

**Study title: Abnormal blood sugar tests in diabetic patients during colonoscopy preparation**

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## **Objectives**

1. Primary: To discover the incidence of abnormal glucose levels after fasting and bowel preparation for colonoscopy in type 2 diabetes subjects.

2. Secondary

- ① Find out the risk factors for abnormal glucose levels
- ② Find out if self-treatment is sufficient to treat hypoglycemia which occurs during fasting and bowel preparation.

## **Background**

Diabetes is rapidly increasing, with about 11% (5.5 million) of the Korean population expected to be diabetic in 2030. Diabetes is a known risk factor for colorectal cancer and diabetes patients are recommended to undergo routine colonoscopic surveillance. Colonoscopy requires fasting and bowel preparation, however, their effects on glucose levels have not been investigated.

Subjects normally undergo 14-20 hours of fasting before colonoscopy. In diabetes patients, 14-17 hours of fasting reduces plasma glucose by 20-40%, which increases the risk of hypoglycemia. Furthermore, subjects are instructed to forgo taking antidiabetic medications during fasting, which may induce hyperglycemic crisis or abnormal glucose levels due to Dawn phenomenon or Somogyi effect. Dehydration during bowel preparation may also increase the risk of abnormal glucose levels. In diabetic patients, autonomic dysfunction may reduce recognition of hypoglycemic symptoms, increasing risk of catastrophic events.

In diabetic patients who underwent ophthalmologic procedures after 8 hours of fasting, hypoglycemia has been reported in 3% and hyperglycemia in 2.4%. One study which investigated abnormal glucose responses in diabetes patients who underwent colonoscopy found a hypoglycemic rate of 20%. Therefore, we aim to investigate the occurrence of abnormal blood glucose levels in diabetes patients during colonoscopy preparation.

## **Subjects**

1. Inclusion criteria: Type 2 diabetes subjects between the ages of 20-75 who have colonoscopy performed at the endoscopy center of International St. Mary's Hospital.

2. Exclusion criteria

- ① Type I diabetes patients
- ② Those who have not completed colonoscopy preparation
- ③ Those who have not met the fasting requirements
- ④ Patients with known ongoing infection
- ⑤ Patients with known cancer, undergoing current treatment

## **Subject numbers**

The incidence of abnormal glucose levels is expected to be between 5 to 10%. 50 positive subjects are required for multivariable analysis, therefore 1000 subjects should be included in this study.

## **Study design**

1. Colonoscopy preparation

- ① Subjects will be instructed to fast from 6pm of the day before colonoscopy.
- ② Subjects will be instructed to abstain from diabetes medication while the subjects fast.
- ③ Subjects who are scheduled to undergo colonoscopy in the morning will take colonoscopy preparation medication (2L (liter) of polyethylene glycol with ascorbic acid) in a split dose (i.e. 1L from 8-10 pm of the day before colonoscopy and 1L 4-6 hours before colonoscopy). Those who will undergo colonoscopy in the afternoon will take 2L of the preparation medication 6 hours before colonoscopy.

- ④ Subjects will be instructed to take the preparation medication at rate of 250 mL every 10 to 15 minutes.

## 2. Confirmation of diabetes

- ① Diabetes history will be rechecked by a trained nurse who is blind to the study at the preparation room of the endoscopy center.
- ② Subjects will fill out a questionnaire and have their plasma glucose checked while awaiting colonoscopy.

## 3. Treatment of abnormal glucose levels

- ① Hypoglycemic patients with a glucose level < 70mg/dL will be given 5% dextrose water.
- ② Hyperglycemic patients with a glucose level > 250mg/dL will be given normal saline.
- ③ Treated subjects will be discharged after confirmation of glucose level restoration to normal values.

## Study variables

- 1. Age, gender
- 2. Amount and total time of colonoscopy preparation. Total fasting time. Time from last antidiabetic medication taken to colonoscopy.
- 3. Diabetes history (years), Diabetes treatment method (exercise/diet, oral medication, methods including insulin), other injected agents, previous history of hypo/hyperglycemia, hypoglycemia awareness
- 4. Plasma glucose level before colonoscopy

## Statistical Analysis

Primary endpoint: Percentage of study subjects with hypo or hyperglycemia

Secondary endpoint

- ① Risk factors of hypo/hyperglycemia
- ② Effect of hypoglycemia self-treatment

Verify the risk factors using T test the  $X^2$  test.

Identify the odds ratios of risk factors by univariable and multivariable analysis.

## References

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