Retrospective Review of Preoperative Optimization of Diabetic Patients

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1. Title page:

1.1. Title:

Full Title: Retrospective Review of Preoperative Optimization of Diabetic Patients

Short Title: Preoperative Optimization of Diabetic Patients

1.2. Principal investigator:

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1.3. Sponsor:

Faculty of Medicine & Dentistry – Department of Anesthesiology & Pain Medicine

1.4. Study Site:

University of Alberta Hospital

2. List of Abbreviation:

DM: Diabetes mellitus

HbA1C: Glycated hemoglobin

3. Summary

3.1. Rationale:

Intraoperative and postoperative hyperglycemia is associated with worse patient outcomes, including increased infections and greater mortality. There are important quality improvement gaps in perioperative glycemic management in Alberta – data shows that 1 in 5 patients with diabetes has no glucose measurements on the day of their surgery and two-thirds will have hyperglycemia (defined as a glucose more than 10 mmol/L).

Diabetic patients, as part of preoperative evaluation, should have glycated hemoglobin (HbA1C) measured. HbA1C provides information on long-term glucose control. There is a suggestion in the literature that elevated A1C levels predict a higher rate of postoperative adverse events, including infections, myocardial infarction, and mortality [1-3]. It is unclear whether chronic glycemia, as reflected in raised HbA1C level, is the risk factor for adverse perioperative events or whether it is a surrogate measure for poor perioperative glucose management. Conversely, in a retrospective analysis of 431,480 surgeries van den Boom et al found that perioperative glucose was predictive of increased 30-day mortality, but that HbA1C was a less useful predictor of this measure [4]. In our experience of at the University of Alberta Pre-admission Clinic there is significant variability with respect to whether diabetic patients have a valid HbA1C measurement i.e. within 3 months of surgery. If a valid measurement is present, there is also considerable variability with respect to diabetes control.

3.2. Objectives:

Perform a retrospective analysis of all surgeries in Alberta from November 2019 to the present time looking for the following:

Primary outcomes:

1. Determine the incidence of diabetes in the surgical population
2. Determine the incidence of valid HbA1C in diabetic patients presenting for surgery
3. Determine long-term diabetes control through assessment of HbA1C values in diabetic patients presenting for surgery

Secondary outcomes:

1. Determine association between HbA1C and post-operative length of stay
2. Determine association between HbA1C and in hospital mortality

4. Methods:

4.1. Design, setting and population:

This is a population-based, retrospective observational cohort study of diabetic patients undergoing surgery in all hospitals in Alberta.

Participants**:** Adults with diabetes having surgery in Alberta since November 2019

4.2. Inclusion criteria:

- Age 18 or greater
- Having any surgical procedure at any hospital in Alberta
- Having a diagnosis of diabetes or prediabetes at any stage preoperatively

4.3. Data collection:

The following data will be collected:

Age

Gender

Weight

Height

Type of surgery

Day surgery or in-patient

Diabetes medications

Medications

Medical history

Pre-operative blood glucose measured on day of surgery: yes/no

Pre-operative glucose value if yes to previous

Intra-operative blood glucose measured on day of surgery: yes/no

Intra-operative blood glucose value if yes to previous: average/highest value

Post-operative blood glucose measured on day of surgery: yes/no

Post-operative blood glucose value if yes to previous

Average and highest day of surgery blood glucose value

Length of hospital stay

In hospital mortality

Complications
HbA1C measurements on record: yes/no
Valid HbA1C (within 3 months of surgery) measurements on record: yes/no
Period of time between HbA1C measurement and surgery date
Values of all HbA1C measurements

The study dataset will be encrypted and password protected, and stored on secure servers at the University of Alberta that can only be accessed through a password protected computer.

4.4. Data Sources:

Data sources will include eCritical Alberta/TRACER and Connect Care/Enterprise data repositories, AHS Data Integration, Management and Reporting (DIMR) administrative databases. Provlab, DAD, DOSE, SCM, Vital Statistics, and Provincial Registry.
Data from eCritical/TRACER and Connect Care/Enterprise provide demographic, diagnostic, and laboratory data.
DIMR provides data elements on health care utilization in Alberta including: admission/discharge/transfers, vital statistics, costing, billing and claims, laboratory, and ambulatory care. Provlab for lab results; DAD, DOSE, SCM for medication use; and Vital Statistics and Provincial Registry for mortality.
Data will be received directly from the data custodian via secure electronic transfer. Prior to transferring the data, the data custodian will replace personal identifiers with unique record numbers. A key linking the identifiers with the unique record numbers will be stored by the data custodian. Linking of data between sources will be performed by AHS analysts prior to receipt of data by the investigators.

4.5. Data Analysis:

Descriptive statistics will be tabulated according to HbA1C status and Univariate comparisons of means, medians and proportions will be performed to evaluate the association of independent variables with primary and secondary outcomes. Normally distributed continuous data will be reported as means with standard deviations (SD). Non-normally distributed continuous data will be reported as medians with interquartile ranges (IQR). Categorical variables will be compared

using Chi-square test for independence. Generalized linear regression models using stepwise variable selection (with default enter and stay criterion) will be used. A p-value <0.05 will be considered significant for all statistical tests.

5. Ethics Considerations:

This study will be a retrospective evaluation of prospectively collected data and does not require any direct patient contact. All data will be de-identified prior to being obtained by the study team and prior to analysis. All data will be housed in encrypted files stored on a secure server at the University of Alberta. Data will only be accessed through password-protected computers. Waiver of consent will be sought.

6. References:

1. Dronge, A.S., et al., *Long-term glycemic control and postoperative infectious complications.* Arch Surg, 2006. **141**(4): p. 375-80; discussion 380.
2. Jones, C.E., et al., *Association Between Preoperative Hemoglobin A1c Levels, Postoperative Hyperglycemia, and Readmissions Following Gastrointestinal Surgery.* JAMA Surg, 2017. **152**(11): p. 1031-1038.
3. Stryker, L.S., et al., *Elevated postoperative blood glucose and preoperative hemoglobin A1C are associated with increased wound complications following total joint arthroplasty.* J Bone Joint Surg Am, 2013. **95**(9): p. 808-14, S1-2.
4. van den Boom, W., et al., *Effect of A1C and Glucose on Postoperative Mortality in Noncardiac and Cardiac Surgeries.* Diabetes Care, 2018. **41**(4): p. 782-788.