The impact of previous history of bariatric surgery on outcome of Covid-19: A nationwide medico-administrative French study.

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Research Article

Keywords: Obesity, Bariatric surgery, Covid-19, Risk, Invasive mechanical ventilation

Posted Date: July 24th, 2020

DOI: https://doi.org/10.21203/rs.3.rs-48313/v1

Version of Record: A version of this preprint was published at Obesity Surgery on November 18th, 2020. See the published version at https://doi.org/10.1007/s11695-020-05120-z.

Abstract

Purpose: To determine the risk of invasive mechanical ventilation and death in obese individuals with history of bariatric surgery compared to standard ones admitted for Covid-19 infection.

Methods: Nationwide retrospective observational study based on electronic health data. 4 248 253 individuals aged 15 to 75 years with a diagnosis of obesity were included. All obese inpatients, undergoing bariatric surgery or not, recorded during a hospital stay by the French National Health Insurance were followed, during a mean observation time of 5.43 ± 2.93 years. This exposition was bariatric surgery (n=389,671) including adjustable gastric banding, sleeve gastrectomy, gastric bypass *versus* no bariatric surgery (n=3,858,582). The primary outcome was Covid-19 related death and the secondary outcome was the need for invasive mechanical ventilation.

Results: 8 286 (0.2%) obese individuals were admitted for Covid-19 infection between January 1st and May 15th 2020 with a diagnosis of Covid-19 infection. 541 (0.14%) had a history of bariatric surgery and 7,745 (0.2%) did not. Invasive mechanical ventilation was necessary in 14.54% of patients and death occurred in 13.58% of cases. The need for an invasive mechanical ventilation and death occurred in 7% and 3.5% in the bariatric surgery group *versus* 15% and 14.2% in the non-bariatric surgery group, respectively (both $p<0.0001$). After a logistic regression, the risk of invasive mechanical ventilation significantly increased with age being higher in the age class 61-75, male gender, and hypertension, whereas bariatric surgery showed an independent protective effect. Mortality was independently associated with increasing age, male gender, known history of heart failure, cancer, and diabetes, whereas BS was in favor with a protective effect.

Conclusion: This nationwide administrative study showed that bariatric surgery is independently associated with a reduced risk of death and invasive mechanical ventilation in obese individuals with Covid-19 infection.

Introduction

Obesity, hypertension, cardiovascular disease, diabetes, chronic respiratory disease and malignancy have all been reported to be associated with severe clinical course and mortality in SARS-CoV-2. Cardio metabolic diseases represent a large morbidity burden worldwide and represent a major challenge during the Covid-19 epidemic. Diabetes is known to increase the susceptibility of acute respiratory infections and, both diabetes and obesity are independent risk factors for severe pneumonia.[1,2] While obesity has been reported to have a protective effect in the setting of acute respiratory distress syndrome[3], several studies have associated obesity with adverse outcomes in individuals with SARS-Cov-2.

The Lille Intensive Care Covid-19 and Obesity study group reported a seven-fold increase in the risk of mechanical ventilation in individuals with a BMI > 35 kg/m² admitted with Covid-19 infection as compared with those having a BMI < 25.[4] In New York City, among individuals younger than 60 years, BMI

between 30-34 and > 35 was associated with a 1.8 and 3.6 higher risk of being admitted to critical care for Covid-19 infection, respectively.[5] Further, the increased prevalence of obesity in older individuals in Italy compared with China has been pointed out as a potential explanation for the differences in mortality that have been reported between the two countries.[6] Several hypotheses have been made to explain the association between obesity and adverse outcomes in individuals with Covid-19 infection. From the mechanical standpoint, obese individuals have a decreased expiratory reserve volume, decreased functional capacity, and lower total respiratory system compliance; in obese patients, lung function is further diminished in supine position.[7] Furthermore, the increased secretion of cytokines in excess adipose tissue have also been claimed to participate to the higher morbidity through the impairment of the immune responses[8] and their effects on lung parenchyma and bronchi. [9,10] Lastly, obesity drives an increased risk of chronic diseases that have been shown to be associated with a severe outcome of Covid-19 infection.

The prevalence of obesity has increased exponentially in the last decades with over half of the European population being now overweight or obese.[11] In France, the prevalence of obesity in 2016 has been estimated to be 21.6% (17.4-25.9) by the World Health Organization.[12]

Bariatric surgery (BS) has been shown to be the only effective mean leading to sustained weight loss[13] and remission or improvement of obesity-related comorbidities.[14,15] Several reports have pointed toward the protective effect of BS against the new onset of chronic diseases as type 2 diabetes[16] and against some cancers.[17,18] For these reasons BS has reached a deep penetration worldwide; in France more than 500 000 individuals had had this surgery by 2018.[19]

Based on these data, we made the hypothesis that the history of BS could have a protective effect against the occurrence of severe form of Covid-19 disease and its related death. We used the French National Health Insurance Information System[20], to compare among individuals with known obesity hospitalized for Covid-19, the need for invasive mechanical ventilation, and death in individuals who had had BS compared with obese individuals not undergoing this surgery.

Materials And Methods

Design and study population

This study is based on exhaustive data from the “Programme de Médicalisation des Systèmes d'Information” database (program for medicalization of information systems, PMSI) of the national health care system, which collects data on all hospital stays, regardless of duration, in French public and private hospitals. In addition to its administrative purpose (monitoring of hospital activity based on the Diagnostic-Related Groups (DRGs) model, to inform pricing and strategic decisions by payers and policy-makers), the database is also used for epidemiological purposes in several areas.[18,21]

Data in PMSI are collected on a real-time basis and include the ciphered identification of the patient, the main diagnostic leading to the hospitalization, associated comorbidities and hospital-related complications, as well as other administrative and medical information, including some treatment modalities. Diagnostic coding relies on the international classification of diseases and follows its updates (ICD, World Health Organization). Coding of medical and surgical procedures is based on the French “Classification Commune des Actes Médicaux” (Common Classification of medical procedures, CCAM). The main diagnosis is allocated by treating clinicians in charge of the patients immediately after discharge.

We followed a two-step procedure: first, we constituted a retrospective working cohort study including all the patients hospitalized for morbid obesity (ICD codes E66.-00 to E66.-09, E66.-20 to E66.-29, E66.-80 to E66.-89, and E66.-90 to E66.-99) and discharged between January 1st 2010 and December 31st 2019. In this retrospective cohort study, BS stays were defined as those containing at least one of the most commonly performed bariatric procedures in France including open (HFMA009, HFMA006) and laparoscopic (HFMC007, HFMC005) adjustable gastric banding, open (HFCA001), and laparoscopic (HFCC003) gastric bypass, open (HFFA011) and laparoscopic (HFFC018) sleeve gastrectomy. Secondly, we identified among these patients, those aged 15-75 years and admitted for a Covid-19 infection (code U07.1* [* in 0, 1, 2, 4, 5]), and discharged between January 1st 2020 and May 15th 2020. This allowed the construction of the study cohort of the present study, composed of two groups: the operated (BS) and the non-operated (NBS), i.e. those who had BS or not. Queries were carried out on June 2nd 2020.

Data were anonymously collected and analyzed. Because of the retrospective analysis on an anonymous database, no informed consent was possible, and IRB approval was unnecessary according to French laws on biomedical research.

For each Covid-19 patient, the following data were extracted: age, gender, comorbidities including hypertension (ICD-10 code: I10), diabetes (ICD-10 codes: E10.-, E11.-, E12.-, E13.-, E14.-), chronic obstructive pulmonary disease (COPD) (ICD-10 codes: J44.-), cardiac failure (ICD-10 codes: I50.-), active cancer (ICD-10 codes: C-), and two main outcomes variables: death and invasive mechanical ventilation (CCAM codes: GLLD004, GLLD006, GLLD008, GLLD013, GLLD015).

Statistics

Continuous variables were presented as the means and standard deviation (SD), and categorical variables were summarized as numbers and percentages. Differences between groups were analyzed by Student's T Test and Pearson's χ^2 test for continuous and categorical variables, respectively. We assessed which characteristics were associated with mortality and need of invasive mechanical ventilation in the whole population and in subgroups. Logistic regression models were then built by entering factors respectively associated to the need of invasive mechanical ventilation and mortality at univariate analysis, to assess the factors independently associated with these outcome parameters in the whole population. For all tests, a two-sided p value < 0.05 was considered statistically significant.

Results

This retrospective, population-based, multicenter, cohort study based on French electronic health data included 4 248 253 obese individuals, aged 15 to 75 years (Figure 1). All inpatients, with a diagnosis of obesity, recorded during a hospital stay between 2010 and 2019 by the French national health insurance information system database, were followed up for a mean (SD) of 5.43 years (±2.93) years for those who did not undergo BS and 5.22 years (±2.45) years for those who underwent BS, taking as the reference date the 1st of the month of earlier hospitalization anonymized date and the 1st of the month of the earlier BS hospitalization anonymized date, for no BS and BS individuals, respectively. Among these 4 248 253 obese individuals, 8 286 (0.2%) were hospitalized between January 1st and May 15th 2020 with a diagnosis of Covid-19 infection; a mean of 1.22 stay per patient was recorded for a total of 10 069 Covid-19 stays. These 8 226 individuals meeting the selection criteria constitute the main cohort of this study (Figure 1). Of note, in the same period, 78 995 additional individuals (0.12% of the French population), with no history of previous hospitalization for obesity, were hospitalized in France with a diagnosis of Covid-19 infection.

Fifty-four per cent of individuals were aged 61 to 75, 23% were men, 7% had COPD, 6.9% had heart failure, 7.3% had a history of cancer, 35.2% were diabetic and 40.2% had hypertension. Five-hundred-forty-one out of 8 226 (6.6%) had history of BS between 2010 and 2019 (BS group), the remaining (n=7 685; 93.4%) constitute the NBS group (Table 1). As expected, individuals in the NBS group were significantly older, more frequently of men sex and there were more individuals with COPD, heart failure, history of cancer, diabetes and hypertension (Table 1).

Invasive mechanical ventilation was necessary in 1 196/8 226 patients (14.54%) and death occurred in 1 117 patients of the whole population (13.58%) (Table 1).

Table 2 indicates that at univariate analysis age, male gender, COPD, cardiac failure, history of cancer, type 2 diabetes, and hypertension were significantly associated with an increased risk of death and all but COPD were associated with an increased risk of invasive mechanical ventilation in the whole study population. At univariate analysis, BS showed a protective effect as 7 % of individuals in the BS group *vs* 15 % of those in the NBS group required invasive mechanical ventilation (p<0.0001) and 3.5% in the BS cohort *versus* 14.2% of those in the NBS cohort died (p<0.0001). The protective effect of BS on both the need of mechanical ventilation (Table 3) and mortality (Table 4) was confirmed at multivariate analysis.

The logistic regression (model including gender, hypertension, classes of age, diabetes, cardiac failure and BS) showed that the risk of invasive mechanical ventilation increased with age being higher in the age class 61-75 (OR 1.59; CI 1.20-2.10; p<0.0001), in male gender (OR 1.76; 95% CI 1.54-2.00; p<0.0001), and in case of hypertension (OR 2.25; 95% CI 1.97-2.56; p<0.0001), whereas BS showed an independent protective effect (OR 0.67; 95% CI 0.48-0.95; p<0.025).

With respect to death, logistic regression (model including sex, age classes, cancer, diabetes, cardiac failure, COPD, or hypertension history, and BS) showed that older age was strongly associated with Covid-

19 related death reaching an OR of 29.87 (95% CI 19.52-45.73) in the age class 61-75 ($p<0.0001$). The risk of mortality was also independently associated with male gender (OR 1.48; 95% CI 1.28-1.69), known history of heart failure (OR 1.53; 95% CI 1.24-1.89; $p<0.0001$), cancer (OR 2.81; 95% CI 2.32-3.41; $p<0.0001$), and diabetes (OR 1.33; 95% CI 1.16-1.52; $p<0.0001$), whereas BS showed a protective effect (OR 0.50; 95% CI 0.31-0.80; $p=0.0039$).

Discussion

In this French medico-administrative nationwide study, the history of BS was independently associated with a significant reduction in the risk of mortality in obese individuals developing Covid-19 infection (OR 0.50; 95% CI 0.31-0.80; $p<0.0039$). Mortality in obese individuals with Covid-19 was 14.2% in those not undergoing BS and 3.5% in those undergoing BS ($p<0.0001$). BS was also independently associated with a reduced risk of invasive mechanical ventilation (OR 0.67; 95% CI 0.48-0.95; $p=0.025$), that was required in 15% of obese individuals without history of BS and 7% in those undergoing BS ($p<0.0001$).

As the epidemic spreads around the world, scientists have raced to identify risk factors for severe forms of Covid-19 infection and death, as the outbreak has challenged the health care systems of all countries touched by the epidemic. Individuals at risk not only have more chances to become infected but also to develop severe forms of the disease including the need for mechanical ventilation and death. Given the shortage of resources, governments must warn more vulnerable individuals to be stringent in observing social distancing measures.[22] For these reasons, high quality data on all potential risk factors are needed to identify vulnerable individuals and help governments to draw reliable guidance to minimize social and economic disruption linked to restrictions measures.[23]

Older age, male sex, hypertension, diabetes, cardiovascular disease and malignancy have been reported as a risk factor for Covid-19 severe disease and death in initial studies [24, 25,26] while no emphasis was put on increased BMI as risk factor. [27,28,29]

A French study then showed that disease severity increases with BMI and that the need for invasive mechanical ventilation is associated with severe obesity (BMI>35) regardless of age, sex, diabetes, and hypertension.[4] These data were confirmed in another French study reporting that obese individuals had higher odds of developing severe Covid-19 than individuals without obesity (adjusted ORs ranging between 1.80 and 2.03).[30] Awareness of obesity as a main risk factor for severe Covid-19 outcome led the French Ministry of Solidarity and Health to produce a "care sheet for people in a situation of obesity during the Covid-19 epidemic" and general practitioners were authorized to provide work stoppages for obese individuals.[31]

BS has developed widely in the last two decades in concomitance with the sharp increase in the prevalence of obesity worldwide.[32] There is a large body of evidence demonstrating that BS is effective in achieving a sustained weight loss, maintained in the long-term.[14] BS-induced weight loss is also effective in reversing the metabolic comorbidities linked to obesity, such as diabetes, which stands among the

most common risk factor for severe outcome of Covid-19 infection, as discussed above.[16,33] For these reasons we made the hypothesis that the history of BS could have a protective effect against mortality and the need of invasive mechanical ventilation in obese individual who had had BS. Interestingly, this study confirmed the findings of previous studies indicating older age, male gender, malignancy, heart failure and diabetes as independent risk factors for increased mortality while hypertension was no more significantly associated with mortality at multivariate analysis.

Other mechanisms that may account for the protective effect of BS include the improvement of the mechanics of respiratory function of obese individuals that occurs with the loss of weight. Finally, the reversal of the low grade systemic inflammation linked to obesity due to BS-induced loss of weight may also play an important role in reducing the risk of severe Covid-19 outcome.[34] All these factors may be claimed to account for the significantly lower mortality and need for invasive mechanical ventilation in obese individuals with a history of BS compared with those no history of BS.

The present study carries some weaknesses linked to the retrospective study design and the potentially missing data on Covid-19 code which has been created *ad hoc* at the beginning of the epidemic. Furthermore, BS group included more women and younger individuals than the NBS control group. However, in spite of differences in characteristics of BS and NBS groups, the independent protective effects of BS on respiratory failure and death is clearly shown by multivariate analysis. Obviously, a different study design would have provided a more stringent evidence. However, propensity score matching would have been impossible because of the relative low number of effectives. To date, the PMSI database has been largely used in the past for epidemiological studies and stands among the largest health databases in the world. Indeed, our analysis confirmed data reported in previous studies on risk factors for Covid-19 related death suggesting the reliability of our findings.

In spite of its retrospective design, this study is the first to report the protective effect of BS against the severity of Covid-19 disease course. This finding provides interesting information from an epidemiologic point of view and provides interesting insights to speculations on pathophysiology of Covid-19 infection, in particular in case of severe presentations.

Declarations

Conflict of Interest Statement

All authors declare that they have no conflict of interest to disclose. They declare that there are no financial or personal relationship that could inappropriately bias the work.

Ethical Approval Statement

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent Statement

Informed Consent does not apply in this study.

Acknowledgments

All authors have contributed equally to this work.

Grant Information

No grant has been received to support this article

Non-blinded COI Statement

Antonio IANNELLI, Samir BOUAM, Anne-Sophie SCHNECK, Sébastien FREY, Jean GUGENHEIM and Marco ALIFANO declare that they have no conflict of interest

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Tables

Table 1. Univariate analysis of preoperative risk factors for Invasive Mechanical Ventilation and death in COVID-19 obese patients.

Characteristic	No. (%) of Patients					
	Invasive Mechanical Ventilation n = 1 196	No Invasive Mechanical Ventilation n = 7 090	*p* Value	Death n = 1 117	Alive n = 7 169	*p* Value
Age, mean (SD), y	61.8 (9.9)	58.7 (13.0)	<.0001	66.6 (7.7)	57.9 (12.8)	<.0001
15-30	6 (0.5)	245 (3.5)	<.0001	3 (0.3)	248 (3.5)	<.0001
31-45	79 (6.6)	978 (13.8)	<.0001	19 (1.7)	1 038 (14.5)	<.0001
46-60	367 (30.7)	2 103 (29.7)	.4738	161 (14.4)	2 309 (32.2)	<.0001
60-75	744 (62.2)	3 764 (53.1)	<.0001	934 (83.6)	3 574 (49.9)	<.0001
Gender, M	793 (66.3)	3 503 (49.4)	<.0001	737 (66)	3 559 (49.6)	<.0001
Gender, F	403 (33.7)	3 587 (50.6)		380 (34)	3 610 (50.4)	
COPD, yes	94 (7.9)	489 (6.9)	.2286	112 (10)	471 (6.6)	<.0001
COPD, no	1 102 (92.1)	6 601 (93.1)		1 005 (90)	6 698 (93.4)	
Cardiac failure, yes	113 (9.5)	456 (6.4)	.0001	144 (12.9)	425 (5.9)	<.0001
Cardiac failure, no	1 083 (90.6)	6 634 (93.6)		973 (87.1)	6 744 (94.1)	
Cancer, yes	73 (6.1)	535 (7.6)	<.0001	197 (17.6)	411 (5.7)	<.0001
Cancer, no	1 123 (93.9)	6 555 (92.5)		920 (82.4)	6 758 (94.3)	
Diabetes, yes	545 (45.6)	2 372 (33.5)	<.0001	531 (47.5)	2 386 (33.3)	<.0001
Diabetes, no	651 (56.3)	4 718 (66.5)		586 (52.5)	4 783 (66.7)	
Hypertension, yes	718 (60)	2 613 (36.9)	<.0001	541 (48.4)	2 790 (38.9)	<.0001
Hypertension, no	478 (40)	4 477 (63.2)		576 (51.6)	4 379 (61.1)	
Bariatric Surgery, yes	38 (3.2)	503 (7.1)	<.0001	19 (1.7)	522 (7.3)	<.0001
Bariatric Surgery, no	1 158 (96.8)	6 587 (92.9)		1 098 (98.3)	6 647 (92.7)	

COPD chronic obstructive pulmonary disease

Table 2. Univariate analysis of preoperative risk factors distribution in COVID-19 obese patients in BS and NBS cohorts.

Characteristic	No. (%) of Patients			
	Whole population	Bariatric Surgery	No Bariatric Surgery	*p* Value
	n = 8 286	n = 541	n = 7 745	
Age, mean (SD), y	59.1 (12.6)	49.8 (12.0)	59.8 (12.4)	<.0001
34-45	251 (3)	33 (6,1)	218 (2.8)	<.0001
15-30	1057 (12.8)	158 (29.2)	899 (11.6)	<.0001
46-60	2470 (29,8)	239 (44.2)	2231 (28.8)	<.0001
60-75	4508 (54.4)	111 (20.5)	4397 (56.8)	<.0001
Gender, M	4296 (51.8)	127 (23.5)	4169 (53.8)	<.0001
Gender, F	3990 (48.2)	414 (76.5)	3576 (46.2)	
COPD, yes	583 (7)	16 (3)	567 (7.3)	<.0001
COPD, no	7703 (93)	525 (97)	7178 (92.7)	
Cardiac failure, yes	569 (6.9)	18 (3.3)	551 (7.1)	.0008
Cardiac failure, no	7717 (93.1)	523 (96,7)	7194 (92.9)	
Cancer, yes	608 (7.3)	11 (2)	597 (7.7)	<.0001
Cancer, no	7678 (92.7)	530 (98)	7148 (92.3)	
Diabetes, yes	2917 (35.2)	66 (12.2)	2851 (36.8)	<.0001
Diabetes, no	5369 (64.8)	475 (87.8)	4894 (63.2)	
Hypertension, yes	3331 (40.2)	109 (20.2)	3222 (41.6)	<.0001
Hypertension, no	4955 (59.8)	432 (78.9)	4523 (58.4)	
Invasive mechanial ventilation, yes	1196 (14.4)	38 (7)	1158 (15)	<.0001
Invasive mechanial ventilation, no	7090 (85.6)	503 (93)	6587 (85)	
Death, yes	1117 (13.5)	19 (3.5)	1098 (14.2)	<.0001
Death, no	7169 (86.5)	522 (96.5)	6647 (85.8)	

COPD chronic obstructive pulmonary disease

Table 3. Multivariate analysis of preoperative risk factors for invasive mechanical ventilation.

	Invasive Mechanical Ventilation		
Characteristic	OR	95% CI	*p* Value
Age, mean (SD), y			<.0001
15-30	1		
31-45	1.17	1.06-1.28	
46-60	1.36	1.13-1.64	
60-75	1.59	1.20-2.10	
Gender, M	1.76	1.54-2.00	<.0001
Hypertension	2.25	1.97-2.56	<.0001
Bariatric Surgery	0.67	0.48-0.95	0.025

Table 4. Multivariate analysis of preoperative risk factors for death.

	Death		
Characteristic	OR	95% CI	*p* Value
Age, mean (SD), y			<.0001
15-30	1		
31-45	3.10	2.69-3.58	
46-60	9.63	7.25-12.79	
60-75	29.87	19.52-45.73	
Gender, M	1.48	1.28-1.69	<.0001
Cardiac failure	1.53	1.24-1.89	<.0001
Cancer	2.81	2.32-3.41	<.0001
Diabetes	1.33	1.16-1.52	<.0001
Bariatric Surgery	0.50	0.31-0.80	0.0039

Figures

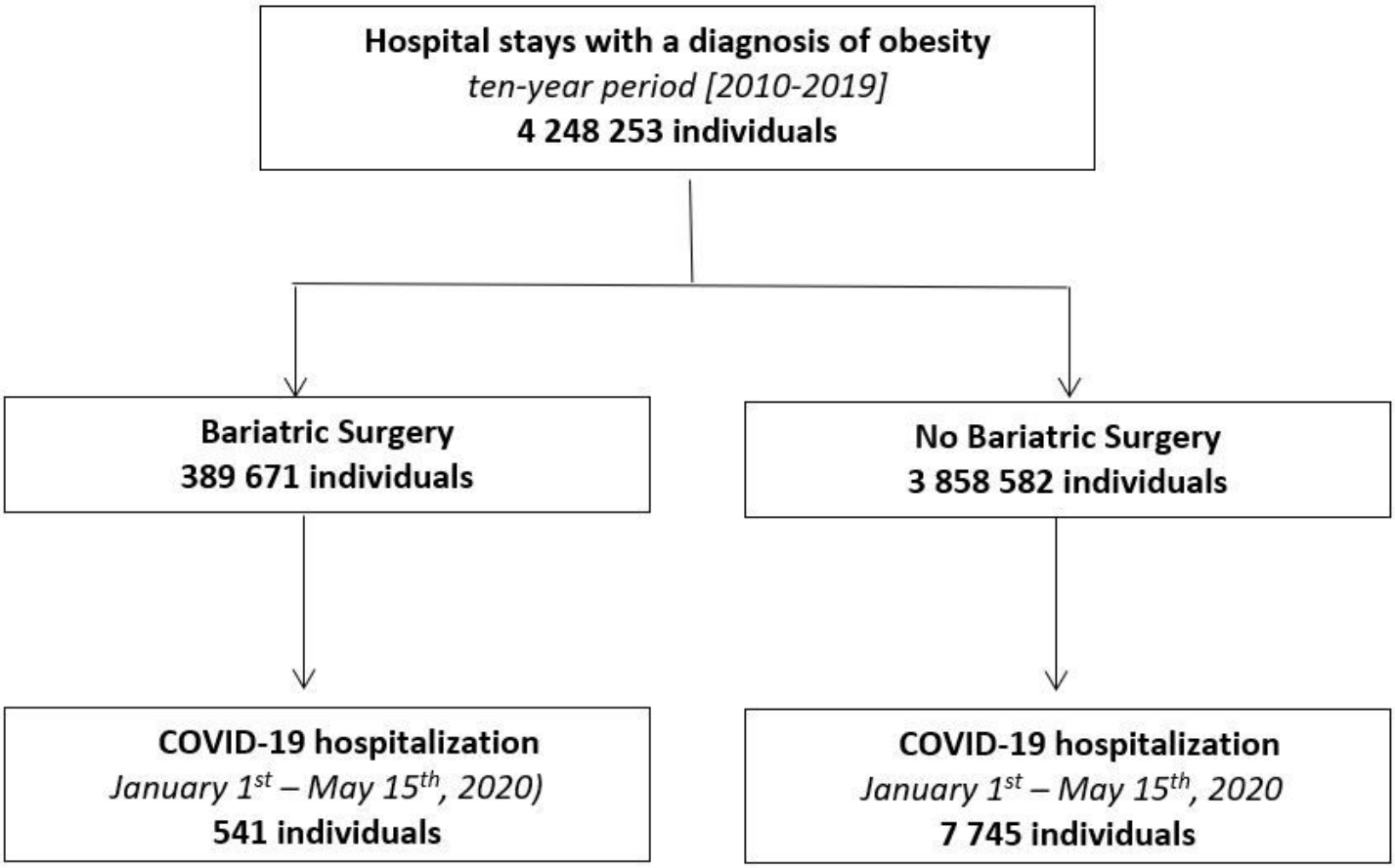

Figure 1

Flowchart of the Study Population