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[Intervention Review]

Tamponade in surgery for retinal detachment associated with proliferative vitreoretinopathy

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ABSTRACT

Background

Retinal detachment (RD) with proliferative vitreoretinopathy (PVR) often requires surgery to restore normal anatomy and to stabilize or improve vision. PVR usually occurs in association with recurrent RD (that is, after initial retinal re-attachment surgery) but occasionally may be associated with primary RD. Either way, a tamponade agent (gas or silicone oil) is needed during surgery to reduce the rate of postoperative recurrent RD.

Objectives

The objective of this review was to assess the relative safety and effectiveness of various tamponade agents used with surgery for retinal detachment (RD) complicated by proliferative vitreoretinopathy (PVR).

Search methods

We searched CENTRAL (which contains the Cochrane Eyes and Vision Group Trials Register) (*The Cochrane Library* 2013, Issue 5), Ovid MEDLINE, Ovid MEDLINE In-Process and Other Non-Indexed Citations, Ovid MEDLINE Daily, Ovid OLDMEDLINE (January 1946 to June 2013), EMBASE (January 1980 to June 2013), Latin American and Caribbean Literature on Health Sciences (LILACS) (January 1982 to June 2013), the *meta*Register of Controlled Trials (*m*RCT) (www.controlled-trials.com), ClinicalTrials.gov (www.clinicaltrials.gov) and the WHO International Clinical Trials Registry Platform (ICTRP) (www.who.int/ictrp/search/en). We did not use any date or language restrictions in the electronic searches for trials. We last searched the electronic databases on 26 June 2013.

Selection criteria

We included randomized controlled trials (RCTs) of participants undergoing surgery for RD associated with PVR that compared various tamponade agents.

Data collection and analysis

Two review authors screened the search results independently. We used the standard methodological procedures expected by The Cochrane Collaboration.

Main results

The review included 516 participants from three RCTs. One study was conducted in the USA and consisted of two trials: the first trial randomized 151 adults to receive either silicone oil or sulfur hexafluoride (SF_6) gas tamponades; and the second trial randomized 271 adults to receive either silicone oil or perfluropropane (C_3F_8) gas tamponades. The third trial was a multi-center international trial and

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randomized 94 participants (age range not specified) to receive heavy silicone oil (a mixture of perfluorohexyloctane (F_6H_8) and silicone oil) versus standard silicone oil (either 1000 centistokes or 5000 centistokes, per the surgeon's preference).

In participants with RD associated with PVR, outcomes after pars plana vitrectomy and infusion of either silicone oil, perfluropropane gas, or sulfur hexafluoride gas appeared comparable for a broad variety of cases. There were no significant differences between silicone oil and perfluoropropane gas in terms of the proportion of participants achieving at least 5/200 visual acuity (risk ratio (RR) 0.97; 95% confidence interval (CI) 0.73 to 1.31) or achieving macular attachment (RR 1.00; 95% CI 0.86 to 1.15) at a minimum of one year. Although sulfur hexafluoride gas was reported to be associated with significantly worse anatomic and visual outcomes than was silicone oil at one year (quantitative data not reported), there were no significant differences between silicone oil and sulfur hexafluoride gas in terms of achieving at least 5/200 visual acuity at two years (RR 1.57; 95% CI 0.93 to 2.66). For macular attachment, participants treated with silicone oil received significantly more favourable outcomes than did participants who received sulfur hexafluoride at both one year (quantitative data not reported) and two years (RR 1.37; 95% CI 1.01 to 1.86). The first two trials did not perform any sample size calculation or power detection. In the third trial, which had a power of 80% to detect differences, heavy silicone oil was not shown to be superior to standard silicone oil. There were no significant differences between standard silicone oil and heavy silicone oil in the change in visual acuity at one year using adjusted mean logMAR visual acuity (mean difference -0.03 logMAR; 95% CI -0.35 to 0.29). Adverse events were not reported for the first two trials. For the third trial, only the total number of adverse events was reported, and adverse events for each group were not specified. Of the 94 participants, four died, 26 had recurrent retinal detachment, 22 developed glaucoma, four developed a cataract, and two had capsular fibrosis.

All three trials employed adequate methods for random sequence generation and allocation concealment. None of the trials employed masking of participants and surgeons, and only the third trial masked outcome assessors. The first trial had a large portion of participants excluded from the final analyses, while the other two trials were at low risk of attrition bias. All trials appear to be free of reporting bias. The first two trials were funded by the National Eye Institute, and the third trial was funded by the German Research Foundation.

Authors' conclusions

The use of either perfluropropane or standard silicone oil appears reasonable for most patients with RD associated with PVR. Because there do not appear to be any major differences in outcomes between the two agents, the choice of a tamponade agent should be individualized for each patient. Heavy silicone oil, which is not available for routine clinical use in the USA, has not demonstrated evidence of superiority over standard silicone oil.

PLAIN LANGUAGE SUMMARY

Tamponade in surgery for retinal detachment associated with proliferative vitreoretinopathy

Review question

We reviewed the effect of tamponade agents used in surgery involving pars plana vitrectomy in participants with retinal detachment (RD) associated with proliferative vitreoretinopathy (PVR).

Background

The retina is the light-sensing tissue in the back of the eye (similar to the film within a camera), and its normal function depends on its attachment to an underlying layer called the retinal pigment epithelium (RPE). RD, a physical separation of the retina from the RPE, remains an important cause of visual loss. The macula is the centermost part of the retina and is responsible for central vision and perception of fine details. RD may or may not involve the macula, but patients with macular detachment typically have more severe visual loss than patients without macular detachment. RD is generally treated with surgery, but surgery is not always successful. In some patients surgery is initially successful but RD may recur months or years later. Most recurrent RDs, and some primary RDs, are associated with varying degrees of PVR, or the growth of fibrous membranes (similar to scar tissue) along the surface of the retina. The only proven therapy for RD with PVR is further surgery; where the membranes must be physically removed from the surface of the retina. In addition, injection of a material to hold the newly attached retina in position, called a tamponade agent, is performed to reduce the rate of fluid flow through open retinal tears, which would cause recurrent RD. The major tamponade agents that are available today are various gases and silicone oils.

Study characteristics

We found three randomized controlled trials (RCTs) involving 516 participants that compared tamponade agents. All participants underwent surgery to treat RD associated with PVR. The Silicone Study compared the use of silicone oil to either sulfur hexafluoride (SF_6) gas or perfluropropane (C_3F_8) gas in two RCTs. Both gases and silicone oil are less dense than water, so that they float upwards or towards the top of the eye while a patient is sitting or standing. This is sometimes but not always beneficial, so a denser-than-water silicone oil called heavy silicone oil has been investigated, primarily outside the US. The Heavy Silicone Oil Study compared the use of heavy silicone oil to standard silicone oil in participants with RD involving the lower parts of the retina. The evidence was current to June 2013.

Key results

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When silicone oil was compared to SF_6 gas, eyes randomized to receive silicone oil more often achieved a visual acuity of 5/200 or better at one year, and more often achieved macular attachment at one year but with no difference at two years. When silicone oil was compared with C_3F_8 gas, there were no significant differences between the groups with respect to visual acuity or macular attachment at one year. When heavy silicone oil was compared to standard silicone oil, there were no significant differences between the groups with respect to retinal re-attachment or visual acuity at one year. Heavy silicone oil did not demonstrate any significant benefit over standard silicone oil. Adverse events were only reported for the Heavy Silicone Oil Study; however, only the total number of adverse events was reported, and the numbers for each group were not specified: of the 94 participants, there were four deaths, 26 recurrent RDs, 22 patients with glaucoma, four patients with cataract, and two patients with capsular fibrosis (scarring behind a lens implant).

Quality of evidence

The overall quality of these studies was moderately satisfactory. Although all trials employed proper randomization methods for participants, the masking of participants was unclear in all of the three RCTs, and masking of outcome assessors was not performed in two RCTs.

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