Novel miRNA Biomarkers for Early Stage Detection of Melanoma

Early detection

Melanoma skin cancer is the 4th most commonly diagnosed cancer in Australia, leading to an estimated 1,800 deaths annually. Melanoma develops in the melanocytes; cells that produce the pigment of the skin. Rare cases of melanoma can also form in the eyes, mouth and even under the nails. It is widely accepted that unprotected exposure to UV radiation from the sun is the most significant risk factor for developing melanoma.

While the overall 5-year survival for melanoma is 91%, metastasis of cancerous cells to other organs (stage IV) can reduce cure rates to less than 15%. Given this, it is imperative to identify melanomas in the early stages so that surgery can effectively remove all cancerous tissue. Currently the standard method to identify potential melanomas includes regular skin checks, both by the patient and by a health practitioner. There are no blood tests on the market which can accurately diagnose early stage melanomas, indicating a clear medical need for a non-invasive early stage detection method.

Technology

Circulating microRNA (miRNA) are small, non-coding RNA molecules that have been widely studied for their utility as biomarkers in a range of malignancies. Researchers at QIMR Berghofer have identified a panel of seven miRNA biomarkers (MELmiR-7) that can provide a sensitive and specific diagnostic for melanoma. Expression levels of the MELmiR-7 markers in human serum can also be used to accurately stage the progress of melanoma in the patient. MELmiR-7 is also expressed in tissue, so a simple microbiopsy could easily distinguish between an atypical mole or other skin cancer and a melanoma that requires further surgery.

In an international, multi-centre study of 385 serum samples, analysis of MELmiR-7 expression was able to identify melanoma with 93% sensitivity and >82% specificity when compared to control samples. Analysis of lactate dehydrogenase (LDH) levels in the blood is currently used to subdivide patients with stage IV disease, however this test has variable sensitivity and specificity, particularly in the early stages of disease. Even for stage IV patients, the LDH test has 79% sensitivity and 92% specificity compared to 98% sensitivity and ≥82% specificity for the serum MELmiR-7 analysis. Given the complexity of the data produced by the assay and the levels of association between individual miRNAs, we are now looking to develop a machine learning algorithm to improve data analysis efficiency.
Melanoma Diagnostic Market

In 2018 there will be over 14,000 new cases of melanoma in Australia alone and close to 400,000 new cases globally. The incidence rate in Queensland exceeds 71 cases per 100,000 people, far greater than the worldwide rate of 5 cases per 100,000 people. The high rate of melanoma and other skin cancers in Australia leads to a considerable economic burden on the health care system; the annual treatment costs are estimated to be close to $300 million. Presumptive surgery on tissue later found to be benign lesions makes up a quarter of this cost. Melanoma is by no means limited to Australia. Incidence rates in the USA have doubled in the last decade and the cost to treat melanomas is estimated to be in excess of US$3.3 billion. Due to the rapid increase in skin cancer rates and treatment costs, a non-invasive early detection diagnostic would find value in reducing the number of unnecessary mole excisions, easing the burden on the health care system.

Intellectual Property

The MELmiR-7 invention is the subject of a PCT application covering the use of the seven microRNA biomarkers in the diagnosis, prognosis and monitoring of melanoma in a patient.

Title: Treatment and Detection of Melanoma, WO2016/029260

Partnering Opportunity

We are now seeking licensing or investment partners with experience in cancer diagnostics to co-develop and commercialise this technology.

Lead researcher

Dr Mitchell Stark is a NHMRC Early Career Research Fellow with a strong background in melanoma genomics research. His research focus involves identifying ‘melanoma-specific’ microRNAs that may be useful for clinical management of disease. In addition to miRNA signatures, one of his ongoing projects is studying the molecular hallmarks of growing and involuting naevi – the key to early detection of primary and invasive melanoma. He is the recipient of a Queensland Government Advance Queensland Innovation Partnerships grant and has over 50 peer-reviews publications.

QIMR Berghofer Medical Research Institute

With more than 900 scientists, students and support staff, QIMR Berghofer is one of Australia’s largest and most successful independent medical research institutes. The QIMR Berghofer Business Development Team manages over 160 patent families, offering a wealth of collaborative and commercial opportunities for industry and government. We have a strong track record of partnering with leading pharmaceutical and biotech companies to further develop early-stage technologies, generating over $21 million in annual commercial revenue in the last financial year. In addition to licensing and partnering outcomes, we facilitate contract research and consulting projects for industry clients. Our team includes specialists in commercialisation, IP protection, patent law, clinical trial and project management and industry-backed grant opportunities.

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