

厚生労働行政推進調査事業費補助金（肝炎等克服政策研究事業）

総括研究報告書

肝がん研究の推進及び肝がん患者等への支援のための
最適な仕組みの構築を目指した研究

平成 29 年度 総括研究報告書

研究代表者 小池 和彦

平成 30（2018）年 5 月

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研究代表者 小池和彦 東京大学医学部附属病院 教授

研究要旨 平成 30 年度より開始される新たな肝がん・重度肝硬変治療研究促進事業開始にあたり、協議の上、対象患者及び対象医療を判定する方法と認定基準、指定医療機関の認定基準を定め、マニュアル等を作成した。肝がんの再発防止等を念頭においた研究を促進するため収集すべき臨床データ項目を肝癌研究会追跡調査項目に準拠して決定し、プラットフォームとして National Clinical Database(NCD)を採用することを決定した。本結果は平成 30 年度からの治療研究促進事業実施に資するものとする。

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1) 認定基準

対象医療の範囲について、自施設の患者リストを参照しながら、ICD-10、医科診療報酬点数表、DPC コード、標準病名マスターデータベースを検索、検討した。

2) 指定医療機関の要件

指定医療機関の要件について、協議した。

3) 臨床データ収集のプラットフォームとして、National Clinical Database(NCD)を念頭に、日本肝癌研究会全国原発性肝癌追跡調査の調査項目を元に収集すべきデータについて協議を行った。

（倫理面への配慮）

自施設の肝がん患者データの閲覧にあたっては、「人を対象とする医学系研究に関する倫理指針」に沿った東京大学医学部附属病院消化器内科「消化器疾患の治療成績・長期予後に関する研究」(承認番号 2058-(3))の範囲内で行った。

C. 研究結果

1) 検討結果、ICD-10 コードでは一つの病名のカバーする範囲が広すぎ、DPC コードでは、原発と続発の区別を付けることができないことが判明した。電子カルテ用 ICD10 対応標準

A. 研究目的

平成 30 年度より開始される新たな肝がん・重度肝硬変治療研究促進事業開始にあたって、対象患者や対象医療を判定する方法と認定基準を定め、マニュアル等を作成すること、同事業における指定医療機関および臨床データ収集医療機関の要件を決定すること、および肝がんの再発防止等を念頭においた研究を促進するために収集すべき臨床データの詳細、およびどのようなプラットフォームを用いてデータ収集を行うかを決定することを目的とした。

B. 研究方法

病名マスターは、「1つの病気（疾患）に1病名表現、1病名コード」を実現するために作成された病名一覧表であり、診療現場では電子カルテ及び診療報酬請求の病名指定に用いられており、実臨床の観点から最適であると判断した。これらを用いて対象患者、医療行為の範囲を決定した。

2) 協議の結果、指定医療期間として「ウイルス肝炎およびそこから生じた肝がん・肝硬変の診療行為を行う事ができる医療機関」と定義し、肝疾患専門医療機関、肝疾患診療連携拠点病院、がん診療連携拠点病院、地域がん診療病院、特定領域がん診療連携拠点病院等を含むものと決定した。

3) NCD事務局と協議の上、NCDデータベース上に本研究のためのプラットフォームを問題なく構築できる事を確認した。収集すべきデータ項目について肝癌研究会追跡調査項目に準拠しつつ、複数回入院のデータを収集できるよう拡張を行った。肝硬変部分に関しては、新たに収集項目の原案を作成した。

D. 考察

具体的かつ妥当な認定要件を設定することができた。データベース構築にあたって、必要な準備は終了したので、平成30年度からはデータベース構築を遅滞なく行う事ができるものと思われる。

E. 結論

当初掲げた3つの目的について必要かつ十分な成果が得られたものと考えられる。本結果は平成30年度からの治療研究促進事業実施に資するものとする。

F. 健康危険情報

特になし。

G. 研究発表

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H. 知的財産権の出願・登録状況 (予定を含む。)

1. 特許取得
なし
2. 実用新案登録
なし
3. その他
なし

研究成果の刊行に関する一覧表

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