Clinical Chemistry

Impact of Implementing Preanalytical Laboratory Standards on the Diagnosis of Gestational Diabetes Mellitus: A Prospective Observational Study

Article: Niamh Daly et al.
Impact of Implementing Preanalytical Laboratory Standards on the Diagnosis of Gestational Diabetes Mellitus: A Prospective Observational Study.
Clin Chem 2016;62:387-391.
http://www.clinchem.org/content/62/2/387.abstract

Guest: Dr. Niamh Daly is a Research Fellow in Obstetrics and Gynecology at the Coombe Women & Infants University Hospital in Dublin.

Bob Barrett: This is a podcast from *Clinical Chemistry*, sponsored by the Department of Laboratory Medicine at Boston Children's Hospital. I am Bob Barrett.

Gestational diabetes mellitus is a common pregnancy complication with potentially serious lifelong consequences for both the mother and her offspring. An accurate diagnosis is important because untreated gestational diabetes is associated with adverse clinical outcomes and has been associated with lifelong risks for both mother and baby.

Glucose measurements are affected by a large number of pre-analytical variables, including protocols for sample handling, temperature of storage, the time interval after collection when analysis is performed, or use of a glucose inhibitor.

The February 2016 issue of *Clinical Chemistry* published a prospective observational study on the impact of implementing pre-analytical laboratory standards on the diagnoses of gestational diabetes. The authors evaluated glucose concentrations and the incidence of gestational diabetes after strict implementation of the American Diabetes Association Pre-Analytical Guidelines, compared with usual hospital conditions.

The lead author of that study is Dr. Niamh Daly; she is the University College Dublin Special Lecturer, and a Research Fellow in Obstetrics and Gynecology at the Coombe Women & Infants University Hospital in Dublin.

Dr. Daly is our guest in this podcast. Doctor, first of all, please tell us a little bit about gestational diabetes mellitus and why accurate diagnosis is so important.

Dr. Niamh Daly: So gestational diabetes is becoming increasingly more common and it's a very important disease or condition to diagnose during pregnancy because, since the HAPO study, it's been associated with an increased risk of adverse pregnancy outcomes. And before, in the 1960s and onwards, and gestational diabetes was diagnosed on the

basis of a risk for mum, or the mother, of developing complications of Type 2 diabetes later in life.

But as we know, particularly as I am an obstetrician, as we know, as clinicians know it's more important to diagnose it during pregnancy for risks that are relevant to the pregnancy. So it has changed a lot over the last few years.

Bob Barrett: Your paper just published in *Clinical Chemistry* is concerned with pre-analytical variables, including sample handling and processing. Tell us a bit about the design of your study, and what do you find out?

Dr. Niamh Daly: So our study was designed as a paired sample study where every patient/doctor has their own control. And because our unit usually uses fluoride/EDTA tubes, we decided to use that as our control also. So we took two samples from each patient and there were over 150 patients in this study, and we compared their glucose concentration of each patient after implementing the NACB or the National Association of Clinical Biochemistry's strict guidelines on pre-analytical handling compared with the usual sample handling that we implement in our unit, which is fluoride/EDTA tubes without placing our samples on an ice slurry, without centrifuging or separation in the samples, and without analyzing them within 30 minutes.

So thus to say that our sample handling would usually involve not so much attention to what happens to the sample from the time that phlebotomy occurs to the time that analysis occurs. And what we found in the difference between the samples was outstanding.

Bob Barrett: So by changing pre-analytical variables the apparent incidence of gestational diabetes was altered. What's the impact of this on research in the area of gestational diabetes worldwide?

Dr. Niamh Daly: So the impact on gestational diabetes worldwide, I think it might change the shift of attention. A lot of attention has been paid recently to the diagnosis of gestational diabetes. So there are always debates ongoing as to who we should screen, at-risk patients or patients with no risk factors, that is, the universal screening; flush and glucose load to use for the oral glucose tolerance test; what diagnostic thresholds to use; whether we should use the Carpenter-Coustan test or the IADPSG test; and what clinical outcomes are important for the diagnosis.

And these clinical issues are contentious and therefore far from resolved I think, but this study highlights the importance of International Laboratory Standards which are endorsed by the American Diabetes Association. That is,

what happens to the glucose samples from the time that the blood is drawn, phlebotomy, to the time that it's analyzed in the lab. And what happens to samples in the lab is usually computerized and standardized, what happens pre-analytically is far from standardized.

Fluoride is the most commonly used antiglycolytic agent, but placement onto an ice slurry and separation analysis within 30 minutes is not standard, that is, it should be standard but in practice it's not, it's not a very practical practice to have. So it's not uncommon for the International Maternity Services to delay transport to the laboratory by up to 24 hours, both in the research and anecdotally.

And we recommend that in the future all research on gestational diabetes would detail the pre-analytical handling of their glucose samples, so that the readers can assess the diagnostic accuracy of the test.

Bob Barrett: Dr. Daly, are there consequences of your findings for the diagnosis of diabetes mellitus apart from gestational diabetes?

Dr. Niamh Daly: Well, I am sure there are, I am not sure whether my research would confirm this, but I think that pre-analytical glycolysis is not limited to gestational diabetics. I think that it would probably ring true for non-gestational diabetics, Type 1 and Type 2 diabetics if the similar practices are implemented.

I think that the focus needs to be on pre-analytical sample handling and how best to harmonize those practices so that all of those results can be harmonized and reproduced.

Bob Barrett: And finally doctor, how will the results of your study change the future of the diagnosis of gestational diabetes?

Dr. Niamh Daly: I think it's clear from our research where, when we didn't implement the NACB Guidelines, the incidence of diabetes was 14.01%, and when we did implement the guidelines strictly, the incidence was 38.1%; that is, we saw an increase in the incidence of gestational diabetes by almost three-fold.

It's imperative that the pre-analytical handling of glucose samples is standardized and harmonized worldwide so the clinicians can manage pregnant women in the same way. And if our findings are reproduced elsewhere, and the incidence of gestational diabetes after strict implementation of the NACB recommendations is as high we have shown, which is almost two-fifths of patients, then the HAPO criteria for the diagnosis of gestational diabetes may need to be revisited.

Bob Barrett: Dr. Niamh Daly is the University College Dublin Special Lecturer and a Research Fellow in Obstetrics and Gynecology at the Coombe Women & Infants University Hospital in Dublin.

She has been our guest in this Podcast from *Clinical Chemistry* on gestational diabetes and the importance of controlling pre-analytical variables.

I am Bob Barrett. Thanks for listening!