


# Incidence of acute postoperative endophthalmitis following macular surgery in France between 2006 and 2016

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## ABSTRACT.

**Purpose:** To report the incidence of acute postoperative endophthalmitis (POE) after macular surgery in France between 2006 and 2016 and to identify associated factors.

**Methods:** This retrospective database study included all hospital discharge records involving a surgical procedure for an epiretinal membrane or a macular hole in France from January 2006 to October 2016. Acute POE was identified by two codes in the tenth edition of the International Classification of Diseases within 42 days of a macular surgical procedure in the French national administrative database.

**Results:** In France, 152 034 macular surgical procedures for epiretinal membranes or macular holes were recorded from 1 January 2006 to 31 October 2016. Suspected acute POE was reported in 381 cases. The incidence of POE was 0.25% overall, 0.30% for epiretinal membrane surgery and 0.14% for macular hole surgery. In multivariable Poisson regression analysis, epiretinal membrane surgery was associated with POE [incidence rate ratio (IRR), 2.24; 95% CI, 1.62–3.11;  $p < 0.001$ ]. For epiretinal membrane surgery, the 2010–2011 period was significantly associated with a higher risk of POE (IRR, 1.66; 95% CI, 1.13–2.42;  $p = 0.03$ ).

**Conclusion:** The incidence of POE after macular surgery was 0.25% overall in France between 2006 and 2016 and twice higher for epiretinal membrane surgery than for macular hole surgery. For epiretinal surgery only, the incidence of POE was higher in 2010–2011 (period of the switch to transconjunctival vitrectomy) than in the rest of the study period.

**Key words:** endophthalmitis – epidemiology – epiretinal membrane – macular hole – pars plana vitrectomy – transconjunctival sutureless vitrectomy

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## Introduction

Epiretinal membrane and macular holes are common macular conditions that

affect 7% and 0.2%, respectively, of individuals aged over 50 years (Mitchell et al. 1997; Liesenborghs et al. 2018). In the case of severe visual acuity loss or

metamorphopsia, these conditions require a surgical intervention (McDonald et al. 1986; Benson et al. 2001). For both epiretinal membranes and macular

holes, the surgical procedure is as follows: a pars plana vitrectomy is performed through three sclerotomy sites, then the posterior cortical hyaloid, epiretinal membranes, and for some surgeons the internal limiting membrane, are removed (McDonald et al. 1986; Benson et al. 2001; Kim et al. 2010). For macular holes only, after a more complete vitreous removal, the vitreous cavity is finally filled with a longlasting gas or silicone oil (Benson et al. 2001). Numerous studies have assessed macular surgery in terms of improvement of visual acuity and quality of life as well as rate of complications such as retinal detachment (Scott et al. 2003; Kim et al. 2010; Rizzo et al. 2010). One of the most sight-threatening postoperative complications is endophthalmitis (Park et al. 2014a). The incidence of postoperative endophthalmitis (POE) has mainly been assessed for all causes of vitrectomies and not specifically for macular surgery (Govetto et al. 2013; Dave et al. 2014; Park et al. 2014b). Furthermore, most studies were limited in time and identified only a small number of cases (Eifrig et al. 2004; Kunimoto & Kaiser 2007; Scott et al. 2011; Park et al. 2014b). Recently, macular surgery benefited from new surgical techniques such as 23-, 25- and 27-gauge transconjunctival sutureless vitrectomy (TSV). These new approaches have overtaken conventional 20-gauge vitrectomy (Fujii et al. 2002; Eckardt 2005). Whether TSV is associated with a higher risk of POE is still a matter of debate. Indeed, initial studies reported a significantly higher risk (Kunimoto & Kaiser 2007; Scott et al. 2008) but subsequent studies did not confirm this finding (Govetto et al. 2013; Park et al. 2014b).

Therefore, we conducted this study to report the incidence of POE following macular surgery (namely epiretinal membrane and macular hole surgery) from 2006 to 2016 on a national scale.

## Materials and Methods

### Study design

We conducted a nationwide retrospective database study over an 11-year period. Our study is part of the French Epidemiology and Safety collaborative program (EPISAFE), which aims to assess the epidemiology and safety of

interventions in ophthalmology (Daïen et al. 2017).

### Data source

The French national administrative database [Programme de Médicalisation des Systèmes d'Information (PMSI)] collects administrative and medical data on every hospital stay. It was created in 1991 and extended to all French public and private hospitals in 1997. Primary and associated diagnoses identified during the hospital stay are encoded following the *International Statistical Classification of Diseases and Related Health Problems, Tenth Revision* (ICD-10) and procedures performed during the hospitalization according to the *French Common Classification of Medical Procedures* (CCAM). Standardized anonymous datasets are collected from each hospital and then compiled at the national level. The allocation of hospital budgets depends on the medical activity described in this database. Its reliability and validity have been previously evaluated. The PMSI provides a vast amount of epidemiological information concerning hospitalized patients in France (Lorgis et al. 2013; Creuzot-Garcher et al. 2016, 2019; Bron et al. 2017).

### Data extraction

The use of the PMSI database was approved by the National Commission for Data Protection (*Commission Nationale de l'Informatique et des Libertés* no. 1576793), and this study adhered to the tenets of the Declaration of Helsinki. We included all hospital discharge records involving a macular surgical procedure in French healthcare facilities between 1 January 2006 and 30 October 2016. Macular surgical procedures were identified by the CCAM codes for epiretinal membrane surgery (BGPA002, 'epiretinal membrane dissection') and for macular hole surgery (BGFA005, 'posterior vitrectomy with internal limiting membrane peeling and gas tamponade'). Patients living in mainland France and in overseas departments were included.

### Main outcome

Acute POE was identified using two ICD-10 codes (H44.0 and H44.1)

appearing in a discharge record as the main or associated diagnosis within 42 days of macular surgery (Endophthalmitis Vitrectomy Study Group 1995). In France, endophthalmitis is only treated during hospitalization in public or private hospitals, according to the recommended treatment.

### Variables studied

#### Periods

The period of the switch to TSV in France was estimated by analysing data from different vitrectomy equipment suppliers. The switch to TSV occurred during 2010–2011 in France. Therefore, three periods were considered: the period before the switch to TSV (2006–2009), the period of the switch to TSV (2010–2011) and the period after the switch to TSV (2012–2016).

#### Covariates

For analysis, we retained the gender and age of the patients categorized into four groups according to the literature dealing with endophthalmitis (Li et al. 2004; West et al. 2005). We considered whether the macular surgical procedure was combined with cataract surgery (BFGA004, 'cataract extraction performed by phacoemulsification with intraocular lens implantation in the capsular bag'). We also searched for a history of cataract surgery in the year preceding the macular surgical procedure.

### Statistical analysis

The incidence of POE was calculated by dividing the number of hospital stays for acute POE within 42 days of a macular surgical procedure by the total number of macular surgical procedures (Endophthalmitis Vitrectomy Study Group 1995). No confidence intervals were estimated as we included the whole French population. We used a Poisson regression and its log-likelihood ratio statistics to assess associations with time periods and demographic and clinical factors. The number of hospital stays involving a macular surgical procedure was used as a population offset. Incidence rate ratios (IRRs) were estimated using Poisson regression for each variable (time period, age, gender, type of macular surgical procedure, combined

surgery and history of cataract surgery in the previous year). Multivariable Poisson regression analysis was then performed to obtain adjusted IRRs.

We subsequently used an interrupted time series analysis to measure changes in POE incidence over time for all the macular surgical procedures as well as for each type of surgical procedure. This model used monthly POE rates over the study period and included a linear time trend. In accordance with seasonal fluctuations, random error was modelled by an autoregressive model with a parameter at a lag of 24 (i.e. two for each month). We thus quantified the impact of the switch to TSV as changes in the level and slope compared with the period before and during the switch. The tests were two-tailed, and p-values <0.05 were considered significant.

## Results

According to the national administrative database, there were 152 034 macular surgical procedures in France from 1 January 2006 to 31 October 2016, including 108 547 epiretinal membrane surgical procedures (71.4%) and 43 487 macular hole surgical procedures (28.6%) (Table 1). Macular surgery increased by 62.1% from 2006 to 2016. The mean age of patients was 69.6 years (SD, 11.1 years), and 53.0% were female. Macular surgical procedures combined with cataract extraction accounted for 20.4% of all the macular surgical procedures. We

identified a history of cataract surgery in the previous year in 12.5% of patients undergoing macular surgical procedures.

We identified 381 cases of suspected POE within 42 days of a macular surgical procedure over our 11-year period. The number of POEs increased by 215.4% from 2006 to 2016. The mean POE incidence was 0.25% overall, 0.30% for epiretinal membrane surgery and 0.14% for macular hole surgery (Table 1). The highest incidence rates were found in 2010 and 2011.

In multivariable Poisson regression analysis, epiretinal membrane surgery was the only variable associated with endophthalmitis (IRR, 2.24; 95% CI, 1.62–3.11,  $p < 0.001$ ) (Table 2). We then analysed epiretinal membrane surgery and macular hole surgery separately. For epiretinal membrane surgery, the 2010–2011 period was significantly associated with a higher risk of POE (IRR, 1.66; 95% CI, 1.13–2.42;  $p = 0.03$ ). For epiretinal membrane surgery as well as for macular hole surgery, combined macular surgery performed with cataract extraction was not associated with POE in comparison with macular stand-alone surgery (IRR, 0.83; 95% CI, 0.58–1.17;  $p = 0.27$  and IRR, 1.01; 95% CI, 0.51–2.01;  $p = 0.98$ , respectively). For epiretinal membrane and macular hole surgery, a history of cataract extraction in the year preceding macular surgery was not associated with POE (IRR 1.07; 95% CI, 0.73–1.58;  $p = 0.72$  and

IRR 0.40; 95% CI, 0.12–1.28;  $p = 0.08$ , respectively). For both types of macular surgery, age and gender were not statistically associated with POE (Table 3).

Using interrupted time series models, between 2006 and 2016, the series exhibited significant linear increasing trends over time with an increase in POE incidence by 0.0019 percentage points per month ( $p = 0.03$ ). This increasing trend disappeared after adjustment for age and sex (0.0022 percentage points,  $p = 0.07$ ). When we considered epiretinal membrane surgery only, this increasing trend in POE incidence was still statistically significant after adjustment for age and sex (0.0036 percentage points,  $p = 0.01$ ). For both types of macular surgery, when we considered the period before and during the switch to TSV (2006–2011) versus the period after the switch to TSV (2012–2016), there was a decrease of 0.0626 percentage points in the level of POE incidence after the switch to TSV, which was not statistically significant ( $p = 0.25$ ; Fig. 1). When we considered epiretinal membrane surgery only, there was a significant decrease of 0.1449 percentage points in the level of POE incidence after the switch to TSV ( $p = 0.04$ ). When we considered three periods (before, during and after the switch to TSV), this decrease was on the border of statistical significance ( $p = 0.07$ ), because of the reduction of the statistical power.

**Table 1.** Number of macular surgical procedures and incidence of acute postoperative endophthalmitis in France from January 2006 to October 2016

	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016*	Total
Overall macular surgery, <i>N</i>	9243	10 309	11 608	12 980	14 049	15 158	15 359	15 546	15 965	16 833	14 984	15 2034
Epiretinal membrane surgery, <i>N</i>	6037	7012	8004	9089	9937	10 900	11 175	11 134	11 697	12 313	11 249	10 8547
Macular hole surgery, <i>N</i>	3206	3297	3604	3891	4112	4258	4184	4412	4268	4520	3735	43 487
Acute POE after overall macular surgery, <i>N</i>	13	23	32	26	45	44	36	37	42	42	41	381
Acute POE after overall macular surgery, %	0.14	0.22	0.28	0.20	0.32	0.29	0.23	0.24	0.26	0.25	0.27	0.25
Acute POE after epiretinal membrane surgery, <i>N</i>	8	18	25	21	39	42	30	28	34	37	40	322
Acute POE after epiretinal membrane surgery, %	0.13	0.26	0.31	0.23	0.39	0.39	0.27	0.25	0.29	0.30	0.36	0.30
Acute POE after macular hole surgery, <i>N</i>	5	5	7	5	6	2	6	9	8	5	1	59
Acute POE after macular hole surgery, %	0.16	0.15	0.19	0.13	0.15	0.05	0.14	0.20	0.19	0.11	0.03	0.14

POE = postoperative endophthalmitis.

\* Data only available from January to October.

**Table 2.** Adjusted incidence rate ratios for acute postoperative endophthalmitis after macular surgery in France from 2006 to 2016, derived from multivariable Poisson regression analysis

	Adjusted IRR (95% CI)	p-Value*
Epiretinal membrane surgery (reference = macular hole surgery)	2.24 (1.62–3.11)	<0.001
Time period (reference = 2006–2009)		
2010–2011	1.42 (1.02–2.00)	0.13
2012–2016	1.17 (0.88–1.57)	
Combined with cataract versus stand-alone macular surgery	0.85 (0.62–1.15)	0.27
Age (reference = <60 years)		
60–69	0.86 (0.60–1.23)	0.26
70–79	0.73 (0.51–1.05)	
≥80	0.70 (0.45–1.07)	
Gender, female versus male	1.00 (0.79–1.26)	0.98

IRR = incidence rate ratio.

\* Log-likelihood ratio statistics from Poisson regression.

**Table 3.** Incidence rate ratios for acute postoperative endophthalmitis after epiretinal membrane surgery and macular hole surgery in France from 2006 to 2016, derived from multivariable Poisson regression analysis

	Epiretinal membrane surgery		Macular hole surgery	
	Adjusted IRR (95% CI)	p-Value*	Adjusted IRR (95% CI)	p-Value*
Time period (reference = 2006–2009)				
2010–2011	1.66 (1.13–2.42)	0.03	0.60 (0.27–1.35)	0.44
2012–2016	1.27 (0.91–1.77)		0.87 (0.50–1.51)	
Combined with cataract versus stand-alone macular surgery	0.83 (0.58–1.17)	0.27	1.01 (0.51–2.01)	0.98
History of cataract extraction in the previous year	1.07 (0.73–1.58)	0.72	0.40 (0.12–1.28)	0.08
Age (reference = <60 years)				
60–69	0.79 (0.53–1.17)	0.08	1.51 (0.61–3.74)	0.36
70–79	0.62 (0.42–0.91)		2.06 (0.85–5.01)	
≥80	0.62 (0.39–1.00)		1.46 (0.49–4.33)	
Gender, female versus male	0.92 (0.71–1.19)	0.53	1.67 (0.95–2.94)	0.07

IRR = incidence rate ratio.

\* Log-likelihood ratio statistics from Poisson regression.

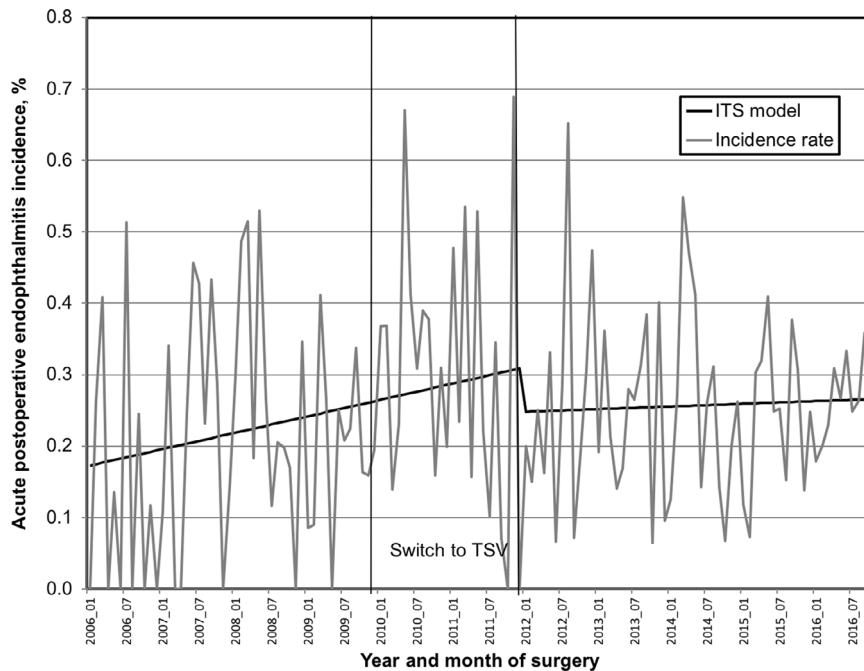
## Discussion

In our study, the mean incidence of POE was 0.25% overall, which was higher than in most studies that found a POE incidence after pars plana vitrectomy of <0.10% (Eifrig et al. 2004; Oshima et al. 2010; Wykoff et al. 2010; Dave et al. 2014), but it was lower than in some other series (Abi-Ayad et al. 2007; Shaikh et al. 2007). However, the use of a national administrative database allowed for a wider detection of POE compared with single-centre studies (Eifrig et al. 2004; Abi-Ayad et al. 2007; Shaikh et al. 2007; Wykoff et al. 2010) and enabled us to include all cases of acute POE reported after macular surgery.

Moreover, most studies included all causes for pars plana vitrectomy (i.e. retinal detachment, vitreous haemorrhage etc.) (Govetto et al. 2013; Dave et al. 2014; Park et al. 2014b). We decided to include only macular surgery so as to select cases and procedures to be as homogeneous as possible. Indeed, in our study, the surgical procedure *per se* seems to play an important role, with a POE incidence twice higher for epiretinal membrane surgery (0.30%) than for macular hole surgery (0.14%). The main differences between epiretinal membrane surgery and macular hole surgery are the fact that vitrectomy is more complete in the latter and that the vitrectomy is ended by an

endotamponade. This finding supports the hypothesis that endotamponade with gas or air protects against POE (Chiang et al. 2011). The same results were found in a recent prospective study including all types of vitrectomy (Bhende et al. 2018). The reasons for this lower rate remain putative: Endotamponade might prevent bacteria proliferation and fluid influx or leakage through sclerotomies (Chiang et al. 2011; Dave et al. 2014).

The POE incidence varied over our study period, and the highest incidence rates were found in 2010 and 2011 (during the switch to TSV). We found a statistically significant association between the type of macular surgery and the time period and therefore analysed epiretinal membrane surgery and macular hole surgery separately. For epiretinal membrane surgery, we found a significantly higher POE incidence during the switch to TSV with multivariable Poisson regression analysis as well as with the interrupted time series model. The initial increased risk of POE during the switch to TSV was probably influenced by the direct incision of the plugs leading to postoperative leakage. We assume this risk disappeared when the incision orientation was changed to an oblique scleral penetration (Fujii et al. 2002; Hsu et al. 2008). These results support the safety of TSV, which has also been pointed out in other studies (Scott et al. 2008; Shimada et al. 2008; Oshima et al. 2010; Wykoff et al. 2010; Govetto et al. 2013; Park et al. 2014a; Bhende et al. 2018). Combined macular surgery performed with cataract extraction was not associated with a higher risk of POE in comparison with macular stand-alone surgery. These findings support the safety of combined macular surgery, which has already been shown in other studies (Dugas et al. 2010; Muselier et al. 2010; Bhende et al. 2018). Another study found a higher risk of POE for combined macular surgery performed with cataract extraction compared to single cataract extraction (Creuzot-Garcher et al. 2019). These results can be explained by a higher POE risk for the macular surgery procedure than for the cataract extraction procedure (Taban et al. 2005; Dave et al. 2014). Therefore, combining macular surgery with cataract extraction does not increase the POE risk compared to macular surgery alone. A history of intraocular surgery within



**Fig. 1.** Trends in the incidence of acute postoperative endophthalmitis after macular surgery (epiretinal membrane surgery and macular hole surgery) in France from 2006 to 2016: interrupted time series analysis. ITS = interrupted time series, TSV = transconjunctival sutureless vitrectomy.

1 year preceding vitreoretinal surgery was mentioned as a potential POE risk factor in other studies (Bhende et al. 2018). In our study, a history of cataract extraction was not associated with POE. For epiretinal membrane surgery and for macular hole surgery, age and gender were not statistically associated with POE.

Our study has several limitations. First, coding in the national administrative database may not always have been accurate over our 11-year study period. Nevertheless, the budget allocation of healthcare facilities relies directly on coding, which encourages accuracy, and coding undergoes regular quality monitoring. The validity of the database was shown in other studies (Quantin et al. 2013, 2014). In France, a case-based payment system was generalized in 2004 to all healthcare facilities. Therefore, in our study period (2006–2016), no change in coding was due to this system implementation. Besides, there was no change in ICD-10 or CCAM codes in ophthalmology in our study period for the conditions and procedures we examined. Second, we could not study some potential POE risk factors such as diabetes since this variable was not reliably reported in our administrative database. Third, similarly we could not include the socioeconomic status of patients.

Fourth, our database also lacks clinical data such as POE clinical presentation and microbiological confirmation as well as details about surgeries. Fifth, the type of gauge vitrectomy for each macular surgical procedure was not available in the medico-administrative database. However, from company reports, the proportion of TSV has grown from 25% in 2006 to 63% in 2010 and to 96% in 2016. Therefore, we analysed the effect of the switch to TSV in France through different time periods (before and after the switch to TSV). The impact of change in procedure, other than the TSV procedure (i.e. high-speed vitrectomy, type of gas for endotamponade and oblique direction of sclerotomy), was impossible to analyse as these details were not available in the database. Sixth, we searched for POE within 42 days of macular surgery, but this is the established delay of acute POE following cataract surgery (Endophthalmitis Vitrectomy Study Group 1995). Moreover, the 42-day delay is used in most studies about POE after macular surgery (Chiang et al. 2011; Park et al. 2014b; Bhende et al. 2018).

However, our study could rely on an exhaustive number of macular surgical procedures including all macular surgeries performed over an 11-year period, on a national scale.

In conclusion, the incidence of POE after macular surgery was 0.25% overall in France between 2006 and 2016. This incidence was twice higher for epiretinal membrane surgery than for macular hole surgery. For macular surgery, the switch to TSV was not associated with a change in POE incidence. However, for epiretinal surgery only, POE incidence was significantly higher during 2010–2011 (period of the switch to TSV) than before this period but decreased immediately after the switch. This observation should stress the rigorous technique used to perform sclerotomy with TSV via both an oblique direction and careful control for the absence of leakage at the end of the procedure. Furthermore, performing an air fill at the end of epiretinal membrane surgery may reduce the risk of POE. This hypothesis needs to be further studied.

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