

# Preoperative laser reduces silicone oil use in primary diabetic vitrectomy

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## Abstract

• **AIM:** To identify the predictive factors and laser photocoagulation associated with the use of silicone oil as endotamponade during primary diabetic vitrectomy.

• **METHODS:** The medical and surgical records of 690 patients (798 eyes) who underwent primary diabetic vitrectomy at a tertiary eye hospital in China from January 2018 to December 2018 were reviewed in this retrospective cohort study. The patients' baseline characteristics and preoperative treatments were recorded. The binary Logistic regression model was used to evaluate the risk factors for the use of silicone oil as endotamponade agent during primary vitrectomy for proliferative diabetic retinopathy (PDR)-related complications.

• **RESULTS:** Among 690 patients with mean age of 52.1±10.5y (range: 18-85y), 299/690 (43.3%) were female. The 31.6% of the eyes received preoperative laser treatment, and 72.4% of the eyes received preoperative anti-VEGF adjuvant therapy. Non-clearing vitreous haemorrhage (VH) alone or combined with retinal detachment was the main surgical indication (89.5%) for primary vitrectomy. Silicone oil was used as endotamponade in 313 (39.2%) eyes. Lack of preoperative laser treatment [odds ratio (OR) 0.66, 95% confidence interval (CI): 0.48-0.92;  $P=0.015$ ] and older age (OR 0.96, 95%CI: 0.95-0.98;  $P<0.001$ ) were predictors of silicone oil tamponade during primary vitrectomy for PDR.

• **CONCLUSION:** The lack of preoperative laser treatment is a significant predictor of silicone oil tamponade during

primary vitrectomy for PDR. However, the severity of PDR relevant to silicone oil use should be further evaluated.

• **KEYWORDS:** proliferative diabetic retinopathy; vitrectomy; laser photocoagulation; silicone oil tamponade; predictive factors

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## INTRODUCTION

Diabetic retinopathy (DR) is the leading ocular complication of diabetes which cause irreversible blindness in working-age adults worldwide<sup>[1]</sup>. Approximately 25% of vision loss in DR patients is a result of severe complications of advanced proliferative diabetic retinopathy (PDR)<sup>[2]</sup>. Due to the aging population and the increasing prevalence of diabetes, the number of people suffering vision-threatening PDR has significantly increased in recent years<sup>[3]</sup>. Pan-retinal photocoagulation (PRP), which prevents the disease progression and reduces the risk of severe visual impairment by 50%, has been the standard treatment of high-risk PDR for decades<sup>[4]</sup>. However, in our experience, several patients miss the best time for laser photocoagulation treatment for various reasons and progress to severe PDR-related complications that require vitrectomy surgery. It was reported that 5.6% of patients progress to severe PDR and require a vitrectomy despite having received adequate PRP<sup>[5]</sup>.

Vitrectomy has been established as the ultimate treatment of severe PDR-related complications and silicone oil has been used as an effective endotamponade agent that increases the success rate of complicated cases undergoing vitrectomy<sup>[6-8]</sup>. However, once silicone oil is used as intraocular tamponade agent, a subsequent surgery for removal is required. It also brings some disadvantages, such as the progression of nuclear cataracts, poor vision prognosis, increased economic burden and may lead to other postoperative complications<sup>[9-11]</sup>. Having a clearer understanding of the risk factors of silicone oil

tamponade in vitrectomy for PDR-related complications might provide novel and more effective preventive strategies. Thus, it is critical to understand the predictive factors of silicone oil tamponade in vitrectomy for PDR-related complications. However, although clinically relevant, the related factors of using silicone oil as intraocular tamponade agent during diabetic vitrectomy still unknown.

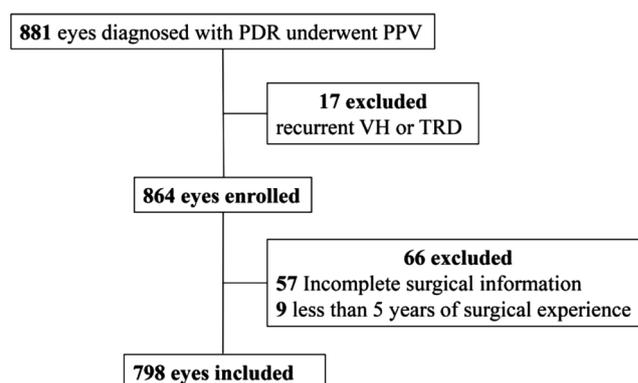
The aim of the present study was to identify the predictive factors for silicone oil tamponade during primary diabetic vitrectomy. In addition, the clinical characteristics of patients who underwent PPV for PDR-related complications, preoperative treatments and duration of symptoms, were also assessed.

## SUBJECTS AND METHODS

**Ethical Approval** Protocol of this cross-sectional, retrospective study was reviewed and approved by the Medical Ethics Committee at Zhongshan Ophthalmic Centre (ZOC) of Sun Yat-sen University (2021KYPJ094). As this was a retrospective study, patient informed consent was waived. The study adhered to the Helsinki Declaration (2008).

**Study Population** Medical and surgical records of all vitrectomy surgeries at the fundus surgery centre of ZOC from 1 January 2018 to 31 December 2018 were identified and reviewed in the electronic medical record system. A total of 881 consecutive cases of vitrectomy were identified. Patients who underwent primary vitrectomy for PDR-related complications were enrolled. Patients undergoing a secondary vitrectomy for recurrent vitreous haemorrhage (VH) or recurrent retinal detachment (RD), patients with incomplete medical or surgical records, and vitrectomies performed by surgeons with less than five years of experience were excluded from this analysis. The final analysis included 690 consecutive patients (798 eyes; Figure 1).

**Surgical Procedures** A standard three-port 23G or 25G pars-plana vitrectomy (PPV) was performed for non-clearing VH, traction retinal detachment (TRD), combined traction and rhegmatogenous retinal detachment (TRRD), or combined VH and RD with a wide-angle viewing system in all the patients. All surgeries were conducted by one of six experienced vitreoretinal specialists, each with more than five years of experience performing vitreoretinal surgery. Intravitreal anti-vascular endothelial growth factor (VEGF) drugs (ranibizumab, aflibercept or conbercept) were administered 3-7d prior to surgery for active neovascularization (NV) or VH at the surgeon's discretion. The blood or opacified vitreous was cleared, vitreoretinal traction was released, and fibrovascular membrane were removed. Laser was applied for retinal breaks and PRP was used in patients who had not previously undergone laser photocoagulation or in patients in whom previous laser photocoagulation was insufficient. Combined phacomusification was performed as indicated. Whether the



**Figure 1 Eligible patients-1 January 2018 to 31 December 2018 enrolment summary** PDR: Proliferative diabetic retinopathy; PPV: Pars-plana vitrectomy; VH: Vitreous haemorrhage; TRD: Traction retinal detachment.

intraocular lens was implanted at the same time depends on the fundus status. Endotamponade was achieved using the balanced salt solution, air or silicone oil, mainly according to the status of the retina at the end of the surgery. However, the patient's general condition and visual acuity of the opposite eye were also taken into consideration as silicone oil filling indicators. Balanced salt solution was used as endotamponade in case of no retinal tears was observed. Air endotamponade was used in case of within two retinal tears in a superior location. Silicone oil (5000 mPa.s; RT SIL-OL 5000; Zeiss, Berlin, Germany) was used in case of inferior retinal tears, large and more than two retinal tears, or fibrovascular membrane that could not be cleaned completely. Silicone oil removal was performed at least three months postoperative. Cataract surgery was performed when the lens opacity affects the observation of the fundus.

**Data Collection** The medical and surgical data of the patients were retrospectively collected *via* the electronic medical record system. The preoperative data included patient demographics, duration of symptoms, best-corrected visual acuity, fasting blood glucose, serum cholesterol, triglycerides, serum creatinine, blood urea nitrogen, history of hypertension, use of anti-VEGF agents prior to vitrectomy, and previous treatments for DR (including local laser, PRP and vitrectomy). The operative and postoperative data collected for this study included intraocular tamponade used at the end of the surgery and recurrence of VH or RD that required subsequent surgeries.

**Statistical Analysis** The statistical analyses were performed with SPSS version 25 (IBM, North Castle, NY, USA).  $P < 0.05$  was considered statistical significant. Variables were calculated using basic descriptive statistics, normally distributed continuous variables were presented as mean  $\pm$  standard deviation; non-normally distributed continuous variables were presented as the median. Categorical variables were presented as number and

percentage. A binary Logistic regression test was performed to identify risk factors associated with the use of silicone oil tamponade at the end of vitrectomy.

## RESULTS

**Patient Demographics and Clinical Characteristics** The mean patient age at surgery was 52.1±10.5y (range: 18-85y), 79 patients (11.4%) were under 40y of age and 158 (20%) were at least 60 years old. Demographics and clinical characteristics of the patients were showed in Table 1.

**Indications for Surgery** The main indication for primary diabetic vitrectomy surgery was non-clearing VH, followed by VH combined with RD, RD affecting macular, RD threatening macular, and active fibrovascular proliferation (Table 2).

**Preoperative Visual Acuity** The preoperative corrected Snellen visual acuity of most patients undergoing surgery was <0.05, while 58 eyes (7.3%) had visual acuity >0.3 before surgery (Table 3).

**Preoperative Treatments** Preoperative anti-VEGF combined with PRP therapy was performed in 191 eyes (23.8%), preoperative anti-VEGF without prior PRP in 387 eyes (48.6%), preoperative PRP treatment alone in 62 eyes (7.8%) and 158 eyes (19.8%) received no adjuvant pretreatment. One hundred and forty-four out of the 798 eyes (18.1%) underwent at least three sessions of PRP.

**Silicone Oil Tamponade and Predictive Factors** Silicone oil was used as an intraocular tamponade agent in 313 eyes (39.2%). The silicone oil tamponade ratio of the RD group was 69.4% (240/346); the non-RD group was 16.1% (73/452), and by performing Chi-square test,  $P<0.001$ . Preoperative photocoagulation treatment [odds ratio (OR)=0.66, 95% confidence interval (CI)=0.48-0.92,  $P=0.015$ ] and younger age [OR=0.96, 95%CI=0.95-0.98,  $P<0.001$ ] were identified as protective factors against the use of silicone oil tamponade during primary vitrectomy for PDR-related complications, while preoperative anti-VEGF therapy did not affect the choice of silicone oil as endotamponade agent (OR=0.64; 95%CI=0.64-1.27;  $P=0.560$ ; Table 4).

**Combined Surgery and Complications** Vitrectomy was combined with phacoemulsification in 26 eyes (3.3%), and one eye (<1%) received combined sclera encircling surgery. The most frequent surgical complications during the one-year follow up period were recurrent RD and recurrent VH. Twenty-nine eyes (3.6%) required reoperation, including 19 (2.4%) for stubborn recurrent VH and 10 (1.2%) for recurrent RD. Six eyes (<1%) developed neovascular glaucoma (NVG) after vitrectomy and underwent shunting device implantation surgery. No patient experienced endophthalmitis and no serious systemic complications occurred after surgery.

**Silicone Oil Removal and Cataract Surgery** During the one-year follow-up period, 201 out of the 313 silicone oil eyes (64.2%) underwent surgery to remove the silicone oil.

**Table 1 Demographic and clinical characteristics of patients in the study** mean±SD, n (%)

Variable	Patients
Eyes	798
Age (y)	52.1±10.5
Gender	
Male	391 (56.7)
Female	299 (43.3)
History of hypertension	
Yes	323 (46.8)
No	367 (53.2)
Creatinine	
Abnormal	184 (26.7)
Normal	506 (73.3)
Triglycerides	
Abnormal	303 (43.9)
Normal	387 (56.1)
Cholesterol	
Abnormal	189 (27.4)
Normal	501 (72.6)

**Table 2 Indications for vitrectomy** n (%)

Main indications	Eyes
Non-clearing VH	427 (53.4)
VH+RD	288 (36.1)
RD affecting macular	29 (3.7)
RD threatening macular	29 (3.7)
Active fibrovascular proliferation	25 (3.1)

VH: Vitreous haemorrhage; RD: Retinal detachment.

**Table 3 Distribution of preoperative visual acuity (Snellen chart)** n (%)

Range (BCVA)	Eyes
LP-0.05	518 (64.9)
0.05-0.3	222 (27.8)
0.3-0.5	41 (5.2)
0.5-1.0	17 (2.1)

BCVA: Best-corrected visual acuity; LP: Light perception.

**Table 4 Binary Logistic regression analysis evaluating predictive factors of silicone oil tamponade**

Items	OR	95%CI	P
Age	0.96	0.95-0.98	<0.001
Gender	1.03	0.74-1.41	0.861
Duration of symptoms	1.01	0.99-1.02	0.150
Hypertension	1.16	0.85-1.59	0.353
Glucose	1.02	0.96-1.08	0.582
Creatinine	1.00	1.00-1.00	0.445
Cholesterol	0.96	0.87-1.07	0.457
Triglyceride	1.04	0.95-1.13	0.438
Anti-VEGF	0.64	0.64-1.27	0.560
Preoperative laser	0.66	0.48-0.92	0.015

VEGF: Vascular endothelial growth factor; OR: Odds ratio; 95%CI: 95% confidence interval.

Ninety-six eyes (30.7%) in the silicone oil tamponade group underwent cataract surgery compared to 19 out of 485 eyes (3.9%) in the non-silicone oil tamponade group ( $P<0.01$ ).

## DISCUSSION

The demographic and clinical characteristics of Chinese patients who underwent PPV for PDR-related complications were explored in this study. Silicone oil tamponade rate was high although anti-VEGF agents were widespread administered prior to diabetic vitrectomy. Moreover, we identified that the lack of preoperative laser treatment was the main reason for the high silicone oil tamponade rate during primary diabetic vitrectomy. Thus, in the anti-VEGF era for DR management, PRP still plays an important role and should not be ignored.

This study reviewed a large number of Chinese patients who underwent PPV for severe PDR-related complications. As digital data collection is increasing, the use of database studies to document clinical outcomes in real-world settings is also increasing<sup>[12]</sup>. The data used in this study were collected from the electronic medical record system, which represented the patients encountered daily by physicians. Although the results of randomised controlled studies are considered as the highest level of clinical evidence, real-world research results are valuable and applicable.

Nevertheless, Antoszyk *et al*<sup>[13]</sup> reported that anti-VEGF alone was not inferior to vitrectomy with PRP in the treatment of VH from PDR in the primary outcome of visual acuity over 6mo following initial treatment; however, vitrectomy surgery, which involves the removal of pathological vitreous and clearance of hemorrhage and scarring tissues relieving vitreoretinal traction, remains the cornerstone of treatment for late complications of PDR, even in patients with a history of optimal laser photocoagulation and other medical therapies<sup>[14]</sup>. The current surgical concept and techniques used in vitrectomies have dramatically advanced since the surgery reported by Diabetic Retinopathy Vitrectomy Study (DRVS)<sup>[15]</sup>, characterizing by the increased use of smaller gauge vitrectomy systems, application of wide-angle viewing system, injection of silicone oil to aid retinal reattachment in complicated cases, and widespread use of anti-VEGF adjuvant therapy for severe PDR-related complications<sup>[16]</sup>.

Few studies reported the baseline characteristics and trends of preoperative treatments in Chinese patients undergoing diabetic vitrectomy. In our study, the mean age of the patients at surgery was 52y and the most frequent indication for diabetic vitrectomy was non-clearing VH. In one of the largest previously-published studies with a series of 890 consecutive patients regarding vitrectomy for PDR-associated complications, the mean age was 51.9y and the most common indications for vitrectomy were TRD (36.6%) and persistent VH (35.4%)<sup>[17]</sup>. Our results are also consistent with those of the Early Treatment Diabetic Retinopathy Study (ETDRS)<sup>[5]</sup>. Few studies regarding the preoperative visual acuity of patients

with PDR undergoing vitrectomy have been reported. One previous study reported that 11.9% of eyes had visual acuity  $\geq 0.1$  at baseline<sup>[18]</sup>, while 24.8% of eyes in our study had a preoperative visual acuity  $>0.1$ , including 7.3% of eyes with a preoperative visual acuity  $>0.3$ . The threshold for performing vitrectomy for patients with PDR has decreased as a result of the advancement of the modern PPV technique, the application of adjuvant therapies, and advances in the management of these patients.

Preoperative anti-VEGF and PRP treatments are common for patients with PDR, which are closely related to the postoperative prognosis<sup>[9,19]</sup>. The adjuvant intravitreal injection of anti-VEGF drugs was first reported in 2006 for the preoperative treatment of patients with PDR with active proliferation<sup>[20]</sup>, which made the procedure significantly less challenging, diminished intraoperative iatrogenic complications, and reduced intra- and postoperative bleeding<sup>[19]</sup>. In our study, 72% of the eyes received preoperative anti-VEGF treatment and 2.1% of the eyes underwent re-vitrectomy due to recurrent VH within the first postoperative year. The re-vitrectomy rate in our study is significantly lower than previously reported rates of 10.4%-23%<sup>[17,21]</sup>. These differences may be due to a relatively higher rate of preoperative anti-VEGF treatment in our study compared with other studies, which ranged from 17%-53.8%<sup>[17,21]</sup>.

Previous studies have reported that preoperative laser treatment improves visual prognosis and reduces the risk of recurrent bleeding after surgery<sup>[9]</sup>. It seems to be the common sense for vitreoretinal surgeons that preoperative laser treatment helps avoid intraoperative complications and reduce the use of silicone oil at the end of the surgery. However, our results provide exact data reference for this conclusion. In this study, only 30% of the eyes underwent PRP treatment prior to surgery, which is significantly less than previously reported PRP rates of 56.8%-83%<sup>[17,22-23]</sup>. These differences may be due to the poor accessibility to or awareness of regular DR screening and timely laser treatment in Chinese patients with diabetes<sup>[24]</sup>. Ophthalmologists and public health policymakers in China should be made aware of these results as China has the largest diabetes mellitus and DR population in the world<sup>[25]</sup>. Silicone oil infusion significantly improves the surgical success rate and postoperative visual acuity in complicated cases<sup>[6]</sup>; however, its use will inevitably increase the number of operations and postoperative complications, especially postoperative nuclear cataracts<sup>[26]</sup>. Iatrogenic injuries should be avoided during DR surgery to reduce the use of silicone oil. The silicone oil tamponade rate was 40% in our study, which was significantly higher than previously reported rates of 5.2%-24.4%<sup>[17,21,27]</sup>. The higher rate may be attributed to the large number of more serious cases included in this study.

The lack of preoperative laser photocoagulation treatment and older age were identified as independent risk factors for the use of silicone oil as endotamponade in this study. The lack of prior PRP treatment may increase the risks of proliferative reticulum and intraoperative iatrogenic holes<sup>[23]</sup>. In our study, the preoperative laser treatment ratio was only 30%, which may explain the high ratio of patients who underwent silicone oil infusion.

Several original studies and Meta-analysis have showed that anti-VEGF pretreatment could shorten operation duration, easy the procedure, reduce intraoperative and postoperative complications and even spare the need for postoperative retinal photocoagulation sometimes<sup>[13,19,28]</sup>. However, controversies regarding the impact of preoperative anti-VEGF drugs on the risk of TRD in eyes with PDR and the use of silicone oil as intraocular tamponade agent in primary diabetic vitrectomy still exist. According to a recent review, the progression to TRD following intravitreal anti-VEGF therapy was noted from 1.5% to 18.4% in different studies, especially common in patients with increased severity of DR with fibrosis<sup>[29]</sup>. On the contrary, another study showed that anti-VEGF therapy for PDR does not increase the risk of TRD in eyes with PDR similar to those enrolled in the DRCR.net protocols for which prompt vitrectomy was not planned<sup>[30]</sup>. Moreover, Uzel *et al*<sup>[28]</sup> reported that preoperative anti-VEGF can reduce the use of silicone oil tamponade at the end of surgery in patients undergoing PPV for diabetic TRD. Recently, Chen *et al*<sup>[31]</sup> evaluated the effects of preoperative ranibizumab intravitreal injection on vitrectomy in patients aged less than 40 years old with PDR-related complications, the results showed that the use of silicone oil tamponade were not affected by preoperative anti-VEGF treatment but affected by the severity of DR. A Meta-analysis also revealed that no significant difference existed between sham control group and preoperative anti-VEGF injection group in reducing the rate of silicone oil tamponade<sup>[32]</sup>. In this study, the use of preoperative anti-VEGF was not associated with the choice of using silicone oil as intraocular tamponade agent, which may be attributed to the fact that most patients with aggressive conditions received injections and the treatment makes no significant difference in patients with mild conditions. Our results also support the concept that the incidence of use of silicone oil tamponade were not affected by preoperative anti-VEGF injection.

This study included a relatively large sample size and consecutive primary vitrectomy data from a single tertiary centre during a one-year period, reflecting the current management of PDR-related complications in China. Surgeries performed by inexperienced surgeons were excluded from this study to reduce external causes of variability. However, this study has

some limitations. The retrospective nature of the study did not allow for the standardization of the measurements, and loss to long-term follow-up may have resulted in the under- or overestimation of the reported outcomes. For example, patients with mild recurrence of VH after surgery that did not require reoperation were not recorded as having recurrent VH. Moreover, some important factors such as: the severity of PDR, the level of glycated haemoglobin, the duration of diabetes and the type of diabetes that may affect the choice of tamponade during the surgery was missing and failed to be evaluated in the present study. And even the patient's general condition and visual acuity of the opposite eye are relevant to the use of silicone oil. Those factors relevant to silicone oil use can be further evaluated.

In conclusion, the lack of preoperative laser treatment was identified as a significant predictive factor of silicone oil tamponade at the end of primary PDR vitrectomy. Although preoperative anti-VEGF therapy can reduce the time and difficulty of the diabetic vitrectomy procedure, it cannot reduce the rate of silicone oil tamponade. Thus, even in the anti-VEGF era, PRP should not be ignored for the treatment of PDR. The results could be served as a reference for the evaluation and management of patients with PDR.

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