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FINAL REPORT

Project / Program Title		Liberal glUcose Control in critically Ill patient with pre-existing type 2 Diabetes (LUCID): a phase IIB multi-centre single-blinded parallel group randomised control trial
Name		Associate Professor Adam Deane
Award Received		2019 RACP Diabetes Australia Research Establishment Fellowship
Report Date		17 April 2020
Chief Investigator / Supervisor		Associate Professor Adam Deane
Administering Institution		University of Adelaide
Funding Period	Start Date:	1 January 2019
	Finish Date:	31 December 2019

PROJECT SUMMARY

Each year more than 30,000 patients with type 2 diabetes (T2DM) require care in an Intensive Care Unit (ICU) in Australia. Outcomes in these patients have been shown to be poor if blood glucose levels are high, so such patients are treated with insulin which is given intravenously. However, this approach leads inevitably to both blood glucose concentrations that are, abnormally low (i.e. hypoglycaemia) and excessive swings in blood glucose (i.e. increased glucose variability), which is important because both hypoglycaemia and glucose variability are associated with worse outcomes. Currently, ICU clinicians treat an elevated blood glucose (>10 mmol/L) in ICU patients with and without diabetes the same, despite evidence to strongly suggest that elevations in blood glucose are less harmful in patients with diabetes. We are performing an important trial across a number of ICUs in Australia and New Zealand to compare the current approach of treating blood glucose in patients with diabetes to a different, and novel, approach where blood glucose is only treated at a higher level (>14 mmol/L) to determine whether complications, particularly hypoglycaemia, are less and outcomes better. The findings of this trial will, according inform the management of patients with type 2 diabetes who are admitted to ICU.

PROJECT AIMS / OBJECTIVES

Aims

To test the following hypotheses.

Primary hypothesis

That a more liberal protocol (commencing insulin when blood glucose is ≥ 14 mmol/L and titrating to blood glucose 10-14 mmol/l) when compared to conventional care(commencing insulin when

blood glucose is ≥ 10 mmol/l and titrating to blood glucose 6-10 mmol/l) will reduce incident hypoglycaemia in critically ill patients withT2DM.

Secondary hypotheses

That a more liberal protocol when compared to conventional care will reduce recurrent and relative hypoglycaemia, and attenuate glycaemic variability.

Tertiary hypotheses

That a more liberal protocol when compared to conventional care will improve patient centred outcomes, including 90-day all-cause mortality, with no signal of harm

Progress to date

Recruitment into the study has been slower than initially anticipated, currently 350 participants have been randomised leaving a further 100 to be enrolled over the coming months. Once the recruitment has been completed the hypothesis will be rejected or supported, based on the evidence.

SIGNIFICANCE AND OUTCOMES

This proposed intervention is inexpensive and, if effective, will change current practice to > 30,000 Australian patients with type 2 diabetes each year, leading to improved outcomes. After completion of our proposed study we will disseminate the results through presentation at relevant national and international meetings. We will also publish our results in a high ranking general medical journal. This strategy has proven effective for previous ANZICS-CTG trials that have changed ICU practice on a worldwide basis. Data from our trial may also impact the care of hospitalised patients with type 2 diabetes who are not admitted to the Intensive Care Unit.

PUBLICATIONS / PRESENTATIONS

Our protocol and statistical analysis plan manuscript has been accepted and is in press

A Poole, M Finnis, J Anstey, R Bellomo, S Bihari, V Biradar, S Doherty, G Eastwood, S Finfer, C French, A Ghosh, S Heller, M Horowitz, P Kar, P Kruger, M Maiden, J Mårtensson, C McArthur, S McGuinness, P Secombe, A Tobin, A Udy, P Young and A Deane; on behalf of the LUCID Study Investigators and the ANZICS Clinical Trials Group, Study protocol and statistical analysis plan for the Liberal Glucose Control in Critically Ill Patients with Pre-existing Type 2 Diabetes (LUCID) trial (Accepted for publication) Critical Care Resuscitation 2020

A Poole, J Anstey, R Bellomo, V Biradar, G Eastwood, S Finfer, M Finnis, C French, P Kar, P Kruger, M Maiden, J Martensson, C McArthur, S McGuinness, P Secombe, A Tobin, A Udy, A Deane ; A Phase II Study of Liberal Glucose Control in Critically Ill Patients WithPre-existing Type 2 Diabetes (LUCID) ANZICS CTG 20th Annual Meeting on Clinical Trials in Intensive Care 2019

A Poole, J Anstey, R Bellomo, V Biradar, A Deane, S Finfer, M Finnis, C French, P Kar, P Kruger, M Maiden, J Martensson, C McArthur, S McGuinness, P Secombe, A Tobin, A Udy, G Eastwood.; Blood glucose management in critically ill patients with pre-existing type 2 diabetes: A survey of intensivists practice.ANZICS/ACCCN Intensive Care Annual Scientific Meeting 2017

A Poole, J Anstey, R Bellomo, V Biradar, G Eastwood, S Finfer, M Finnis, C French, P Kar, P Kruger, M Maiden, J Martensson, C McArthur, S McGuinness, P Secombe, A Tobin, A Udy, A Deane ; A Phase II Study of Liberal Glucose Control in Critically Ill Patients With Pre-existing Type 2 Diabetes (LUCID).ANZICS Winter Research Forum 2017

A Poole, J Anstey, R Bellomo, V Biradar, G Eastwood, S Finfer, M Finnis, C French, P Kar, P Kruger, M Maiden, J Martensson, C McArthur, S McGuinness, P Secombe, A Tobin, A Udy, A Deane; A Phase II Study of Liberal Glucose Control in Critically Ill Patients With Pre-existing Type 2 Diabetes (LUCID)ANZICS CTG 20th Annual Meeting on Clinical Trials in Intensive Care 2017

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