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Strabismus outcomes after surgery: the nationwide SOS France study

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Abstract

Purpose To describe the types of strabismus operated on, the surgical procedures performed, and the 2-year reoperation rate in France.

Methods Entire population 5-year cross-sectional analysis of a national medico-administrative database in France between January 2013 and December 2017 included all patients who underwent a first strabismus surgery, with a 2-year follow-up. Patient identification was based on the diagnostic codes of the 10th International Classification of Diseases and surgical procedures on the codes of the Common Classification of Medical Acts. A subgroup analysis comparing non-paralytic and paralytic strabismus was performed.

Results Among the 56,654 patients included (women: 50.8%), 26,892 (47.5%) patients were under 10 years old. Overall, 52,711 (93%) were diagnosed with non-paralytic strabismus and 3,943 (7%) with paralytic strabismus. Among the non-paralytics, the most frequent diagnosis was esotropia (21,282, 37.6%), followed by exotropia (14,392, 25.4%) and vertical strabismus (2,017, 3.6%). Among the paralytics, fourth cranial nerve palsy (1,499, 2.6%) was more frequent than sixth cranial nerve palsy (691, 1.2%) and third cranial nerve palsy (431, 0.8%). The 2-year reoperation rate was 7.7% (4,362 patients), the lowest for non-paralytic (7.4%) and the highest for paralytic (11.4%).

Conclusion This first French population-based study about strabismus will contribute to the evaluation of practices at a national level and permit comparisons between countries. Although the 2-year reoperation rate was found to be 1 out of 13 patients, it should be interpreted with caution. Long-term follow-up is still warranted due to considerable variability of the type and severity of strabismus as well as surgical practices.

Keywords Esotropia · Exotropia · Oculomotor surgery · Paralytic strabismus · Reoperation

Key messages

- This is the first study on entire population evaluating strabismus requiring surgery in France.
- Among the 56,654 patients included in this study, 93% had non-paralytic strabismus and 7% had paralytic strabismus.
- The reoperation rate was found to be highly variable and was higher in patients with paralytic compared to nonparalytic strabismus (11.4% versus 7.4%).

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Abbreviations

- ICD-10 10Th edition of the International Classification of DiseasesPMSI Programme de Médicalisation des Systèmes
- d'Information

Introduction

The prevalence of strabismus is highly variable in the literature, depending on the definition used and the geographical regions studied [1-5]. Patients with strabismus may require surgery to reduce ocular deviation, improve cosmetic appearance, and, at best, restore ocular alignment and fusion in case of normal retinal correspondence. Surgery is an important step in the treatment process, although some cases such as those with large deviations may require reoperation [6]. In an analysis of the US IRIS registry by Repka et al. [7], 4.8% of patients with a diagnosis of strabismus received their first surgical management, among which 6.7% received a reoperation within 1 year. In France, data concerning patients undergoing ocular surgery are collected through the medico-economic system called "Programme de Médicalisation des Systèmes d'Information" (PMSI). This database contains the diagnostic codes and surgical procedures performed for each patient, along with demographic information and hospital follow-up information. Previous studies have highlighted the usefulness of this database to perform large population-based epidemiological investigations in France (e.g., trends in glaucoma surgery [8], endophthalmitis following cataract surgery [9], or intravitreal injections [10]).

This study aimed to describe the types of strabismus operated on, the surgical procedures, and the 2-year reoperation rate in France.

Material and methods

Study design and participants

This French retrospective, multicenter, population-based study was conducted using data for the period from January 1st, 2011, to December 31st, 2020, from the national PMSI hospital discharge databases. According to the French law and regulation (MR005), 10-year data are available corresponding of the last decade (i.e., from 2011 to 2021). All

patients who underwent strabismus surgery in France and French overseas departments (*Guadeloupe*, *Martinique*, *Guyane*, *Mayotte*, and *La Réunion*) between 2013 and 2017 were included in the cohort and represented the study population. The previous 2-year period 2011–2012 was necessary to accurately define the patient population of first strabismus surgery by excluding patients with a previous strabismus surgery in the past 24 months before the inclusion period. Patients who had therapeutic codes corresponding to a reoperation (BJMA008, BJMA009) were also excluded. Finally, only patients considered as having a first strabismus surgery were considered in the current study and followed over a 2-year period post-surgery.

The study was approved by the National Commission on Informatics and Liberty (n°2205437) and was in accordance with the ethical principles established in the Declaration of Helsinki. The institutional review board of the University Hospital of Tours approved this study.

Diagnostic and therapeutic codes

The French national administrative database PMSI collects administrative and medical (i.e., diagnoses and procedures) information on all hospital stays in France for epidemiological and financial purposes. Since 2005, the PMSI has been used for the implementation of activitybased pricing, the current remuneration system for French healthcare hospitals, both public and private. For each hospital stay, diagnostic codes based on the 10th edition of the International Classification of Diseases (ICD-10) and procedure codes from the Common Classification of Medical Acts [11] (CCAM: French common procedural terminology CPT) are collected.

As a patient can have a primary and several secondary ICD-10 diagnosis codes, prioritization was performed to retain only the diagnostic code corresponding to an etiological diagnosis rather than codes limited to an anatomical description (e.g., if the same patient was coded vertical strabismus and trochlear nerve palsy, only trochlear nerve palsy was retained) (Table 1).

For a given patient, several CPT codes can be found (e.g., displacement of a rectus muscle and displacement of an oblique muscle). Thus, the number of CCAM procedures was greater than the number of patients in the current study.

Data collection

For each patient, the following data were collected: demographics such as age (grouped by decade except for the first decade for which an interval of 2 years was chosen for greater accuracy, as patients under the age of 10 represented half of the cohort) and gender, hospital data such as public or

Table 1	Types of strabismus	and corresponding ICD-10	diagnostic codes
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Oculomotor disorders	ICD-10 codes			Public		Private	
		Num- ber of patients	Percentages	Num- ber of patients	Percentages	Num- ber of patients	Percentages
Non-paralytic							
Convergent concomitant strabismus	H500	21,282	37.6%	8,247	39.6%	13,035	36.4%
Divergent concomitant strabismus	H501	14,392	25.4%	5,829	28.0%	8,563	23.9%
Vertical strabismus	H502	2,017	3.6%	722	3.5%	1,295	3.6%
Intermittent heterotropia and other and unspecified heterotropia	H503/H504	278	0.5%	164	0.8%	114	0.3%
Heterophoria	H505	184	0.3%	76	0.4%	108	0.3%
Mechanical strabismus	H506	435	0.8%	170	0.8%	265	0.7%
Other specified strabismus	H508	7,503	13.2%	1,242	6.0%	6,261	17.5%
Strabismus, unspecified	H509	6,110	10.8%	2,173	10.4%	3,937	11.0%
Palsy of conjugate gaze	H510	65	0.1%	≤ 10	< 0.1%	63	0.2%
Convergent insufficiency and excess	H511	21	< 0.1%	11	< 0.1%	≤ 10	< 0.1%
Internuclear ophthalmoplegia	H512	≤10	< 0.1%	0	0	≤ 10	< 0.1%
Other specified and unspecified disorders of bin- ocular movement	H518/H519	51	0.1%	39	0.2%	12	< 0.1%
Nystagmus and other irregular eye movement	H55	372	0.7%	170	0.8%	202	0.6%
		52,711	93.0%	18,845	90.5%	33,866	94.5%
Paralytic							
Third nerve palsy/injury of oculomotor nerve	H490/S041	431	0.8%	254	1.2%	177	0.5%
Fourth nerve palsy/injury of trochlear nerve	H491/S042	1,499	2.6%	407	2.0%	1,092	3.0%
Sixth nerve palsy/injury of abducens nerve	H492/S044	691	1.2%	406	1.9%	285	0.8%
Total ophthalmoplegia	H493	≤ 10	< 0.1%	≤ 10	< 0.1%	≤ 10	< 0.1%
Progressive external ophthalmoplegia	H494	≤10	< 0.1%	≤ 10	< 0.1%	≤ 10	< 0.1%
Other paralytic strabismus and paralytic strabis- mus, unspecified	H498/H499	1,307	2.3%	897	4.3%	410	1.1%
Total		3,943 56,654	7.0% 100%	1,975 20,820	9.5% 100%	1,968 35,834	5.5% 100%

Bold values corresponding to the sum of patients

private hospital, and length of stay (i.e., outpatient surgery, 1 night stay, or longer). The proportion of strabismus surgeries was calculated as the ratio of strabismus surgical procedures to all ophthalmological surgical therapeutic procedures. Non-surgical therapeutic procedures, procedures performed during consultation or in a dedicated room different from the operating room (e.g., removal of superficial foreign bodies, laser treatment performed during consultation, and intravitreal injection), and duplicates were excluded.

Reoperation rate within 24 months

The 2-year reoperation rate was defined by at least one supplementary strabismus surgery during the following 24 months (codes BJMA008 and BJMA009, corresponding to iterative surgeries, considered as exclusion criteria at inclusion were included in the calculation of the reoperation rate). Where applicable, the time to reoperation and the number of interventions were provided. The 2-year reoperation rate was compared between non-paralytic and paralytic strabismus groups.

Postoperative endophthalmitis

Acute postoperative endophthalmitis was identified using two ICD-10 specific codes (i.e., H440 for purulent endophthalmitis and H441 for other endophthalmitis) if it occurred during the 42 days following strabismus surgery [12].

Results

A total of 56,654 patients (50.8% women) were included in the study. Surgery was performed in a public versus a private hospital in 36.7% and 63.3%, respectively. Twenty-six

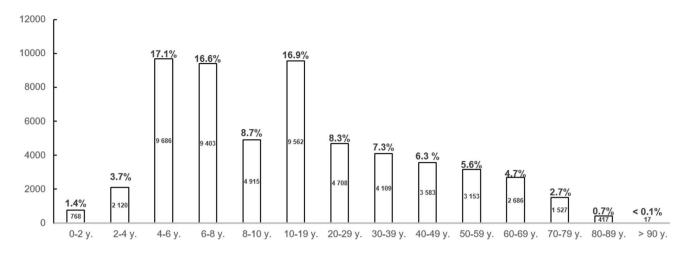


Fig. 1 Number of strabismus procedures according to age

thousand eight hundred and ninety-two (47.5%) were under the age of 10 years old. All age groups were concerned by strabismus surgery. The demographic distribution of patients operated on for strabismus is shown in Fig. 1. A total of 40,080 (70.7%) patients were treated as outpatients, 10,910 (19.3%) required a 1 night stay, and 5,664 (10%) required more than 1 night stay. The mean length of stay was 0.48 day in public hospitals and 0.41 day in private hospitals.

Strabismus types

The different types of strabismus are described in Table 1. Non-paralytic and paralytic strabismus corresponded respectively to 93% (52,711) and 7% (3,943) of all strabismus.

Therapeutic procedures

The 72,342 therapeutic procedures corresponding to a first surgery are described in Supplemental Table 1. The two most common procedures were unilateral (BJMA005) and bilateral (BJMA003) strengthening, weakening, or displacement of the insertion of two extraocular muscles corresponding respectively to 24.7% and 23.1%.

For non-paralytic esotropia and exotropia, surgery was most often performed on two extraocular muscles (respectively 61.2% and 62.9% (BJDA001 + BJMA003 + BJMA005)). Non-paralytic vertical strabismus was managed with a single-rectus muscle (BJMA002) surgery in 25.9% of cases and a single-oblique muscle surgery in 22.6% (BJMA004).

For paralytic strabismus, surgeries were mainly performed on one eye, irrespective of the type of strabismus. In cases of third cranial nerve palsy, procedures were highly variable although two-muscle surgery (BJMA005) was performed in 30.2% of cases. In case of fourth cranial nerve palsy, a strengthening, weakening, or displacement of the insertion of a single-oblique muscle (BJMA004) or an extraocular muscles transposition (BJEA001) was performed respectively in 41% and 29.7% of cases. In cases of sixth cranial nerve palsy, surgery was most often performed on one or two extraocular muscles, 21.6% on one muscle (BJMA002) and 25.7% on two muscles (BJMA005).

Strabismus surgery with adjustable sutures accounted for 3.5% of cases, while retroequatorial Cüppers myopexy for 12.3% and botulinum toxin injection for 1.4%.

Reoperation rate within 24 months

The 2-year reoperation rate was 7.7% (4,362) over the study period. In total, 6,996 (12.3%) required at least one reoperation from January 2013 to December 2020 (i.e., a maximum of 84 months for the first patient included in the study and a minimum of 36 months for the last patient included in the study). The median time between the first surgery and the first reoperation was 513 days (i.e., 1.4 years; Q1=257, Q3=1,022). Among the 6,996 patients who underwent at least one reoperation, 6,132 (87.7%) had a single reoperation, 706 (10.1%) 2 reoperations, 117 (1.7%) 3 reoperations, and 41 (0.6%) at least 4 reoperations.

The 2-year reoperation rate was higher in the paralytic group compared with the non-paralytic group (11.4% versus 7.4%).

In the non-paralytic strabismus group, 284 (14.1%) patients with vertical strabismus, 1,140 (7.9%) patients with exotropia, and 1,247 (5.9%) patients with esotropia had at least one reoperation within 24 months.

In the paralytic strabismus group, 74 (17.2%) patients with third cranial nerve palsy, 115 (16.6%) with sixth cranial

nerve palsy, and 140 (9.3%) with fourth cranial nerve palsy had at least one reoperation within 24 months.

Postoperative endophthalmitis

Endophthalmitis was reported in only 3 cases during the 42 postoperative days among the 56,654 patients.

Discussion

This national cross-sectional study of more than 56,000 patients provides a contemporary view of strabismus management occurring over the 5-year period for patients hospitalized for surgery with a 24-month follow-up. We observed that strabismus surgery accounts for 2% of all eye surgery procedures and mainly concerns children (1 out of 2 aged below 10 years). In more than 9 out of 10 patients, indication was non-paralytic strabismus, including 37.6% of convergent deviations, 25.4% of divergent deviations, and 3.6% of vertical deviations. The 2-year reoperation rate was 7.7%, but was highly variable between groups. Paralytic strabismus displayed a higher rate of reoperation when compared to non-paralytic strabismus (11.4% versus 7.4%). Within the non-paralytic group, the reoperation rate was higher for vertical deviations followed by divergent and convergent deviations. Moreover, the large dataset allowed an assessment of the risk of endophthalmitis, and highlighted the rarity of the occurrence.

The use of medico-administrative databases has already proven its usefulness and relevance in several ophthalmological conditions. Daien et al. [13] evaluated epidemiological factors and safety of ophthalmological procedures in France (thanks to the EPISAFE program (Epidemiology and Safety in Ophthalmology)). Other French studies have investigated the rate of postoperative endophthalmitis following vitreoretinal and combined surgery [9, 14]. Several population-based studies have been performed worldwide on various databases: the IRIS registry in the USA [15], the UK Ophthalmology Database [16], and the Swedish National Cataract Register [17]. Despite this, strabismus has been poorly studied using this "big data" approach. To date, the study performed by Repka et al. [7] on the IRIS registry is one of the largest of its kind on strabismus and the only population-based study that can be compared with the current findings.

In France, strabismus surgery is performed for onethird in public hospitals and for two-thirds in private hospitals. These hospitals are not distributed uniformly on the French territory and access to care is unequal for all French citizens. Most strabismus surgeries are performed on an outpatient basis. Nevertheless, this represents only two-thirds (70.7%) of patients. The trend towards outpatient care will increase in the coming years.

In our study, 93% of patients operated on had non-paralytic strabismus (of whom 37.6% had esotropia and 25.4% exotropia) and 7% had paralytic strabismus. In comparison, Repka et al. reported 30.6% of esotropia, 21.8% of exotropia, and 3.4% of paralytic strabismus [7]. Our findings are similar to those from the IRIS registry, suggesting that the proportions of each strabismus category requiring surgery may be comparable between countries.

One out of 13 patients was re-operated on during the following 24 months after initial strabismus surgery. The reoperation rate was highly variable and correlated with the type of strabismus (i.e., higher for paralytics) as well as the type of deviation (i.e., highest for non-paralytic vertical deviations while lowest for non-paralytic convergent deviations). The 2-year reoperation rate found in our study is comparable with the 1-year reoperation rate found by Repka et al. (6.7%) [7]. In their study, no subgroup analysis based on the type of strabismus was performed, but the 1-year reoperation rate positively correlated with age. This correlation could be related to the higher incidence of paralytic strabismus in older patients and could therefore represent a confusion bias. A retrospective single-center study performed in Canada over a 21-year period on 6177 patients found a reoperation rate of 15.7% [6]. The longer the followup period, the higher the reoperation rate. This assumption is supported by an increase in the reoperation rate from 7.7 over a 2-year period to 12.3% with a maximum follow-up period of 7 years in our study. In both Benson et al.'s study and the current study, most patients required only one reoperation (respectively 77.7% and 87.7%), while fewer patients underwent 2 reoperations (respectively 17.1% and 10.1%). The mean time for reoperation was comparable between Benson et al. and our study (respectively 2.3 and 1.9 years). Together, this suggests that when necessary, reoperation is mainly performed within 2 years following initial intervention. Reoperation cannot be solely considered as a failure of initial surgery. The reoperation rate should be interpreted with caution as reoperation can be a necessary step to correct complex cases or due to failure or recurrence. On the contrary, reoperation may not be performed in some patients even despite failure or recurrence. The surgical indication for strabismus must take into account the extent of deviation, the symptoms, the impact on vision-related quality of life, and the aesthetic discomfort experienced by the patient.

Strabismus surgery is presented as a safe procedure in terms of infectious complications. Despite this, endophthalmitis can occur even in the absence of scleral perforation while performing muscle recession or resection [18]. Considering the rarity of such complications, large-scale studies are needed. Our population-based findings confirm that endophthalmitis is an uncommon complication following strabismus surgery. Since endophthalmitis is a visionthreatening condition, it would seem unlikely that patients with such a complication were missed because not treated. Moreover, the corresponding diagnostic code is systematically implemented when a patient is hospitalized.

Studies based on medical administrative databases are classified at an intermediate level according to the Oxford Evidence Based Medicine Recommendations [19]. These studies, however, are complementary to randomized controlled trials, which have a higher level of scientific evidence, the latter being carried out under ideal follow-up conditions for a smaller number of selected patients. Population-based investigations under real conditions of practice avoid center effects and allow the study of rare events. These data can then be used to evaluate the epidemiology of diseases on a country-wide scale and to adapt medical care accordingly based on the completeness, routine implementation, and follow-up of the cases.

Furthermore, as the PMSI contributes to the financing of French public and private healthcare establishments, its database is all the more exhaustive, as complete filing for each patient by physicians is an essential prerequisite for the reimbursement of healthcare structures by the health agencies. By comparison, the IRIS registry is implemented with data reported by volunteer ophthalmologists who represent only 42% of the ophthalmologists in the USA. This allows for an analysis of current clinical practices, but does not permit an epidemiological assessment at the national level.

Several limitations to this study must be acknowledged. First, the use of administrative hospital databases introduced an inherent bias to importantly consider. The strengths and limitations of using healthcare databases for epidemiological purposes have already been extensively discussed [20–24]. Hence, while the PMSI is designed for billing purposes, it occurs now to be a powerful tool for epidemiological surveillance. One must keep in mind, however, that observed changes in disease patterns could be biased by variations in coding practices due to financial incentives for obtaining higher reimbursement rates [25]. In our study, 24% of patients were operated on for unspecified non-paralytic strabismus (H508, H509), thus limiting the interpretation of the data obtained. Second, some concerning issues are not recorded in the hospital discharge database; for instance, there are no clinical data (e.g., amplitude of the deviation or the therapeutic codes do not specify which muscles were operated on and whether it was a recession, plication, or resection). Third, since this study was performed in only one country, the extrapolation of our findings to other countries may be limited. Fourth, surgical practices can be highly variable owing to a wide range of strabismus types, severity, and aetiologies as well as differences between surgeons' personal experience.

To date, this is the first population-based study in France for patients with strabismus requiring surgery. These findings will serve as a reference for comparisons between countries. A national medico-administrative database contributes to the evaluation of clinical practices and provides patients and surgeons with reliable epidemiological data on their disease and the 2-year reoperation rate (1 out of 13). Still, patients should undergo life-long follow-up since surgery does not represent a cure as strabismus are most often not related to a muscular problem but rather to an impairment of the eye movement control system.

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Author contribution QC, JC, SA, PJP, LGG, and RKK were involved in drafting the article or revising it critically for important intellectual content, and all authors approved the final version to be published. RKK had full access to all of the data in the study and takes responsibility for the integrity and the accuracy of the data.

Declarations

Ethical approval 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. The local Ethics Committee of the University Hospital of Tours approved this study. No nominative, sensitive, or personal data on patients were collected. Our study involves the reuse of already recorded and anonymized data. The study falls within the scope of the French reference methodology MR-005 according to 2016–41 law dated January 26th, 2016, on the modernization of the French health system, which requires neither information nor non-opposition of the included individuals. Access to linked anonymous file in the PMSI databases was approved by the French National Commission for Data Protection and Liberties (CNIL MR-005 number 3014040220).

Conflict of interest The authors declare no competing interests.

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