厚生労働科学研究費補助金（肝炎等克服緊急対策研究事業）
分担研究報告書（平成23～25年度）

B型肝炎ウイルス感染の病態別における宿主因子等について、網羅的な遺伝子解析を用い、新規診断法及び治療法の開発を行う研究

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分担研究課題：ウイルスマーカーの臨床的有効性評価

研究要旨：全国多施設共同研究により収集された症例の中で、HBs抗原陽性の肝がん患者238例検体と、年齢を一致させた非肝がん患者(無症候性キャリア、慢性肝炎) 171例をコントロールとして、ウイルス遺伝子解析を行った。結果：男性の割合($p<0.0001$)、genotype Cの割合($p<0.0001$)、A1762T/G1764A変異($p<0.05$)が肝がん患者で有意に高かった。また、C1653T変異も肝がん患者において高い傾向が認められた。これらは、従来から肝がんとの関連性が報告されているウイルス変異である。今後は宿主因子と組み合わせることで、より精度の高い診断が期待される。

A. 研究目的

本研究班の目的は、B 型肝炎ウイルス感染に起因する各種の病態形成に関わる宿主(ヒト)因子を網羅的ゲノム解析により同定し、新たな診断法や治療法の開発に寄与することにある。分担研究として、同一個体内でのウイルスゲノムの解析や遺伝子機能解析も実施することにより、各種病態形成に関わる宿主遺伝要因間や宿主遺伝要因とウイルス因子間の相互作用も明らかにすることである。

B. 研究方法

全国多施設共同研究により、検体および対応する臨床データと患者情報(付帯情報)の収集を行った。各施設において検体とデータは、連結可能な匿名化を行った上で提出頂いた。

研究期間を通じて、肝がん 273 例、年齢を一致させた非肝がん(無症候性キャリア、慢性肝炎を含む) 262 例のゲノム DNA、血清、検体付帯情報を収集した。この中で、ゲノムワイド関連解析を施行し、ゲノム情報を有する肝がん 238 例と、非肝がん 171 例をコントロールとして、検体を採取、DNA 抽出、ウイルス遺伝子配列を決定し、肝がん特異的変異の有無を検索した。

（倫理面への配慮）

ヒト由来試料の解析にあたり、新規試料については必ずインフォームドコンセントを取得し、既存試料についてはインフォームドコンセントの取得されたもののみを取り扱い、解析データの公表に際しては個人情報保護を徹底する。

C. 研究結果

肝がん患者 238 例と、非肝がん患者 171 例について付帯情報を比較した結果、男性の割合と genotype C の割合が肝がん患者で有意に高かった($p<0.0001$)。これらの内、ウイルス遺伝子データが得られた肝がん患者 156 例と、非肝がん患者 138 例検体について解析を行った結果、A1762T/G1764A 変異が肝がん患者で有意に高かった($p<0.05$)。また、C1653T 変異も肝がん患者において高い傾向が認められた。

D. 考察

従来から報告されている、コアプロモーター領域の A1762T/G1764A 変異が発がんと関連していること、加えてエンハンサーII に存在する C1653T 変異も発がんに関連する傾向が認められた。また、肝がん患者に genotype C の割合が高いことが示された。

収集した検体の中には、核酸アナログ投与による治療で HBV-DNA 量が 2.0 log copy/ml 未満の検体もあった。これらは宿主側因子の解析には問題がなかったものの、ウイルス遺伝子解析を行うには十分なウイルス量ではなく、そのため全ての検体について解析することができなかった。今後は、宿主因子とウイルス因子の相関について検討することを前提として、可能な限りウイルス量の高い治療前の検体も併せて収集する等の改善が必要とされる。

E. 結論

本研究で検体を収集した日本人集団において、HBV 感染に起因する肝がんに関連したウイルス因子が同定された。さらに宿主因子と組み合わせることで、より精度の高い診断が期待される。

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G.　知的所得権の出願・登録状況

1. 特許取得

なし

2. 実用新案登録

なし

3. その他

なし

Ⅲ. 研究成果の刊行一覧

研究成果の刊行に関する一覧表

平成 23 年度

雑誌

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