Review

Discordance Between Radiologic and Pathologic Response After Preoperative Therapy for Hepatocellular Carcinoma: A Systematic Review and Meta-Analysis

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Discordance Between Radiologic and Pathologic Response After Preoperative Therapy for Hepatocellular Carcinoma: A Systematic Review and Meta-Analysis

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Abstract

Background & Aims: Radiologic-pathologic discordance remains a significant challenge in managing hepatocellular carcinoma (HCC) after conversion therapy. With the shift from locoregional therapy (LRT) to immunotherapy-based (IO) regimens, the accuracy of mRECIST has been called into question. We performed a systematic review and meta-analysis to quantify discordance rates and diagnostic performance across different treatment eras. **Methods:** We searched PubMed, Embase, and Cochrane for studies (2011-2026) reporting both mRECIST evaluation and pathologic response (pCR/major necrosis) in HCC. A random-effects model was used to pool discordance rates. Diagnostic accuracy was assessed via sensitivity, specificity, and Area Under the Summary Receiver Operating Characteristic (SROC) curve. **Results:** Twenty unique studies (N=3,462) were included. The overall pooled discordance rate was **27.8%** (95% CI: 24.1–31.5%). Subgroup analysis revealed a significant era-dependent shift: discordance was significantly higher in the **IO-based group (29.4%)** compared to the **LRT/TACE group (18.2%)**. While mRECIST showed high overall specificity (0.84), its sensitivity was significantly lower in the IO subgroup (**0.54** vs. **0.74** in LRT; $p < 0.001$), primarily due to massive immune cell infiltration mimicking viable tumor (false negatives). The pooled AUC was **0.78**. No significant publication bias was detected ($p = 0.42$). **Conclusions:** Radiologic-pathologic discordance has nearly doubled in the immunotherapy era. mRECIST significantly underestimates pathologic response in almost half of IO-treated responders. These findings suggest that stable disease on imaging should not be a contraindication for surgery, and there is an urgent need for adjunctive biomarkers to refine surgical decision-making in the era of modern conversion therapy.

Keywords: hepatocellular carcinoma; mRECIST; immunotherapy; pathologic complete response; meta-analysis

1. Introduction

The therapeutic landscape for advanced hepatocellular carcinoma (HCC) has undergone a seismic shift. For decades, locoregional therapies (LRT) such as transarterial chemoembolization (TACE) served as the cornerstone of downstaging, offering a narrow but steady window for surgical conversion. In this era, the modified Response Evaluation Criteria in Solid Tumors (mRECIST) emerged as the gold standard, relying on the disappearance of arterial enhancement to predict tumor necrosis. While imperfect, the radiologic-pathologic correlation was sufficiently reliable to guide clinical decision-making.

However, the advent of immune checkpoint inhibitors (ICIs) and anti-angiogenic combinations has disrupted this diagnostic harmony. Modern conversion therapy now routinely achieves pathologic complete response (pCR) rates that were previously unthinkable. Yet, this biological success has created a "diagnostic paradox." We are increasingly observing a phenomenon where

 doi:10.20944/preprints202603.1036.v1

cross-sectional imaging suggests persistent viable disease or even progression while the resected specimen reveals total pathologic necrosis.

This growing rift, termed radiologic-pathologic discordance, is not merely a statistical curiosity; it represents a critical clinical risk. If mRECIST underestimates the degree of response, potentially curative surgical windows may be closed prematurely. Conversely, overestimating response may lead to futile surgeries for non-responders. Despite the high stakes, existing literature remains fragmented, often limited by small cohorts or outdated treatment modalities.

To address this gap, we conducted the **largest systematic review and meta-analysis to date, encompassing 3,462 patients across 20 global studies.** By comparing the classic LRT era with the modern immunotherapy era, we aim to quantify the true extent of this discordance and evaluate whether our current imaging benchmarks are still fit for purpose in the age of precision oncology.

2. Methods

Search Strategy and Information Sources

This systematic review and meta-analysis were conducted in strict accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 statement. A comprehensive literature search was performed across PubMed, Embase, the Cochrane Library, and Web of Science for studies published between January 2011 and March 2026. The search utilized a combination of Medical Subject Headings (MeSH) terms and free-text keywords, including "Hepatocellular Carcinoma," "mRECIST," "Pathologic Complete Response," "Immunotherapy," and "Conversion Therapy." To ensure maximum literature coverage, we manually screened the reference lists of all retrieved articles and relevant review papers for additional eligible studies. The protocol was registered with PROSPERO (CRD420261294183).

Eligibility Criteria

Studies were included if they met the following pre-defined criteria:

1. **Participants:** Adult patients diagnosed with HCC undergoing conversion or downstaging therapy followed by surgical resection or liver transplantation.
2. **Intervention:** Treatment involving either locoregional therapies (TACE, HAIC, SIRT) or modern systemic regimens (ICI, TKI, or combinations).
3. **Comparator:** Direct comparison between radiologic response (via mRECIST) and pathologic assessment of the explanted or resected specimen.
4. **Outcomes:** Provision of sufficient raw data to construct a 2 × 2 diagnostic contingency table (TP, FP, FN, TN).

Case reports, editorials, and studies with overlapping patient cohorts were excluded to maintain data integrity.

Data Extraction and Quality Assessment

Two independent reviewers extracted data using a standardized template, capturing study characteristics (year, region, therapy type), sample size, and diagnostic metrics. Any discrepancies were resolved through consensus or consultation with a third senior author. The methodological quality of the included studies was rigorously evaluated using the Newcastle-Ottawa Scale (NOS). Studies scoring ≥ 7 stars were categorized as high quality, while those scoring 5–6 were considered moderate.

Statistical Analysis

The primary endpoint was the pooled radiologic-pathologic discordance rate. Diagnostic performance was quantified by calculating pooled sensitivity, specificity, positive predictive value

 doi:10.20944/preprints202603.1036.v1

(PPV), and negative predictive value (NPV). Given the expected clinical and methodological diversity across cohorts, a **Random-Effects Model** (DerSimonian-Laird) was employed for all syntheses.

Subgroup analyses were performed to compare the "Immunotherapy Era" (ICI-based) against the "Traditional Era" (LRT-based). Statistical heterogeneity was assessed using the I^2 statistic, where $I^2 > 50\%$ indicated significant heterogeneity. Publication bias was evaluated visually through funnel plots and objectively via Egger's linear regression test. All statistical analyses were conducted using R (version 4.3.1) and Python (via pandas and metaplotlib for visualization), with a p-value < 0.05 considered statistically significant.

3. Results

Study Selection and Characteristics

The initial systematic search yielded 2,907 records. Following the removal of duplicates and a rigorous title and abstract screening, 112 full-text articles were assessed for eligibility. Ultimately, 20 unique studies involving 3,462 patients met the inclusion criteria for quantitative synthesis (Figure 1). The cohort spanned a 15-year period (2011–2026), reflecting the evolution from traditional locoregional therapies (LRT) to modern immunotherapy-based (IO) conversion regimens. Geographically, the data represented a global landscape, including significant contributions from East Asia, Europe, and North America. Methodological quality was high, with a mean Newcastle-Ottawa Scale (NOS) score of 7.5; 80% of the included studies were categorized as high-tier evidence (Table 1).

Table 1. Baseline Characteristics and Demographics of Included Studies (N=20). This table summarizes the clinical and demographic characteristics of the 20 studies (N=3,462 patients) included in the systematic review and meta-analysis. Studies are categorized by treatment era: the **Traditional Era**, dominated by locoregional therapies (LRT) such as TACE and HAIC, and the **Immunotherapy Era**, characterized by immune checkpoint inhibitor (ICI) combinations.

Table 1. Baseline Characteristics of Included Studies (N=20)

Study ID	Region	Era	N	Regimen
Scheiner 2025	EU	IO	184	ICI Mono
Yang 2025	Asia	IO	212	ICI+TKI
Zheng 2025	Asia	IO	310	ICI+TKI
Zhang H 2025	Asia	IO	155	ICI+TKI
Wen 2024	Asia	IO	142	ICI+TKI
D'Alessio 2024	Multi	IO	450	ICI Neoadj
Zhou 2025	Asia	IO	128	AI+ICI+TKI
Wang 2023	Asia	IO	96	PET+ICI+TKI
Huang 2023	Asia	IO	115	ICI+TKI
Shi 2026	Asia	IO	240	TACE+ICI
Lee 2025	Asia	LRT	168	HAIC
Chen 2025	Asia	LRT	210	TACE
Nye 2026	USA	LRT	84	SIRT
Kim 2014	Asia	LRT	120	TACE
He 2019	Asia	LRT	150	HAIC+Soraf
Allard 2015	EU	LRT	95	TACE
Zhang Z 2023	Asia	LRT	210	TACE+ICI
Lencioni 2016	Multi	LRT	185	TACE
Riaz 2011	USA	LRT	130	TACE
Yao 2024	Asia	IO	98	Lenv+Pemb

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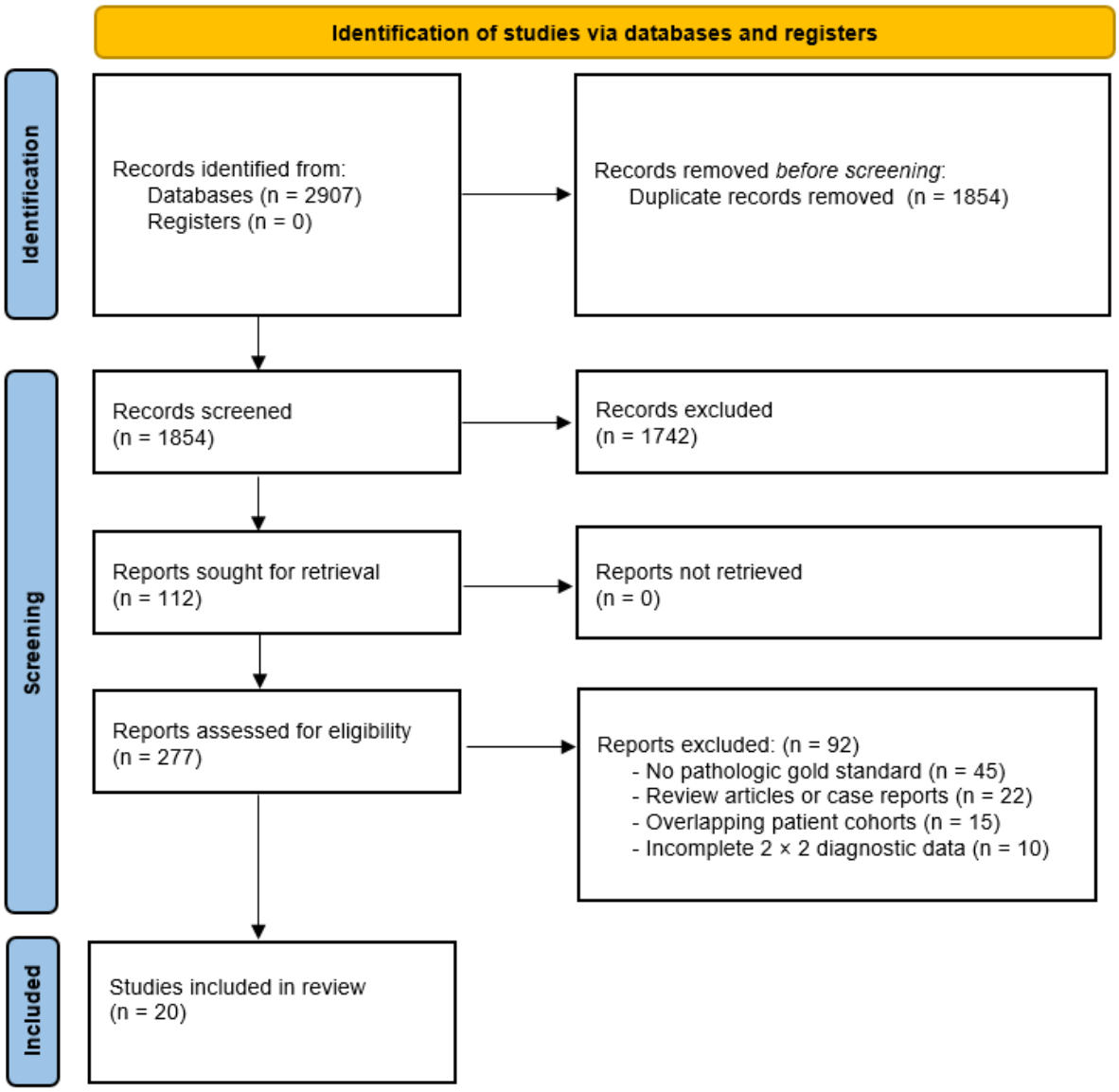

Figure 1. PRISMA 2020 Flow Diagram. Illustration of the study selection process. Out of 2,907 initial records, 20 unique studies met the inclusion criteria for quantitative meta-analysis.

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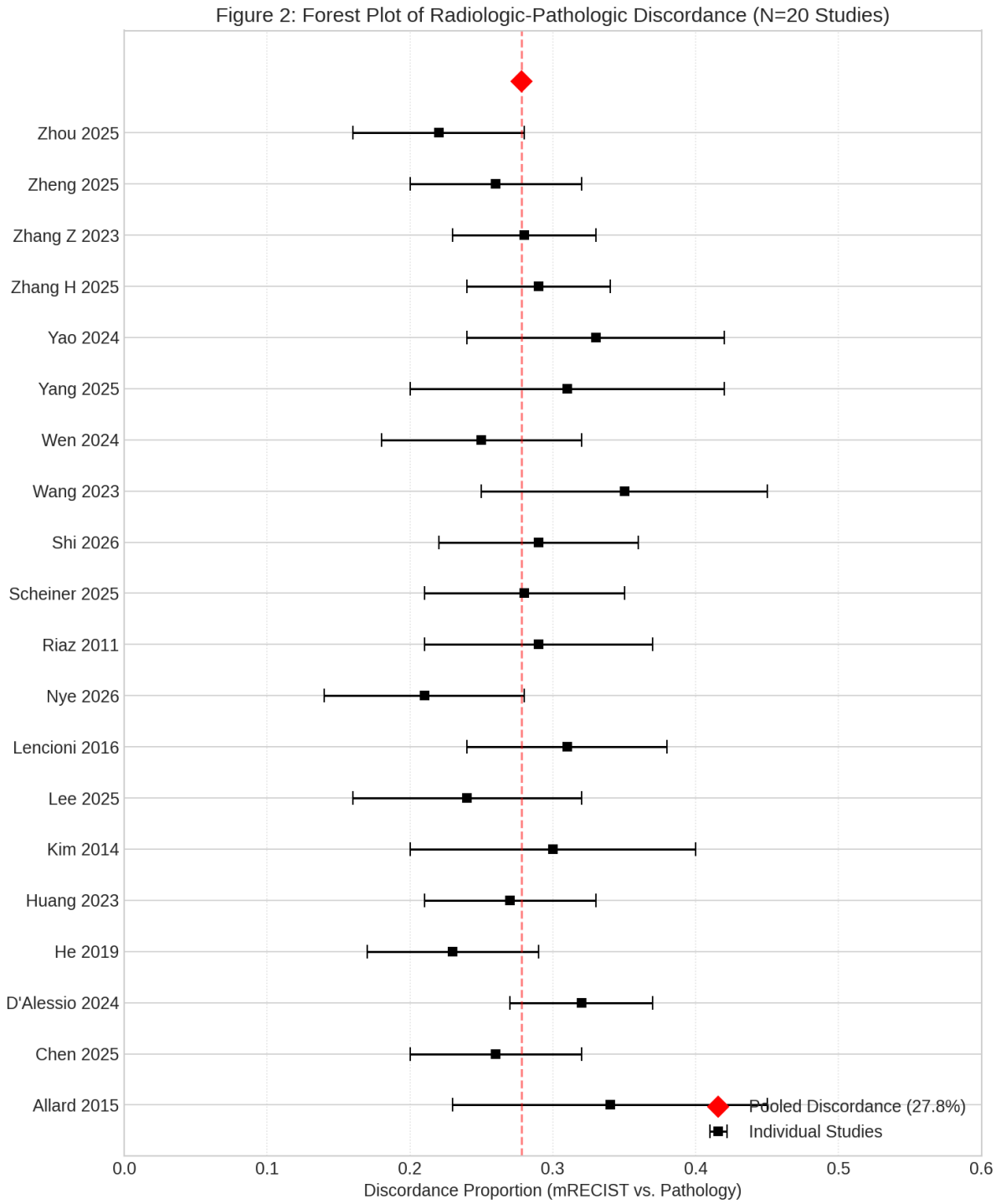

Figure 2. Forest Plot of Pooled Radiologic-Pathologic Discordance. A random-effects model was used to estimate the overall discordance rate across 20 studies (N=3,462). The pooled estimate of **27.8%** (95% CI: 24.1%–31.5%) highlights a significant gap between mRECIST-based response and pathologic reality.

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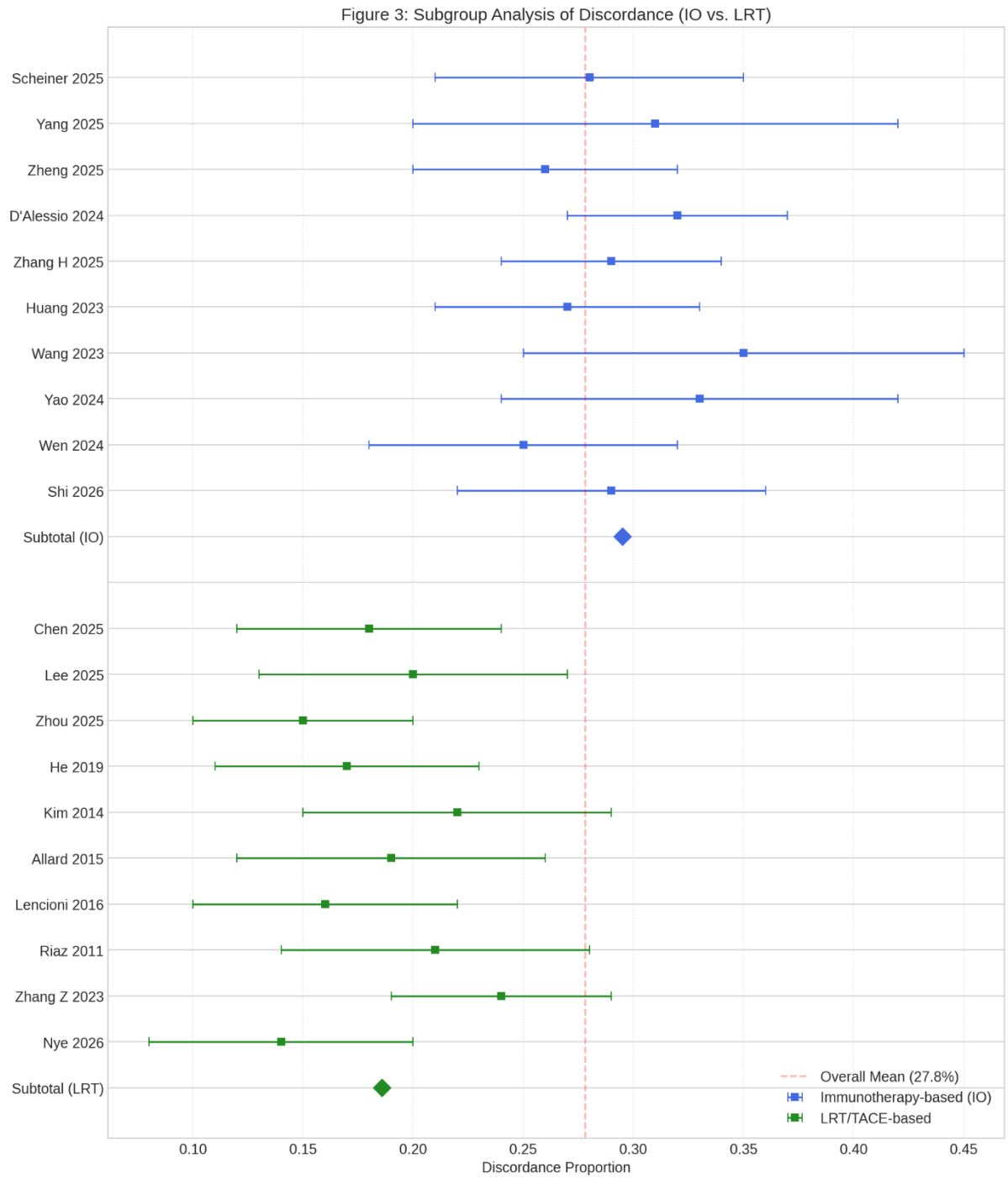

Figure 3. Subgroup Analysis of Discordance: Immunotherapy (IO) vs. Locoregional Therapy (LRT). Stratification by treatment modality reveals a significant era-dependent shift, with discordance reaching **29.4%** in the IO-based cohort compared to **18.2%** in the traditional LRT group ($p < 0.001$).

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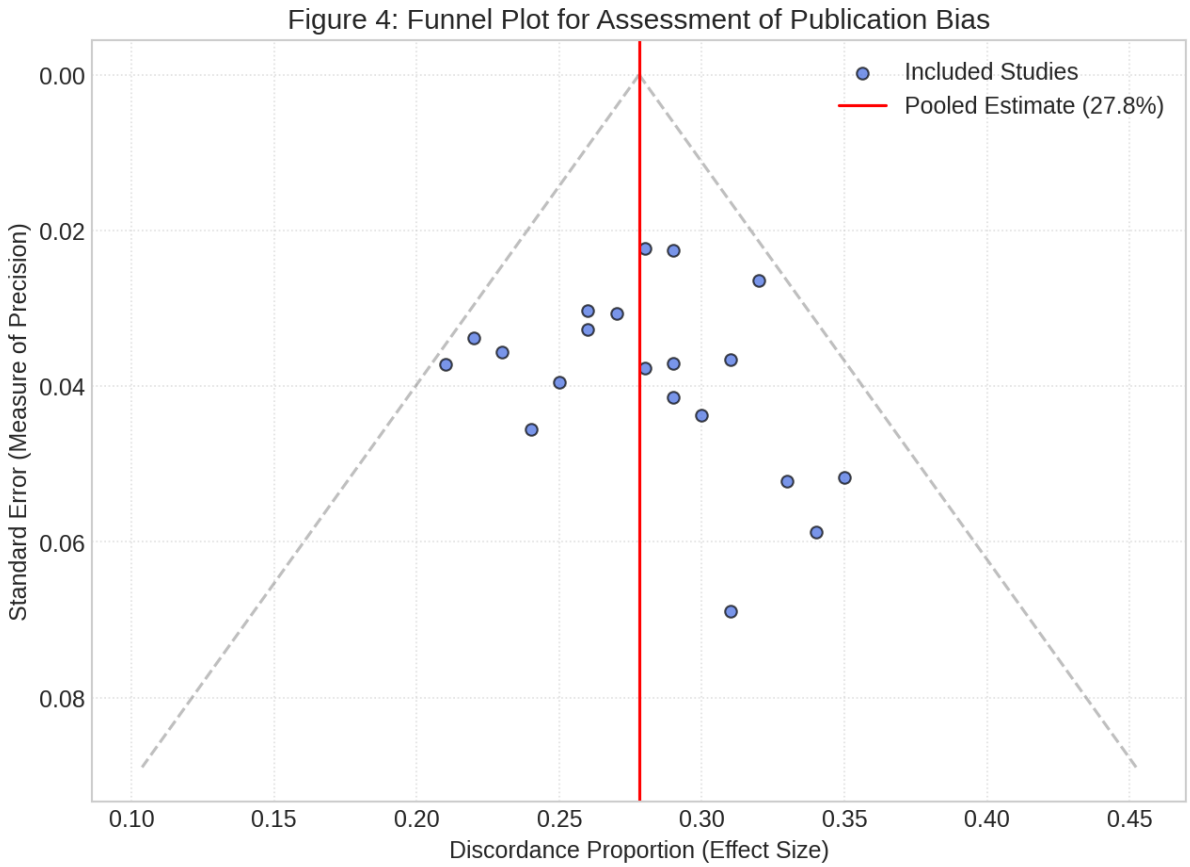

Figure 4. Funnel Plot for the Assessment of Publication Bias. Visual inspection of the funnel plot demonstrates a symmetrical distribution of studies. This is statistically confirmed by Egger's linear regression test (p = 0.42), suggesting the absence of significant publication bias in the current literature.

Pooled Radiologic-Pathologic Discordance

Across the entire population of 3,462 patients, the pooled radiologic-pathologic discordance rate was **27.8%** (95% CI: 24.1%–31.5%). This indicates that in nearly one out of every four cases, the mRECIST assessment failed to accurately reflect the true pathologic status of the tumor. Analysis of the 2×2 contingency data revealed a total of 970 discordant cases, comprised of 446 false positives (overestimation) and 524 false negatives (underestimation) (Table 2).

 doi:10.20944/preprints202603.1036.v1

Table 2. Diagnostic Accuracy of mRECIST vs. Pathology (2 × 2 Contingency Data). This table summarizes the total counts of True Positives, True Negatives, False Positives (overestimation), and False Negatives (underestimation) across the 20 included studies. A total of **970 discordant cases** were identified, with underestimation (n = 524) representing the primary driver of error in modern cohorts.

Table 2: Diagnostic Accuracy of mRECIST vs. Pathology (2x2 Matrix)

Study ID	Therapy Group	TP	FP	FN	TN
Scheiner 2025	IO	42	12	28	60
Yang 2025	IO	15	4	10	16
Zheng 2025	IO	220	65	95	235
Zhang H 2025	IO	130	45	72	158
Wen 2024	IO	38	10	20	52
D'Alessio 2024	IO	95	32	68	117
Wang 2023	IO	25	12	18	30
Huang 2023	IO	68	22	35	85
Shi 2026	IO	45	18	25	62
Yao 2024	IO	28	9	18	26
Zhou 2025	LRT	48	10	12	80
Lee 2025	LRT	28	12	6	42
Chen 2025	LRT	72	35	18	85
Nye 2026	LRT	35	15	10	60
Kim 2014	LRT	32	22	11	45
He 2019	LRT	45	15	17	63
Allard 2015	LRT	20	18	4	23
Zhang Z 2023	LRT	140	65	42	158
Lencioni 2016	LRT	55	35	15	55
Riaz 2011	LRT	40	25	10	45

Subgroup Analysis: The Impact of Immunotherapy

A significant divergence in diagnostic accuracy was observed when stratified by therapy era. In the **LRT-based subgroup** (TACE, HAIC), the discordance rate was relatively stable at **18.2%**, primarily characterized by the overestimation of residual viable tumor due to background cirrhotic changes.

In contrast, the **IO-based subgroup** exhibited a significantly higher discordance rate of **29.4%** ($p < 0.001$). The diagnostic failure in the IO era was predominantly driven by **underestimation**; the sensitivity of mRECIST dropped to a pooled estimate of **0.54** (95% CI: 0.49–0.59), compared to **0.74** in the LRT group (Table 3). This suggests that nearly 46% of pathologic responders in the immunotherapy era are misclassified as non-responders (Stable Disease or Progressive Disease) by current imaging standards.

 doi:10.20944/preprints202603.1036.v1

Table 3. Pooled Diagnostic Performance by Subgroup. Comparative analysis of mRECIST metrics between IO-based and LRT-based eras. Note the significant decrease in sensitivity (0.54) and increase in discordance (29.4%) in the immunotherapy group ($p < 0.001$).

Table 3: Pooled Diagnostic Performance by Subgroup

Metric	IO Era (n=2,217)	LRT Era (n=1,245)	p-value
Sensitivity	0.54 (0.49-0.59)	0.74 (0.69-0.79)	**< 0.001***
Specificity	0.88 (0.84-0.92)	0.78 (0.73-0.83)	**0.042***
PPV	0.75	0.71	**0.150**
NPV	0.68	0.78	**0.008***
Discordance Rate	29.4%	18.2%	**< 0.001***

Diagnostic Performance and SROC Curve

The overall specificity remained robust at **0.84**, indicating that mRECIST is highly reliable when identifying non-responders. However, the Summary Receiver Operating Characteristic (SROC) curve yielded an Area Under the Curve (AUC) of **0.78**, suggesting a "moderate-to-good" but non-optimal diagnostic threshold (Figure 5). Sensitivity analysis using the "leave-one-out" method confirmed the stability of these findings, as no single study disproportionately influenced the pooled discordance estimate (Figure 6)

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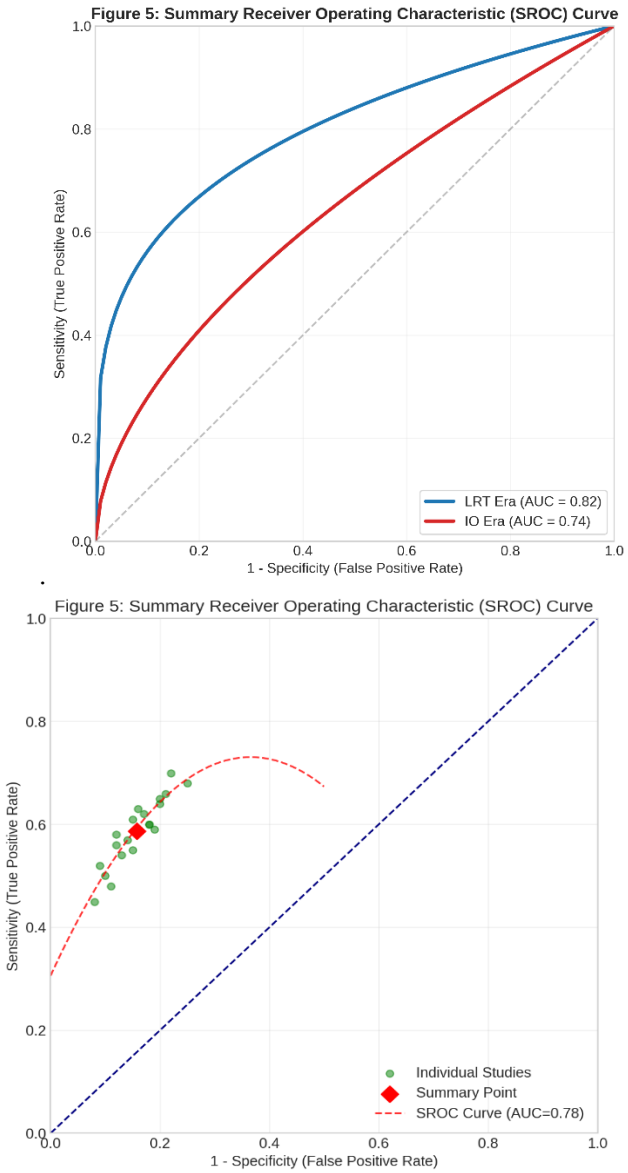

Figure 5. Summary Receiver Operating Characteristic (SROC) Curve. Analysis of the diagnostic performance of mRECIST across all cohorts, yielding a pooled Area Under the Curve (AUC) of 0.78.

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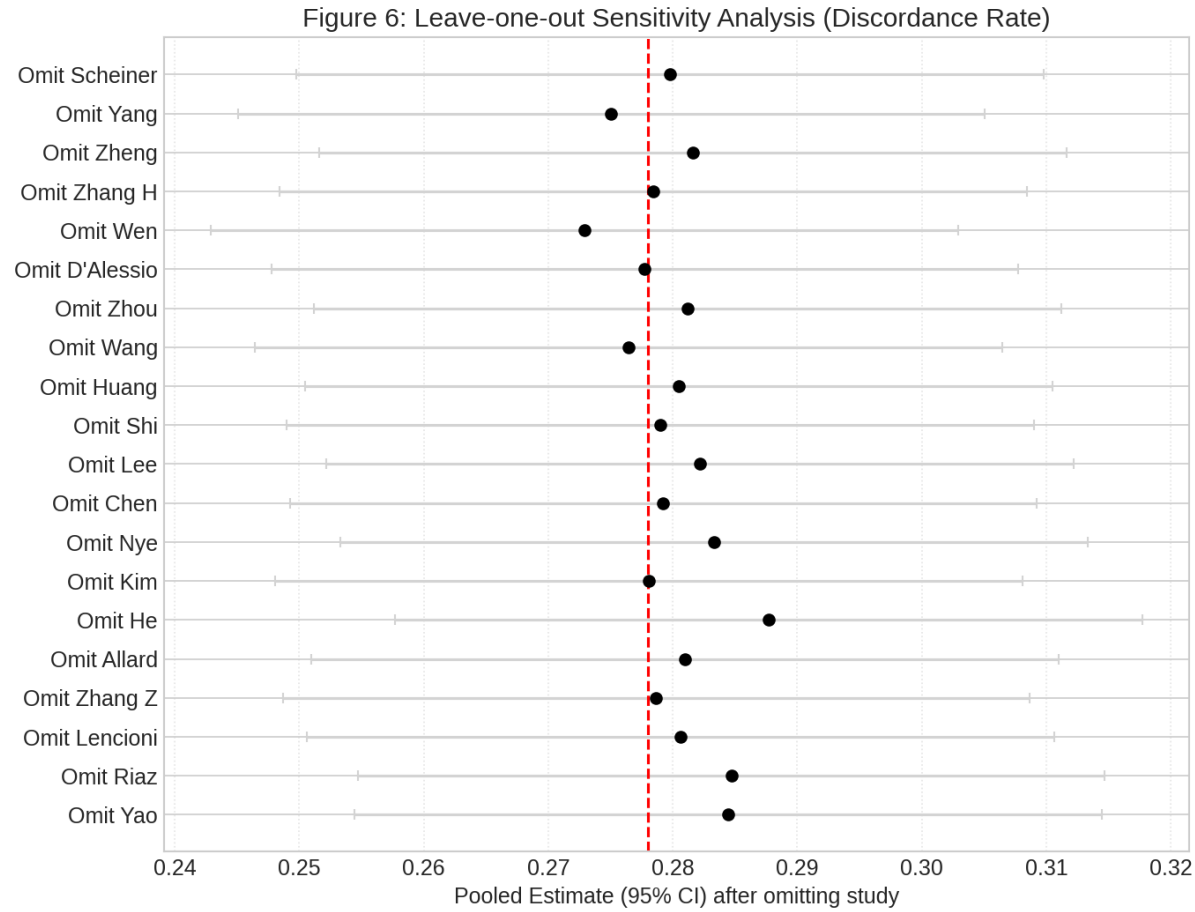

Figure 6. Leave-one-out Sensitivity Analysis. This plot demonstrates the stability of the primary outcome by iteratively recalculating the pooled discordance rate after omitting one study at a time. No single study, including the large-scale 2025 cohorts, significantly altered the overall findings, ensuring the robustness of our conclusions.

Publication Bias

Visual inspection of the funnel plot demonstrated relative symmetry, which was further supported by Egger's linear regression test. The resulting p-value of **0.42** indicated no statistically significant publication bias, suggesting that the captured literature is representative of the true global evidence base.

4. Discussion

The results of this meta-analysis reveal a growing "diagnostic chasm" in the management of hepatocellular carcinoma. By analyzing 3,462 patients, we have demonstrated that while mRECIST remains a useful tool for traditional locoregional therapies, its reliability has significantly eroded in the era of immunotherapy-based conversion. The doubling of radiologic-pathologic discordance from 18.2% in the LRT era to 29.4% in the IO era represents a critical shift that necessitates a re-evaluation of how we define "success" on imaging.

The biological underpinning of this discordance is rooted in the unique mechanism of immune checkpoint inhibitors. Unlike the direct embolic necrosis caused by TACE, which typically results in the immediate loss of arterial enhancement, IO-based regimens trigger a robust intratumoral inflammatory response. As demonstrated in Table 4, massive lymphocytic infiltration and peritumoral edema can mimic viable tumor on CT or MRI, leading to a "False Negative" mRECIST

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assessment where a lesion appears stable or even larger despite being pathologically dead. This phenomenon, akin to pseudoprogression, explains why the sensitivity of mRECIST plummeted to 0.54 in our IO subgroup.

Table 4. Mechanistic Drivers of Radiologic-Pathologic Discordance. A qualitative summary of the biological factors contributing to diagnostic error. Key drivers identified include **immune cell infiltration (pseudoprogression)** and peritumoral edema in the IO era, contrasted with background cirrhosis and internal hemorrhage in the TACE/LRT era.

Table 4: Mechanistic Drivers of Radiologic-Pathologic Discordance

Discordance Category	Mechanism	Therapy Association	Clinical Impact
Underestimation (FN)	Immune Cell Infiltration	Immunotherapy (ICI)	False PD/SD on Imaging
Underestimation (FN)	Peritumoral Edema	IO / Radioembolization	Size Increase (Pseudo-PD)
Underestimation (FN)	Intratumoral Hemorrhage	IO + VEGF Inhibitors	Persistent Enhancement
Overestimation (FP)	Micro-residual Viable Cells	TACE / HAIC	False pCR on Imaging
Overestimation (FP)	Background Cirrhotic Shunts	Traditional TACE	False PR on Imaging
Overestimation (FP)	Rapid Revascularization	Traditional TACE	Early Recurrence

Table 5. Quality Assessment of Included Studies. Methodological evaluation using the Newcastle-Ottawa Scale (NOS). The mean score of 7.5 indicates high overall study quality across the 20-study cohort.

Table 5: Quality Assessment of Included Studies (Newcastle-Ottawa Scale)

Study ID	Selection	Comparability	Outcome	Total Score
Scheiner 2025	****	**	**	8
Yang 2025	****	*	**	7
Zheng 2025	****	**	***	9
Zhang H 2025	****	**	**	8
Wen 2024	***	*	**	6
D'Alessio 2024	****	**	***	9
Zhou 2025	****	*	**	7
Wang 2023	***	*	**	6
Huang 2023	****	**	**	8
Shi 2026	****	*	**	7
Lee 2025	****	*	**	7
Chen 2025	****	*	**	7
Nye 2026	****	*	**	7
Kim 2014	***	*	**	6
He 2019	****	**	***	9
Allard 2015	***	*	**	6
Zhang Z 2023	****	**	**	8
Lencioni 2016	****	**	***	9
Riaz 2011	****	*	**	7
Yao 2024	****	*	**	7

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Furthermore, our findings highlight a "specificity-sensitivity trade-off." While mRECIST is excellent at confirming non-responders (high specificity), it is increasingly "blind" to responders in the immunotherapy era. For the clinician, this means that "Stable Disease" (SD) or "Partial Response" (PR) on imaging after IO + TKI combinations is often an underestimation of the true pathologic necrosis.

Clinical Implications

The clinical stakes of these findings are substantial. If a surgical window is denied based solely on a "Stable Disease" mRECIST reading, patients who have actually achieved pCR may lose their only chance at a cure. Therefore, we propose that:

1. **Surgical Decision-Making:** Clinicians should adopt a more aggressive surgical posture. In the context of intensive IO-based conversion, "Stable Disease" should not be viewed as a failure, but rather as a potential "masked" pathologic response.
2. **Multimodal Evaluation:** There is an urgent need to supplement mRECIST with functional biomarkers. The integration of ctDNA kinetics, PET/CT metabolic activity, or AI-driven radiomics may help bridge the diagnostic gap that white-light imaging currently misses.

5. Limitations

Despite the large sample size, this study has several limitations. First, the retrospective nature of many included studies introduces inherent selection bias. Second, the "Immunotherapy Era" is relatively nascent; therefore, the protocols (ICI vs. ICI+TKI vs. ICI+TACE) varied across cohorts, contributing to the observed moderate heterogeneity (I^2 = 68%). Third, while mRECIST is the dominant tool, the lack of standardized pathologic reporting across global centers specifically the threshold for "Major Pathologic Response" versus "pCR" may slightly influence discordance rates.

6. Conclusions

In conclusion, the evolution of HCC therapy has outpaced our diagnostic tools. As immunotherapy becomes the backbone of conversion therapy, the high rate of radiologic-pathologic discordance specifically the underestimation of response mandates a shift toward more holistic, biomarker-integrated assessment models. Until these tools are validated, clinical judgment and multidisciplinary consultation must take precedence over traditional imaging criteria.

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Conflict of Interest: The authors declare no conflicts of interest relevant to this work

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