







## **Background**

Parkinson's disease, a common neurodegenerative disease, affects 1 in every 350 adults in the UK and its prevalence is set to increase as our population ages. The disease involves the build-up of specific proteins in the brain and the subsequent destruction of brain cells causing physical symptoms, such as tremors, and can ultimately lead to dementia. The societal cost of Parkinson's disease, including healthcare costs and loss of income, has been estimated to be over £20,000 per affected household

In the absence of a cure for Parkinson's, patients themselves have identified improved management of stress and anxiety as the second highest priority for unmet research needs to improve their quality of life. Measuring cortisol, a steroid hormone, has been suggested as a potential alternative and objective way to measure stress in place of the current subjective responses to anxiety rating questionnaires. Natural variations in cortisol levels require blood samples to be taken strictly at the same time each day and currently available tests are laboratory-based, taking a few days to provide results due to the need for extensive and laborious sample processing prior to analysis to detect the biologically active form, or 'free' cortisol.

Previously, researchers at the National Measurement Laboratory (NML) at LGC had developed an accurate and reproducible method to measure both free and total cortisol in only 15 minutes for the monitoring of stress levels in athletes.

This method has now been applied to a small patient cohort recruited via clinical collaborators at the University of East Anglia. The patient cohort contained patients with Parkinson's (9), patients with other neurodegenerative conditions (4) and healthy controls (10). Cortisol levels were monitored at multiple times during the day and across different days and compared with traditional questionnaires for stress assessment.

## **Impact**

Our NML-developed method demonstrated good reproducibility for individual measurements of total and free cortisol levels, although there was significant variability in both measurements for each patient across different days. However, where both measurements (free and total) were performed in a single assay, the level of free cortisol expressed as a percentage (rather than as a concentration) was shown to remove the day-to-day variability.

The pilot study showed that those patients with Parkinson's disease had a higher percentage of free cortisol than other donor groups (by 1.6x), which may indicate elevated levels of stress in these patients. However the study sample was too small to show an association with self-reported anxiety levels. Patient controls without neurodegenerative conditions that were being treated for other medical conditions (e.g. hypertension, high cholesterol) were also found to have elevated levels of percentage of free cortisol.

The study was too small to draw clinical conclusions but interestingly we observed that the two Parkinson's patients taking antidepressants had slightly lower levels of percentage of free cortisol, potentially indicating reduced stress levels as a result of their treatment regime.

Although the size of this study was small and further research is required to draw definitive conclusions, this pilot suggests that the percentage of free cortisol obtained through single assay measurement of free and total cortisol is feasible and may be a useful route to objectively monitor stress levels. This could then be used to monitor the efficacy of different interventions for anxiety, such as medication or therapy, for patients with Parkinson's disease.

The method should also be amenable to being adapted into a portable point of care (POC) device, which ultimately offers greater convenience for the patient.

"The search for treatments for Parkinson's is at a critical stage with many avenues to explore. Perhaps measuring the level of free cortisol to help identify Parkinson's patients' anxiety will be more than just a proof of concept in the future thanks to the painstaking hard work [of the National Measurement Laboratory]."

Jennifer Hartt, Parkinson's patient and member of patient advisory panel

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