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Primary vitrectomy for rhegmatogenous retinal detachment in pseudophakic eyes: 20-gauge versus 25-gauge vitrectomy

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ABSTRACT.

Purpose: **To report anatomical and functional outcome of 20-gauge versus 25-gauge primary pars plana vitrectomy for management of complex rhegmatogenous retinal detachment in pseudophakic eyes.**

Methods: **Prospective single-centre randomized comparative pilot trial. Fifty patients with retinal detachment (RD) not complicated by proliferative vitreoretinopathy grade B or C, who cannot be treated with a single meridional sponge, were randomized (1:1) from November 2006 to January 2010 to either 20-gauge or 25-gauge vitrectomy as first surgical intervention and followed up over a 12-month period, evaluating change in best-corrected visual acuity, anatomical success and intraocular pressure dysregulation.**

Results: **Mean visual acuity improved by 0.88 (SD 0.67) from 1.22 logMAR (SD 0.63) to 0.34 logMAR (SD 0.31) in the 20-gauge group and by 0.53 (SD 0.91) from 0.86 logMAR (SD 0.73) to 0.34 logMAR (SD 0.46) in the 25-gauge group. Final anatomical success rate was 100% and primary success rate was 69% at 6 months of follow-up. In the 20-gauge group, the retina was attached after one single procedure in 18 eyes (72%) and in 21 eyes (84%) of the 25-gauge group. Two patients in the 25-gauge group had hypotony at the first postoperative day which normalized within 6 weeks.**

Conclusion: **In our series, transconjunctival sutureless 25-gauge and 20-gauge vitrectomy showed comparable results in pseudophakic RD not suitable for single sponge surgery with respect to visual outcome and retinal reattachment. Postoperative hypotony does not seem to be a significant problem of transconjunctival sutureless vitrectomy.**

Key words: 25-gauge vitrectomy – pars plana vitrectomy – pseudophakic – retinal detachment – transconjunctival sutureless vitrectomy

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Introduction

The proportion of aphakic/pseudophakic patients with rhegmatogenous retinal detachment (RD) has increased to 30% during the past decade due to the increasing numbers of cataract operations performed. Pseudophakic rhegmatogenous retinal detachment (RRD) can be treated with different surgical procedures, and there is still controversy about the preferable operating method of more complex RDs not complicated by proliferative vitreoretinopathy (PVR). Primary pars plana vitrectomy (PPV) has gained popularity in the last years in the treatment of RD, especially in pseudophakic eyes. The results of the Scleral Buckling Versus Primary Vitrectomy in Rhegmatogenous Retinal Detachment Study (SPR Study), which compared primary vitrectomy and scleral buckling techniques in patients with RRD not complicated by PVR, demonstrated better anatomical outcomes with primary vitrectomy in pseudophakic eyes. However, in the SPR Study, vitrectomy was solely performed using 20-gauge PPV as transconjunctival PPV systems had not been available for inclusion in the study protocol (Heimann et al. 2001, 2007; Stangos et al. 2004).

While transconjunctival sutureless vitrectomy (TSV) for epimacular disorders is accepted, its use in the treatment of RRD surgery is still discussed, especially with regard to the ongoing debate on impact of encircling bands on surgical outcome (Orlin et al. 2014; Falkner-Radler et al. 2015). Safety and efficacy of TSV PPV for RD surgery has been reported in recent publications with the majority of these representing retrospective analyses of case series (Mura et al. 2009; Von Fricken et al. 2009; Bourla et al. 2010; Colyer et al. 2010; Kobayashi et al. 2010; Kunikata & Nishida 2010; Lewis et al. 2011) or non-comparative prospective studies (Tsang et al. 2008). Therefore, we designed the first prospective single-centre randomized trial to compare functional and anatomical results of 25-gauge transconjunctival PPV versus 20-gauge transscleral PPV including laser photocoagulation and gas tamponade for primary repair of RRD not complicated by PVR grade B or C and unsuitable for treatment with a single meridional sponge. Anatomical results included redetachment rate known as a quality indicator in RRD surgery (Hajari et al. 2015).

Patients and Methods

The presented prospective single-centre randomized comparative pilot trial included 50 patients presenting with primary pseudophakic RRD between November 2006 and January 2010 at the University Eye Hospital, Tuebingen. Patients were randomized (1:1) to either 20-gauge (n = 25) or 25-gauge (n = 25) vitrectomy, both without additional encircling band, as first surgical intervention. The randomization list was generated by the statistician Reinhard Vonthein. In practice, 50 closed envelopes consecutively labelled with the patient number and the study title, containing a document indicating the type of vitrectomy for the respective study participant, were stored in the operating theatre. The envelope was opened in the operation theatre immediately before surgery. In all cases, the randomly allocated treatment was conducted. The study followed the Declaration of Helsinki guidelines for research involving subjects and was approved by the local ethical committee board (379/2005). All patients enrolled in the study provided signed informed consent for study participation before inclusion into the trial and surgical intervention.

Outcome measures

All outcome measures were performed in a blinded manner. The outcome of RD surgery was evaluated using three main end-point criteria: (i) primary end-point was functional outcome defined as change in visual acuity (BCVA; logMAR scale) from the initial examination using letter-by-letter scoring on ETDRS charts to the final examination defined as last observation, (ii) secondary end-point included anatomical success defined as (a) primary retinal reattachment without any reoperation at 6 months and (b) final retinal reattachment after 1 year with any kind of reoperation permitted, (iii) tertiary end-point analysed intraocular pressure (IOP) dysregulation (hypotony/hypertony) at the first postoperative day and the follow-up visits.

Every patient was scheduled to be examined at four intended follow-up visits: at the first day after surgery, 6 weeks after surgery, 6 months after surgery and 1 year after surgery. Baseline and follow-up exams included best-corrected visual acuity (BCVA; logMAR scale) using ETDRS charts, IOP, optical coherence tomography (OCT) using Spectralis OCT (Heidelberg Engineering), fundus and slitlamp photography. Additional examinations were performed in the case of reoperations or at any additional unscheduled visit. Primary end-point of the study was 6 months after initial surgery.

Inclusion criteria

Patients were included if they were older than 18 years and presented with primary pseudophakic RD not complicated by PVR grade B or C that could not be treated with a single meridional sponge (e.g. unclear hole situations preoperatively, central extension of brake, multiple brakes, different localizations in anterior–posterior direction). Patients had to be willing and capable of participating in the study including follow-up visits. Exclusion criteria comprised previous vitreoretinal surgery, ocular trauma, or other accompanying retinal pathologies including macular hole, and diabetic retinopathy. Patients presenting with dense vitreous haemorrhage not allowing for detailed fundus examination, giant tears or PVR grades B and C were excluded. Patients with myopia of 7 dpt. or more before cataract surgery were excluded. In patients presenting with bilateral RD, only one eye could be included as study eye.

Surgical technique

All patients were operated by two surgeons following a defined surgical protocol: complete PPV with induction of posterior vitreous detachment, peripheral vitreous dissection under scleral depression, perfluorocarbon liquid, laser photocoagulation of retinal breaks, fluid/air exchange followed by air/gas exchange using 16% hexafluoroethane (C2F6). Surgical posterior capsulotomy was created in all eyes to prevent the influence of a developing aftercataract on visual outcome; no Nd-YAG laser capsulotomy had been performed previously.

In the 20-gauge group, 180° conjunctival peritomy was performed at the beginning of surgery, and sclerotomies and conjunctiva were closed using vicryl 7.0 (Ethicon, Johnson & Johnson Intl, St. Stevens-Woluwe, Belgium) sutures at the end of surgery. In the 25-gauge group, the one-step 25-gauge disposable trocar system was used. For introduction of the trocar system, the conjunctiva was displaced and the trocars introduced by scleral tunnelization. At the end of surgery, trocars were withdrawn and gentle pressure was applied to the sclerotomies. Antibiotic (gentamycine) and steroid (dexamethasone) ointment was applied to all eyes before patching and continued for 14 days.

Statistical analysis

Based on the study protocol, the trial is classified and conducted as pilot study. Thus, the statistical analysis is descriptive in nature (Thabane et al. 2010). The results for change in BCVA and IOP were given by mean and standard deviation, and we calculated the 95% confidence interval for the mean change. Rates were described by frequencies, and 95% confidence intervals were given to describe rate differences. The analysis population was defined by the available data at the final examination. SAS software [9.3 (TS1M2); SAS Institute Inc., Cary, North Carolina, USA] under Windows X64_7PRO was used for computations.

Results

Recruitment

In total, 119 patients were assessed for eligibility to participate in this prospective pilot study. Sixty-nine patients had to be excluded: 29 did not meet the inclusion criteria, and 40 declined participation because of transportation problems to the university hospital for the regular control visits (for details see Fig. 1).

Baseline characteristics

Preoperative baseline data are summarized in Table 1. The 20-gauge PPV-group and the 25-gauge PPV-group appeared to be similar concerning baseline characteristics. Forty-two of the 50 patients (84%) completed the 6-month follow-up; 43 patients (86%) completed the 12-month follow-up.

There was no difference in procedure times between the 20-gauge and 25-gauge groups: surgery time ranged from 15 to 80 min in the 25-gauge (median: 40.0 min, mean: 43.0 min) and from 20 to 70 min in the 20-gauge group (median: 45.0 min, mean: 45.6 min).

Functional outcomes

Mean visual acuity improved by 0.88 (SD 0.67) from 1.22 logMAR (SD 0.63) to 0.34 logMAR (SD 0.31) in the 20-gauge group and by 0.53 (SD 0.91) from 0.86 logMAR (SD 0.73) to 0.34 logMAR (SD 0.46) in the 25-gauge group. The gain appears to be similar. The 95% confidence interval for the difference in mean change between the treatment groups was (95% CI: −0.23, 0.24, not statistically significant).

The course of the BCVA measurements in logMAR over the time shows a parallel shape in both groups with a peak at the 1-day visit and a decreasing trend in the following months.

Anatomical outcomes

Primary single-surgery reattachment rate at 6 months was 69% overall. In the 20-gauge group, the retina was attached after one single procedure in 18 eyes (72%) and in 21 eyes (84%) of the 25-gauge group at the final visit. Primary retinal reattachment without any reoperation at 6 months was 73% in the 20-gauge group and 65% in the 25-gauge group. Final anatomical success rate 1 year after enrolment was 100% in all patients who underwent the 12-month visit (86%). The number of revision surgical procedures was 1.3 per patient in the 20-gauge group and 1.5 in the 25-gauge group. Time interval between initial and revision surgery for retinal redetachment ranged from 1 to 6 months overall. Mean interval was 1.8 months in the 20-gauge group and 1.1 months in the 25-gauge group.

IOP outcomes

The course of the IOP measurements over the time shows a parallel shape in both treatment groups with a peak at the 1-day visit and a decreasing trend in the following months.

Day 1 after surgery, hypotony defined as IOP < 10 mmHg occurred in two patients in the 25-gauge group and none in the 20-gauge group. Intraocular pressure in these patients returned to normal values within the first 6 weeks; no persistent hypotony was present at the 6-week follow-up examination. At the 6-week visit and after 1 year, one patient in each group showed hypotony. At the 6-month visit, two patients in the 25-gauge group had hypotony. Three patients (12%) in either group had an IOP higher than 25 mmHg at day 1. In all patients but one, IOP returned to normal within days. This single patient in the 25-gauge group had a history of primary glaucoma controlled by topical antiglaucoma treatment. In further three patients of the 25-gauge group, higher IOP than 25 mmHg occurs at the 6-week visit.

Complications

Early postoperative complications

Cystoid macular oedema was detected in two eyes in the 20-gauge group and in one eye in the 25-gauge group postoperatively. At the 12-month follow-up, macular oedema had resolved in all eyes. Macular pucker was detected in three eyes in the 20-gauge group and two eyes in the 25-gauge group. Surgery for macular pucker was performed in three eyes in the 20-gauge

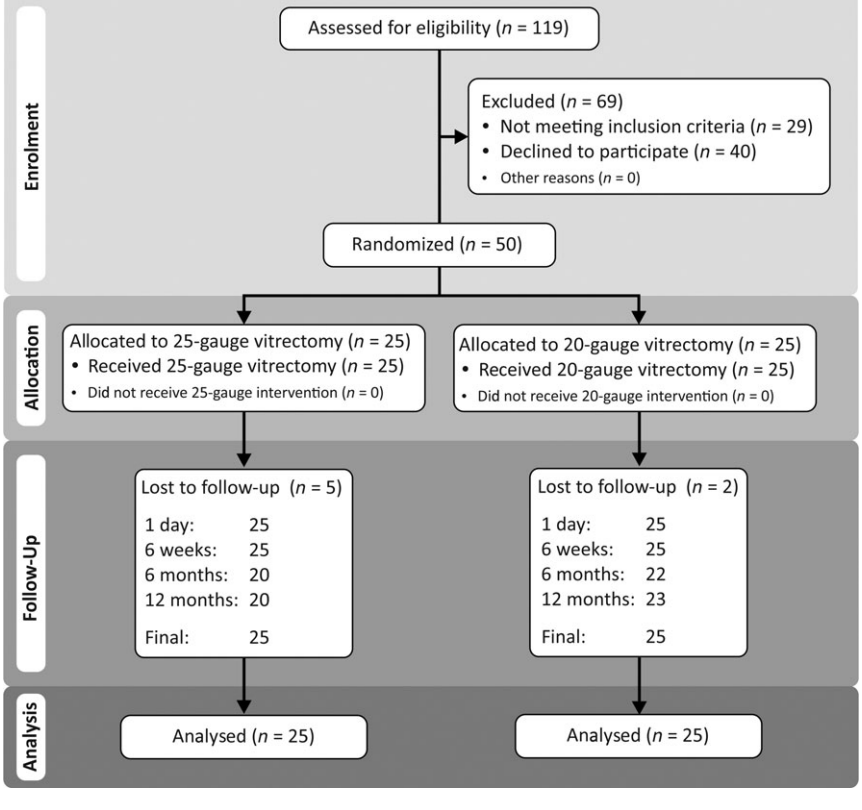

Fig. 1. Flow sheet of study progress (*n* = number of observations). The basis for calculations concerning the primary end-point is based on the final examination defined as last observation taken for each individual patient. Regular follow-up visits are at the first day after surgery, 6 weeks after surgery, 6 months after surgery and 1 year after surgery. However, some patients show remarkable longer observational time (up to 1095 days) and some not.

Table 1. Baseline characteristics of the study groups.

Characteristics	20-gauge (n = 25)	25-gauge (n = 25)
Mean age ± SD, years	66.3 ± 9.4	64.7 ± 10.7
Sex (%)		
Male	68	76
Female	32	24
Eye, n		
RE	14	10
LE	11	15
Mean logMAR ± SD	1.22 ± 0.63	0.86 ± 0.73
Mean IOP ± SD, mmHg	11.7 ± 4.4	13.4 ± 4.8
Macula, n (%)		
On	4 (16)	7 (28)
Off	21 (84)	18 (72)
Mean follow-up time ± SD (range), days	446 ± 173 (142–843)	507 ± 297 (11–1095)

SD = standard deviation, RE = right eye, LE = left eye, IOP = intraocular pressure.

group and in one eye in the 25-gauge group. The remaining patients demonstrating with a macular pucker decided against surgery.

Acute endophthalmitis or pronounced inflammatory reaction was not observed in any eyes in either group of this study population.

Discussion

The advantages of transconjunctival surgery include more rapid visual recovery, less postoperative discomfort and minimal conjunctival scarring (Wimpissinger et al. 2008). The 25-gauge cutters are effective in shaving vitreous especially from mobile areas of detached retina and reduce the risk of creating iatrogenic holes (Tuft et al. 2012). Disadvantages include reduced flow and aspiration as well as higher flexibility and lower rigidity of instruments. In our series, transscleral vitrectomy showed no disadvantage over 20-gauge vitrectomy in pseudophakic patients presenting with RD not suitable for single sponge surgery. We here report similar functional and anatomical outcomes as well as complication rates for both surgical techniques supporting the assumption that TSV PPV represents a safe and appropriate technique in the management of rhegmatogenous RD in pseudophakic eyes.

The aim of a comparative study in RRD surgery is to clarify superiority of certain surgical methods for specific indications in order to finally define a standardized procedure. These questions are ideally answered by randomized controlled comparative clinical trials. Previous reports on RRD surgery trials especially the SPR reports highlighted the difficulties of comparing surgical techniques for RD management due to the high variety of accompanying factors that have to be taken into consideration (Heimann et al. 2001, 2007; Heussen et al. 2011). Therefore, we designed the first prospective single-centre randomized trial comparing functional and anatomical results of 25-gauge PPV versus 20-gauge PPV in the management of RRD in pseudophakic eyes. Exclusion criteria included known factors that may influence functional and/or anatomical outcome, for example high myopia, PVR grade B/C or history of ocular trauma to keep the population as homogenous as possible in the *per se* heterogeneous pathology.

Functional results with BCVA being chosen as main outcome criteria in our study were similar to those reported either for 20-gauge or 25-gauge and 23-gauge TSV PPV in RD surgery. Results after 25-gauge TSV for RRD have been reported in several retrospective series and small non-comparative prospective studies (Mura et al. 2009; Von Fricken et al. 2009; Colyer et al. 2010; Kobayashi et al. 2010; Kunikata & Nishida 2010; Lewis et al. 2011; Iwahashi-Shima et al. 2013; dell'Omo et al. 2013). Comparison is limited by the variety of influencing factors including macular status, duration of symptoms, number and formation of breaks, or presence of PVR (Stangos et al. 2004; Albrieux et al. 2011; Heussen et al. 2011). Albrieux and co-authors (2011) presented one of the first prospective comparative studies using 23-gauge PPV in the management of RD including phakic as well as pseudophakic eyes stating that TSV provided anatomical and visual results similar to the 20-gauge technique for management of uncomplicated rhegmatogenous RD.

The anatomical success rates, single-surgery success rate and final success rate, presented in this study in the 20-gauge group, were comparable to those described in prospective trials using 20-gauge PPV without additional buckle procedure in pseudophakic eyes (Mendrinos et al. 2008; Heussen et al. 2011). In our series, redetachment rate was lower in the 25-gauge group compared to the 20-gauge group without statistical significance. These data are in concordance with results from comparative retrospective series showing similar success rates for both groups (Von Fricken et al. 2009; Colyer et al. 2010; dell'Omo et al. 2013; Michalewska et al. 2014).

Complications following RD surgery in our series were rare and comparable in both groups. Defining hypotony as an IOP < 10 mmHg, we observed a higher rate of postoperative hypotony in the 25-gauge group compared to the 20-gauge group. Our data are comparable to those presented for 25-gauge surgery for various indications and are slightly higher compared to the results given for 23-gauge surgery (Stangos et al. 2004; Lakhanpal et al. 2005; Kunikata & Nishida 2010; Singh et al. 2010). On the other hand, temporary hypertony is observed more frequently after 20-gauge PPV. Interestingly, in our series, the only patient with prolonged elevated IOP had been operated on using the 25-gauge system; this patient, however, had a known history of glaucoma.

Sutureless vitrectomy has been accused for bearing the potential of persistent fluid egress and potential influx of pathogens (Wimpissinger et al. 2008; Inoue et al. 2009; Kunikata & Nishida 2010). Theoretically, in TSV, risk for developing endophthalmitis in these eyes might be increased. In our series, no case of endophthalmitis and no pronounced postoperative inflammation were detected in either group. However, the sample size of our study would not allow for final judgement in this critical question.

The strengths of the presented study consist in the prospective design of the trial including 1:1 randomization, blinding of the examiners and the standardized surgical technique for all surgical steps. The interpretation of data is limited by the relatively small number

of patients given the previously described problems in the recruitment of a fairly homogenous study population presenting with pseudophakic RRD. Since design and recruitment for this trial, 25-gauge PPV systems have been widely replaced by 23-gauge PPV systems. Further prospective randomized comparative studies including 23-gauge PPV systems as well as the option of adjuvant buckling elements are required to address still unanswered questions in the choice of best surgical treatment for (pseudophakic) patients with RRD.

In conclusion, our data from the here presented prospective study suggest no advantages of 20-gauge vitrectomy compared to 25-gauge TSV in the treatment of moderate complex rhegmatogenous RD in pseudophakic patients.

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