

平成 29 年 5 月 31 日

平 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) 革新的がん医療実用化研究事業
(英 語) Practical Research for Innovative Cancer Control

研究開発課題名 : (日本語) 高齢者 MDS におけるクローン進化の経時的理解に基づく新たな治療戦略の構築
(英 語) New therapeutic strategies for myelodysplastic syndromes based on chronological evaluation of their clonal dynamics.

研究開発担当者 (日本語) 京都大学・大学院医学研究科・腫瘍生物学・教授・小川 誠司
所属 役職 氏名 : (英 語) Department of Pathology and Tumor Biology, Graduate School of Medicine, Kyoto University, Professor, Seishi Ogawa

実 施 期 間 : 平成 28 年 4 月 1 日～平成 29 年 3 月 31 日

分担研究 (日本語) MDS における空間的多様性の解明に基づく至適な検体採取法の開発
開発課題名 : (英 語) Development of the sampling methods suitable for the analysis of special heterogeneity of MDS
研究開発分担者 (日本語) 長崎大学 原爆後障害医療研究所 血液内科学・教授・宮崎泰司
所属 役職 氏名 : (英 語) Department of Hematology, Atomic Bomb Disease Institute, Nagasaki University, Professor, Yasushi Miyazaki

分担研究 (日本語) MDS におけるクローン進化の遺伝学的理理解に基づく、
開発課題名 : 新規バイオマーカー・治療標的分子の同定とこれを用いた早期診断・
予防技術・治療層別化技術の開発
(英 語) Developing new strategies of early diagnosis, effective prevention, and risk stratification through understanding of clonal dynamics in MDS.
研究開発分担者 (日本語) 金沢大学 医薬保健研究域医学系 細胞移植学・血液学・教授・中尾眞二
所属 役職 氏名 : (英 語) Department of Hematology, Graduate School of Medical Sciences, Kanazawa University, Professor, Shinji Nakao

分担研究 (日本語) MDS における空間的多様性の解明に基づく至適な検体採取法の開発
開発課題名 : (英 語) Development of appropriate sampling for determination of clonal architecture of in MDS heterogeneity.
研究開発分担者 (日本語) 東京医科大学・血液内科学・教授・大屋敷一馬
所属 役職 氏名 : (英 語) Tokyo Medical University, Department of Hematology,
Professor: Kazuma Ohyashiki

分担研究 (日本語) MDS におけるクローン進化の遺伝学的理解に基づく、
新規バイオマーカー・治療標的分子の同定とこれを用いた早期診断・予防
技術・治療層別化技術の開発
開発課題名 : (英 語) Identification of novel biomarkers and targeted molecules, and investigation of early diagnosis, prevention, and appropriate therapies based on genetic evidence of clonal evolution in MDS.
研究開発分担者 (日本語) 筑波大学 医学医療系 血液内科・准教授・坂田麻実子
所属 役職 氏名 : (英 語) Department of Hematology, Faculty of Medicine, University of Tsukuba
Associate professor, Mamiko Sakata-Yanagimoto

II. 成果の概要（総括研究報告）

(和文)

骨髓異形成症候群（MDS）は、高齢者に高頻度に認められ、有効な治療が確立されていない代表的ながんである。本研究では、この代表的な高齢者のがんにおけるクローン進化の遺伝学的理解に基づく、新規バイオマーカー・治療標的分子の同定とこれを用いた早期診断・予防技術・治療層別化技術の開発を行った。

主な研究成果は以下の 2 点である。

①MDS における時間的クローン進化の解明

京都大学 大学院医学研究科・腫瘍生物学 小川誠司教授は、次世代シーケンス技術を用い、時系列で複数回の解析を行うことによって、MDS におけるクローン進化を解明した。その結果に基づき、新規バイオマーカーおよび治療標的分子を検索し診断および予後に関する解析を行った。さらに、金沢大学医薬保健研究域医学系細胞移植学・血液学 中尾眞二教授は、高頻度に MDS へ進展する前 MDS 状態である再生不良性貧血におけるクローン性造血から MDS へ進展するクローン進化を、次世代シーケンス技術を用いて解明した。続いて、筑波大学医学医療系血液内科 坂田麻実子准教授は、MDS における加齢に伴う造血細胞の変化を、ゲノム異常のみならず遺伝子発現異常に注目して解析し、MDS におけるクローン進化をゲノムとエピゲノムの異常の組み合わせから解明した。特に、メチル基をヒドロキシメチル化する TET 酵素群に注目して解析し、クローン進化の新たなメカニズムを明らかにした。

MDS におけるクローン進化の遺伝学的理解に基づく、新規バイオマーカー・治療標的分子の同定とこれを用いた早期診断・予防技術・治療層別化技術の開発に関しては、京都大学の小川教授が国際共同研究により、数百例の MDS 症例の全エクソンシーケンス解析により体細胞変異ならびに胚細胞変異よりバ

イオマーカーを抽出した。続いて数千例の MDS 症例においてシーケンス結果を解析することにより、白血病進展を診断する技術開発を行った。この成果を *Nature Genetics* 誌に報告し(牧島、小川ら *Nature Genetics* 2017)、予想以上の成果が得られた。プレスリリースを行い機関誌に取り上げられている。

京都大学・AMED・東京大学医科学研究所

http://www.kyoto-u.ac.jp/ja/research/research_results/2016/161220_1.html

http://wwwAMED.go.jp/news/release_20161220-01.html

http://www.ims.u-tokyo.ac.jp/imsut/jp/research/papers/_2.php

アメリカ血液学会機関誌【ASH clinical news】・【The Hematologist】・ライフサイエンスレビュー

<https://www.ashclinicalnews.org/news/literature-scan/investigating-clonal-dynamics-of-different-mutations-in-myelodysplastic-syndromes/>

<http://www.hematology.org/Thehematologist/Diffusion/7096.aspx>

<http://first.lifesciencedb.jp/archives/15045>

②MDS における空間的多様性の解明に基づく至適な検体採取法の開発

長崎大学原爆後障害医療研究所・血液内科学 宮崎泰司教授は、MDS 関連疾患である急性骨髓性白血病(AML) 治療後に寛解に至り、その 2 年後に骨髄増殖性腫瘍(MPN) を発症した症例について、エクソームシーケンス、ターゲットシーケンスを用いて、造血細胞の空間的クローン構成を詳細に検討した。さらには、東京医科大学・血液内科学 大屋敷一馬教授は、MDS において、骨髄における微小環境を検討し、MDS 細胞と間質細胞の相互作用におけるシグナル伝達を明らかにすることによって、MDS における、空間的多様性を明らかにした。特に、間質細胞のエクソソームに内包された液性因子が MDS の発症に関与することを証明した。

(英文)

Myelodysplastic syndromes (MDS) are a typical group of chronic myeloid neoplasms which are frequent in the elderly. Therefore MDS are refractory to most treatments and no curative therapy is available. In this study, we developed new strategies of early diagnosis, effective prevention, and risk stratification through understanding of clonal dynamics in such a typical cancer in old patients (MDS). Main subjects in this study are chronological assessment (①) and spatial analysis (②) of clonal dynamics in this disease.

① Chronological assessment of clonal dynamics in MDS

Professor Ogawa, Kyoto University clarified clonal dynamics in MDS by next-generation sequencing at multiple time points using serial samples. His team searched for new biomarkers and molecular targets, which were used for further developing the strategies of precise diagnosis and prognostic prediction. Using chronological samples, professor Nakao, Kanazawa University clarified clonal dynamics during MDS evolution from aplastic anemia, which is pre-MDS disease. By combined analysis of genome and epigenome, associate professor Sakata, Tsukuba University identified abnormal gene-expression profile associated with senescence of hematopoietic stem cells. Her team focused their study on TET enzymes to elucidate a novel mechanism of clonal dynamics.

For developing new strategies of early diagnosis, effective prevention, and risk stratification through understanding of clonal dynamics in MDS, professor Ogawa, Kyoto University collaborated with multiple international groups to discover various germline and somatic mutations and detected

novel biomarkers and molecular targets among them. His group and collaborators analyzed the results from more than 2,000 cases with MDS and novel biomarkers significantly associated with leukemic evolution. They reported these findings in *Nature genetics* (Makishima H, Ogawa S et al. 2017).

② Spatial analysis of clonal dynamics in MDS

Professor Miyazaki, Nagasaki University analyzed spatial architecture of neoplastic clones in MDS-related diseases, which evolved from acute myeloid leukemia into myeloproliferative neoplasms. Moreover, professor Ohyashiki, Tokyo Medical University analyzed microenvironment in bone marrow of MDS patients and studied signal transduction associated with interaction between MDS and stromal cells. His group clarified spatial heterogeneity of MDS owing to pathogenic humoral factors included in exosomes. These findings were confirmed and already submitted as manuscripts.

The journals “ASH clinical news” and “The Hematologist” picked up this study.

<https://www.ashclinicalnews.org/news/literature-scan/investigating-clonal-dynamics-of-different-mutations-in-myelodysplastic-syndromes/>

<http://www.hematology.org/Thehematologist/Diffusion/7096.aspx>

III. 成果の外部への発表

(1) 学会誌・雑誌等における論文一覧 (国内誌 0 件、国際誌 44 件)

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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
該当なし

(4) 特許出願
該当なし