ENTECAVIR VS TENOFOVIR IN HEPATOCELLULAR CARCINOMA PREVENTION IN CHRONIC HEPATITIS B INFECTION: A SYSTEMATIC REVIEW AND META-ANALYSIS

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Keywords: nucleotide analogue, nucleoside analogue, liver cancer, HBV

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**Pubmed**

(("entecavir"[Supplementary Concept] OR "entecavir"[All Fields]) AND ("tenofovir"[MeSH Terms] OR "tenofovir"[All Fields])) AND ("carcinoma, hepatocellular"[MeSH Terms] OR ("carcinoma"[All Fields] AND "hepatocellular"[All Fields]) OR "hepatocellular carcinoma"[All Fields] OR ("liver"[All Fields] AND "cell"[All Fields] AND "carcinoma"[All Fields]) OR "liver cell carcinoma"[All Fields]) OR ("liver neoplasms"[MeSH Terms] OR ("liver"[All Fields] AND "neoplasms"[All Fields]) OR "liver neoplasms"[All Fields]) OR ("liver"[All Fields] AND "tumor"[All Fields]) OR "liver tumor"[All Fields]) OR ("liver neoplasms"[MeSH Terms] OR ("liver"[All Fields] AND "neoplasms"[All Fields]) OR "liver neoplasms"[All Fields] OR ("hepatic"[All Fields] AND "neoplasm"[All Fields]) OR "hepatic neoplasm"[All Fields]) OR ("carcinoma, hepatocellular"[MeSH Terms] OR ("carcinoma"[All Fields] AND "hepatocellular"[All Fields]) OR "hepatocellular carcinoma"[All Fields] OR ("hepato carcinoma"[All Fields])) OR ("carcinoma, hepatocellular"[MeSH Terms] OR ("carcinoma"[All Fields] AND "hepatocellular"[All Fields]) OR "hepatocellular carcinoma"[All Fields] OR ("hepato carcinoma"[All Fields])) OR ("carcinoma, hepatocellular"[MeSH Terms] OR ("carcinoma"[All Fields] AND "hepatocellular"[All Fields]) OR "hepatocellular carcinoma"[All Fields] OR ("hepato carcinoma"[All Fields])) OR ("carcinoma, hepatocellular"[MeSH Terms] OR ("carcinoma"[All Fields] AND "hepatocellular"[All Fields]) OR "hepatocellular carcinoma"[All Fields] OR ("hepato carcinoma"[All Fields])) OR ("carcinoma, hepatocellular"[MeSH Terms] OR ("carcinoma"[All Fields] AND "hepatocellular"[All Fields]) OR "hepatocellular carcinoma"[All Fields] OR ("hepato carcinoma"[All Fields])) OR ("carcinoma, hepatocellular"[MeSH Terms] OR ("carcinoma"[All Fields] AND "hepatocellular"[All Fields]) OR "hepatocellular carcinoma"[All Fields] OR ("hepato carcinoma"[All Fields])) OR ("carcinoma, hepatocellular"[MeSH Terms] OR ("carcinoma"[All Fields] AND "hepatocellular"[All Fields]) OR "hepatocellular carcinoma"[All Fields] OR ("hepato carcinoma"[All Fields])) OR ("carcinoma, hepatocellular"[MeSH Terms] OR ("carcinoma"[All Fields] AND "hepatocellular"[All Fields]) OR "hepatocellular carcinoma"[All Fields] OR ("hepato carcinoma"[All Fields])))
Embase

1. entecavir
2. tenofovir
3. 1 AND 2
4. liver cell carcinoma
5. liver tumor
6. hepatic neoplasm
7. hepatocellular carcinoma
8. liver cancer
9. hepatoma
10. hepatocarcinoma
11. liver neoplasm
12. 4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11
13. 3 AND 12

Cochrane Library

(enterovir or tenofovir) AND (liver cell carcinoma or liver tumor or hepatic neoplasm or hepatocellular carcinoma or liver cancer or hepatoma or hepatocarcinoma or liver neoplasm)
## Table 1. Quality assessment according to Newcastle-Ottawa quality assessment scale (NOS)

| References | Kim BG 2018 | Choi J 2019 | Kim SU 2019 | Lee SW 2019 | Yip TCF 2019 | Hsu YC 2019 | Paptheod oridis GV 2019 | Pols S 2019 | Kim WR 2019 | Gordon SC 2019 | Ha I 2020 | Lee HW 2020 | Oh H 2020 |
|------------|-------------|-------------|-------------|-------------|--------------|-------------|-------------------------|--------------|-------------|---------------|------------|-------------|-----------|
| Selection  | Representativeness of exposed cohort | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Selection of non-exposed cohort | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Ascertainment of exposure | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Demonstration that outcome of interest was not present at the start of study | 1 | 1 | 1 | 1 | 1 | 1 | 1 | Unclear | 1 | Unclear | 1 | 1 | 1 |
| Comparability | Controls for age or gender | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Controls for additional factor | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Outcome | Assessment of outcome | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Follow-up long enough for outcomes to occur | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Adequacy of follow-up of cohort | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Total | 9 | 9 | 9 | 9 | 9 | 9 | 8 | 9 | 8 | 9 | 9 | 9 | 9 |
## eTable 2. Leave-one-out sensitivity analysis using random effects model

| Study*                  | Ethnicity | Pooled HR | 95% CI     | p-value |
|-------------------------|-----------|-----------|------------|---------|
| Kim BG 2018             | Asian     | 0.83      | 0.67 – 1.01| 0.067   |
| Choi J 2019             | Asian     | 0.85      | 0.68 – 1.07| 0.158   |
| Kim SU 2019             | Asian     | 0.77      | 0.64 – 0.93| 0.008   |
| Papatheodoridis GV 2019 | Non-Asian | 0.79      | 0.64 – 0.98| 0.033   |
| Pol S 2019              | Mixed     | 0.82      | 0.67 – 1.01| 0.068   |
| Kim WR 2019             | Non-Asian | 0.85      | 0.69 – 1.04| 0.117   |
| Gordon SC 2019          | Asian     | 0.82      | 0.67 – 1.01| 0.059   |
| Gordon SC 2019          | Non-Asian | 0.81      | 0.66 – 0.99| 0.036   |
| Lee SW 2020             | Asian     | 0.80      | 0.65 – 0.98| 0.035   |
| Yip TC 2020             | Asian     | 0.84      | 0.69 – 1.03| 0.089   |
| Hsu YC 2020             | Mixed     | 0.81      | 0.66 – 1.00| 0.051   |
| Ha I 2020               | Asia      | 0.77      | 0.64 – 0.92| 0.004   |
| Lee HW 2020             | Asian     | 0.81      | 0.66 – 1.00| 0.045   |
| Oh H 2020               | Asian     | 0.82      | 0.66 – 1.03| 0.085   |

* Individual study in each row was excluded to calculate the pooled HR to assess impact of single study on the pooled effect estimate

Abbreviations: HR, hazard ratio; 95% CI, 95% confidence interval
eTable 3. Pooled HR by excluding the study by Choi J et al using random effects model

|                             | Pooled HR | 95% CI       | p-value |
|-----------------------------|-----------|--------------|---------|
| Main result                 | 0.85      | 0.68 – 1.07  | 0.158   |
| Cirrhosis                   | 0.82      | 0.65 – 1.03  | 0.087   |
| Non-cirrhosis               | 0.84      | 0.45 – 1.59  | 0.592   |
| Asian population            | 0.87      | 0.64 – 1.19  | 0.386   |
| Non-Asian population        | 0.80      | 0.53 – 1.22  | 0.301   |
| Studies using electronic    | 0.52      | 0.36 – 0.75  | <0.001  |
| databases                   |           |              |         |
| Studies using clinical      | 0.97      | 0.80 – 1.18  | 0.787   |
| records                     |           |              |         |

Abbreviations: HR, hazard ratio; 95% CI: 95% confidence interval
Figure legend

eFigure 1. Funnel plot for detecting publication bias

eFigure 2. Comparison between ETV and TDF on hepatocellular carcinoma preventive effect among Asian CHB patients (random effects model)
Abbreviations: ETV, entecavir; TDF, tenofovir disoproxil fumarate; CHB, chronic hepatitis B; HR, hazard ratio; RE, random effects

eFigure 3. Comparison between ETV and TDF on hepatocellular carcinoma preventive effect among non-Asian CHB patients (random effects model)
Abbreviations: ETV, entecavir; TDF, tenofovir disoproxil fumarate; CHB, chronic hepatitis B; HR, hazard ratio; RE, random effects

eFigure 4. Comparison between ETV and TDF on hepatocellular carcinoma preventive effect among studies using electronic databases (random effects model)
Abbreviations: ETV, entecavir; TDF, tenofovir disoproxil fumarate; HR, hazard ratio; RE, random effects

eFigure 5. Comparison between ETV and TDF on hepatocellular carcinoma preventive effect among studies using clinical records (random effects model)
Abbreviations: ETV, entecavir; TDF, tenofovir disoproxil fumarate; HR, hazard ratio; RE, random effects
eFigure 6. Comparison between ETV and TDF on hepatocellular carcinoma preventive effect among CHB patients by pooling results from multivariable analysis (random effects model)

Abbreviations: ETV, entecavir; TDF, tenofovir disoproxil fumarate; CHB, chronic hepatitis B; HR, hazard ratio; RE, random effects
eFigure 1. Funnel plot for detecting publication bias
### Study and Ethnicity

| Study and Ethnicity | HR (log scale) | Weight | HR [95% CI] |
|---------------------|----------------|--------|-------------|
| Kim BG 2018, [Asian] | ➡️             | 5.37%  | 0.56 [0.21, 1.52] |
| Choi J 2019, [Asian] | ⬅️             | 25.06% | 0.68 [0.60, 0.78] |
| Kim SU 2019, [Asian] | ➡️             | 13.39% | 1.25 [0.76, 2.06] |
| Gordon SC 2019, [Asian] | ➡️             | 6.04%  | 0.73 [0.29, 1.84] |
| Lee SW 2020, [Asian] | ⬅️             | 8.52%  | 1.08 [0.52, 2.24] |
| Yip TC 2020, [Asian] | ➡️             | 7.91%  | 0.39 [0.18, 0.84] |
| Hsu YC 2020, [Asian] | ➡️             | 7.15%  | 0.73 [0.32, 1.67] |
| Ha I 2020, [Asian] | ➡️             | 8.70%  | 1.84 [0.90, 3.78] |
| Lee HW 2020, [Asian] | ➡️             | 3.33%  | 0.87 [0.23, 3.27] |
| Oh H 2020, [Asian] | ➡️             | 14.53% | 0.77 [0.49, 1.22] |
| RE Model | ➡️             | 100.00%| 0.82 [0.63, 1.06] |

**eFigure 2.** Comparison between ETV and TDF on hepatocellular carcinoma preventive effect among Asian CHB patients (random effects model)

Abbreviations: ETV, entecavir; TDF, tenofovir disoproxil fumarate; CHB, chronic hepatitis B; HR, hazard ratio; RE, random effects
eFigure 3. Comparison between ETV and TDF on hepatocellular carcinoma preventive effect among non-Asian CHB patients (random effects model)

Abbreviations: ETV, entecavir; TDF, tenofovir disoproxil fumarate; CHB, chronic hepatitis B; HR, hazard ratio; RE, random effects
**eFigure 4.** Comparison between ETV and TDF on hepatocellular carcinoma preventive effect among studies using electronic databases (random effects model)

Abbreviations: ETV, entecavir; TDF, tenofovir disoproxil fumarate; HR, hazard ratio; RE, random effects
**Study and Ethnicity** | **HR (log scale)** | **Weight** | **HR [95% CI]**  
--- | --- | --- | ---  
Kim BG 2018, [Asian] |  | 3.67% | 0.56 [0.21, 1.52]  
Kim SU 2019, [Asian] |  | 14.67% | 1.25 [0.76, 2.06]  
Papatheodoridis GV 2019, [Non-Asian] |  | 29.15% | 1.00 [0.70, 1.42]  
Pol S 2019, [Mixed] |  | 6.20% | 0.71 [0.33, 1.53]  
Gordon SC 2019, [Asian] |  | 4.27% | 0.73 [0.29, 1.84]  
Gordon SC 2019, [Non-Asian] |  | 2.58% | 1.21 [0.37, 3.97]  
Lee SW 2020, [Asian] |  | 6.84% | 0.97 [0.52, 2.24]  
Hsu YC 2020, [Mixed] |  | 6.12% | 0.89 [0.41, 1.93]  
Ha I 2020, [Asian] |  | 7.05% | 1.84 [0.90, 3.78]  
Lee HJ 2020, [Asian] |  | 2.08% | 0.87 [0.23, 3.27]  
Oh H 2020, [Asian] |  | 17.37% | 0.77 [0.49, 1.22]  
--- | --- | --- | ---  
RE Model |  | 100.00% | 0.97 [0.80, 1.18]  

**eFigure 5. Comparison between ETV and TDF on hepatocellular carcinoma preventive effect among studies using clinical records (random effects model)**

Abbreviations: ETV, entecavir; TDF, tenofovir disoproxil fumarate; HR, hazard ratio; RE, random effects
### Study and Ethnicity

| Study and Ethnicity          | HR (log scale) | Weight | HR [95% CI] |
|------------------------------|----------------|--------|-------------|
| Kim BG 2018, [Asian]         |                | 3.99%  | 0.58 [0.27, 1.26] |
| Choi J 2019, [Asian]         |                | 18.03% | 0.68 [0.60, 0.78] |
| Kim SU 2019, [Asian]         |                | 13.74% | 0.98 [0.75, 1.28] |
| Papatheodoridis GV 2019, [Non-Asian] |            | 10.93% | 1.00 [0.70, 1.42] |
| Pol S 2019, [Mixed]          |                | 4.05%  | 0.71 [0.33, 1.53] |
| Kim WR 2019, [Non-Asian]     |                | 9.16%  | 0.86 [0.37, 1.53] |
| Gordon SC 2019, [Asian]      |                | 2.95%  | 0.73 [0.29, 1.84] |
| Gordon SC 2019, [Non-Asian]  |                | 1.91%  | 1.21 [0.37, 3.97] |
| Lee SW 2020, [Asian]         |                | 10.73% | 0.97 [0.68, 1.39] |
| Yip TC 2020, [Asian]         |                | 4.52%  | 0.33 [0.16, 0.68] |
| Hsu YC 2020, [Mixed]         |                | 5.16%  | 0.81 [0.42, 1.56] |
| Ha I 2020, [Asian]           |                | 4.49%  | 1.84 [0.90, 3.76] |
| Lee HJ 2020, [Asian]         |                | 1.57%  | 0.87 [0.23, 3.27] |
| Oh H 2020, [Asian]           |                | 8.73%  | 0.79 [0.51, 1.23] |

**RE Model**

100.00% 0.80 [0.67, 0.95]

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**eFigure 6. Comparison between ETV and TDF on hepatocellular carcinoma preventive effect among CHB patients by pooling results from multivariable analysis (random effects model)**

Abbreviations: ETV, entecavir; TDF, tenofovir disoproxil fumarate; CHB, chronic hepatitis B; HR, hazard ratio; RE, random effects
| Section/topic | # | Checklist item                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Reported on page # |
|--------------|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| TITLE        |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                   |
| Title        | 1 | Identify the report as a systematic review, meta-analysis, or both.                                                                                                                                                                                                                                                                                                                                                     | 1                 |
| ABSTRACT     |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                   |
| Structured summary | 2 | Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.                                                                                                                                                                                                                   | 3, 4              |
| INTRODUCTION |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                   |
| Rationale    | 3 | Describe the rationale for the review in the context of what is already known.                                                                                                                                                                                                                                                                                                                                         | 5, 6              |
| Objectives   | 4 | Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).                                                                                                                                                                                                                                                                                   | 5, 6              |
| METHODS      |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                   |
| Protocol and registration | 5 | Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.                                                                                                                                                                                                                                                  | 7                 |
| Eligibility criteria | 6 | Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.                                                                                                                                                                                                                   | 7, 8              |
| Information sources | 7 | Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.                                                                                                                                                                                                                                           | 7                 |
| Search       | 8 | Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.                                                                                                                                                                                                                                                                                             | Supplementary material |
| Study selection | 9 | State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).                                                                                                                                                                                                                                                  | 7, Figure 1       |
| Data collection process | 10 | Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.                                                                                                                                                                                                                                              | 7, 8              |
| Data items   | 11 | List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.                                                                                                                                                                                                                                                                                   | 7, 8              |
| Risk of bias in individual studies | 12 | Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.                                                                                                                                                                                                                   | 8, 9              |
| Summary measures | 13 | State the principal summary measures (e.g., risk ratio, difference in means).                                                                                                                                                                                                                                                                                                                                         | 8, 9              |
## PRISMA 2009 Checklist

**Synthesis of results**

| Section/topic | # | Checklist item | Reported on page # |
|---------------|---|----------------|-------------------|
| Risk of bias across studies | 15 | Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies). | 9 |
| Additional analyses | 16 | Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified. | 9 |

### RESULTS

#### Study selection

| Section/topic | # | Checklist item | Reported on page # |
|---------------|---|----------------|-------------------|
| Study selection | 17 | Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram. | 11, Figure 1 |

#### Study characteristics

| Section/topic | # | Checklist item | Reported on page # |
|---------------|---|----------------|-------------------|
| Study characteristics | 18 | For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations. | 11, 12, Table 1 |

#### Risk of bias within studies

| Section/topic | # | Checklist item | Reported on page # |
|---------------|---|----------------|-------------------|
| Risk of bias within studies | 19 | Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12). | 12,13,14 |

#### Results of individual studies

| Section/topic | # | Checklist item | Reported on page # |
|---------------|---|----------------|-------------------|
| Results of individual studies | 20 | For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot. | Figures 2-4, eFigures2-6 |

#### Synthesis of results

| Section/topic | # | Checklist item | Reported on page # |
|---------------|---|----------------|-------------------|
| Synthesis of results | 21 | Present results of each meta-analysis done, including confidence intervals and measures of consistency. | 12,13,14 |

#### Risk of bias across studies

| Section/topic | # | Checklist item | Reported on page # |
|---------------|---|----------------|-------------------|
| Risk of bias across studies | 22 | Present results of any assessment of risk of bias across studies (see Item 15). | 12,13,14 |

#### Additional analysis

| Section/topic | # | Checklist item | Reported on page # |
|---------------|---|----------------|-------------------|
| Additional analysis | 23 | Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]). | 12,13,14 |

### DISCUSSION

#### Summary of evidence

| Section/topic | # | Checklist item | Reported on page # |
|---------------|---|----------------|-------------------|
| Summary of evidence | 24 | Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers). | 15,16,17 |

#### Limitations

| Section/topic | # | Checklist item | Reported on page # |
|---------------|---|----------------|-------------------|
| Limitations | 25 | Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias). | 17,18 |

#### Conclusions

| Section/topic | # | Checklist item | Reported on page # |
|---------------|---|----------------|-------------------|
| Conclusions | 26 | Provide a general interpretation of the results in the context of other evidence, and implications for future research. | 18 |

### FUNDING
### PRISMA 2009 Checklist

| Funding | 27 | Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review. | 2 |

*From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097*

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