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ORIGINAL RESEARCH

Lights and Shadows of Bariatric Surgery: Insights from a Nationwide Administrative Database of People Living with Type 1 Diabetes and Obesity

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ABSTRACT

Introduction: The study aimed to describe the population of patients living with type 1 diabetes who had access to bariatric surgery (BS) in France, analyzing the changes in healthcare resource use and associated costs in the 3 years following this surgery.

Methods: An observational longitudinal study based on the French national health insurance database was conducted on all adult patients that underwent a first BS from 2015 to 2020. Cost analyses were conducted on a sub-population who underwent BS from 2016 to 2017 for sufficient observation time using a pre-post methodology.

Results: A total of 437 patients were identified as living with type 1 diabetes among the 234,077 patients who had undergone surgery over 6 years (2015–2020). The most frequently performed interventions were sleeve gastrectomy ($n=272$; 62.2%) and gastric bypass ($n=154$; 35.2%), with the majority of patients being women (77.8%) and an average age of 42.3 (±12.0) years, consistent with the general population undergoing BS in France. While no significant differences were found in the overall healthcare costs when comparing the 3 years before and after BS, there was an increase in the frequency of biological measurements. Expenditures related to antidiabetic medications and insulin decreased significantly ($p<0.0001$). The number of hospitalizations for

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severe hypoglycemia, coma, and ketoacidosis more than doubled in the 3 years following surgery compared with the period before ($p = 0.04$). ***Conclusions***: The risks of severe hypoglycemia or ketoacidosis in patients with type 1 diabetes undergoing BS remains a real concern and emphasizes the importance of involving the diabetologist in the operative decision with joint follow-up with the nutritionist.

Keywords: Type 1 diabetes; Bariatric surgery; Ketoacidosis; Hypoglycemia; Insulin

Key Summary Points
Why carry out this study?
The risk-benefit ratio and medico-economic impact of bariatric surgery in people with Type 1 Diabetes remains largely unstudied and debated.
This study aims to describe the population of patients living with type 1 diabetes who had access to bariatric surgery in France.
What was learned from the study?
After bariatric surgery, overall healthcare costs remained stable with an increase in biological monitoring, a significant decrease in anti-diabetic medication and insulin costs, but more than a twofold increase in hospitalizations for severe hypoglycemia, coma, and ketoacidosis.
Risks of severe hypoglycemia and ketoacidosis in patients with type 1 diabetes undergoing bariatric surgery highlight the need for diabetologist involvement in the surgical decision.
Significant reductions in reimbursements for anti-diabetic drugs and increased nutritional marker assays emphasize the importance of joint monitoring with a nutritionist.

INTRODUCTION

Contrary to historical teaching, it is now well established that people living with type 1 diabetes are not spared from suffering from overweight or obesity [1]. There is a worrying increase in the reported prevalence of overweight and obesity among children and young adults living with type 1 diabetes (T1D) [2, 3], with European data already showing an increased prevalence of obesity in patients living with type 1 diabetes similar to that of the general population [4–6]. Weight gain can be explained by genetics, lifestyle, and/or aging as in the general population but may also be a consequence of insulin replacement therapy in patients with type 1 diabetes [7]. Data on patients living with T1D, from the Swedish National Diabetes Registry have shown that a body mass index (BMI) ≥ 25 kg/m^2 is associated with an increased risk of mortality, major cardiovascular disease, and heart failure, with a stronger association in men than women [8]. Thus, the concept of *double diabetes*, a combination of T1D with features of insulin resistance (and type 2 diabetes), proposed that weight gain is associated with an increased risk of cardiovascular disease, demonstrating the relationship between weight gain, insulin resistance, glycemic control, and cardiovascular outcome in this cohort [9, 10]. Beyond cardiometabolic outcomes, epidemiological research has shown that overweight and obesity are important risk factors for numerous diseases in people without diabetes, largely affecting reproductive health, respiratory function, and mental health. There is no reason to expect this to be different or potentially worse in people living with T1D and for these reasons, many weight management strategies have been tried; from dangerous insulin omission/underdosing to recognized approaches such as lifestyle changes, drugs (metformin or GLP-1 receptor agonists) and bariatric surgery (BS) [11, 12]. Whether these treatment strategies are effective, or even safe, in this population is unknown as all approaches to weight loss can present specific difficulties [13].

BS for severe obesity has shown major long-term benefits for weight loss, cardiovascular

and metabolic complications, and even mortality [14]. While the risk–benefit ratio of BS is favorable in patients with type 2 diabetes, the risk–benefit ratio is still debated in people living with T1D particularly due to concerns about glycemic control, and the risk of hypoglycemia and ketoacidosis [15, 16]. A recent observational study in patients with T1D, showed a lower risk of cardiovascular disease, cardiovascular mortality and stroke, but no improvement in glycemic control and a higher risk for hypoglycemic events and substance misuse in the bypass group compared with the control group [17]. Other smaller studies have reported similar concerns regarding glycemic control and metabolic risks, but all have emphasized the need for larger and longer-term studies [18–22]. To our knowledge, no study has reported on the medico-economic consequences of BS in patients with T1D.

For our review, we accessed a nationwide health insurance database to study the inpatient and outpatient care pathways and healthcare costs of a cohort of patients living with T1D who had undergone BS.

METHODS

We conducted a population-based cohort study using data from the French national health insurance database (Système national des données de santé, SNDS) [23, 24]. It contains individual data for all healthcare expenditures reimbursed by the mandatory French national health insurance for > 99% of the French population (68 million inhabitants in 2021); including billing and reimbursement of outpatient healthcare consumption and data from the national hospital discharge database. First, patients who had BS were identified in the hospital database between 2015 and 2020 using the reference catalog of medical procedures used in France (CCAM, see the appendix in the electronic supplementary material) including those who underwent sleeve gastrectomy (SG), Roux-en-Y gastric bypass (GB), adjustable gastric band (AGB) and biliopancreatic diversion (BPD). Patients with T1D were identified using successively a diabetes selection algorithm and a diabetes classification algorithm [25]: (1) an individual was considered as having diabetes if receiving at least three reimbursements for any antidiabetic medication (oral or injectable) or at least two reimbursements if one large pack size was dispensed over 1 year, or beneficiating of a long term disease (LTD) status qualified with the same codes by the National Sickness Fund or having been hospitalized at least once with a diagnostic code E10 (T1D), E11 (Type 2 diabetes), E13 (other specified diabetes) or E14 (Unspecified diabetes) over the past 2 years (2) the classification algorithm has been described elsewhere [26]. To avoid any potential misclassification, the diagnosis of T1D was confirmed by an expert endocrinologist through an individual review of treatment regimens delivered to the selected patients over 2 years before they underwent BS.

Among the population of adult patients with T1D benefiting from a first BS, a sub-population that underwent BS between 2016 and 2017 was identified to conduct healthcare resource and cost analyses. These analyses were carried out by considering the included patients as their controls (before-after comparison in a time frame of 6 years). All costs were estimated using a societal perspective in current euros and considering only direct costs. No patients were censored in the follow-up period due to death or other reasons.

This study was registered on the Health Data Hub website (T47730692021061). In accordance with current regulations, the study protocol was submitted to the 'committee for research, studies, and evaluations in the field of health' (Comité d'Expertise pour les Recherches, les Etudes et les Evaluations dans le domaine de la Santé [CEREES]) for approval and was authorized by the French data protection authority (Commission Nationale de l'Informatique et des Libertés [CNIL], [CNIL authorization number DR-2021-235]). The authorization permitted the implementation of data processing for a study on the epidemiological and economic aspects of BS in France, requiring access to SNIIRAM (système national d'information interrégimes de l'Assurance Maladie) and PMSI (programme de médicalisation des systèmes d'information) data, components of the SNDS for the years 2013 to 2020 (Authorization request no. 921320).

RESULTS

We identified a cohort of 437 patients as living with T1D among the 31,000 patients who were treated for diabetes and had undergone BS between 2015 and 2020 (i.e., 1.4%) (Fig. 1). Sleeve gastrectomy (SG) ($n=272$; 62.2%) and gastric bypass (GB) ($n=154$; 35.2%) were the two most frequent techniques (Fig. 1). Patients were mostly women (77.8%) with a mean age of 42.3 (± 12.0) years old and a body mass index ≥ 40.0 kg/m^2 in 41.4% of them (Table 1). A substantial proportion of patients were in a precarious socioeconomic situation (22.1%), being in the lowest quintile index deprivation. The ratio of patients receiving antihypertensive, lipid-lowering, and obstructive sleep apnea treatments was 47.1%, 37.1% and 32.0%, respectively. Sleep apnea syndrome was identified as severe, defined as being treated, in one-third of the patients (32%); indeed, screening is recommended before BS. By definition, all patients received fast-acting insulin but half of them also received long-acting insulin (50.6%) and up to a third received additional metformin treatment (33.6%). The median hospitalization stay associated with the BS procedure was 5.1 days predominantly in a public hospital (57.8%). None of the patients undergoing BS died during the hospital stay and most patients returned home after their surgery (93.5%, data not shown).

We then analyzed a sub-cohort of 154 patients with BS in 2016 and 2017 for whom data were available during the 3 years preceding and following this surgery. No difference in total health expenditure was found (Table 2). Comparing healthcare use, we found some changes after BS compared to prior. If the patients maintained the frequency of their visits to a diabetologist, then visits to a cardiologist, gastroenterologist, or psychiatrist were less frequent after surgery ($p<0.0001$). Conversely, the use of home nurses was significantly more frequent in the years following surgery. Nutritional biological measurements were also more frequent following BS, particularly albumin, ferritin, calcium, and vitamins D, B12, and A ($p<0.0001$). No differences were found in the frequency of anxiolytic, antidepressant, neuroleptic, antihypertensive,

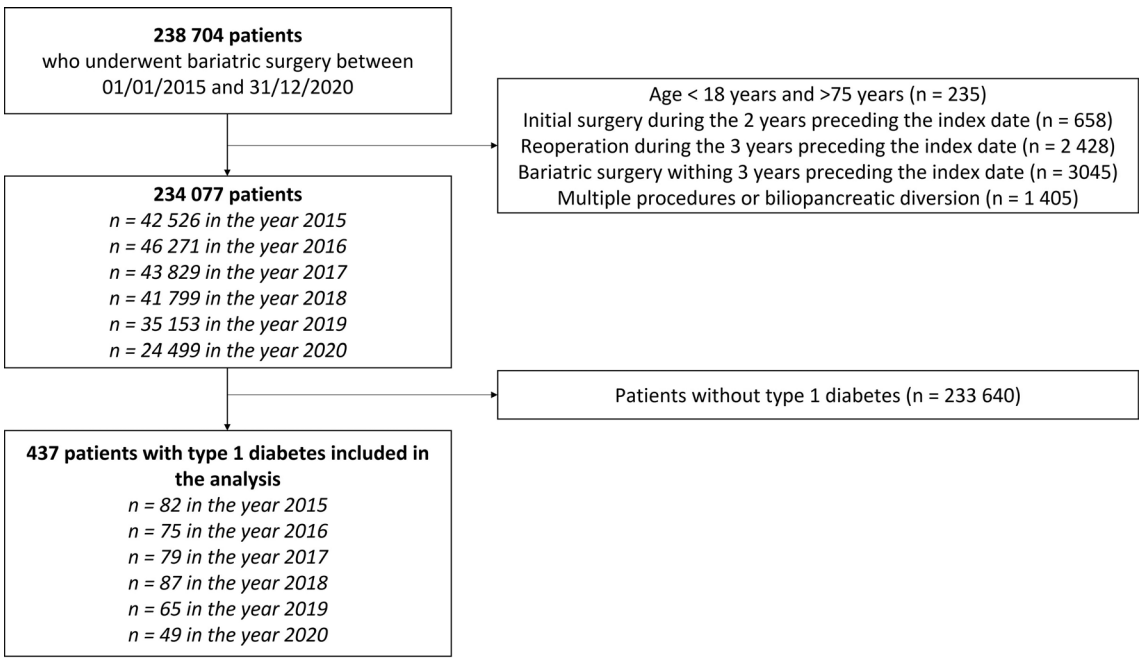

Fig. 1 Flowchart describing the identification of patients living with type 1 diabetes of all bariatric surgery patients in France over 2015–2020

Table 1 Description of the population (437 patients with type 1 diabetes who had undergone bariatric surgery between 2015 and 2020)

	N (%)
Bariatric surgery procedures	
Sleeve gastrectomy	272 (62.2%)
Gastric bypass	154 (35.2%)
Gastric banding/others	11 (2.5%)
Age (mean ± SD) years	42.3 ± 12.0
Women *N* (%)	340 (77.8%)
Body mass index classes *N* (%)	
30–39.9 kg/m^2	143 (32.7%)
40–49.9 kg/m^2	157 (35.9%)
≥ 50 kg/m^2	24 (5.5%)
Unspecified*	113 (25.9%)
Deprivation index (*N* %)**	
Quintile most deprived	94 (22.1%)
Quintile least deprived	58 (13.6%)
Charlson comorbidity index (mean ± SD)	0.9 ± 1.3
Sleep apnea (continuous airway pressure treatment) *N* (%)	140 (32.0%)
Antihypertensive use *N* (%)	206 (47.1%)
Lipid-lowering agent use *N* (%)	162 (37.1%)
Analgesic use *N* (%)	114 (26.1%)
Psychotropic use *N* (%)	107 (24.5%)
Antidiabetic treatment *N* (%)	
Fast-acting insulin	437 (100.0%)
Long-acting insulin	221 (50.6%)
Metformin	147 (33.6%)

SD standard deviation

*This high % of missing data is related to the fact that body mass index is available only for some hospitalized patients

**Missing data in 12 patients

lipid-lowering agent, or analgesic delivery. In contrast, the number of deliveries of glucose-lowering medications significantly fell during the 3-year period following BS ($p < 0.0001$). This drop in antidiabetic agents was mainly related to a decrease in insulin or insulin analog. As expected in patients living with T1D, there was no change in medical device reimbursement. It should be noted that, during the study period, the vast majority of patients living with T1D already benefited from continuous glucose monitoring covered by the French national health insurance, while the deployment and support of closed-loop pump systems had not yet begun.

The total number of hospitalizations for severe hypoglycemia in the pre- vs. post-surgery period was 1 vs. 5, respectively. Similarly, diabetic ketoacidosis (DKA)-related hospital stays were three in the pre-surgery versus seven in the post-surgery period (Table 3). Finally, the total number of hospitalizations for acute metabolic events (severe hypoglycemia, coma, and DKA) more than doubled in the 3 years following BS compared with the period before surgery ($p = 0.04$).

DISCUSSION

Our study provides an epidemiological view of the use of BS in people with T1D in France as

Table 2 Comparison in the healthcare use and costs from the 3-year periods before and after bariatric surgery in the subpopulation of patients living with type 1 diabetes operated in 2016–2017 ($N = 154$)

Healthcare use	T1D 3 years before BS	T1D 3 years after BS	*p* value
Hospital care (mean ± SD)			
Stays of any cause	4.1 (5.7)	6.3 (20.4)	0.0236
Surgical stays	5 (0.9)	0.8 (1.2)	0.0066
Ambulatory care (mean ± SD)			
Diabetologist	5.2 (6.1)	5.2 (5.2)	0.8596
Neurologist	0.3 (1.1)	0.5 (1.3)	0.0926
Cardiologist	2.1 (2.6)	1.1 (2.1)	< 0.0001
Gastroenterologist	1.2 (2.0)	0.9 (2.0)	< 0.0001
Psychiatrist	4.9 (25.0)	2.3 (8.3)	< 0.0001
Nurse at home	28.1 (102.6)	40.2 (91.1)	< 0.0001
Emergency unit	1.2 (2.3)	1.2 (2.1)	0.9254
Biology (mean ± SD)			
Albumin	1.5 (2.3)	4.2 (4.0)	< 0.0001
Ferritin	2.3 (2.7)	5.4 (4.3)	< 0.0001
Calcium	2.8 (5.1)	5.4 (6.7)	< 0.0001
OH vitamin D	2.3 (2.6)	4.3 (3.2)	< 0.0001
Vitamin A	0.2 (0.4)	1.0 (1.7)	< 0.0001
Vitamin B12	1.0 (1.5)	4.1 (3.2)	< 0.0001
Drug delivery (average N/3 years)			
Anxiolytic	4.3 (9.8)	4.4 (10.3)	0.5981
Antidepressant	6.6 (13.3)	6.2 (12.1)	0.3459
Neuroleptic	1.7 (7.7)	1.5 (6.7)	0.6893
Antihypertensive	12.3 (14.6)	9.4 (12.6)	0.0659
Lipid-lowering agent	6.7 (10.7)	5.3 (9.2)	0.2146
Analgesic	12.5 (12.1)	12.7 (15.8)	0.5856
Antidiabetic agents	29.9 (9.4)	24.3 (10.3)	< 0.0001
Costs (mean ± SD) euros	**T1D 3y before BS**	**T1D 3y after BS**	***p* value**
Total healthcare expenditure	35,842 (31,876)	34,853 (37,347)	0.3559
Hospitalization	8041 (14,410)	8360 (16,801)	0.6049
Ambulatory care	27,800 (24,296)	26,493 (24,106)	0.3898
Physicians	5197 (11,264)	4780.9 (7547)	0.5174

Table 2 continued

Costs (mean ± SD) euros	T1D 3y before BS	T1D 3y after BS	*p* value
Paramedics	934 (3541)	1175.2 (3231)	0.0012
Pharmacy (overall)	7608 (6429)	6088 (8051)	< 0.0001
Antidiabetic agents	3979.3 (2926)	1826.5 (1136)	< 0.0001
Insulin and insulin analogs	3368 (2483)	1618 (1051)	< 0.0001
Medical devices	11,126 (9449)	10,953 (9004)	0.8693
Biology	919 (893)	1164 (1065)	0.0004

BS bariatric surgery, *SD* standard deviation, *T1D* type 1 diabetes

Table 3 Comparison in the hospitalized metabolic acute events associated with diabetes before and after bariatric surgery in patients with type 1 diabetes

	T1D 3 years before BS ($n = 154$)	T1D 3 years after BS ($n = 154$)	*p* value
Hypoglycemia	1	5	0.21
Coma	0	1	1
Ketoacidosis	3	7	0.34
Total metabolic acute events	4	13	0.04

BS bariatric surgery, *T1D* type 1 diabetes

a first assessment of its healthcare cost consequences in the real world.

The most commonly performed procedure in French patients living with T1D is sleeve gastrectomy as in the general population [27]. This is not the case in the pre-existing reported data in people living with T1D who had mostly undergone gastric bypass surgery [16, 17]. A probable excess risk of hypoglycemia and DKA after BS has been established in T1D [16] and we observed the same trend in our population. The risks of severe hypoglycemia or ketoacidosis in patients living with T1D remain a real concern, but may be reduced in the future by the widespread use of new closed-loop intelligent pump systems; a potential prerequisite for BS in the future. In addition, this emphasizes the importance of involving a diabetologist in the operative decision and ensuring that the patient knows how to adapt insulin doses to the diet (functional insulin therapy). As shown in the very recent systematic review by Parmar et al. [16], despite an increase in metabolic acute complications, there was no increased risk of mortality (data not shown).

Interestingly, at least one-third of our cohort had metabolic syndrome characteristics of mild obesity (32.7% with BMI 30–39.9 kg/m^2), hypertension (47.1%), dyslipidemia (37.1%) and antidiabetic treatment, including metformin (33.6%), in addition to insulin therapy. Though metformin is used to improve insulin resistance in people with T1D [11], in the large Swedish nationwide matched observational cohort [17], only 7% of patients undergoing gastric bypass surgery were treated by metformin. Similarly, the Swedish patients were less likely to be treated with lipid-lowering treatments (7.8%), although a similar proportion of patients were treated with antihypertensive treatments (54.4%). There is no difference in gender (predominantly female > 77%) or age (41–42 years old) between our cohort and the Swedish cohort that could explain the differences in treatment of these metabolic parameters. Interestingly, we did not observe any difference in the frequency of antihypertensive and lipid-lowering agent delivery before and after BS conversely to the results obtained in a long-term cohort of Spanish patients [28]. This could be related to the metabolic profile of the targeted patients with T1D undergoing BS or a result of therapeutic inertia in France without any possibility of distinguishing between these two explanations.

The higher risk of severe obesity (BMI > 35 kg/m^2) among women, who showed a 45% higher risk of severe obesity, compared with men is well known [29] if this higher prevalence of severe obesity among T1D women cannot be easily explained. Possible explanations related to gender include differences in age, insulin therapy over time, socioeconomic status, etc.

As expected, we show a net reduction in healthcare costs mainly related to antidiabetic agents (especially insulin) associated costs after BS. Weight loss is accompanied by a de facto reduction in insulin doses per kilo of body weight, as well as a very likely improvement in insulin sensitivity [30]. Conversely, there was an increase in healthcare costs related to biology due to the increased frequency and close monitoring of nutritional biological parameters (especially vitamin levels) after BS. What is more difficult to interpret is the rise in home nursing care expenditure or the increase in the number of nursing services performed after BS. This trend is probably the result of a combination of factors: an aging population, increasing use of insulin pumps, and greater delegation of medical tasks to nurses.

Ultimately, while healthcare expenditure is no different overall, for hospital and outpatient care inclusive, the trend observed in a pre-post comparison is towards a slight decline in total expenditure while average healthcare expenditure per patient with diabetes has increased over the same period of time in France [31]. Our study's limitations lie in the before-and-after approach taken to review individual patients. Even when used correctly, this approach may only suggest that the outcome is impacted by the intervention and does not take into consideration other factors that may also change when said intervention was implemented. Therefore, changes in healthcare resource use and costs observed in our study cannot be fully attributed to BS. This database also does not have clinical data except for hospitalizations for acute events related to diabetes, which are rare events in our study. In addition, the data does not allow us to determine the weight and/or the HbA1c benefit. Moreover, given the modest duration of follow-up, no effect on cardiovascular events could be demonstrated in our cohort. Finally, only reimbursement data were available but not out-of-pocket expenses, which are known to be significant for patients with obesity [32].

CONCLUSIONS

Our analyses of real-world data shows that BS is not rare in patients with T1D and suggests the potential clinical interest of such surgery in this population. The risks of severe hypoglycemia or ketoacidosis in patients with T1D undergoing BS remains a real concern and emphasizes the importance of involving the diabetologist in the operative decision. Significant decreases in reimbursements for antidiabetic drugs, including insulin, and the increase in biological assays of nutritional markers, show the importance of joint monitoring with the nutritionist. Finally, literature is scarce, and post-operative management still raises unsolved questions. Real-life prospective studies are needed.

Author Contributions. Claire Carette, Bruno Detournay, and Sébastien Czernichow contributed to the conception and design of the study, as well as the interpretation of the results. Data extraction and statistical analysis were performed by Elodie Torreton and Bruno Detournay. Claire Carette and Bruno Detournay drafted the initial version of the manuscript, and all authors (Claire Carette, Claire Rives-Lange, Nicholas Shoung, Aurélie Phan, Elodie Torreton, Anne Dutour, Bruno Detournay, Sébastien Czernichow) contributed to its editing, review, and final approval.

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Data Availability. The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy.

Declarations

Conflict of Interest. Claire Carette reported receiving personal fees from Boehringer Ingelheim, Axis Santé, Pfizer, Bioprojet Pharma, Novo Nordisk, AstraZeneca, Novartis, Ipsen, MSD, Eli Lilly and Publicis Health and nonfinancial support from Rhythm, Novo Nordisk, MSD, Novartis, Eli Lilly, Sanofi, AstraZeneca, Bristol-Myers Squibb, Abbott, Amgen, Vifor and Fresenius Kabi outside the submitted work. Sébastien Czernichow has received consulting and lecturing fees from Lilly, Fresenius, Novartis, Novo Nordisk, BMS, Boehringer Ingelheim, Pfizer, and Bariatek outside the current manuscript. Claire Rives-Lange: Personal fees from Nestlé Health Science. Supports for attending meetings: Nestlé home care and Fitform. Nicholas Shoung, Aurélie Phan, Elodie Torreton, Anne Dutour, Bruno Detournay have nothing to disclose.

Ethical Approval. This study was registered on the Health Data Hub website (T47730692021061). In accordance with current regulations, the study protocol was submitted to the 'committee for research, studies, and evaluations in the field of health' (Comité d'Expertise pour les Recherches, les Etudes et les Evaluations dans le domaine de la Santé [CEREES]) for approval and was authorized by the French data protection authority (Commission Nationale de l'Informatique et des Libertés [CNIL], [CNIL authorization number DR-2021-235]). The authorization permitted the implementation of data processing for a study on the epidemiological and economic aspects of BS in France, requiring access to SNIIRAM (système national d'information interrégimes de l'Assurance Maladie) and PMSI (programme de médicalisation des systèmes d'information) data, components of the SNDS for the years 2013 to 2020 (Authorization request no. 921320).

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