaluated the impact of the prevalence of HRV on the performance of Expanded Baveno VI criteria. The group of patients within the Expanded Baveno VI criteria comprises those who are within Baveno VI, and those beyond Baveno VI. The latter is the group that either shows a LSM of 20–25 kPa or a platelet count between 110 and 150. The pointwise risk of HRV of a LSM of 25 and a platelet count of 110 according to the ANTICIPATE model is ~12% [4]. Therefore, patients beyond Baveno VI but within Expanded Baveno VI would have a predicted risk of HRV between 5% and 12%. The prevalence of varices in patients within the Expanded Baveno VI criteria would depend largely on the distribution of the patients

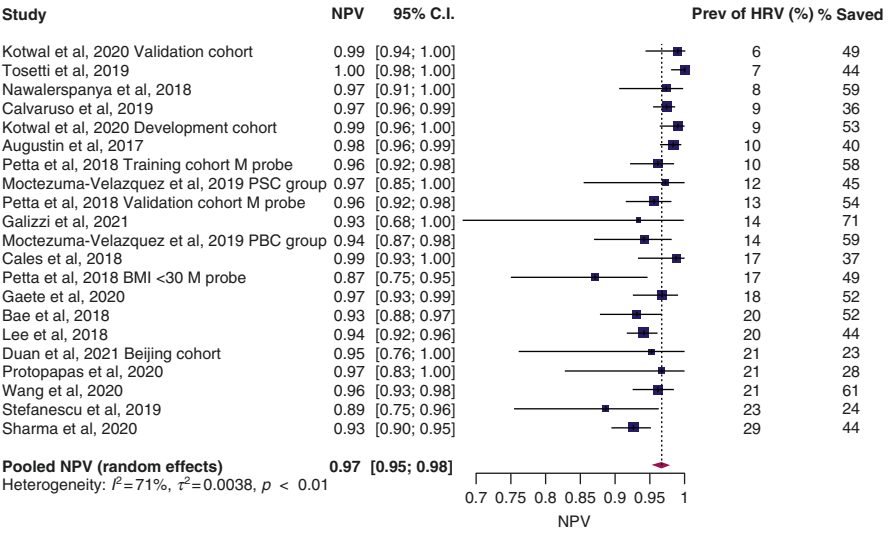

Fig. 10.4 Forest plot showing NPVs of Expanded Baveno VI validation studies. Studies were ordered by prevalence. Methodology to pool the NPVs was similar to that shown in Fig. 10.2

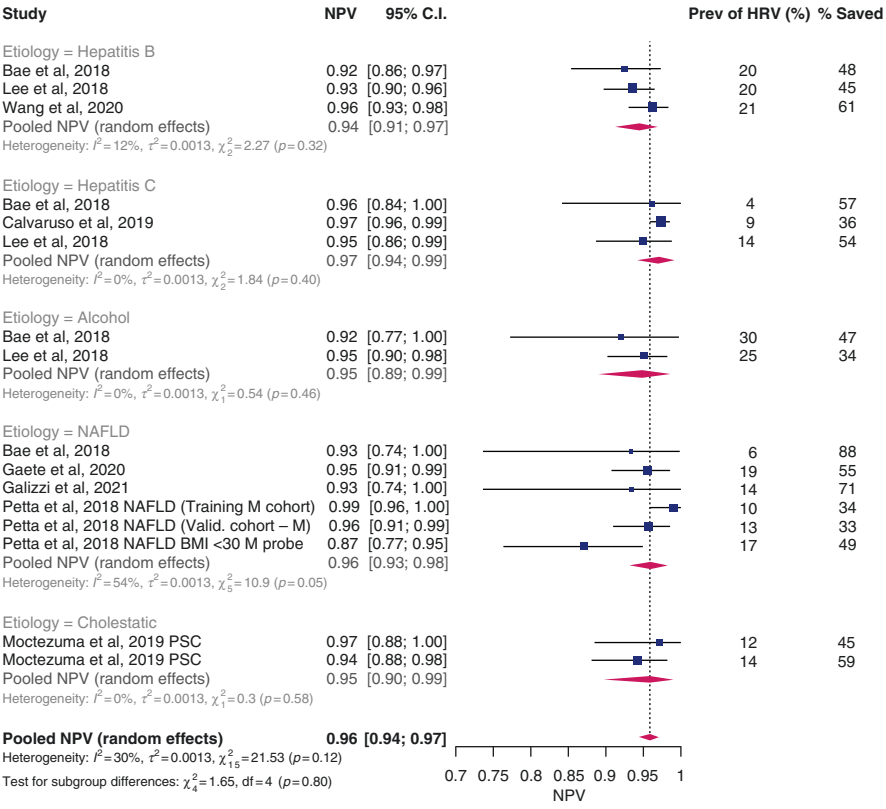

Fig. 10.5 Stratified meta-analysis of NPVs of Expanded Baveno VI criteria according to etiology. There were no significant subgroup differences across different etiologies

in those two groups (within Baveno VI and beyond Baveno VI). We therefore predicted that in series with higher prevalence of HRV, that would predictably have a higher number of patients beyond Baveno VI, the NPV of Expanded Baveno VI would decrease.

To assess this hypothesis, we performed a meta-regression analysis of NPV on the prevalence of HRV. There was a strong association between NPV and prevalence of HRV (Fig. 10.6a), with prevalence explaining 77% of the heterogeneity in NPVs observed across studies. There was no significant association between prevalence of HRV and the NPV of original Baveno VI (Fig. 10.6b), which is likely explained by the fact that all patients within Baveno VI have a theoretical <5% risk of HRV [4].

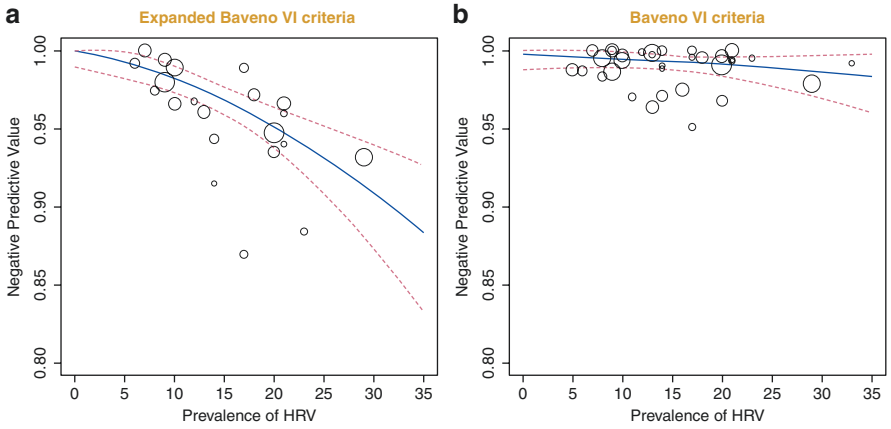

Fig. 10.6 Meta-regression assessing the association between prevalence of HRV and NPV of the Expanded Baveno VI criteria (**a**) and Baveno VI criteria (**b**)

Other Elastography Methods and Baveno VI Criteria

Point shear wave elastography (pSWE) and 2D-SWE have witnessed increased use in the last few years [35]. The main unsolved issue with these methods is the multiplicity of devices with proprietary algorithms that lead to differences in the quantification of the speed of shear wave, and consequently provide values of liver stiffness that are not identical [35–39]. Therefore, the same liver stiffness thresholds defined for TE cannot be directly applied to pSWE or 2D-SWE [40].

Methods Beyond Baveno VI and Expanded Baveno VI Criteria

Several other models have been proposed for the noninvasive prediction of HRV, including the use of spleen stiffness, spleen diameter or blood-based tests, with only limited or no external validation. Several of these models are reviewed in specific chapters of the book.

Summary and Conclusions

The Baveno VI criteria have been extensively validated as a decision rule for not doing an endoscopy in patients with compensated cirrhosis. The pooled NPV in series with a wide range of prevalences of HRVs (from 5% to 33%) is 99% (95% CI 99%–100%). The expanded Baveno VI cannot be recommended at the present time in any etiology.

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