ISRCTN62397779 https://doi.org/10.1186/ISRCTN62397779

Can weight loss surgery help improve sleep apnea and metabolic health? A long-term study of sleeve gastrectomy outcomes

Submission date
08/07/2025

Recruitment status
No longer recruiting

Registration date
10/07/2025

Overall study status
Completed

Last Edited
09/07/2025

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Obstructive Sleep Apnea (OSA) significantly impacts both health and quality of life and is associated with multiple comorbid conditions, including uncontrolled hypertension, type 2 diabetes mellitus, stroke, and obesity hypoventilation syndrome. As obesity is a major risk factor for the development of OSA, metabolic and bariatric surgery—particularly sleeve gastrectomy—has gained recognition in recent years as an effective intervention. It has demonstrated substantial benefits in achieving significant weight loss and improving or even resolving OSA and related cardiometabolic conditions such as type 2 diabetes, hypertension, and dyslipidemia. This prospective observational cohort study aimed to assess the prevalence and long-term outcomes /effects (at five years) of sleeve gastrectomy on OSA and other commonly associated cardiovascular diseases (type 2 diabetes, hypertension, and dyslipidemia). Specifically, the study evaluated whether these conditions showed complete resolution or improvement following surgery.

Who can participate?
The study included adult patients aged 18 to 60 years diagnosed with obesity in our bariatric medicine and bariatric surgery clinics at Hamad Medical Corporation in Doha, Qatar. Eligible patients met international criteria for sleeve gastrectomy and had no contraindications for surgery. All participants provided informed consent and met the study's inclusion criteria.

What does the study involve?
Preoperatively, patients were assessed by multidisciplinary teams of specialists, including bariatric surgery, bariatric medicine, pulmonary medicine and sleep laboratory technicians. The assessment included detailed history, physical examination and laboratory testing screening as well as a sleep study. The patients were initially assessed by bariatric surgeons to determine eligibility, select the appropriate procedure, and obtain informed consent. Then they were evaluated by bariatric medicine for medical evaluation, risk stratification and optimization. The STOP BANG questionnaire was administered during this visit, and the score was recorded. Following this, patients were referred to sleep laboratory technicians to be educated on how to use the device. The current study used the Alice PDx home screening polysomnography device

to diagnose/screen for OSA. The sleep study results were analyzed and documented by a sleep laboratory technician and reviewed by a pulmonary/sleep physician. Patients with moderate /severe OSA are referred to the pulmonary sleep clinic for further management.
Data collected before surgery were demographics [e.g. age, sex], medical comorbidities, type of and number of medications and insulin therapy use, anthropometric parameters [e.g. weight, height, neck circumference (NC), waist circumference (WC)]. Systolic blood pressure (SBP) and diastolic blood pressure (DBP) were also recorded. Laboratory tests included fasting blood glucose (FBS), hemoglobin A1c (HBA1C), insulin level, triglycerides (TG), high-density lipoprotein (HDL), low-density lipoprotein (LDL), and total cholesterol (TC). Postoperatively, all information collected was collected again, including blood tests, Stop Bang questionnaire and polysomnography parameters [apnea hypopnea index (AHI), oxygen desaturation index (ODI)].

What are the possible benefits and risks of participating?
Participation in the study provided patients with a comprehensive cardiometabolic assessment and screening for undiagnosed OSA before surgery, ensuring appropriate management of related conditions before undergoing bariatric surgery. There were no risks or harms associated with the study, as all diagnostic procedures, including blood tests and OSA assessments (using approved devices), were safe and non-invasive.

Where is the study run from?
Hamad Medical Corporation, the main governmental healthcare provider in Doha, Qatar

When is the study starting and how long is it expected to run for?
May 2017 to December 2020

Who is funding the study?
Hamad Medical Corporation, Qatar

Who is the main contact?
Dr. Wahiba Elhag, WElhag1@hamad.qa, hibahamid@hotmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Wahiba Elhag Elhag

ORCID ID
https://orcid.org/0000-0002-7630-2668

Contact details
Doha-Qatar - Zone, street, House
Doha
Qatar
3050
+97433065586
WElhag1@hamad.qa

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Long-term effects of sleeve gastrectomy on metabolic parameters, and obstructive sleep apnea resolution: a prospective observational study

Study objectives
The objective of this prospective cohort study is to evaluate the five-year impact of sleeve gastrectomy (SG) on the following outcomes:

Changes in anthropometric and cardiometabolic parameters, including blood pressure, glycemic control, lipid profile, and sleep apnea indices. Remission of obesity-related comorbidities such as hypertension, type 2 diabetes mellitus (T2DM), and dyslipidemia and the prevalence and rate of resolution and/or improvement of obstructive sleep apnea (OSA), as confirmed by polysomnographic data.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 22/05/2017, Hamad Medical Corporation Institutional Review Board (Medical Research Center, Doha, 3547, Qatar; +974 44390614; irb@hamad.qa), ref: 16416/16

Study design
Prospective observational cohort study

Primary study design
Observational

Study type(s)
Diagnostic, Treatment, Efficacy

Health condition(s) or problem(s) studied
Long-term impact of metabolic and bariatric surgery, specifically sleeve gastrectomy, on obstructive sleep apnea and cardiometabolic disorders in patients with obesity: A five-year follow-up study.

Interventions

This is a prospective observational cohort conducted by the Bariatric Medicine, Bariatric Surgery and the Pulmonary Medicine departments at Hamad Medical Corporation.

Preoperatively, patients were assessed by multidisciplinary teams of specialists, including bariatric surgery, bariatric medicine, pulmonary medicine and sleep laboratory technicians. The assessment included detailed history, physical examination and laboratory testing screening as well as a sleep study. The patients were initially assessed by bariatric surgeons to determine eligibility, select the appropriate procedure, and obtain informed consent. Then they were evaluated by bariatric medicine for medical evaluation, risk stratification and optimization. The STOP BANG questionnaire was administered during this visit, and the score was recorded. Following this, patients were referred to sleep laboratory technicians to be educated on how to use the device. The current study used the Alice PDx home screening polysomnography device to diagnose/screen for OSA. The sleep study results were analyzed and documented by a sleep laboratory technician and reviewed by a pulmonary/sleep physician. Patients with moderate /severe OSA are referred to the pulmonary sleep clinic for further management.
Data collected before surgery were demographics [e.g. age, sex], medical comorbidities, type of and number of medications and insulin therapy use, anthropometric parameters [e.g. weight, height, neck circumference (NC), waist circumference (WC)]. Systolic blood pressure (SBP) and diastolic blood pressure (DBP) were also recorded. Laboratory tests included fasting blood glucose (FBS), hemoglobin A1c (HBA1C), insulin level, triglycerides (TG), high-density lipoprotein (HDL), low-density lipoprotein (LDL), and total cholesterol (TC). Postoperatively, all information collected was collected again, including blood tests, Stop Bang questionnaire and polysomnography parameters [apnea hypopnea index (AHI), oxygen desaturation index (ODI)].

Intervention Type
Procedure/Surgery

Primary outcome(s)
The following outcome variables assess changes in anthropometric and cardiometabolic parameters at baseline and five years after the surgery, including:
Types of medical comorbidities, type of and the number of medications and insulin therapy use, anthropometric parameters [e.g. weight, height, neck circumference (NC), waist circumference (WC)]. Systolic blood pressure (SBP) and diastolic blood pressure (DBP) were also recorded. Laboratory tests included fasting blood glucose (FBS), hemoglobin A1c (HBA1C), insulin level, triglycerides (TG), high-density lipoprotein (HDL), low-density lipoprotein (LDL), and total cholesterol (TC). Postoperatively, at five years, all information was collected again, including blood tests, Stop Bang questionnaire and polysomnography parameters [apnea hypopnea index (AHI), oxygen desaturation index (ODI)].

The following outcome variables assess the remission/improvement of obesity-related comorbidities of type 2 diabetes mellitus, hypertension, and dyslipidemia before and after surgery:
Blood test parameters and the number of medications used for each disease studied. For type 2 diabetes mellitus: HBA1C, fasting blood sugar, insulin use, number of medications used, for hypertension: blood pressure readings and the number of medications used, for dyslipidemia: lipid profile: total cholesterol, triglyceride, HDL, LDL, and the number of medications used.

Key secondary outcome(s))

Remission/ improvement /worsening of obstructive sleep apnea (OSA) measured using polysomnography and improved repeat score of AHI (Apnea Hypopnea Index) on the screening tool compared with preoperative. Decreased severity of disease on repeat objective testing with PSG: AHI < 5 (e.g., going from severe to mild or from mild to normal) before and after surgery.

Completion date
12/12/2020

Eligibility

Key inclusion criteria
1. Adults aged between 18 to 60 years old
2. Eligible for metabolic and bariatric surgery, and selected the sleeve gastrectomy as their procedure
3. Agreed to participate in the research

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Total final enrolment
72

Key exclusion criteria
1. Previous bariatric procedure (e.g. gastric band, intragastric gastric balloon)
2. Current use of steroids
3. Uncontrolled psychiatric illness
4. Alcohol or substance abuse

Date of first enrolment
16/05/2018

Date of final enrolment
30/11/2020

Locations

Countries of recruitment
Qatar

Study participating centre
Hamad Medical Corporation
Doha-Qatar
Doha
Qatar
3547

Sponsor information

Organisation
Hamad Medical Corporation

ROR
https://ror.org/02zwb6n98

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hamad Medical Corporation

Alternative Name(s)
, HMC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Qatar

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analyzed during the current study are not expected to be made publicly available due to institutional data storage regulations. As per these regulations, the principal investigator is not permitted to share data stored on a personal, password-protected computer. The raw data files are securely stored on the principal investigator’s device and will not be shared unless formally requested and approved by the relevant institutional authorities.

• Data-sharing details: Row data available at the Excel sheet in the Principal Investigator's laptop under password protection.
• The name and email address of the investigator/body who should be contacted for access to the datasets: Dr. Sama Abdulrazzaq Asal (sama.asal@yahoo.com), while institutional (SALjuboori@hamad.qa)
• The type of data that will be shared: an Excel sheet that contains the demographics, cardiometabolic and disease status parameters at baseline and five years after the sleeve gastrectomy.
• Timing for availability: Upon request.
• Whether consent from participants was required and obtained: yes, obtained on the day of recruitment.
• Comments on data anonymization: Each patient has a code entered in the Excel sheet -the code is a number that
• Any ethical or legal restrictions: The ethical approval was obtained from Hamad Medical Corporation -IRB
• Any additional comments: As the study is a comprehensive medical assessment for the cardiometabolic risks and what sleeve gastrectomy can change at five years.

IPD sharing plan summary

Stored in non-publicly available repository, Available on request