Natural History of Adjustable Gastric Banding: Lifespan and Revisional Rate: A Nationwide Study on Administrative Data on 53,000 Patients

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6 authors, including:

Andrea Lazzati

Centre Hospitalier Intercommunal Creteil

luca angelo Paolino

Hôpital Joseph Ducuing

Francesco Martini

Hôpital Joseph Ducuing

Antonio Iannelli

Centre Hospitalier Universitaire de Nice

Natural History of Adjustable Gastric Banding: Lifespan and Revisional Rate

A Nationwide Study on Administrative Data on 53,000 Patients

Andrea Lazzati, MD, PhDc,† *Marie De Antonio, PhDc,*† *Luca Paolino, MD,*‡ *Francesco Martini, MD,*‡ *Daniel Azoulay, MD, PhD,*§ *Antonio Iannelli, MD, PhD,*¶|| *and Sandrine Katsahian, MD, PhD*†**††

Objective: The aim of this study was to analyze the adjustable gastric banding (AGB) natural history on a national basis.

Background: Adjustable gastric banding represented the most common bariatric procedure in France until 2010. Since then, the number of AGBs has decreased and the rate of band removal and revisional surgeries has progressively increased.

Methods: For analysis, we included all adult patients operated on with AGB in France between 2007 and 2013. Data were extracted from a national administrative database ("Programme De Médicalisation des Systèmes d'Information," PMSI), which is an exhaustive source of all surgical procedures performed in France. The Cox proportional hazard model was used to test univariate and multivariate associations with band survival and revisional rate. To control for center-specific effects, we performed a frailty analysis, in which each center was assumed to have a random effect indicating the possibility of different baseline risks for patients at different centers.

Results: During the study period, 52,868 patients underwent AGB, and 10,815 bands were removed. The removal rate at 5, 6, and 7 years was 28%, 34%, and 40%, respectively. Female sex, body mass index >50 kg/m^2, type 2 diabetes, hypertension, dyslipidemia, and sleep apnea were found to be significantly associated with band removal by multivariate analysis. A significant center effect was also found, but this did not change the impact of the highly significant factors already identified. After band removal, the median time to revisional surgery was 1 year (95% confidence interval 1.0–1.1) and the conversion rate at 7 years was 71%.

Conclusions: With a removal rate of about 6% annually and the need for revisional surgery for more than two-thirds of patients after removal, AGB does not appear to provide a long-term solution for obesity.

Keywords: adjustable gastric banding, administrative data, bariatric surgery, center effect, survival

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From the *Department of General Surgery, Center Hospitalier Intercommunal de Créteil, Paris, France; †INSERM, UMR_S 1138, Université Paris Descartes, Center de Recherche des Cordeliers, Paris, France; ‡Pole de Coeliochirurgie, Hôpital Joseph Ducuing, Toulouse, France; §Department of Digestive, Hepatopancreatobiliary, and Liver Transplantation Surgery, Hôpital Henri Mondor, Paris, France; ¶Digestive Unit, Archet 2 Hospital, University Hospital of Nice, Nice, France; ||INSERM, U1065, Hepatic Complications of Obesity, University of Nice Sophia-Antipolis, Nice, France; **Assistance Publique, Hôpitaux de Paris, Hôpital Européen Georges-Pompidou, Unité d'Épidémiologie et de Recherche Clinique, Paris, France; and ††INSERM, Center d'Investigation Clinique 1418, module Épidémiologie Clinique, Paris, France.

Reprints: Andrea Lazzati, MD, PhDc, Department of General Surgery, Center Hospitalier Intercommunal de Créteil, 40 avenue de Verdun, 94000 Créteil, Paris, France. E-mail: andrea.lazzati@chicreteil.fr.

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Adjustable gastric banding (AGB) has been a very popular bariatric procedure worldwide for 2 decades for several reasons. It was the first bariatric procedure performed laparoscopically by most of the surgeons, and it is considered entirely reversible and offers the possibility to calibrate the outlet. Furthermore, the surgical technique is simple, straightforward, and is associated with a low postoperative morbidity and mortality.[1] However, data on the long-term efficacy of AGB are contradictory. Indeed, most series indicate that the rate of complications leading to AGB removal increases with time,[2] whereas other authors report good results in the long term.[3] Furthermore, these data are issued from single-center series and include a variable rate of patients lost to follow up.

AGB has been widely practiced in France since 1995 with more than 160.000 procedures performed to date.[4] However, a sharp decrease in the use of this procedure has been recorded over the last 5 years, with increases in other procedures, such as sleeve gastrectomy and gastric bypass.[5] Similarly, the number of band removals has progressively increased and, since 2012, more bands were removed than were placed.[4]

Although the rate of AGB removal is known to increase with time, the survival of the device and the revisional rate have not been investigated on a national basis in any country so far. As AGB has been widely used in France and has been practiced for more than 20 years, we aimed to define the lifespan of AGB and the preoperative factors associated with its removal on a national basis. We also describe the revisional rate and the type of bariatric surgery performed after band removal.

MATERIALS AND METHODS

Study Population

Data were extracted from the Programme De Médicalisation des Systèmes d'Information (PMSI) database, which is national prospective database providing information on all hospital stays, irrespective of hospital affiliation, including academic and nonacademic public hospitals and private clinics. Information is retrieved as standardized discharge reports consisting of one or more abstracts for each medical unit in charge of the patient. The discharge report contains primary and associated diagnoses based on the International Classification of Disease, 10th edition (ICD-10) and therapeutic procedures based on the Common Classification of Medical Acts [Classification Commune des Actes Médicaux (CCAM), 11th edition], which is a national standardized classification of medical procedures. CCAM was introduced in France in 2005 to establish the reimbursement for all medical procedures. It is used to establish the diagnosis-related group (DRG) and the pricing of hospital stays. It consists of a hierarchical coding, where each code is composed of four letters and three numbers. Letters indicate the anatomical part (apparatus and organ), the type of action, and the surgical approach (or technique) used. Digits are used to differentiate between acts with four identical letter keys.

Each patient in the PMSI database is identified with a unique alphanumerical anonymous identifier, created before anonymization with the patient's social security number, date of birth, and gender, which enables all patient hospitalizations to be followed. Since discharge reports are obligatory and constitute the basis of hospital funding, the PMSI database provides exhaustive information on all surgical interventions in France. As the PMSI database is anonymous and publicly available, patients' consent was not obtained.

Inclusion and Exclusion Criteria

We obtained data for all bariatric procedures performed in France between January 1, 2007, and December 31, 2013, inclusive. Our analysis was restricted to adults (aged >18 yrs) operated on for AGB. Patients were identified through the CCAM codes HFMC007 for laparoscopic AGB and HFMA009 for open-surgery AGB. Band removals and replacements were respectively identified through the codes HFMC008 and HFKC001 for laparoscopic approach, and through the codes HFMA011 and HFKA002 for open procedures. Patients that had more than one AGB in the selected period were included only for the time span of the primary procedure.

Outcomes

The main outcome of this study is the assessment of device survival of all AGBs placed in France between 2007 and 2013. The secondary outcome was the revisional rate after band removal.

Confounders

We adjusted the risk of band removal for age, sex, body mass index (BMI), comorbidities (hypertension, dyslipidemia, type 2 diabetes, and obstructive sleep apnea syndrome), year of AGB positioning, hospital affiliation (private or public), surgical approach (laparoscopic, open), hospital volume, and modification of surgical practice.

Hypertension (HT) was identified with the ICD-10 code I10. We included the codes E780–785, E788, and E789 for dyslipidemia, and the code G473 for obstructive sleep apnea syndrome (OSAS). Type 2 diabetes (T2D) was identified through the codes E10.X–E14.X.

ICD-10 codes for obesity are the codes E66.X. In the French version of ICD-10, obesity is stratified into four categories (obesity with a BMI from 30 to 40 kg/m^2, from 40 to 50 kg/m^2, >50 kg/m^2, and BMI unspecified). Patients in the category "BMI unspecified" were excluded from the analysis.

Hospital procedural volume was defined as the number of AGBs performed per year in each hospital irrespective of the number of surgeons affiliated with each hospital. Hospital volume was coded as a binary variable. We used the 50th percentile of the total number of AGBs to define the cut-off point (ie, 51% of AGBs are positioned in hospitals with ≤50 procedures per year, 49% in hospitals with >50 procedures per year).

To evaluate the modification of surgical practice of each bariatric center, we created a variable called "AGB reduction." We assessed for each center the proportion of AGBs as a part of the total number of bariatric procedures. A coefficient was computed for each center with a linear regression. The coefficient was then dichotomized, taking the value of "0" when the coefficient was equal to zero or positive (ie, the proportion of AGBs that did not decrease over the study period) or "1" when the coefficient was negative (ie, the proportion of AGBs that decreased over the study period).

Statistical Analyses

We used mean and SD for continuous variables and frequencies for categorical variables for descriptive statistics. Main outcomes were assessed through a survival analysis using the Kaplan-Meier method with 2-sided 95% confidence intervals (CI) of hazard ratios (HRs). Factors significant at $P < 0.10$ in the univariate analyses were used in the multivariate model. The Cox proportional hazard model was used to test univariate and multivariate associations with band survival. A model was first developed to determine demographic risk factors for the outcomes of interest. The second model was then developed to determine hospital risk factors in the presence of baseline factors identified in the first model. Then we implemented the two first models to control for center-specific effects, performing a frailty analysis. In the frailty model, each center was assumed to have a random effect, which indicated the possibility of different baseline risks for patients at different centers. All analyses were performed by using R, version 3.1.2. (R Foundation for Statistical Computing, Vienna, Austria), and "survival" package.

RESULTS

Between January 1, 2007, and December 31, 2013, 57,917 AGBs were placed in France. Among these AGBs, we excluded 1265 patients undergoing a second AGB and patients less than 18 years of age (n = 398). All patients presenting the code for BMI unspecified or missing were also excluded (n = 3534). Therefore, the study group consisted of the remaining 52,868 AGBs.

The baseline characteristics of patients included in the study are presented in Table 1. The procedure was mainly performed in patients with a BMI <50 kg/m^2 with only 5.0% of super-obese patients (BMI > 50 kg/m^2) undergoing AGB. Hypertension was the most common obesity-related comorbid condition, which was found in 17.6% of patients undergoing AGB, whereas type 2 diabetes (T2D), obstructive sleep apnea syndrome (OSAS), and dyslipidemia were found in 8.0%, 8.8%, and 8.6% of patients, respectively (Table 1).

Band Removal

Overall, 10,815 patients underwent AGB removal during the study period. The removal of the band was performed in an emergency

TABLE 1. Patients' Baseline Characteristics

	No.	%
Sex		
Male	7549	14.3
Female	45319	85.7
Age, mean ± SD (range)	36.3 ± 11.2	(18–79)
Age		
18–30	18735	35.4
30–40	16079	30.4
40–50	11155	21.1
50–60	5769	10.9
>60	1130	2.1
BMI, kg/m^2		
30–40	18673	35.3
40–50	31571	59.7
>50	2624	5.0
T2D		
No	48640	92.0
Yes	4228	8.0
HT		
No	43586	82.4
Yes	9282	17.6
OSAS		
No	48192	92.2
Yes	4676	8.8
Dyslipidemia		
No	48346	91.4
Yes	4522	8.6

BMI indicstes body mass index; HT, arterial hypertension; OSAS, obstructive sleep apnea syndrome; T2D, type 2 diabetes.

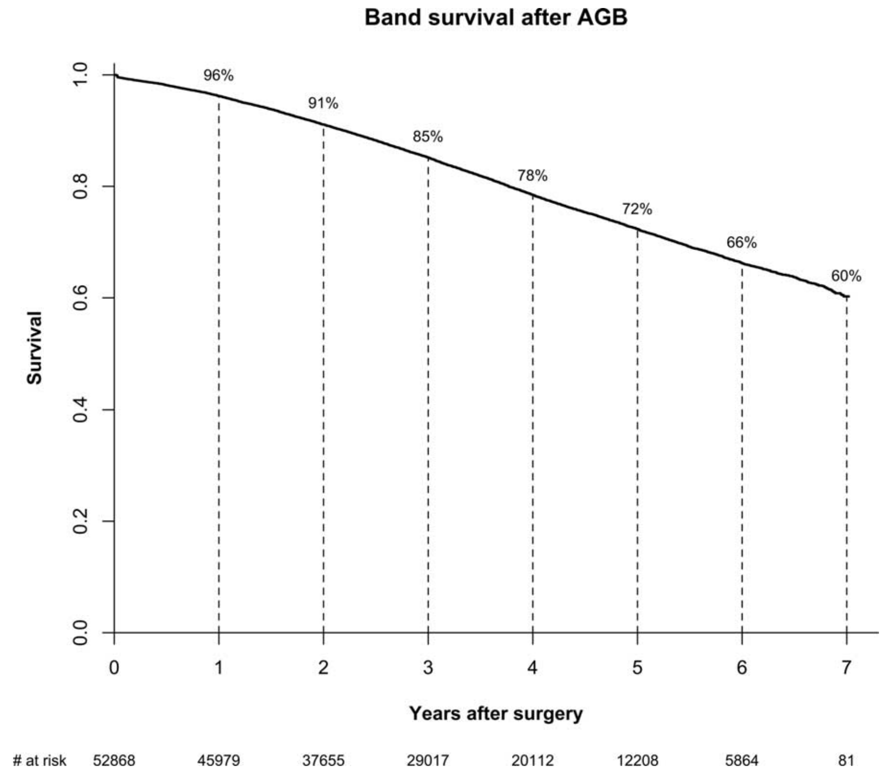

FIGURE 1. Band survival of adjustable gastric banding in France between 2007 and 2013.

setting for 6.3% of patients and as a scheduled operation for the remaining 93.7%. Most of the bands (63.1%) were removed in a different hospital from the one in which the band had been positioned. In discharge abstracts after band removal, the most common primary diagnoses were mechanical complications of the device (39.2%, codes T85.5x) followed by obesity (28.0%, codes E66.x), dysphagia and vomiting (4.5%, codes K91x, R11, and R13), and GERD (1.1%, codes K21x). The survival curve of the band indicates that 28% of AGB were removed at 5 years, 34% at 6 years, and 40% at 7 years (Fig. 1).

Figure 2 shows the band lifespan plot of AGBs stratified by hospital volume. The majority of hospitals (n = 486) performed less than 51 procedures per year with a variable rate of device implantation time. In hospitals performing more than 50 AGB procedures per year (n = 16), the band survival ranged from 83% to 58% at 5 years postoperatively, and from 77% to 45% at 7 years.

Univariate analysis is presented in Table 2. Two variables (year of surgery and surgical approach) were not significant at $P <$ 0.10 and therefore were excluded in multivariate analyses. All other factors were included in the multivariate model (Table 3).

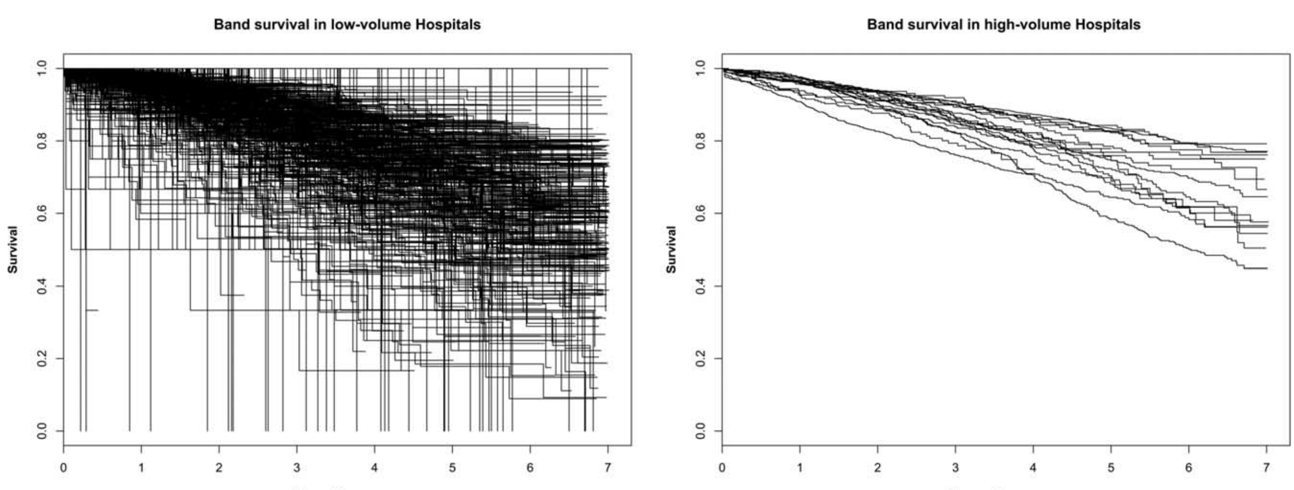

FIGURE 2. Band survival of adjustable gastric banding for low-volume hospitals (<50 procedures per year, n = 486) and high-volume hospitals (>50 procedures per year, n = 16).

TABLE 2. Univariate Analysis for Graft Survival

	HR	95%CI	P
Sex			
Male	reference		
Women	1.46	1.37–1.54	<0.001
Age, yrs			
18–30	reference		
30–40	1.01	0.96–1.05	0.719
40–50	0.98	0.93–1.03	0.543
50–60	0.95	0.89–1.01	0.132
>60	0.69	0.59–0.81	<0.001
BMI			
<40	reference		
40-50	1.19	1.14–1.24	<0.001
>50	1.95	1.80–2.13	<0.001
T2D			
No	reference		
Yes	1.25	1.18–1.33	<0.001
HT			
No	reference		
Yes	1.19	1.14–1.25	<0.001
OSAS			
No	reference		
Yes	1.39	1.31–1.48	<0.001
Dyslipidemia			
No	reference		
Yes	1.28	1.21–1.36	<0.001
Surgical approach			
Laparoscopic	reference		
Open	1.13	0.89–1.45	0.314
Hospital affiliation			
Public	reference		
Private	0.88	0.84–0.92	<0.001
Hospital volume			
≤50	reference		
>50	0.81	0.78–0.84	<0.001
Year*	1.01	0.99–1.025	0.19
AGB reduction			
No	reference		
Yes	1.21	1.11–1.32	<0.001

BMI indicates body mass index; CI, confidence interval; HR, hazard ratio; HT, arterial hypertension; OSAS, obstructive sleep apnea syndrome; T2D, type 2 diabetes.
*Year: indicates the year of surgery (2007–2013).

In the first model, we used a Cox model on patients' characteristics only. Factors with the greatest HR were BMI >50 kg/m^2 and female sex (HR 1.83 and HR 1.62, respectively). All comorbidities of obesity were significantly associated with AGB removal. HRs of age showed a progressive decrease, although the association with band survival only became significant after 40 years of age. The model suggests that age has a protective effect against band removal.

In the second model, we included three factors related to centers with a fixed effect. All patient-related risk factors remained significant. Hospital affiliation, which was significant in univariate analysis, was no longer associated with band survival. The variable AGB reduction was highly significant. Similarly, hospital volume was strongly related to the outcome, suggesting that bands positioned in high-volume centers have a longer lifespan. After inclusion of the random effect to assess the center effect, hazard ratios and *P* values did not change in the third model (patients' characteristics and random effect). In the fourth model, the variable "AGB reduction" was only barely significant (HR 1.23, 95%CI 1–1.51, $P = 0.05$).

Revisional Surgery After Band Removal

Among the 10,815 patients who had the band removed, 5992 had a revisional bariatric procedure either at the same time as the band removal (21% of patients) or as a second procedure. Sleeve gastrectomy was the most common revisional procedure (n = 2657, 44.3%), followed by gastric bypass (n = 1804, 30.1%), a second AGB (n = 1498, 25.0%), and biliopancreatic diversion (n = 33, 0.6%). The median time to revision was 1 year (95 CI 1.0–1.1), and the cumulative risk of revisional surgery after band removal at 7 years was 71% (Fig. 3).

DISCUSSION

The strengths of the PMSI database lie both in the number of eligible patients and in the exhaustive data available from every hospital in the country. As a result, we were able to fully explore AGB natural history at a level not previously possible in a bariatric population. Our study shows that the band survival decreased progressively and constantly over time, with an average of 5.6% of AGBs removed each year in France between 2007 and 2013.

Several studies have reported high reoperation and removal rates in the medium and long term.[6,7] Recently, Aarts et al[8] published 14 years of results with a 99% follow-up rate for 201 patients. The authors found a 46% band survival rate and a reoperation rate of 67%. Similarly, Victorzon et al[9] reported a removal rate of 48% and a reoperation rate of 63% in a series of 60 patients at 15 years with a high follow-up rate. A much lower removal rate in the long term (5.6%) was reported by O'Brien et al.[10] Nevertheless, revisional or reversal surgery was necessary in 43% of patients. Such differences between these studies can be explained by the authors' policy of repositioning the AGB in cases of complications, such as erosion or proximal gastric dilation, or even in the case of bariatric failure. Whatever the strategy used after complications, most of the articles suggest that in the long term, about half of patients with an AGB will be reoperated on. There are two major limitations to all the aforementioned studies. First, they are all issued from centers of excellence or those with a high specialization in the field of bariatric surgery. Hence, it may be questioned whether these results can be generalized to all bariatric centers. The second limitation of most of these studies is the rate of patients lost from follow up. Indeed, in the current study, most AGBs (63.1%) were placed and removed in different hospitals. With such a high rate of hospital variation, it becomes difficult to estimate the removal rate of the band. In contrast to all previous studies, we were able to assess the band lifespan for every patient and for all bariatric centers in the whole country in spite of any loss from follow up at the center where the AGB had been positioned.

Univariate and multivariate analyses identified several patient-level variables associated with band lifespan. Female sex, younger age, higher BMI, and the presence of comorbidities (T2D, HT, OSAS, and dyslipidemia) were all significantly associated with a shorter band survival.

It is difficult to compare our results with previous studies as most of them do not consider the same outcome measures. Indeed, we focused on band survival, whereas usually weight loss and resolution of comorbidities are used as the dependent variables. Older age, high preoperative BMI, and male sex are some of the risks factors that have been previously associated with lower weight loss and comorbidity resolution.[11–14] Some factors, like BMI, are indeed associated with postoperative complications leading to band removal, as shown in previous studies. Nevertheless, other factors, like female sex and younger age, which seem inconsistent with previous studies, could be interpreted in a different setting. Women and younger patients could be more "aggressive" in their weight loss

TABLE 3. Multivariate Analysis of Graft Survival

	MODEL 1: Cox Model Including Only Patients' Characteristics			MODEL 2: Cox Model Including Patients' And Hospitals' Characteristics			MODEL 3: Frailty Model Including Patients' Characteristics			MODEL 4: Frailty Model Including Patients' And Hospitals' Characteristics		
	adjHR	95% CI	*P*	adjHR	95% CI	*P*	adjHR	95% CI	*P*	adjHR	95% CI	*P*
Patient-level variables												
Sex												
Male	reference			reference			reference			reference		
Female	1.62	1.52–1.72	<0.001	1.61	1.51–1.71	<0.001	1.60	1.5–1.7	<0.001	1.60	1.5–1.7	<0.001
Age, yrs												
<30	reference			reference			reference			reference		
30–40	0.99	0.94–1.03	0.55	0.98	0.94–1.03	0.49	0.99	0.95–1.04	0.72	0.99	0.95–1.04	0.71
40–50	0.90	0.86–0.96	<0.001	0.90	0.86–0.95	<0.001	0.91	0.86–0.96	<0.001	0.91	0.86–0.96	<0.001
50–60	0.77	0.72–0.83	<0.001	0.77	0.72–0.83	<0.001	0.77	0.71–0.82	<0.001	0.77	0.71–0.82	<0.001
>60	0.54	0.46–0.64	<0.001	0.54	0.46–0.63	<0.001	0.53	0.45–0.63	<0.001	0.53	0.45–0.63	<0.001
BMI												
<40	reference			reference			reference			reference		
40–50	1.18	1.13–1.23	<0.001	1.18	1.13–1.23	<0.001	1.27	1.21–1.32	<0.001	1.26	1.21–1.32	<0.001
>50	1.83	1.68–1.99	<0.001	1.84	1.69–2	<0.001	2.01	1.85–2.19	<0.001	2.01	1.84–2.19	<0.001
HT	1.17	1.11–1.23	<0.001	1.16	1.1–1.23	<0.001	1.15	1.09–1.22	<0.001	1.15	1.09–1.22	<0.001
T2D	1.15	1.07–1.23	<0.001	1.14	1.07–1.22	<0.001	1.14	1.07–1.23	<0.001	1.14	1.07–1.23	<0.001
OSAS	1.39	1.31–1.49	<0.001	1.38	1.3–1.47	<0.001	1.43	1.34–1.53	<0.001	1.43	1.34–1.53	<0.001
Dyslipidemia	1.26	1.19–1.34	<0.001	1.27	1.19–1.35	<0.001	1.35	1.26–1.44	<0.001	1.35	1.26–1.44	<0.001
Hospital-level variables												
Hospital affiliation												
Public				reference						reference		
Private				1.00	0.95–1.05	0.98				1.02	0.9–1.15	0.77
Hospital volume												
≤50 per year				reference						reference		
>50 per year				0.82	0.79–0.86	<0.001				0.79	0.7–0.89	<0.001
AGB reduction												
No				reference						reference		
Yes				1.23	1.12–1.35	<0.001				1.23	1–1.51	0.05
Center effect							variance = 0.26		<0.001	variance = 0.22		<0.001

BMI indicates body mass index; CI, confidence interval; HR, hazard ratio; HT, arterial hypertension; OSAS, obstructive sleep apnea syndrome; T2D, type 2 diabetes.
Model 1 and 2: Cox proportional hazard model.
Models 3 and 4: Frailty model.

treatment, preferring to move toward revisional surgery to improve the obtained weight loss that is perceived as poor even in the absence of a real AGB complication.

Our findings document an important center effect on band survival. One way to describe the variability among hospitals is depicted in Figure 2, in which we present the AGB lifespan according to hospital volume. In low-volume hospitals (≤50 procedures per year), the band survival plot is difficult to interpret because of the variability in the results. Nevertheless, a general trend seems to outline a band survival rate between 80% and 50% at 5 years. This interval can be precisely measured for high-volume hospitals resulting in a survival rate of between 83% and 58% at 5 years and between 77% and 45% at 7 years after surgery.

By multivariate analysis, we tested three hospital-level variables as fixed effects: hospital affiliation, hospital volume, and the modification of surgical practice. First, hospital affiliation (public vs private), which was significant in the univariate analysis in favor of private clinics after adjustment for patients' covariates, was no longer associated with band survival, suggesting that baseline patient characteristics explain the difference between the private and public centers.

Then we assessed the relationship between AGB survival and number of procedures per year. Hospital volume has already been associated with postoperative morbidity in bariatric surgery.[15] Unsurprisingly, our model confirms that bands positioned in higher-volume centers have a longer survival than AGBs positioned in low-volume hospitals.

To include in our analysis the evolution in the panel of bariatric procedures practiced in each center, we created a variable assessing the reduction of AGBs compared with other bariatric procedures. This variable is associated with band removal, suggesting that the reduction in AGBs and the augmentation of other procedures could accelerate band removal. This trend could be explained by the fact that in hospitals where AGB is no longer offered or is significantly reduced, the access to postoperative care for AGBs may become more difficult. Hence, this could lead to the interruption of follow up. Several studies have shown that a regular follow up is associated with better results in patients with AGB.[16–18] We may also argue that the diffusion of other procedures, such as sleeve gastrectomy and gastric bypass, which are associated with better weight loss, may have accelerated the phenomenon of AGB removal. The advent of more effective procedures could have encouraged bariatric surgeons to propose and patients to seek revisional surgery to improve weight loss, comorbidity resolution, and quality of life.

We also performed frailty models to consider the unexplained variability from different centers. A significant center effect was found when we included only patient-level variables (Table 3, model 3) or when we also included hospital-level variables (Table 3, model 4). The variance in the random effect slightly

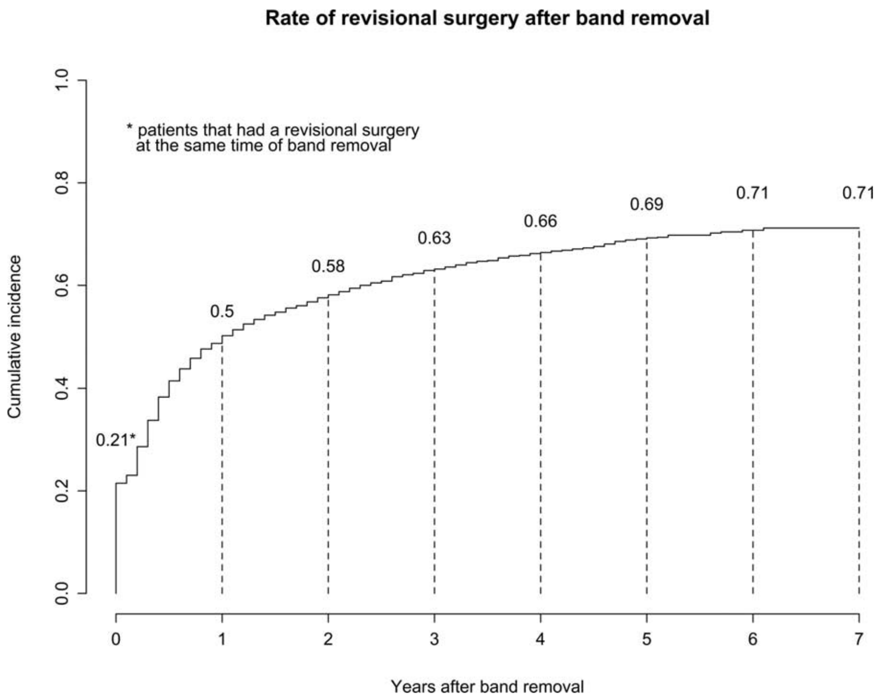

FIGURE 3. Cumulative risk of revisional surgery after band removal.

decreased from 0.26 to 0.22 between models 3 and 4, suggesting that the three hospital-related factors partially explain the difference between hospitals. Nevertheless, the center effect remains strongly significant, indicating that other latent factors influence the difference between surgical centers.

Finally, we analyzed the revisional rate after band removal. We found a 71% cumulative risk of conversion to another bariatric procedure among patients that had their band removed. This data suggests that the majority of patients still seek a surgical solution for their obesity. In fact, at revision, 55.1% of patients still had a BMI $>40\,kg/m^2$.

The main limitation of the current study lies in the lack of information on the indication for AGB removal. However, although this information would have added considerably to the current knowledge on the mechanisms leading to AGB removal, the crude information we provide is relevant in itself to guide the bariatric surgeon and his or her patients in the process of choosing the most appropriate bariatric procedure. The other potential bias concerns those patients undergoing AGB removal in a country other than France and those undergoing removal in France of an AGB that had been placed in a country other than France. However, as AGB is offered with no additional fee by the national French healthcare system to all patients meeting the ‘‘Haute Autorité de Santé’’ indications for bariatric surgery, which overlap those of the NIH, this bias remains only a remote possibility.

In conclusion, the main strength of this study relies on the fact that the information on the PMSI database is exhaustive, as it includes all discharge records of patients undergoing AGB placement and removal during the study period. The current study is the first to the authors' knowledge to provide a definitive measure of the band survival and revisional rate after removal in a large national sample. The results of the current study question the long-term efficacy of AGB, as 40% of bands are removed at 7 years and more than two-thirds of patients need a revisional surgery after removal.

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