

平成28年度 委託研究開発成果報告書

I. 基本情報

- 事業名： (日本語) 循環器疾患・糖尿病等生活習慣病対策実用化研究事業  
(英語) Practical Research Project for Life-Style related Diseases including Cardiovascular Diseases and Diabetes Mellitus
- 研究開発課題名： (日本語) 心房細動発症リスクと重症化リスクの層別化指標の確立を目的とした大規模コホート・レジストリー共同研究  
(英語) Pooled analyses for identifying risk factors and developing scoring system for atrial fibrillation and cardioembolic stroke in the Japanese population
- 研究開発担当者 所属 役職 氏名： (日本語) 国立大学法人弘前大学大学院医学研究科 客員研究員 奥村 謙  
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- 実施期間： 平成28年4月1日 ～ 平成29年3月31日
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## II. 成果の概要（総括研究報告）

### 研究開発代表者による報告の場合

心房細動は高齢者に多く、その最も大きな問題は心原性脳塞栓症の主たる原因となることである。これは心原性脳塞栓症が他の病型の脳梗塞に比して重症となりやすく、寝たきり～致命的となる患者の割合が高いためである。心房細動を対象とした臨床研究はわが国でも数多く実施されてきたが、心房細動の新たな発症自体に関する危険因子の評価は十分でなく、また発症予知を目的としたリスクの層別化法は確立されていない。わが国では非弁膜症性心房細動患者の心原性脳塞栓症発症リスクの評価・層別化と抗血栓療法の適応基準として、**CHADS<sub>2</sub>**スコアに基づくリスク管理法が用いられている。これまでの研究により、年齢（75歳以上）、高血圧、そして脳梗塞/一過性脳虚血発作の既往の3つが心原性脳塞栓症発症の有意な危険因子であり、日本人では必ずしも**CHADS<sub>2</sub>**スコアの構成因子のすべてが心原性脳塞栓症発症に寄与するわけではないことが示された。

本研究では、心房細動の新たな発症に関与する危険因子の同定とその発症を予測するリスク層別化法（スコア化）開発を目指し、既存の確立された地域住民コホート研究のデータを用いてメタ解析を行った。さらに、心原性脳塞栓症発症に関与する危険因子の同定とその発症を予測するリスク層別化法（スコア化）開発のため、既存の確立された大規模心房細動レジストリー研究のデータを用いて統合解析を行った。

まず、3つの地域コホート（久山町研究、**CIRCS**、吹田研究）によるメタ解析では、年齢、男性、肥満、高血圧（収縮期）、虚血性心疾患の既往、飲酒（現在あるいは過去の過度の飲酒）が新規心房細動発症のリスク因子として同定された。各々のリスク因子を積み付けし、心房細動の10年発症確率を予測するスコアを作成した。このリスク層別化法は茨城県健康研究における10年発症確率と強い相関を示し、スコアの妥当性が検証された。次に、5つの心房細動レジストリー（**J-RHYTHM Registry**、**Shinken Database**、**Fushimi AF Registry**、**慶應 KiCS-AF Registry**、**北陸 plus 心房細動登録研究**）の統合データによる解析では、脳梗塞の既往、低BMI（18.5kg/m<sup>2</sup>未満）、年齢（75歳以上）、心房細動のタイプ（持続性）、高血圧が脳塞栓症発症のリスク因子として同定された。各々のリスク因子を積み付けし新たなスコアシステムを開発した。そのスコアシステムは、従来の**CHADS<sub>2</sub>**スコアシステムよりも有用であり、日本人に即した心原性脳塞栓症発症の新しいリスク層別化法であることが示された。これらの研究成果は、第81回日本循環器学会学術集会 **Late Breaking Cohort Studies**（2017年3月金沢）で発表された。

個別の地域コホート研究ならびに心房細動レジストリー研究においても、多数の学会発表や論文発表がなされ、研究活動は精力的に行われた。

The prevalence of atrial fibrillation (AF) increases with the aging of the population. The most important problem of AF is to become a main cause of cardioembolic stroke, which is the most severe stroke subtype in the ischemic stroke, leading to severe disability or death. Although many clinical studies for AF have been conducted in Japan, there has been few information available for risk factors and development of risk stratification system for new-onset AF. In this study, we conducted a meta-analysis to develop and validate a risk score for new-onset AF risk score in the Japanese general population. We found that risk factors for new-onset AF are age, male, obesity, hypertension, coronary heart disease, and excess alcohol using 3 major Japanese cohort studies (the Suita Study, the CIRCS, and the Hisayama Study). Furthermore, we developed a risk score that predicts the 10-year incident AF risk in Japan based on these classical risk factors. This new risk score was validated by the Ibaraki Prefectural Health Study.

The use of CHADS<sub>2</sub> score has been recommended for risk stratification for thromboembolism and indication of anticoagulation therapy in non-valvular atrial fibrillation (NVAF) patients in the Japanese guidelines 2013. However, it is shown that all components of CHADS<sub>2</sub> score are not a significant risk factor in Japanese NVAF patients. In this study, we combined the data of 5 major AF registries in Japan, J-RHYTHM Registry, Fushimi AF Registry, Shinken Database, Keio interhospital Cardiovascular Studies, and Hokuriku plus AF Registry, and analyzed these database. We found that prior stroke, low BMI (<18.5kg/m<sup>2</sup>), age (>75 years), AF type (permanent/persistent), and hypertension were significant risk factors for incidence of ischemic stroke. We developed a new risk stratification scheme for incidence of ischemic stroke in Japanese NVAF patients.

Furthermore, studies regarding a risk score for new-onset AF and that for incidence of ischemic stroke were actively performed in individual cohort study and AF registry.

### III. 成果の外部への発表

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(3) 「国民との科学・技術対話社会」に対する取り組み

(4) 特許出願