厚生労働科学研究費補助金（難治性疾患克服研究事業）
分担研究報告書

副腎ホルモン産生異常に関する研究（3）

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研究要旨

国立研究開発法人日本医療研究開発機構（AMED）難治性疾患実用化研究事業、日本内分泌学会臨床重要課題検討委員会、国立国際医療研究センター研究班（主任　田辺晶代）と連携し、副腎ホルモン産生異常のうち原発性アルドステロン症（PA）および褐色細胞腫・パラガングリオーマ（PPGL）の疾患レジストリを構築し、診療に関するわが国独自のエビデンスを創出した。すなわちレジストリから、PA 約 4000 例、PPGL 約 500 例の診療情報の移行を完了した。

A. 研究目的

原発性アルドステロン症（PA）および褐色細胞腫・パラガングリオーマ（PPGL）の疾患レジストリを構築し、診療に関するわが国独自のエビデンスを創出する。

B. 研究方法

日本医療研究開発機構（AMED）難治性疾患実用化研究「難治性副腎疾患の診療に直結するエビデンス創出研究」（研究代表者　成瀬光栄）、国立国際医療研究センター国際医療研究開発事業（NCGM）「疾病研究分野」ACPA-J（研究代表者田辺晶代）、日本内分泌学会臨床重要課題褐色細胞腫検討委員会、厚労省難治性疾患政策医療研究班が連携し、疾患レジストリを構築した。

（倫理面への配慮）

文部科学省・厚生労働省「人を対象とする医学系研究に関する倫理指針（平成29年一部改正）」に準拠し、各施設倫理委員会および京都大学医の倫理委員会の承認を得て実施した。

C. 研究結果

難病プラットフォームの標準化レジストリに準拠して新規「副腎レジストリ」を構築し、既存レジストリから、PA約4000例、PPGL約500例の診療情報を移行した。診療情報登録に関わる研究者のクライアント認証作業、倫理審査のIRBからCRBへの移行、データクリーニングなどを行った。得られたデータセットの解析に基づき、診療ガイドラインの質向上に資する多様なエビデンスの論文化を行った。

D. 考察

副腎難病の診療水準向上のためには、全国多施設の症例を集積し、長期的な経過・予後観察、診療効果の検証が可能なレジストリが必須である。我々はAMED/JPAS・JRAS研究班、NCGM/ACPA-J研究班との連携より、長期的な副腎難病対策を可能とする標準化「副腎レジストリ」を構築、運用可能とした。またその診療情報を解析し、論文化を行った。今後、日本内分泌学会臨床重要課題の当該委員会、厚労省難治性疾患政策研究班と連携して、診療ガイドライン改訂作業を行う。

E. 結論

原発性アルドステロン症（PA）および褐色細胞腫・パラガングリオーマ（PPGL）の疾患レジストリを構築し、運用した。

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H. 知的財産権の出願･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