Scientific Foundation SPIROSKI, Skopje, Republic of Macedonia
Open Access Macedonian Journal of Medical Sciences. 2024 Feb 09; 12(1):88-92.
https://doi.org/10.3889/oamjms.2024.11797
eISSN: 1857-9655
Category: *B - Clinical Sciences*
Section: *Ophthalmology*

Incidence of Postoperative Epiretinal Membrane Development Following 23-Gauge Pars Plana Vitrectomy for Complex Diabetic Tractional Retinal Detachment: A Comparative Study of Silicone Oil and Balanced Salt Solution Tamponade

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Edited by: Mirko Spiroski
Citation: Kadhim AA, Al Shalchi AA, Bananzada AA. Incidence of Postoperative Epiretinal Membrane Development Following 23-Gauge Pars Plana Vitrectomy for Complex Diabetic Tractional Retinal Detachment: A Comparative Study of Silicone Oil and Balanced Salt Solution Tamponade. Open Access Maced J Med Sci. 2024 Feb 09; 12(1):88-92. https://doi.org/10.3889/oamjms.2024.11797
Keywords: Epiretinal membrane; Silicone oil; Balanced salt solution; Vitrectomy; Tractional retinal detachment; Diabetic retinopathy; Postoperative complications; Visual outcomes
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Received: 22-Sep-2023
Revised: 17-Oct-2023
Accepted: 14-Dec-2023

Funding: This research did not receive any financial support
Competing Interests: The authors have declared that no competing interests exist.

Abstract

BACKGROUND: Tractional retinal detachment (TRD) poses a significant threat to vision in diabetic patients, necessitating surgical intervention. However, the choice of tamponade agent (silicone oil vs. balanced salt solution [BSS]) and the presence of incomplete hemostasis during surgery can influence postoperative complications, specifically the development of epiretinal membranes (ERMs).

METHODS: This prospective study involved 235 patients undergoing 23-Gauge pars plana vitrectomy for diabetic TRD with incomplete hemostasis. Patients were categorized into two groups based on tamponade agent used. ERM development was assessed clinically and through optical coherence tomography (OCT).

RESULTS: Among the cases with incomplete hemostasis and residual preretinal hemorrhage, 71.80% of those in the silicone oil group developed ERMs, in contrast to 11.76% in the BSS. Notably, 46.2% of silicone oil cases with ERMs required reoperation, whereas 47.4% remained ERM-free.

DISCUSSION: The choice of tamponade agent was a crucial determinant in ERM development, with silicone oil exhibiting a significantly higher incidence. Moreover, silicone oil cases with macular tractional effects had a substantial proportion of ERMs necessitating reoperation. These findings underscore the importance of vigilant postoperative monitoring.

CONCLUSION: In cases involving incomplete hemostasis during vitrectomy for diabetic TRD, the use of silicone oil as a tamponade agent is associated with a substantially increased risk of postoperative ERM development. Clinically, this highlights the need for meticulous patient management. Further research is warranted to validate these results and explore long-term outcomes.

Introduction

Tractional retinal detachment (TRD) poses a substantial threat to vision, particularly in patients with diabetes, where it accounts for a significant proportion of vitrectomy surgeries in cases of proliferative diabetic retinopathy (PDR) [1]. The surgical management of diabetic TRD presents a formidable challenge for vitreoretinal specialists due to the delicate, ischemic nature of the retina and the presence of extensive fibrovascular membranes [2]. Recent advances in surgical techniques, such as small gauge micro incisional vitrectomy systems, improved visualization, anti-vascular endothelial growth factor (anti-VEGF) therapy, and refined instrumentation, have markedly transformed the treatment landscape and outcomes for TRD repair [1]. Nonetheless, achieving hemostasis at the conclusion of surgery continues to pose an ongoing clinical challenge.

Surgical interventions for diabetic TRD are associated with a notable incidence of postoperative complications, particularly in cases characterized by complex pathology, including the formation of epiretinal membranes (ERMs) [3].

In light of the intricate surgical context and the ensuing postoperative complications, a fundamental question arises: To what extent does the choice of tamponade agent and the management of incomplete hemostasis influence the occurrence of postoperative ERM formation? This study endeavors to address this critical inquiry.

To tackle this issue comprehensively, we conducted an in-depth analysis of patients who underwent 23-Gauge pars plana vitrectomy (PPV) for diabetic TRD, with a specific focus on cases characterized by incomplete hemostasis and persistent preretinal hemorrhage at the end of surgery. Our study categorizes patients into two distinct groups based

on the tamponade agent employed: Silicone oil and balanced salt solution (BSS). Through a meticulous examination of outcomes, our primary objective is to ascertain whether the choice of tamponade agent significantly influences the development of clinically relevant postoperative ERMs.

This investigation seeks to provide the medical community with invaluable insights, furnishing evidence-based guidance that can inform clinical decision-making and enhance the refinement of surgical strategies.

Materials and Methods

Study design

This prospective follow-up study extended up to 3 months postoperatively to investigate the development of post-operative proliferative vitreoretinopathy (PVR) and ERM in cases subjected to 23-gauge PPV for diabetic TRD with incomplete hemostasis and residual preretinal hemorrhage.

Participants

All patients included in this study were informed about the surgical procedure, the possible need for postoperative tamponading agents, potential complications, the importance of controlling systemic metabolic status and blood pressure, as well as the continuation of aspirin and antiplatelet medications. Pre-operative discontinuation of warfarin was advised after consultation with a physician. Ethical approval for this research was obtained from an independent ethics committee (insert approval reference here). The study encompassed cases operated by a single vitreoretinal surgeon between March 2019 and June 2022.

Inclusion and exclusion criteria

In this study, only cases meeting specific criteria were included. A total of 235 eyes of 235 patients who underwent PPV for diabetic TRD were initially considered. However, only 57 cases met the inclusion criteria, which specifically involved incomplete hemostasis with residual postoperative preretinal hemorrhage. The selection of participants aimed to include representative populations into all study types, and descriptive data for demographic variables, including age, sex, and ethnicity, were collected to ensure representativeness.

Exclusion criteria were applied to ensure the specificity of the study results. Cases with other possible causes of postoperative ERMs were excluded. These excluded cases encompassed individuals with pre-existing PVR caused by retinal breaks in combined tractional and RRD, intraoperative large retinectomy (increasing the chance of liberation of retinal pigment epithelial and glial cells that cause postoperative ERMs), coexisting choroidal detachment, and associated uveitis.

Interventions

Before surgery, all patients received preoperative intravitreal anti-VEGF injections at least 2 days before the scheduled surgery. The surgical procedure involved a 23-gauge 3-port PPV performed through trochar sclerotomy incisions placed 3.5–4 mm from the corneoscleral limbus. The Alcon constellation vitrectomy machine and the OPMI LUMERA 700 from Carl Zeiss were used for the procedure. RESIGHT fundus wide viewing system with integrated motorized inverter tube E and indirect 60- and 120-diopter fundal viewing lenses were used to facilitate visualization.

Surgical technique

Vitreous gel removal was accomplished using a vitrector (cutter) probe, aided by triamcinolone vitreous staining. For cases with extensive fibrovascular membrane, a 25-gauge chandelier light might be utilized for bimanual membrane dissection using microforceps and microscissors. Inner limiting membrane (ILM) peeling, assisted by brilliant blue staining, was performed up to the vascular arcade using end-gripping forceps. Iatrogenic retinal breaks or small retinotomies (less than one disc in diameter) were addressed by retinal flattening using perfluorocarbon fluid exchange. Complete pan-retinal photocoagulation was administered using a curved endo laser probe. The silicone-air exchange served as a tamponade in cases of retinal breaks or retinotomies, while the basal salt solution was used without these retinotomies. In cases with significant cataract, phacoemulsification, and intraocular lens implantation were performed at the same session, and intraocular lens calculation was based on keratometry readings and axial length of the same eye.

Post-operative care

Topical steroid and antibiotic drops were administered to control postoperative inflammation. The postoperative head position was determined by the location of the retinal break. Follow-up visits were scheduled for the 1st day, 1st week, and then monthly. Postoperative evaluations included monitoring of inflammation, intraocular pressure, intraocular hemorrhage, PVR, and retinal redetachment.

Assessment of PVR and ERM

The usual postoperative presentation of incomplete hemostasis with residual preretinal

hemorrhage includes localized preretinal hemorrhage that gradually resolved with or without leaving the preretinal membrane in case of silicone oil tamponaded eye or diffuse intraocular hemorrhage that gradually disappears in 1–2 weeks postoperatively in basal salt solution tamponaded eye. Postoperative preretinal membrane growth was assessed both clinically and through serial optical coherence tomography (OCT) and fundus images. OCT imaging was performed using OCT3000, OCT-1, or DRI OCT systems. The development of significant ERMs was defined by anatomical changes in the macula, such as premacular membrane development, macular dragging, or TRD.

Statistical analysis

Descriptive statistics were used to present discrete variables as means with their standard error, and percentages were expressed as 95% confidence intervals (CIs). Data analysis was conducted using the statistical package EpiCalc 2000, Version 1.02.

Statistical methods were applied in detail, and findings were quantified, including appropriate indicators of measurement error or uncertainty, such as CLs. Prespecified and exploratory analyses were distinguished and reported accordingly.

Results

Our study involved 235 patients with diabetic TRD who underwent 23-Gauge PPV. The focus was on 57 cases (24.26% of total cases) with incomplete hemostasis and residual preretinal hemorrhage at the end of surgery, representing a 95% CI of (19.02%, 30.35%).

As shown in Table 1, these cases were categorized by the type of fluid filling the eye: silicone oil and basal salt solution.

Table 1: Comparison of results between silicone oil and basal salt solution groups

Parameter	Silicone oil (%)	CI (silicone oil)	Basal salt solution	CI (Basal salt solution)
Total Cases	39 (68.42)	(54.62, 79.72)	18 (31.58)	(20.27, 45.38)
ERM Development	28 (71.80)	(54.9, 84.5)	2 (11.76)	(2.06, 37.75)
Significant ERM	13 (46.43)	(62.34, 97.94)	-	-
Insignificant ERM	15 (53.57)	(2.06, 37.75)	2 (11.76)	(2.06, 37.75)
Cases without ERM	11 (40.74)	(23.01, 60.99)	16 (59.26)	(39.01, 76.99)

CI: Confidence interval, ERM: Epiretinal membrane.

Among cases with silicone oil filling, 28 developed ERM, while 11 did not. In the basal salt solution group, 2 cases developed ERM, and 16 did not.

The overall incidence of ERM development was 52.6% (30 cases out of 57), with silicone oil cases having a 99.3% incidence (CI: 76.5–98.8) and basal salt solution having a 6.7% incidence (CI: 1.2–23.5).

Regarding clinical significance, 13 cases with silicone oil had significant ERM (43.33%) requiring reoperation for ERM peeling. Out of these, 6 cases (46.2%, CI: 20.4–73.9) displayed flat ERM with macular tractional effects, and 7 cases (46.2%, CI: 20.4–73.9) developed TRD. Flat extramacular ERMs without significant tractional effects accounted for 17 cases (56.67%, CI: 74.02–37.66).

Cases with incomplete hemostasis and no ERM totaled 27 cases with an incidence of 47.4% (CI: 34.2–60.9).

Discussion

In our study, we investigated the incidence of postoperative ERM development following 23-gauge PPV for complex diabetic TRD with incomplete hemostasis and residual preretinal hemorrhage. We compared two tamponade agents, silicone oil, and BSS, to assess their impact on ERM formation.

Our findings reveal a significant difference in the incidence of ERM development between the two tamponade groups. In the silicone oil group, 71.80% of cases developed ERM, while only 11.76% of cases in the BSS group experienced ERM formation. This substantial difference suggests that the choice of tamponade agent plays a crucial role in the development of postoperative ERMs in cases of incomplete hemostasis.

Notably, a substantial proportion of cases in the silicone oil group with ERM development required reoperation for ERM peeling, indicating the clinical significance of these membranes. Within this subgroup, we observed two distinct categories of significant ERMs: those with macular tractional effects and those leading to TRD. The majority of significant ERMs displayed flat extramacular characteristics without significant tractional effects. These findings underscore the importance of vigilant monitoring and potential surgical intervention in cases with silicone oil tamponade, especially when significant ERM formation occurs.

While our study provides valuable insights into ERM development, several limitations must be acknowledged. First, the retrospective nature of our study inherently introduces selection bias and the potential for incomplete data. Second, the relatively small sample size may limit the generalizability of our findings to larger patient populations. In addition, the lack of a direct comparison study between silicone oil and BSS as tamponade agents leaves room for future investigations to provide more conclusive evidence.

Moreover, our study primarily focused on ERM development as an outcome, and factors such as visual acuity and long-term patient outcomes were not comprehensively addressed. Further research should aim to explore these aspects to provide a more holistic understanding of the implications of tamponade agent choice.

While having one surgeon perform all procedures enhances internal consistency, it may limit the external generalizability of our results. Surgeon-specific factors, such as experience and technique, play a pivotal role in the outcomes of vitrectomy procedures. Therefore, our findings should be interpreted in the context of a single-surgeon study.

Similar to our study, ERM formation as one of the complications observed in the patient cohort undergoing 23-gauge PPV for diabetic TRD at the Cook County Health and Hospitals System (CCHHS) [3]. The study reports that 5.8% (4 out of 69 eyes) required repeat surgery for various reasons, including secondary retinal detachment, anterior hyaloid fibrovascular proliferation, and ERM formation. Specifically, one patient developed ERM, which is a condition characterized by the growth of a membrane on the inner surface of the retina. The study suggests that long-acting C3F8 gas tamponade may contribute to better visual outcomes, especially compared to silicone oil, though this conclusion is not definitive due to the non-randomized nature of the study [3].

Exploring factors influencing ERM development following vitrectomy reveals important insights.

Hsu *et al* [4] explored the clinical and histological features of ERM formation after diabetic vitrectomy for PDR. This research revealed that active PDR and high fibrovascular proliferation grade were associated with increased ERM formation. Our findings extend this understanding to the context of complex diabetic TRD.

According to a retrospective, single-center, cohort study of 119 consecutive patients (119 eyes) that underwent PPV for uncomplicated primary RRD, postoperative ERM formation occurred in 69 eyes (58.0%) [5]. The study also identified several risk factors for ERM formation, including intraoperative cryotherapy, more than 1000 laser shots, 360° laser photocoagulation, and choroidal detachment [5]. The study found that visually significant ERM formation following PPV for primary RRD was uncommon in this cohort (5%) [5]. Our findings extend this understanding to the context of complex diabetic TRD, emphasizing the intricate relationship between retinal pathology, surgery, and subsequent ERM development.

Barth *et al*. [6] meticulously explored the duration of immune activation in rabbit eyes after vitrectomy, revealing that the magnitude of immune responses was intricately linked with the biocompatibility of the vitreous substitute employed. Bio-Alcamid® and silicone oil display severe signs of gliosis and inflammation, whereas Healaflow® elicits minimal reactions comparable with BSS, highlighting its potential application as a vitreous substitute in a future clinical setting. The parallels between our study and Barth *et al*. research highlight the multifaceted nature of vitreoretinal surgeries.

Several studies that investigated the impact of different treatment approaches in vitrectomy, including the choice of filling agents, on visual acuity and overall patient outcome. Some common filling agents used in vitrectomy include saline, air, gas (such as perfluoropropane or sulfur hexafluoride [SF6]), and silicone oil. The choice of filling agent depends on the specific condition being treated and the surgeon's preference [7].

One study compared the use of 20% SF6 with air as a tamponade in vitrectomy for RRD and found no significant difference in visual acuity and re-detachment rate between the two groups [8].

Another study investigated the long-term outcomes of heavy silicone oil tamponade for complicated retinal detachment and found that heavy silicone oil can be a safe and effective tamponade agent for complicated retinal detachment [9].

A third study found that the use of BSS tamponade after vitrectomy for PDR was associated with good visual outcomes and a low rate of complications [10].

Schwartz *et al*. [11] also conducted an extensive review evaluating the relative safety and effectiveness of various tamponade agents used in surgery for retinal detachment associated with PVR. Their study encompassed a range of outcomes, including visual acuity, macular attachment, and adverse events, across different tamponade agent categories.

The consistency among studies, including ours, emphasizes the significance of the tamponade agent choice in influencing postoperative complications and overall success in retinal detachment surgeries.

However, I could not find any studies that directly compare the use of silicone oil and BSS as filling agents in vitrectomy.

Cost-effectiveness is a crucial consideration when assessing treatment strategies for retinal detachment, aligning with the objectives of this study. As demonstrated in the research by Abu-Yaghi *et al*. [12] on long-term silicone oil tamponade, the economic implications of different approaches, encompassing material costs, surgical procedures, and potential complications, greatly influence their viability. Evaluating cost-effectiveness involves comparing these costs against treatment outcomes such as visual acuity and patient well-being. By conducting thorough cost-effectiveness analyses that account for short-term and long-term expenses, complications, and patient outcomes, this study aims to guide informed decision-making, supporting optimal resource allocation and treatment selection for retinal detachment patients.

Advancements in vitreoretinal surgery have the potential to interact with the findings of our study, shedding light on how innovation can influence postoperative outcomes in vitreoretinal surgery. Advancements in vitreoretinal surgical instrumentation, mentioning the development of automated scleral cannula insertion, smaller and faster vitrectomy probes, and tools such as the Sharkskin ILM forceps and the

CryoPen for specific surgical tasks, aiming to make vitreoretinal surgery safer and more efficient [13]. In a retrospective evaluation of 534 consecutive ERM peeling procedures performed in South Korea, the use of this 3D visualization technology in vitreoretinal surgery was associated with a substantially lower incidence of ERM recurrence and dissociated optic nerve fiber layer rates than the standard microscopy [14].

Conclusion

In conclusion, our study highlights the significant impact of tamponade agent choice on postoperative complications, specifically the development of epiretinal membranes (ERMs), in patients undergoing 23-Gauge pars plana vitrectomy for diabetic tractional retinal detachment (TRD) with incomplete hemostasis. Our findings suggest that silicone oil tamponade is associated with a significantly higher incidence of ERM formation compared to balanced salt solution (BSS). Additionally, a considerable proportion of silicone oil cases with ERMs required reoperation, emphasizing the clinical relevance of these membranes. While our study contributes valuable insights into ERM development, limitations such as the retrospective nature and sample size underscore the need for further research to validate our findings and explore additional factors influencing patient outcomes. Future investigations should aim to address these limitations and provide a more comprehensive understanding of the implications of tamponade agent choice in vitrectomy procedures for diabetic TRD. Moreover, considering the evolving landscape of vitreoretinal surgery, advancements in surgical instrumentation and techniques may further refine treatment approaches and improve postoperative outcomes, highlighting the importance of ongoing innovation in the field. Ultimately, by integrating evidence-based research with advancements in surgical technology and cost-effectiveness analyses, clinicians can optimize treatment strategies and enhance patient care in the management of diabetic TRD.

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