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French health insurance data for chronic rhinosinusitis with nasal polyps between 2011 and 2018: a STROBE-compliant analysis

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Abstract

Aims: The main aim of the present study was to report the annual volume of surgeries performed for chronic rhinosinusitis with nasal polyps (CRSwNP) in France, based on health insurance data. The secondary objectives were to describe the different characteristics of the surgeries and their complications, and to estimate the number of patients eligible for biotherapy.

Material and Methods: This was a descriptive observational retrospective study using data from French national health insurance databases for the period 2011-2018. Inclusion criteria comprised all hospital stays with procedures related to CRSwNP according to the French Common Classification of Medical Acts and consistent with French practices.

Results: 92,141 patients for 92,884 admissions for CRSwNP surgery were analyzed, providing an accurate representation of CRSwNP surgery in France between 2011 and 2018. The revision surgery rate for patients operated on in 2011 was 13.0% (1,457/11,212), corresponding to an average annual rate of 1.86% over 7 years. In the 11,750 sinus surgery admissions in 2018, the complications rate was only 0.65% (77/11,750).

Conclusion: Sinus surgery is safe (0.65% complications) and reliable (estimated revision rate, 5.5%: 5,078/92,884). This study provides the first evaluation of the target population for biotherapy in France.

Keywords: chronic rhinosinusitis with nasal polyps; surgery; complications; epidemiology

1. Introduction

Chronic rhinosinusitis with nasal polyps (CRSwNP) severely impacts quality of life [1,2]. It also incurs high health-care costs, at \$8,000 per patient per year in the USA [3,4]. Biotherapies have recently been included in the therapeutic strategy for CRSwNP patients [5]. In France, this is a salvage treatment when control is insufficient with medication (50% of patients resorting to surgery [6]) and primary surgery (20% of patients with recurrence requiring revision [7]) (<https://www.legifrance.gouv.fr/eli/jo/2021/7/27/0172>). In the USA, 257,000 sinus procedures are performed each year [8]. In England and Wales, about 9,000 polypectomies are performed each year [9]. These were the only two studies reporting representative national data, and are now more than 15 years old, limiting extrapolation.

Using the French PMSI medical database to analyze the hospital care pathway of patients undergoing surgery for CRSwNP could help assess a population potentially eligible for biotherapy. The rate of surgical revision varies from 11.8% to 27%, depending on the report [9–11].

The main aim of the present study was to determine the number of primary and revision surgeries for CRSwNP in France, based on national health insurance data. The secondary objectives comprised detailing the types of surgery, and estimating the number of patients potentially eligible for biotherapy.

2. Methods

2.1 Study design

A descriptive observational study was performed for the period 2011-2018, using the national PMSI medical database of the French national health insurance agency. Data were acquired by the PKCS consultancy from the ATIH Hospital Data Technical Agency via the CASD Secure Data Access Center. The study was registered with the CNIL data protection commission as being of public interest according to the MR006 reference methodology. All data were strictly anonymous.

2.2 Study population

Two populations were studied: i) patients operated on in 2011 and followed up until 2018 (7 years' data: 2011-2018), and ii) in a transverse analysis, patients operated on in 2018 (with analysis of history). The study design is shown in **figure 1**.

The inclusion criteria covered all hospital stays involving CRSwNP surgery according to the French Common Classification of Medical Acts (CCAM) and consistent with French practices. The PMSI database described all hospital stays, with one principal diagnosis, one related diagnosis and, if appropriate, one significant associated diagnosis. The methodology was finalized by close analysis of the available data, ICD-10 codes and CCAM codes and coding variants. The CCAM acts included were: GAFD002 (intranasal polypectomy), LAFA022 (total bilateral endoscopic ethmoidectomy) LAFA020 (total bilateral endoscopic ethmoidectomy with nasal septoplasty), LAFA019 (total bilateral endoscopic ethmoidectomy with nasal septoplasty and sphenoidotomy), LAFA018 (total bilateral endoscopic ethmoidectomy with sphenoidotomy), and GBFA008 (anterior bilateral endoscopic ethmoidectomy with nasal septoplasty). As the surgical algorithm could associate meatotomy, hospital stays with meatotomy were also included if the patient was subsequently admitted with one of the above CRSwNP-related codes. Older codes, no longer used but still in

use in 2011, were also included: GBFE012 (anterior bilateral endoscopic ethmoidectomy with septoplasty), LAFE004 (total bilateral endoscopic ethmoidectomy with sphenoidotomy), LAFE005 (total bilateral endoscopic ethmoidectomy with nasal septoplasty and sphenoidotomy), LAFE006 (total bilateral endoscopic ethmoidectomy with nasal septoplasty), and LAFE008 (total bilateral endoscopic ethmoidectomy).

Admissions with invalid anonymous chaining code were excluded from patient-based analysis, and admissions in “major category” 90 were excluded, as this category includes two groups identified during the grouping process for which the hospital admission was unclassifiable: “Invalid diagnosis as principal diagnosis in some circumstances” and “Other errors detected during the grouping process”.

2.3 Description of revision surgeries

Data for revision surgeries were analyzed on an annual basis, to obtain a precise description of practices. The overall revision rate, estimated for 2018 on the basis of patients operated on in 2011 (with 7 years’ follow-up), was calculated as the proportion of patients undergoing more than 1 procedure between 2011 and 2018; The annual revision rate was calculated by dividing the overall rate by 7 (i.e., the 7 years between 2011 and 2018). For reasons of data availability, operations performed before 2011 were not considered for analysis.

2.4 Description of hospital stays in 2018

The PMSI database featured hospital stays in 2018, with type and location of the center, and data for gender, age, principal pathology and associated pathologies. Type of admission (outpatient or inpatient) and type of center (private hospital, non-profit private hospital, hospital center, or regional (including university) hospital center) were entered. Length of stay (nights) and economic data (“price per activity”: T2A)

were collected for 2018. Acts performed during hospital stay were analyzed by subgroup (septoplasty, meatotomy, ethmoidectomy, polypectomy) in order to identify associated procedures and determine the most frequent procedure.

2.5 Description of surgical complications

In 2018, specific complications requiring revision surgery comprised:) meningeal breach, meningocele, intra-orbital hematoma, subdural empyema, and intra-cerebral abscess. The proportion of complications after CRSwNP surgery requiring revision surgery was calculated from the number of procedures and the number of revision procedures for complications. Procedures identified by CCAM codes comprised: osteomeningeal breach closure (ABSA011), meningocele closure (ABSA012), orbital decompression (LAPA012 or LAPA003), and intracranial abscess drainage (AAJH001, AAJH003, or AAJA001).

2.6 Population eligible for biotherapy

The number of patients potentially eligible for biotherapy was estimated from the proportion of patients requiring a second procedure (<https://www.legifrance.gouv.fr/eli/jo/2021/7/27/0172>).

2.7 Statistics

PMSI data were analyzed. This database includes all hospital stays. The methodology was finalized using ICD-10 and CCAM codes, taking account of coding variants. Categorical variables were reported as number and percentage, and continuous variables as mean and standard deviation. Intergroup comparison used chi² or Fisher test as appropriate for categorical variables and Student t or Wilcoxon test for continuous variables. The significance threshold was set at p<0.05. Analyses used R software, v. 4.1.2 (R Foundation for Statistical Computing, Vienna, Austria, www.r-project.org).

3. Results

3.1 Population

There were 92,884 admissions for CRSwNP surgery. Table 1 shows demographic data for 2018 (11,695 patients for 11,750 admissions). There were 64.1% males. Mean age was 49.5 years; the most common age group was 50-59 years (22.6%, 2,660/11,750); 12.2% of admissions were for under-30 year-olds (1,439/11,750), and 1.96% for over-80 year-olds (230/11,750).

3.2 Description of revision surgeries

Data for 2011-2018 showed a revision surgery rate of 5.5% (5,078/92,884) in terms of more than 1 admission for 1 patient with whatever length of follow-up. For patients with 7 years' follow-up (11,212 patients operated on in 2011 with data extracted in 2018), there were 1,449 revision surgeries in 1,252 patients: i.e., a rate of 13.0% (1,449/11,212). The mean annual rate of revision surgery was thus estimated at 1.86% (13.0% over 7 years). Mean stay for revision surgery of whatever type was shorter than for primary surgery: respectively, 1.1 versus 1.5 days. As seen in figure 2, Regional Hospitals were more frequently involved in revision (29.3%; 341/1,162) than in primary surgery (20.0%; 233/1,162), and the private sector less frequently (52.1%; 606/1,162) than in primary surgery (59.8%; 695/1,162).

3.3 Description of hospital stays in 2018

The annual number of patients undergoing CRSwNP surgery between 2011 and 2018 was stable, with 11,342 admissions in 2011 and 11,750 in 2018. The private sector

performed 59.8% of surgeries (695/1,162) and the public sector 40.2% (467/1,162): 20.1% (233/1,162) in regional hospitals, 14.9% (173/1,162) in local hospitals and 5.2% (61/1,162) in non-profit private hospitals (Table 1). Regarding number of days' stay: 37.3% (4,381/11,750) of admissions were for day surgery, 39.9% (4,687/11,750) for 1 night, 15.7% (1,850/11,750) for 2 nights, 4.15% (476/11,750) for 3 nights and 3.0% (356/11,750) for ≥ 4 nights. Stays exceeding 5 nights accounted for 1.8% of stays (215/11,750). In 2018, the proportion of patients undergoing polypectomy as day surgery was greater than for polypectomy with 1 night's hospital stay: 27.0% (1,181/4,381) vs 9.9% (465/4,687), respectively).

Table 2 shows procedures associated to ethmoidectomy or polypectomy in CRSwNP surgery. In the 11,750 admissions in 2018, 17,573 procedures were performed, with 1-stage associations (e.g., ethmoidectomy + meatotomy + polypectomy); 55.8% of procedures (n=9,815/17,573) were ethmoidectomies. Ethmoidectomy was either isolated (54.3%, n=5,330/9,815), or associated (45.7%, n=4,485/9,815), notably to meatotomy (34.0% of cases; n=3,332/9,815) (Table 2).

3.4 Description of surgical complications

In the 11,750 admissions in 2018, 77 complications required surgery. Sixty concerned closure of an osteodural breach or meningocele drainage, 15 concerned orbital decompression, and 2 concerned craniotomy to evacuate an extracerebral intracranial empyema. Thus, the complications rate for 2018 was 0.65%.

3.5 Description of the population eligible for biotherapy

In 2011-2018, 5,078 patients were operated on at least twice: i.e., a revision rate of 5.5% (5,078/92,884).

4. Discussion

92,141 patients, for 92,884 hospital admissions for CRSwNP surgery, provided an accurate representation of CRSwNP surgery in France for the period 2011-2018. The surgical revision rate for patients operated on in 2011 was 13.0% (1,457/11,212), with a mean annual rate of 1.86% over 7 years. Only 0.65% of the 11,750 admissions in 2018 (77/11,750) incurred specific complications requiring revision. Overall, for the period 2011-2018, 5,078 patients were operated on at least twice; these patients constitute the potential indications for biotherapy in 2018.

Despite the large number of admissions for CRSwNP surgery, French national data for type of admission and perioperative complications are sparse. This contrasts with the situation in other countries. In the UK, NHS (national health service) audits of ENT procedures are published on many aspects of nasal and sinus day surgery: type and length of stay, rate of reoperation, specific quality-of-life data, type and rate of complications [7,9,12,13]. Some of these parameters are also covered in the French PMSI database.

Firstly, the surgical revision rate for patients operated on in 2011 (13.0%, 1,457/11,212) was close to that reported in large series: Hopkins *et al.* in 2006 (11.8% at 3 years (153/2,176) [9]), Hopkins *et al.* in 2009 (20.6% at 5 years, n=215/1045 [11]), Loftus *et al.* (24.9% at 5 years, n=84/338 [14]) and Smith *et al.* (29.9% at 20 years; n = 2,743/9,177) [15]. Attention must be paid to follow-up time in comparing reported results. The revision rate reported by Smith *et al.* was higher than in the present study (15.9%, 4,760/29,934), but with a mean 20 years' follow-up [15], while it was lower for Hopkins *et al.* in 2006 (11.8%, 153/2,176) at 3 years' follow-up [9]. Thus follow-up time plays a major role. Concerning predictive factors for revision, Hopkins *et al.* found a significant

relative reduction in risk on multivariate analysis with first-line ethmoidectomy rather than simple polypectomy (adjusted odds ratio = 0.66; $p = 0.04$) [7]. Recurrence rates may correlate with the extent of sinus surgery [16–18]. Other independent risk factors comprise: advanced age at primary surgery, female gender, and associated asthma or allergy [15].

Secondly, hospital stay was related to the type of procedure. In the 11,750 admissions in 2018, type of procedure and type of admission (day surgery or overnight stay) varied together. 37% of admissions for primary surgery were on an outpatient basis, and 77% of stays were of 1 day or less. In day surgery, the proportion of polypectomies was higher than in overnight admission: 27.0% vs 9.9%, respectively. This is fairly natural, as polypectomy is a less heavy procedure than ethmoidectomy. Only 1.8% of stays were for 5 days or more; this was for organizational reasons or reflected recruitment, as some centers mainly treated patients with severe comorbidity. The main associated diagnoses affecting length of stay were hypertension, asthma, sleep disorder and diabetes. In the present study, only 4.8% of admissions (563/11,750) concerned asthma patients, which was less than the comorbid asthma rate generally reported (47% for Philpott *et al.* [19]). Coding bias for associated diagnoses may have led to underestimation of the true prevalence of asthma in CRSwNP.

Thirdly, in the 11,750 admissions for sinus surgery in 2018, only 0.65% (77/11,750) showed specific complications requiring surgical revision. This proportion may be underestimated, as the number and type of complications were analyzed separately based on CCAM codes, and only complications requiring surgery could be identified and those managed medically in consultation were not included: e.g., orbital breach managed by monitoring or epistaxis managed by packing. In 2006, Hopkins *et*

al. reported a 1% rate of postoperative hemorrhage in 3,128 sinus surgery patients [12]. In the Utah Population Database, where sinonasal surgery is one of the most frequent annual day surgeries, audits give access to national data for complications rates [20]. With a low complications rate, like in the present study, in the 600,000 sinonasal procedures (sinus, septoplasty, rhinoseptoplasty, etc.) in 2006, the readmission rate for minor or major postoperative complications, managed by monitoring or surgery, was only 2.65%, with a 0.1% emergency consultation rate [20].

This national study based on the exhaustive data of the PMSI medical information database was the first to be conducted in France. Even so, the estimate of the number of patients eligible for biotherapy is to be taken with caution. Several aspects of study design may have led to overestimation: i) primary-to-revision surgery time; ii) lack of information on indications for revision; and iii) type of primary procedure preceding revision. Even so, given the number of biotherapy candidates, the present analyses would be worth continuing. A cost/benefit analysis or economic analysis would also be useful. A medico-economic analysis for dupilumab, the first biotherapy for nasal polyposis available in France, was conducted by the HAS health authority and concluded that defining the target population was a key factor in estimating costs impact.

The main strong-point of the present study was the exhaustiveness and representativeness of the national-level data. Certain limitations, however, are to be mentioned. Firstly, there was selection bias. Data for the main diagnosis and comorbidities were often lacking or insufficient due to the data extraction method via CCAM and ICD-10 codes. Some chronic sinusitis surgeries may not have involved CRSwNP. Even so, using these codes, few pathologies other than CRSwNP were likely

to have been involved. Secondly, missing data introduced bias. The indication for revision surgery was not known, as the data were anonymous and no reading of the records could indicate the revision indication, which might be for recurrence of CRSwNP or equally for late complications, and notably mucocele [21]. According to the literature [12,20], however, the rate of complications is low, although surgery may be indicated to avoid potentially severe consequences, especially ophthalmologic.

5. Conclusions

Annually, 11,000 patients underwent sinonasal polyposis surgery in France in the period 2011-2018. The procedure was safe, with a 0.65% rate of complications, and reliable, with a surgical revision rate of 5.5% (5,078/92,884). The 5,078 patients operated on at least twice during the study period constitute a first estimate of biotherapy eligibility in France in 2018, although this figure is doubtless an overestimation.

Disclosure of interest

The authors have no conflicts of interest to disclose.

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Figure 1. Study design

Dotted gray line: patients operated on in 2011 and followed up until 2018; dashed black line: patients operated on in 2018, for whom history was taken; black box: transverse analysis of sinus procedures in 2018.

Figure 2. Types of health-care center (private hospital, non-profit private hospital, local hospital, regional hospital) for first and last procedure in patients operated on in 2011 and reoperated on between 2011 and 2018.

Abbreviations: LH, local hospital; RH: regional hospital; PH: private hospital; NPPH: non-profit private hospital.

Table 1: Population and hospital stay data for patients operated on in 2018.

Surgery admissions, 2018	n = 11,750
General data	
Age (years)	49.5 [10-90]
Female gender	4,217 (35.9%)
Comorbidities	
Hypertension	661 (5.6%)
Asthma	563 (4.8%)
Obesity	308 (2.6%)
Sleep apnea	292 (2.5%)
Surgery data	
Type of stay	
Outpatient	4,381 (37.3%)
1 night	4,687 (39.9%)
2 nights	1,850 (15.7%)
3 nights	476 (4.1%)
≥4 nights	356 (3.0%)
Type of surgery according to length of stay	
Outpatient	
Ethmoidectomy	3,137 (71.6%)
Polypectomy	1,183 (27.0%)
Other	61 (1.4%)
1 night	
Ethmoidectomy	4,181 (89.2%)
Polypectomy	464 (9.9%)
Other	42 (0.9%)
Distribution between centers *	
n = 1,162	
LH	173 (14.9%)
RH	233 (20.1%)
Private	695 (59.8%)
Non-profit	61 (5.2%)

Categoric variables reported as number (percentage), and quantitative variables as mean [range].

*Types of center (primary center) for the subgroup of 1,162 patients operated on twice for whom data were available.

Abbreviations: LH, local hospital; RH, regional (including university) hospital

Table 2: Main and associated procedures in patients operated on in 2018

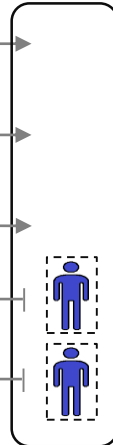
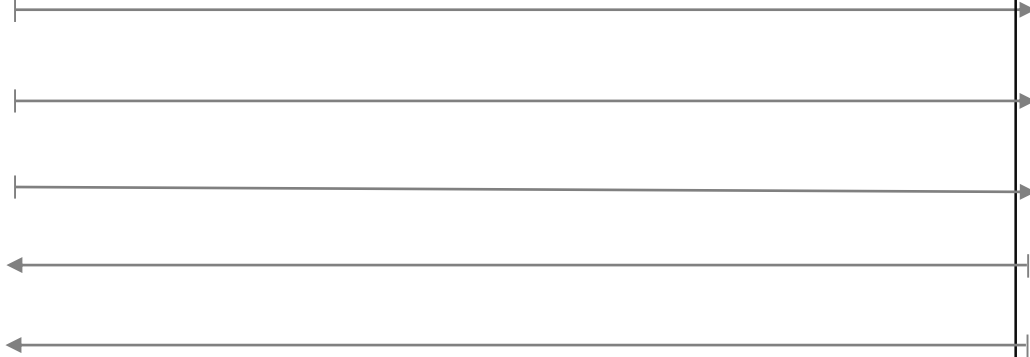
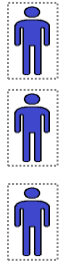
	Main procedure	
	Ethmoidectomy	Polypectomy
<u>Associated procedures</u>		
Ethmoidectomy	5,330	87
Meatotomy	3,332	564
Polypectomy	87	940
Septoplasty	63	182
Turbinoplasty	659	104
Sinusotomy	122	
Meatotomy and turbinoplasty	118	
Meatotomy and ethmoidectomy		56
Polypectomy and meatotomy	56	
Otherassociations	48	141
Total	9,815	2,074

Values are numbers per procedure. Isolated procedures (ethmoidectomy and polypectomy) are shown in **bold**. Empty cell: redundant, so that total main procedure values correspond. To simplify reading, procedures systematically performed in association are not shown: medial meatotomy (n=4,206), septoplasty (n=356), turbinoplasty (n=973) and sinusotomy (149).

2011

2018

Patients operated on in 2011, followed up 2011 -2018



Patients operated on in 2018, retrospective analysis of history 2011 -2018

First surgery

Last surgery

