

Peri-operative management of surgical patients with diabetes

Study Protocol

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Introduction

The care of patients with diabetes is complex and this is particularly true of those undergoing surgical intervention. More than 15% of patients undergoing surgical procedures are known to have diabetes and poor control is associated with poorer results.

The pathway of care crosses numerous clinical boundaries and it is essential that all staff caring for this group are competent and confident to provide co-ordinated and appropriate care. Training and education of all staff who will care for patients with diabetes is very important. Whilst the adequate monitoring of blood glucose to detect hyperglycaemia and hypoglycaemia - both of which can be serious and lifethreatening complications is very important, the management goes beyond the control of blood glucose alone. Indeed, the elective patient pathway starts long before the patient reaches the operating theatre. It starts with the patient's own control of their diabetes which also involves their GP and local diabetes team before progressing through to pre-assessment, the hospital admission, discharge and follow-up.

For patients admitted for emergency surgery the pathway is less clear and the need to be aware and confident to manage a patient's diabetic status is equally important⁵.

There are existing national guidelines for the care of this patient group. The Joint British Diabetes Societies (JBDS) for inpatient care (JBDS-IP) is supported by Diabetes UK, the Association of British Clinical Diabetologists (ABCD) and the Diabetes Inpatient Specialist Nurse UK Group and their aim is to improve inpatient diabetes care throughout the UK. They have developed detailed evidence and consensus based guidelines,¹ the Association of Anaesthetists of Great Britain and Ireland,² British Association of Day Surgery³ and NHS Diabetes⁴ have also produced guidelines, however, despite all these guidelines the proposers of the study have raised concerns about aspects of the clinical care provided to patients across the UK and have questioned how well the guidelines are being adhered to.

NCEPOD was therefore asked to assess the quality of care given to patients with diabetes undergoing surgery. The study will therefore aim to identify areas for improvement in the organisation of services for patients with diabetes undergoing surgery.

This study will include assessment of care at an organisational level and a clinical level within hospitals and by external peer review of selected cases.

Aims and objectives

Aim

The aim of this study is to identify and explore remediable factors in the process of care in the peri-operative management of surgical patients with diabetes across the whole patient pathway from referral for surgery (elective or emergency) to discharge from hospital.

Objectives - elective admission

Primary care

- Timing and assessment of blood glucose and HbA1c
- Community diabetic nurse/practice nurse specialist assessment
- Referral procedures for optimisation of glycaemia control pre-surgery
 Urgency of referral

Hospital care

- Surgical outpatients
- Pre-assessment(s) prior to surgery
- Route of admission
- Urgency of admission
- Multi disciplinary review
- Assessment of blood glucose/HbA1c and insulin safety
- Management of nutrition and fluids
- Medications management
- Risk assessment used
- Delays in the process
- Theatre and recovery
- Enhanced recovery after surgery
- Step down from critical care
- Discharge planning
- Discharge letter
- Planned follow-up time after discharge
- Documentation, record sharing
- Management of any critical incidents including diabetic ketoacidosis

Objectives - emergency admission

Was the patient admitted as an emergency whilst on a waiting list

Route of admission

Urgency of admission

Initial assessment

- Medications
- Investigations
- Decision to operate
- Senior review

Multi disciplinary review

- Involvement of diabetes team, diabetes nurse specialist review

Assessment of blood glucose and insulin safety

Management of nutrition and fluids

Medications management

Risk assessment

Delays in the process

Enhanced recovery after surgery

Step down from critical care

Discharge planning

Discharge letter

Planned follow-up – time after discharge

Documentation, record sharing

Management of any critical incidents – including diabetic ketoacidosis

Objectives - organisational factors

Pathways of care – emergency, elective surgery for patients with diabetes

Specialist staff – Diabetes nurse specialist, diabetologists – out of hours, clinical lead

Operating lists – priority for patients with diabetes – booking systems for emergencies

Services and facilities – capillary blood glucose, ketone testing

Audit

Patient education, blood glucose monitoring, safety netting

- Crib sheets/ patient passport
- What to do in an emergency hypo and hyperglycaemia recognition sick day rules

Training clinical staff – capillary blood glucose, ketone testing, mandatory insulin safety training

- Protocols

Administration of medication

Polices and protocols and guidelines

- Records of medications
- Prescriptions of medications who can stop and start and restart
- Pharmacy aid
- Day surgery
- Selection for surgery
- Patient self management of insulin/monitoring

Management of day surgery –variable rate intravenous insulin infusion, insulin, modification of medications, potassium, GIK, glucose

Methods

Population/Inclusions

- 1. Patients aged 16 and over
- 2. Who are admitted as an elective or emergency admission
- 3. Who have a ICD10 code for Diabetes Mellitus (E10.0 E11.0)
- 4. Who have had a length of stay in hospital of at least 1 night post surgery
- 5. All major OPCS codes will be included in the study

Exclusions

- 1. Obstetrics
- 2. Day cases
- 3. Patients who underwent a minor procedure (list available to view on study web page, please see Appendix A)

Case identification

Patients will be identified within each hospital by a Local Reporter who will be asked to complete a spreadsheet listing all patients who meet the relevant study criteria for the study period. Patient identifiers including the hospital and NHS number alongside the details of the consultant surgeon who performed the operation and anaesthetist.

Sampling

A two-month period from 1st February 2017 – 31st March 2017 will be used to identify a large sample of cases – this is to ensure that enough patients with Type 1 diabetes can be selected as stated below.

Using national datasets to calculate an expected overall sample size - 8000 patients will be identified during the two month period, from which a sample of approximately 2000 cases will be semi-randomly selected for more detailed review. Up to 8 cases will be selected per hospital at a ratio of 4 Emergency to 4 Elective with each 4 comprising 2 patients with Type 1 diabetes and 2 patients with Type 2 diabetes. If the total number of cases selected reduces then the ratio will be maintained where possible.

Data collection

Spreadsheet

Key data will be collected via case identification spreadsheet disseminated to our Local Reporters to collect information from the PAS record. This includes: dates of admission/discharge, OPCS code(s) of primary procedure, ICD10 codes for diabetes plus date of ICU admission (if applicable), discharge destination, source of admission, elective/ emergency admission/ specialty admitted to, named surgeon/ anaesthetist, named clinician at discharge

Clinician questionnaires

1) Surgeon Questionnaire

A questionnaire will be sent to the consultant surgeon who was responsible for patient's care at the time of the procedure. This will collect data around the objectives listed above.

2) Anaesthetist Questionnaire

A second questionnaire will be disseminated to the responsible anaesthetist to collect data on the pre-assessment and the anaesthesia.

Case notes

Case note extracts for the period of the patient's admission will be requested. These will include:

- GP related notes and referral letter
- Outpatient clinic notes
- Medical notes from admission to discharge
- Notes from MDT meetings
- Imaging reports
- Consent forms
- Pre-anaesthetic assessment records
 - Previous ones relating to this procedure
- Pre- assessment clinic notes/ proforma
- Operation notes
- Anaesthetic charts
- Drug charts
- Fluid balance charts
- Bloods, HbA1C whole period
- Haematology and biochemistry data on the peri-operative blood glucose
- Critical care charts and notes and blood gas charts
- Insulin/glucose charts
- Recovery room records
- Integrated care pathways
- Nursing notes
- DNA-CPR documentation
- Autopsy report (where applicable)
- End of life care pathway
- Discharge summaries

Organisational questionnaire

An organisational questionnaire will be disseminated to all participating sites and collect data on organisational aspects of peri-operative management of surgical patients with diabetes.

GP survey

An online questionnaire allowing GPs to comment on the information they receive following discharge to help them manage a patient's diabetes.

Participating hospitals – case data

All hospitals providing surgical services for patients with diabetes.

Participating hospitals – organisational data

All hospitals providing surgical services for patients with diabetes.

Method test

A test of the data collection materials will be undertaken to ensure that they are robust.

Analysis and Review of Data

Reviewers (peer review)

A multidisciplinary group of Reviewers will review the data collected and provide opinion on the care received by this group of patients, from admission to discharge. The Reviewer group will comprise surgeons, anaesthetists, intensivists, diabetologists, acute physicians, diabetes specialist nurses, pre-operative assessment nurses, dietitians, pharmacists and peri-operative physicians. General practitioners will also be recruited for the review of primary care notes.

Data entry

All clinician questionnaire data will be electronically scanned and combined with data from the assessment form completed by the Reviewers. Quantitative data analysis will be undertaken using Excel and qualitative analysis will be undertaken by reviewing the themes arising from the Reviewer meetings.

Confidentiality and data protection

Once the data have been extracted by the NCEPOD researchers, the questionnaires and case notes will be anonymised to remove patient identifiers prior to review by the Reviewers.

All electronic data are held in password protected files and all paper documents in locked filing cabinets. As soon as possible after receipt of data NCEPOD will encrypt electronic identifiers and anonymise paper documents. Section 251 (England and Wales) and Public Benefit and Privacy Panel for Health and Social Care (NHS Scotland) approval will have been obtained to perform this study without the use of patient consent.

Dissemination

On completion of the study a report will be published and widely disseminated according to the NCEPOD communications strategy.

References

1 Association of British Clinical Diabetologists -

www.diabetologistsabcd.org.uk/JBDS/JBDS.htm -

https://www.diabetes.org.uk/Documents/Professionals/Reports%20and%20statistics/Surgical%20guidelines%202015%20-

%20full%20FINAL%20amended%20Mar%202016.pdf

2 Association of Anaesthetists of Great Britain and Ireland

https://www.aagbi.org/sites/default/files/Diabetes%20FINAL%20published%20in%20 Anaesthesia%20Sept%2015%20with%20covers%20for%20online[1].pdf

- 3 British Association of Day Surgery www.daysurgeryuk.net/en/home/
- 4 NHS Diabetes www.nhs.uk/Conditions/Diabetes/Pages/Diabetes.aspx
- 5 British Journal of Anaesthesia https://academic.oup.com/bjaed/article-abstract/doi/10.1093/bjaed/mkw056/2629524/Perioperative-management-of-the-patient-with?redirectedFrom=fulltext

Timescale

	Oct 16	Nov 16	Dec 16	Jan 17	Feb-17	Mar-17	Apr-17	May-17	Jun-17	Jul-17	Aug-17	Sep-17	Oct-17	Nov-17	Dec-17	Jan-18	Feb-18	Mar-18	Apr-18	May-18	Jun-18	Jul-18	Aug-18	Sep-18	Oct-18	Nov-18
Form the SAG																										Н
Write the protocol																										H
Design the questionnaires																										
Write the strategy of analysis																										
Write the database																										
Advertise the study																										
Advertise for Reviewers										_																
Test data collection methods																										
Meet with SAG																										
Final protocol to SG + IAG																										
Start data collection																										
Run Reviewer meetings							Ì																			
Data analysis																										
Presentation to SAG and Rev.																										
Presentation to SG																										
CORP IAG																										
Write the report																										
First draft to Reviewers/SAG																										
Second draft to Rev/ SAG																										
Report design and print																										
Embargo copies sent																										П
Publish the report																										
Disseminate findings																										