LABORATORY DIAGNOSTIC TEST ENTERS CLINICAL PRACTICE

A blood test that improves the management pre-eclampsia has been introduced into routine practice, write Laboratory Manager **Tim James** and Consultant Obstetrician **Manu Vatish**.

Pre-eclampsia is a serious condition that can affect women in the later stages of pregnancy. While it only occurs in 4% of pregnancies, pre-eclampsia can cause kidney failure, liver failure and seizures. The health of both mothers and babies can be compromised. It is, therefore, important to identify those at risk.

The issue

Until now, there has been no test that can conclusively rule out pre-eclampsia during pregnancy. Consequently, expectant mothers who are suspected of having pre-eclampsia may be admitted to hospital for conservative clinical management and may stay there for several days, while additional testing is undertaken using both ultrasound and laboratory services. This time-consuming process can cause undue stress and anxiety for the mothers-to-be and their families, and will sometimes lead to early induction of labour.

Evidence that the newer markers of pre-eclampsia serum placental growth factor (PlGF) and soluble fms-like tyrosine kinase (sFlt-1) may be of value in its diagnosis have emerged over the last decade. However, studies demonstrating outcome improvements have been limited. To develop evidence that these new markers can be of benefit, a joint project involving the laboratories at Oxford University Hospitals NHS Foundation Trust (OUH) has been conducted over the last three years.

The study

The main study was planned and developed by Dr Manu Vatish, OUH Consultant Obstetrician and Senior Clinical Fellow with the University of Oxford's Nuffield Department of Women's and Reproductive Health, and was funded by Roche Diagnostics. Testing took place at OUH's John Radcliffe Hospital under the guidance of IBMS Fellow Professor Tim James, who is Head Biomedical Scientist and Laboratory Manager in Clinical Biochemistry at OUH.

The biochemistry department's laboratory team measured both PlGF and sFlt-1 in women presenting to obstetrics with clinical symptoms. During pre-eclampsia sFlt rises and PLGF falls and it is thought that the best diagnostic expression of these results is in the form of a single ratio of sFlt:PLGF. The biomedical scientists reported the results and the ratio to clinicians, and were able to demonstrate excellent negative predictive value.

Dr Vatish said: "The stress experienced by mums and their families can be put into context when we see that almost 70% of patients admitted don't actually have pre-eclampsia.

"With this study, and the previous work that has been undertaken, we have shown that we can virtually eliminate all those patients who have no risk of developing pre-eclampsia, allowing us to focus our attention on those with an increased risk."

Tim added: "We gained confidence in the results both through the patient outcomes and analytical performance on the Roche e411 instrument. The value of the study was evident in that clinicians who evaluated the clinical data from the study were wishing to have the service as soon as the study data was assessed. We were able to present the preliminary outcomes to senior hospital staff and were able to present a costs-neutral case for its introduction, which is associated with a significant improvement in patient safety."

Initial method verification work was presented at the 2017 IBMS Congress and staff from Clinical Biochemistry won the best poster competition.

IMAGE: ISTOCK

Routine service for the tests

Following the study, concurrent work streams were undertaken – the development of the clinical protocol for identification and management of pre-eclampsia by the obstetric team, further laboratory verification of method performance and financial assessment of service introduction. The outcome of this work was a routine service for women in Oxfordshire to provide this test as of 1 October 2018. It is now part of the routine repertoire of tests provided by the biochemistry laboratory at Oxford University Hospitals – the first hospital in the UK to provide this.

Tim said: "Historically, our markers of pre-eclampsia have been weak. Therefore, this is a step change in diagnostic accuracy, and provision of this service is the right thing to do for patients.

"We are able to run these tests within a relatively short time frame, and are working towards a turnaround time of 60-90 minutes."

This short timeframe for diagnostic results will allow doctors to rule out pre-eclampsia among patients quickly, and will in turn reduce patient waiting times, free up beds for patients and allow many patients to avoid unnecessary days spent in hospital, possibly unnecessary inducement, as well as easing the anxiety felt by mothers-to-be and their families.

This accuracy of the test has been shared with the Oxford Academic Health Science Network, which is encouraging other laboratories to introduce the service.

Tim concluded: "The beauty of these tests is that they are not reliant on analysers that are only available in Oxford. The instruments are available at many hospital sites, meaning that the benefits we have demonstrated can be expanded across the UK relatively rapidly and easily, and pregnant women everywhere should be able to benefit. I am aware of a number of other laboratories assessing these tests in the context of trials and studies. I am sure it will be common practice to provide these tests for routine care in the near future." BMS

For more information about the test, visit the OUH website.

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