BMJ Open

Korean OBEsity Surgical Treatment Study (KOBESS): protocol of a prospective multicentre cohort study on obese patients undergoing laparoscopic sleeve gastrectomy and Roux-en-Y gastric bypass

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To cite: Park YS, Park DJ, Lee JH, *et al*. Korean OBEsity Surgical Treatment Study (KOBESS): protocol of a prospective multicentre cohort study on obese patients undergoing laparoscopic sleeve gastrectomy and Roux-en-Y gastric bypass. *BMJ Open* 2017;**7**:e018044. doi:10.1136/bmjopen-2017-018044

► Prepublication history for this paper is available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2017-018044).

Received 2 June 2017
Revised 17 August 2017
Accepted 13 September 2017

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ABSTRACT

Introduction Bariatric surgery effectively induces long-term weight loss in Western populations. However, its effectiveness in Asians remains to be confirmed objectively. The Korean Society for Metabolic and Bariatric Surgery proposes the first prospective cohort study on Koreans undergoing bariatric surgery.

Methods and analysis The Korean OBEsity Surgical treatment Study (KOBESS) is a prospective, multicentre, single-arm, observational, cohort study on morbidly obese patients who undergo primary sleeve gastrectomy or Roux-en-Y gastric bypass in Korea. In total, 100 consecutive obese Asian patients who will undergo bariatric surgery will be recruited in 2016–2017; follow-up will be for 1 year. Primary outcomes are change in body weight and waist circumference at 1 year. All patients will undergo anthropometry, laboratory tests, bioelectrical impedance analysis, gastrofibroscopy, polysomnography and fat-measuring CT before and after surgery. Patients with diabetes will also undergo perioperative oral glucose tolerance and endocrinological hormone tests. Hypertensive patients will also undergo perioperative echocardiography and carotid Doppler ultrasonography. Female patients suspected of having polycystic ovarian syndrome will also undergo perioperative hormone tests and abdominal ultrasonography. Visceral and subcutaneous fat will be harvested during surgery. Blood, stool and urine samples will be taken at various perioperative time points. Although the cohort is small and the follow-up duration is relatively short, this study will determine whether bariatric surgery induces satisfactory weight loss in obese Koreans. Significantly, the tissue samples will also facilitate many studies examining the effects of bariatric surgery and their mechanisms.

Ethics and dissemination Ethics approval was obtained from the institutional review board of each participating hospital. All findings arising from this cohort study will be published in open-access peer-reviewed journals and will be presented at national and international meetings. All KOBESS investigators will be able to propose research studies and potential publications based on KOBESS data and tissue samples.

Trial registration number NCT03100292; Pre-results.

Strengths and limitations of this study

- This study will confirm whether bariatric surgery induces weight loss in Asians.
- This study will generate blood, urine, stool and fat samples that will facilitate studies on the effects of bariatric surgery.
- Despite the small study sample (n=100), the study is amply powered to test the study hypothesis.

INTRODUCTION

Multiple studies have shown that bariatric surgery effectively induces long-term weight loss and comorbidity remission and decreases overall mortality.[1–3] However, these studies targeted Western populations. While retrospective observational studies show that bariatric surgery also effectively induces long-term weight loss and beneficial metabolic effects in Asians, prospective clinical studies assessing the effect of bariatric surgery on morbidly obese Asian patients have not been reported.[4–6]

The incidence of bariatric surgery in Korea is extremely low.[7 8] To some degree, this reflects the fact that the morbid obesity incidence in Korea is not as high as it is in North America or Europe. However, the main reason relates to the national health insurance system; until recently, it did not recognise morbid obesity as a disease. Consequently, bariatric surgery was considered to be cosmetic surgery and

bariatric surgery patients had considerable out-of-pocket expenses. However, several studies showed that bariatric surgery in Korea achieves good weight loss outcomes and improves patient quality of life (QoL) in a cost-effective manner.[5 9 10] Therefore, and given the increasing morbid obesity prevalence in Korea, the national health insurance programme will start covering bariatric surgery in 2018. This change induced the need for clinical trials that define morbid obesity in the Korean population and establish indications for bariatric surgery.

A retrospective Korean multicentre cohort study showed that, compared with medical therapy, bariatric surgery induced more weight loss, comorbidity resolution and QoL improvements.[5] However, prospective multicentre cohorts of patients undergoing bariatric surgery in Korea have not been established. Therefore, the Korean Society for Metabolic and Bariatric Surgery (KSMBS) issued a research proposal to generate a prospectively recruited cohort of morbidly obese Korean patients who undergo bariatric surgery. This led to the Korean OBEsity Surgical treatment Study (KOBESS), which received funding from the Korea Ministry of Health & Welfare in 2016. In KOBESS, the effect of bariatric surgery on weight loss, comorbidities and QoL will be assessed by accurate perioperative tests. Significantly, KOBESS will generate fat, blood, urine and stool samples at various perioperative time points, which will be useful for studies on the effects of bariatric surgery. The KOBESS design is described here.

OBJECTIVES

The study objective is to establish a prospectively recruited cohort of 100 morbidly obese Korean patients who will undergo bariatric surgery, namely, sleeve gastrectomy (SG) or Roux-en-Y gastric bypass (RYGB). Clinical outcomes, adverse events and the cost-effectiveness of bariatric surgery will be determined 1 year after surgery.

Primary outcomes are change in body weight (kg) and waist circumference (cm) 1 year after surgery. Secondary outcomes include rates of remission in obesity-related comorbidities (hypertension, type 2 diabetes, dyslipidaemia and obstructive sleep apnoea (OSA)) and incidence of morbidity and mortality 1 year after surgery. Moreover, the effect of surgery on QoL, micronutrient status and body composition will be measured, and the cost-effectiveness of surgical intervention will be examined.

STUDY METHODS

Study design

This is a prospective, multicentre, single-arm, observational cohort study of Korean patients who will undergo primary SG or RYGB. In total, 100 patients will be recruited over a 2-year period in 2016–2017 at seven tertiary hospitals in Korea. Eligible subjects who consent to participate will be followed after surgery for 1 year.

Sample size justification and data analysis plan

The research support for KOBESS will also fund a concomitant prospective randomised controlled trial (RCT) examining the effect of the weight loss drug locaserin on body weight. Participants will be free to decide which clinical trial (RCT for weight control drug or KOBESS) they want to enrol in. We will compare the KOBESS and locaserin-treated patients after matching for age, initial body mass index (BMI) and comorbidities. The hypothesis being tested is that the body weight change (%) and the type 2 diabetes remission rate (%) at 1 year will be greater in the surgery group than in the locaserin group. The sample size was calculated on the basis of this analysis plan: we assumed based on Heo *et al*[5] that the body weight changes (%) and type 2 diabetes remissions rates of the surgery and locaserin groups after 1 year will be 22.4% versus 6.7%, and 18.4% versus 0.9%, respectively. We calculated that 73 patients in the surgery and locaserin groups will provide 80% power to detect a difference between the two groups using a two-sided α of 0.05. Assuming a 10% loss to follow-up, it will be necessary to recruit 94 patients/arm. Considering the possibility of additional loss during follow-up, we decided to recruit 100 patients/arm. Fifty patients will be assigned to the SG group and the RYGB group, respectively, and stratification will be performed according to the BMI of each patient.

Primary outcomes of change in weight and waist circumference (%) will be summarised at 0 (baseline), 1, 4, 12, 24 and 48 weeks, and 95% CIs will be calculated. The t-test will be used to compare study outcomes between the surgery and locaserin groups at each time point. The generalised estimating equation model will be used to balance confounding factors at baseline. Remission rates (%) of comorbidities will be compared using χ^2 test at 48 weeks after interventions. Patients who did not meet the criteria for a given comorbidity will be considered to have recovered from that comorbidity. The definition of each comorbidity is described below.

Participants

All consecutive patients aged 20–65 years with a BMI of ≥35 kg/m^2 alone or a BMI of ≥30 kg/m^2 plus comorbidities (hypertension, glucose intolerance, dyslipidaemia and OSA) who visit the participating outpatient clinics in 2016–2017 to consider bariatric surgery will be invited to participate in KOBESS. Comorbidities will be determined by history taking, laboratory tests to measure complete blood counts and fasting plasma glucose (FPG), triglyceride and high-density lipoprotein (HDL) cholesterol levels, blood pressure (BP) measurements and polysomnography. Hypertension, glucose intolerance and dyslipidaemia will be defined according to the International Diabetes Federation.[11] Thus, hypertension will be defined as systolic BP ≥130, diastolic BP ≥85 mm Hg or current treatment of previously diagnosed hypertension. Glucose intolerance will be defined as FPG ≥100 mg/dL or a previous diagnosis of type 2 diabetes. Dyslipidaemia

will be defined as raised triglycerides (≥150 mg/dL), reduced HDL cholesterol (<40 mg/dL in males, <50 mg/dL in females) and/or current treatment of these lipid abnormalities. OSA will be defined as apnoea-hypopnoea index of >5 on polysomnography.

Other inclusion criteria are suitability for general anaesthesia, ability to give informed consent and commitment to follow-up. Female patients must have a negative urine pregnancy test at screening (no detectable urine human chorionic gonadotropin) and must agree to use a reliable contraceptive method during follow-up.

Exclusion criteria include any prior bariatric surgery, non-Korean speaking, American Society of Anesthesiology class ≥IV and malignancy diagnosis within 5 years of recruitment.

Allocation of surgical procedures

Eligible patients will undergo esophagogastroduodenoscopy and a rapid urease test to determine surgical procedure allocation. If esophagogastroduodenoscopy indicates Barrett's oesophagus, SG is not permitted. Inflammatory bowel disease and *Helicobacter pylori* infection on a rapid urease test are contraindications for RYGB. The study timeline and the investigation plan are summarised in table 1.

In Korea, gastric cancer is the second most prevalent malignant neoplasm and the third leading cause of cancer death.[12] Therefore, the national health insurance service in South Korea covers esophagogastroduodenoscopy for everyone over the age of 40 years every 2 years. If patients undergo RYGB, they can no longer have their remnant stomach evaluated by esophagogastroduodenoscopy every 2 years. This means that randomisation of surgical interventions, namely, SG and RYGB, can be ethically problematic in Korea. To overcome this potential problem, the trial patients will choose a surgical procedure after being fully informed about the strengths and weaknesses of the procedures. Exceptions will be patients who meet procedure contraindications. If the patients who undergo RYGB want regular checkups for gastric cancer, double-balloon endoscopy will be performed to evaluate the remnant stomach.

Surgical interventions and postoperative follow-up

For SG, a sleeve is fashioned starting 4–6 cm proximal to the pylorus by using serial applications of linear staplers over a 36–40 Fr orogastric bougie. The last firing is 1–2 cm away from the angle of His. Antrum resection is performed with a stapler with a closed height of 2.0 mm or taller. Moving from the incisura angularis to the angle of His involves staplers with a closed height of 1.5 mm or taller.

For RYGB, a lesser curve-based gastric pouch (approximately 30 mL in volume) is created by using linear staplers. In all patients, the length of the Roux limb is 100 cm. The length of the bilipancreatic limb is 100 and 40 cm in patients with and without glucose intolerance, respectively. Gastrojejunostomy is created by using a linear stapler; the anastomosis length is 20 mm. Jejunojejunostomy is created by using a 45 or 60 mm linear stapler. Both entry holes are closed by handsewing. All mesenteric defects are closed with a running suture made of non-absorbable materials.

All patients will visit outpatient clinics before and 1, 4, 12, 24 and 48 weeks after surgery (table 1).

Quality control

The KSMBS introduced a surgeon certification system in 2016. Thus, all surgeons who have KSMBS certification can participate in this trial. All participating surgeons will review the videos of the other participants performing bariatric surgery and will discuss the standardisation of the laparoscopic procedures with each other before starting KOBESS. To maintain the quality of the operations, video-based reviews and discussions will be held regularly after KOBESS starts.

Assessment of outcomes

Weight, height and body composition

Height will only be measured before surgery. Weight and body composition will be measured before surgery and during the five postoperative visits. Body composition (muscle mass, body fat mass, abdominal fat mass and per cent body fat) will be measured by bioelectrical impedance analysis (BIA).

Fat-measuring CT will be performed before and 48 weeks after surgery. Visceral and subcutaneous fat area at the third lumbar vertebra will be measured by using a Hounsfield unit threshold of −50 to 150 for visceral adipose tissues and −190 to −30 for subcutaneous adipose tissues. Although CT can provide a better indication of abdominal fat distribution than BIA, CT scans will be performed only twice because of the risk of radiation, and repeated evaluations of fat distribution changes thereafter will be done using BIA. Fat-measuring CT will include a single image of the liver at 12th thoracic vertebra; an average of the Hounsfield unit at three different locations of the liver parenchyma will be used to evaluate hepatic steatosis.

Comorbidities

After resting for at least 10 min, BP will be measured before surgery and at the five postoperative visits. Patients with hypertension patients will undergo echocardiography and carotid Doppler ultrasonography before and 48 weeks after surgery. Echocardiography will determine cardiac structure and function (eg, left ventricular size, mass and ejection fraction). Carotid Doppler ultrasonography will measure carotid intima-media thickness and peak systolic velocity at the common carotid artery and proximal internal carotid artery.

FPG will be measured before surgery and at all postoperative visits. If patients meet glucose intolerance criteria, they will undergo the 75 g oral glucose tolerance test (OGTT) before and 1, 12, 24 and 48 weeks

Table 1 Study timeline and investigations

	Baseline	During surgery	Week 1	Week 4	Week 12	Week 24	Week 48
All patients							
Height	O						
Weight, bioelectrical impedance, blood pressure	O		O	O	O	O	O
Fat-measuring CT	O						O
Laboratory tests							
CBC, liver panel, renal panel, urine analysis (including hCG)	O		O	O	O	O	O
Lipid panel	O				O	O	O
Fasting blood glucose	O		O	O	O	O	O
Ferritin, iron, TIBC, vitamin B_{12}, folate	O				O	O	O
Thyroid function test, parathyroid hormone, Vitamin D	O						O
Gastrofibroscopy	O						O
Polysomnography	O						O
Quality of life survey	O					O	O
Tissue samples							
Stool	O			O	O	O	O
Blood	O		O	O	O	O	O
Urine	O			O	O	O	O
Visceral and subcutaneous fat		O					
Patients with glucose intolerance							
C-peptide	O						
HbA1c	O		O	O	O	O	O
Hormone tests, including insulin, glucagon, GLP-1, GIP and others	O		O		O	O	O
Oral glucose tolerance test	O		O		O	O	O
Patients with hypertension							
Echocardiography	O						O
Carotid Doppler ultrasound	O						O
Patients with polycystic ovarian syndrome							
Hormone test, including testosterone, FSH, LH, DHEA-S and others	O						O
Abdominal ultrasound	O						O

CBC, complete blood count; DHEA-S, dehydroepiandrosterone sulfate; FSH, follicle-stimulating hormone; GIP, gastric inhibitory polypeptide; GLP-1, glucagon-like peptide-1; HbA1c, glycated haemoglobin; hCG, human chorionic gonadotropin; LH, luteinising hormone; TIBC, total iron-binding capacity.

after surgery. Serum levels of hormones, including insulin, glucagon, glucagon-like peptide-1 and gastric inhibitory polypeptide, will be measured before surgery and at all postoperative visits. If the patient refuses the OGTT because of uncomfortable symptoms such as dumping syndrome when taking glucose, the OGTT can be omitted.

The lipid profile (triglycerides, total cholesterol, HDL cholesterol and low-density lipoprotein cholesterol) will be checked before and 12, 24 and 48 weeks after surgery. Polysomnography will be performed before surgery and again at 48 weeks after surgery in patients with OSA.

Anaemia and other laboratory tests

Anaemia will be defined as haemoglobin <12 g/dL in women and haemoglobin <13 g/dL in men.[13] Iron deficiency will be defined as serum ferritin <20 µg/dL. Vitamin B_{12} deficiency will be defined as serum vitamin B_{12} <200 pg/mL. Iron deficiency anaemia will be defined as anaemia with concomitant iron deficiency; anaemia from vitamin B_{12} deficiency will be defined as megaloblastic anaemia (mean cell volume >100 fL) with vitamin B_{12} deficiency. Serum haemoglobin, mean cell volume, ferritin, iron, total iron-binding capacity, vitamin B_{12} and folate will be measured before and 4, 12, 24 and 48

weeks after surgery. Serum calcium, phosphate, vitamin D and parathyroid hormone levels will be measured before and 48 weeks after surgery. Thyroid function tests will be conducted on the same schedule.

Polycystic ovarian syndrome

Female patients with suspected polycystic ovarian syndrome (oligoovulation, anovulation or signs of androgen excess such as acne, hirsutism, hypermenorrhea and/or androgenic alopecia) will undergo antimullerian hormone, sex hormone-binding globulin, dehydroepiandrosterone sulfate, testosterone, 17α-hydroxyprogesterone, follicle-stimulating hormone, luteinising hormone and prolactin tests and pelvic ultrasonography before and 48 weeks after surgery.

Postoperative morbidity and mortality

Surgical complications associate with the surgical technique or the operation field. In KOBESS, they will include wound morbidities (eg, infection, dehiscence and incisional hernia), gastrointestinal leakage or fistula, postoperative bleeding, intra-abdominal abscess, stricture, adhesive ileus, reflux esophagitis, marginal ulceration, dumping syndrome and internal hernia. Systemic complications do not associate with the operation field. In KOBESS, they will include lung morbidities (eg, atelectasis, pneumonia, pleural effusion and pulmonary embolism), heart morbidities, urinary morbidities and others. Hospital mortality will be defined as postoperative death from any cause within 30 days of admission or death during the same hospitalisation period.

Quality of life

Participants will complete questionnaires about QoL and cost-effectiveness before and 24 and 48 weeks after surgery. To assess QoL, EuroQol-5D three levels (EQ-5D-3L), Impact of Weight on QoL (IWQoL), Moorehead-Ardelt QoL questionnaire II (MA-II) and Obesity-related Psychosocial Problem scale (OP-scale) will be used. EQ-5D-3L and the EQ-5D visual analogue scale are general health questionnaires. EQ-5D-3L consists of five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression), each of which is scored as no/some/extreme problems.[14] The dimension scores are converted into health utility scores ranging from 0 (death) to 1 (perfect health). IWQoL, MA-II and OP-scale are obesity-specific questionnaires. IWQoL has five dimensions (physical function, self-esteem, sexual life, public distress and work). MA-II has six items (general self-esteem, physical activity, social contacts, satisfaction concerning work, pleasure related to sexuality and focus on eating behaviour). All items are scored according to a 10-level Likert scale (−0.5 to 0.5); all have the same weight. OP-scale was developed during a Swedish study on obese people to measure psychosocial problems in obese people.[15] OP-scale consists of eight items that measure the bothersome impact of body weight on given situations (eg, private gatherings in their own home, private gatherings at their friend or relative's home and going to a restaurant).

Study samples

Blood, stool and urine samples of all enrolled patients will be collected before and 4, 12, 24 and 48 weeks after surgery. Blood samples will also be obtained from patients with diabetes during their OGTTs before and 1, 12, 24 and 48 weeks after surgery. Sera from the centrifuged blood samples will be stored at −80°C. Visceral and subcutaneous fat samples collected during surgery and stool and urine samples will be stored at −20°C.

Cost-effectiveness

We will conduct a cost–utility analysis comparing bariatric surgery to non-surgical interventions. Thus, lifetime expected costs and quality-adjusted life years (QALYs) will be calculated. The surgery group will consist of patients who underwent RYGB or SG; the non-surgical intervention group will consist of patients who enrolled in the locaserin group of the concomitant RCT. We will categorised the subgroup based on baseline characteristics such as age and BMI that may affect the outcomes. For the base case, we will select the group of 30 years old with initial BMI of 30–40 kg/m^2. The various sensitivity analysis for other groups will be conducted.

The model will be a combined decision tree and Markov process model. In the decision tree model, the patients treated with bariatric surgery or conventional intervention are followed for 1 year. In the surgery arm, patients undergo RYGB or SG and either die due to surgical complications or survive. Some of the surviving patients may require corrective surgery within a year of the initial surgery. In the second year, all patients move into the Markov transition model with a lifetime horizon. The health status comprises five states: no comorbidity, mild/moderate comorbidity (diabetes and/or hypertension and/or dyslipidaemia), severe comorbidity (myocardial infarction and/or ischaemic heart disease and/or stroke), death due to coronary vascular disease and death due to other causes. In KOBESS, the obesity-related comorbidities include diabetes, hypertension, dyslipidaemia, myocardial infarction, ischaemic heart disease and stroke, as described previously.[16–18] We assume that a patient could simultaneously experience a maximum of three kinds of obesity-related comorbidities depending on the severity of the comorbidity. Throughout follow-up, patients could die of an age-specific death or an obesity comorbidity-related death. The cycle length is 1 year. The incremental cost per additional QALY gained from bariatric surgery compared with the QALY gained by non-surgery interventions will be calculated.

ETHICS AND DISSEMINATION PLANS

The study protocol was approved by the institutional review board of each participating hospital (eg, B-0510/025–004 in Seoul National University Bundang

Hospital). The study protocol was registered at clinicaltrials.gov (NCT03100292) after starting KOBESS. The results of KOBESS and ancillary studies will be presented at national and international meetings. All publications will be published in open-access peer-reviewed journals. All KOBESS investigators will be able to propose research suggestions and write potential publications based on KOBESS data. A publication committee will approve the proposals by prioritising the study contributions.

ADVANTAGES AND LIMITATIONS

The main advantage of KOBESS is the fact that comorbidity-related conditions will be evaluated precisely. The data will allow multiple valuable substudies on bariatric surgery-induced body changes. This is also the first multicentre study in Korea that will collect blood, urine and faecal samples of obese patients undergoing bariatric surgery. This is significant because the primary outcome of KOBESS is likely to confirm previous observations in Western populations; thus, this objective is neither particularly interesting nor novel. However, the tissue samples that will be collected before and after (and sometimes during) bariatric surgery will make possible many different studies on the effects of bariatric surgery in morbidly obese patients. This cohort will continue to be followed up after postoperative 1 year and data about patients' weight, comorbidities, and nutritional status will be collected prospectively under the supervision of the primary investigators in each hospital.

The other advantage of this trial is the standardisation and upward levelling of bariatric surgical techniques through repeated video-based review by each surgeon. This will provide a solid basis for the design of future nationwide multicentre clinical trials of bariatric surgery in Korea.

The main limitation of KOBESS is its relatively small sample size. However, this sample is not small considering the low number of annual SG and RYGB cases in Korea currently and the fact that the planned enrolment period is 2 years. We will also seek to minimise loss to follow-up by providing *gratis* perioperative tests (the funder will pay for these tests); this will encourage the patients to visit an outpatient clinic regularly.

CONCLUSIONS

This article presents the protocol of a prospective, multicentre, single-arm, observational, cohort study that will recruit obese patients who will undergo primary SG or RYGB in Korea. Since bariatric surgery will soon be covered by the national health insurance system in Korea, the KOBESS results will help to define the indications and guidelines of bariatric surgery. Moreover, the data and tissue samples collected from this cohort will facilitate multiple studies on the effects of bariatric surgery in Asians.

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Funding This work was supported by grants from the Korean Health Technology R&D Project (HC15C1322), Ministry of Health & Welfare, Republic of Korea (for YH).

Competing interests None declared.

Ethics approval Approved by the institutional review board of each participating hospital.

Provenance and peer review Not commissioned; peer reviewed for ethical and funding approval prior to submission.

REFERENCES

1. Sjöström L, Narbro K, Sjöström CD, *et al*. Effects of bariatric surgery on mortality in Swedish obese subjects. *N Engl J Med* 2007;357:741–52.
2. Sjöström L, Lindroos AK, Peltonen M, *et al*.Lifestyle, diabetes, and cardiovascular risk factors 10 years after bariatric surgery. *N Engl J Med* 2004;351:2683–93.
3. Schauer PR, Bhatt DL, Kirwan JP, *et al*. Bariatric Surgery versus Intensive Medical Therapy for Diabetes - 5-Year Outcomes. *N Engl J Med* 2017;376:641–51.
4. Haruta H, Kasama K, Ohta M, *et al*. Long-Term Outcomes of Bariatric and Metabolic Surgery in Japan: Results of a Multi-Institutional Survey. *Obes Surg* 2017;27:754–62.
5. Heo YS, Park JM, Kim YJ, *et al*. Bariatric surgery versus conventional therapy in obese Korea patients: a multicenter retrospective cohort study. *J Korean Surg Soc* 2012;83:335–42.
6. Hsu CC, Almulaifi A, Chen JC, *et al*. Effect of Bariatric Surgery vs Medical Treatment on Type 2 Diabetes in Patients With Body Mass Index Lower Than 35: Five-Year Outcomes. *JAMA Surg* 2015;150:1117–24.
7. Korea centers for disease control and prevention. Ministryof health and welfare, korea centers for disease control and prevention. Korea Health Statistics 2015:KoreaNational health and nutrition examination survey (KNHANES VI-3). 2012.
8. Lee HJ, Ahn HS, Choi YB, *et al*. Information committee of korean society of bariatric and metabolic surgery. Nationwide survey on bariatric and metabolic surgery in Korea: 2003-2013 Results. *Obes Surg* 2016;26:691–5.
9. Oh SH, Song HJ, Kwon JW, *et al*. The improvement of quality of life in patients treated with bariatric surgery in Korea. *J Korean Surg Soc* 2013;84:131–9.
10. Song HJ, Kwon JW, Kim YJ, *et al*. Bariatricsurgery for the treatment of severely obese patients in SouthKorea-is it cost effective? *ObisSurg* 2013;23:2058–67.

11. Alberti KG, Zimmet P, Shaw J. IDF epidemiology task force consensus group. The metabolic syndrome-a new worldwide definition. *Lancet* 2005;366:1059–62.
12. Jung KW, Won YJ, Cm O. Cancer statistics in Korea: incidence, mortality, survival, and prevalencein 2014. *Cancer Res Treat* 2017.
13. World Health Organization. 1994. Indicators and strategies for iron deficiency and anemia programmes. Geneva, Switzerland: Report of the WHO/UNICEF/UNU consultation.
14. EuroQol G. EuroQol Group. EuroQol-a new facility for the measurement of health-related quality of life. *Health Policy* 1990;16:199–208.
15. Sullivan M, Karlsson J, Sjöström L, *et al*. Swedish obese subjects (SOS)–an intervention study of obesity. Baseline evaluation of health and psychosocial functioning in the first 1743 subjects examined. *Int J Obes Relat Metab Disord* 1993;17:503–12.
16. Picot J, Jones J, Colquitt JL, *et al*. The clinical effectiveness and cost-effectiveness of bariatric (weight loss) surgery for obesity: a systematic review and economic evaluation. *Health Technol Assess* 2009;13:1–190 iii iv.
17. Sjöström L, Peltonen M, Jacobson P, *et al*. Bariatric surgery and long-term cardiovascular events. *JAMA* 2012;307:56–65.
18. Salem L, Devlin A, Sullivan SD, *et al*. Cost-effectiveness analysis of laparoscopic gastric bypass, adjustable gastric banding, and nonoperative weight loss interventions. *Surg Obes Relat Dis* 2008;4:26–32.