Primary Retinal detachment Outcomes: The (PRO) Study

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For the PRO Study group

Financial disclosure
- Dr. Ryan - Alcon surgical – instrument patents licensed
- Study support from Phillips Eye Institute Foundation
- And Vitreoretinal Surgery Foundation

Summary
- RRD repair techniques continue to evolve
  - SB > vit/SB > vit alone > MIVS
  - Trend is away from both scleral buckling and vit/SB
  - But all of these have some role – we think
- Do we have good evidence to support the choice of procedure for each case? Is the evidence current?
- This talk will update you regarding a large, multicenter, retrospective cohort study we are undertaking
- And will show examples of how our findings may shape case management

Current trends
- ASRS PAT Survey 2015
  - >50% of surgeons place a SB in fewer than 20% of RRD cases.
  - Some surgeons (Steve Charles, Don D’Amico) advocate that a buckle is never needed
  - Now >95% of vitrectomies use MIVS
- For some surgeons all primary RRDs are managed using MIVS

Why is this study needed?
- Most recent reviews are small, single-center, and limited in scope
- Evidence from large randomized controlled trials (RCTs) is from 10-15 years ago, before MIVS was common
  - SPR (Europe)
  - Retina s Project (Spain)
- Without evidence comparing different approaches for repairing anatomically similar RDs, we don’t really know which method is better for a given anatomy.

Current evidence - SPR
- In phakic patients, SB had similar anatomic outcomes to PPV, but had superior visual outcomes
  - And lower rate of cataract progression
- In pseudophakic patients, SB and PPV had similar visual outcomes, but PPV had superior anatomic outcomes
  - Addition of an SB appeared to improve anatomic outcomes, but use was surgeon choice – not part of study design
  - These cases all predated small gauge vitrectomy
Multicenter study of 1° RRD repair: Cohort study most useful

- RCT would be best, but prohibitively expensive
- SPR Study from Europe very valuable, but...
- Pre-dated small-gauge vitrectomy; 15 years old
- Next best study option (after RCT) is a cohort study
  - With a very large dataset
  - Compulsively documented
  - Data entry done while naïve to outcomes
- With a well-done cohort study, one can compare similar cases managed different ways
  - This is commonly used for clinical research

Cohort study inspiration

- 3 very similar cases; sched as PPV, PPV/SB, and SB
- Realized that similar cases could be compared, if data entered masked to surgeon, procedure, and outcome
- Need pool of well-trained surgeons, skilled in all three approaches
- Need a huge number of well-documented cases
  - This would give best chance of reliable, mostly unbiased outcomes analysis comparing PPV to PPV/SB to SB

Next steps...

- Persuaded Phillips Eye Institute Foundation to fund the trial
- Recruited 5 groups of surgeons, ranging from pure private practice to mixed academic to fully academic
- Developed plan for thorough(!) dataset (256 items) and developed process for assuring data entry quality
- Began entering data Fall of 2016, data entry complete(?)
  - Jan 2018

Primary Retinal detachment Outcomes (PRO) Study Group

- Minneapolis
  - Vitek Retinal Surgery PA – Edwin Ryan MD (lead), Rob Mittra MD, David Almeida MD, D. Wilkin Parke MD
  - Retina Center – Geoff Emerson MD
  - Nora Forbes MS (statistics), Claire Ryan BA (coordinator)
- St. Louis
  - The Retina Institute – Daniel Joseph MD (lead), Gaurav Shah MD, Kevin Blinder MD
- Detroit
  - Associated Retinal Consultants – Antonio Capone MD (lead), George Williams MD
- Boston
  - Mass Eye and Ear – Yoshihiro Yonekawa MD (lead), Dean Elliott MD
- Philadelphia
  - Mid-Atlantic Retina – Omesh Gupta MD (lead), Jason Hsu MD, Carl Regillo MD

Data entry strategy

- Data grouped into prep, operative, and postop sets
- Preop data entry done without knowledge of surgery type, surgeon, or outcome
  - Reduces likelihood of bias
- PHI protected
- Surgeon information masked
- All data stored on REDCap for now
  - Collaborative research database housed at Vanderbilt
Study goals

- Collect all primary RRD cases treated surgically from 2015 from the 5 centers
- Some centers couldn't commit to all cases, so cases were entered in a random fashion to minimize bias
- To be usable, cases have to have good preoperative data including RD anatomy, adequate surgical documentation, and postoperative follow up 90 or more days
- From the total case series, we select cases of moderate complexity for comparison of surgical approaches
- Do this analysis for both phakic and pseudophakic cases

Total cases vs useable cases

- Total number of unique cases identified was 2760
- Total number of cases with adequate documentation (RD anatomy, operative description, and 90+ day follow up) was 2190
- So 79% of the total number of cases were useable
- Follow up biggest challenge – this was due to a huge effort by many people!!

Overall results (1/9/18)

- 2190 total primary RRDs
- 1380 (63.1%) were male
- Mean age was 60 (± 13) years
- 1206 (55.1%) were phakic, 969 (44.2%) pseudophakic, and 15 (0.7%) were aphakic at initial repair

Overall results

- 294 (13.4%) were treated with SB
- 1125 (51.4%) were treated with PPV
- 771 (35.2%) were treated with PPV/SB
- Mean follow up was 372 (± 163) days

Overall outcomes

- Single surgery anatomic success (SSAS) was seen in:
  - 269/294 (91.5%) SB cases
  - 945/1125 (84.0%) PPV cases
  - 694/771 (90.0%) PPV/SB cases
- Reattachment rate at final follow up was 97.5%
- SSAS with SB and PPV/SB were superior to PPV (p<0.001)

What can we conclude?

- That all these approaches do pretty well at reattaching the retina in primary RRD cases
- PPV did more poorly for SSAS than SB or PPV/SB in the group as a whole
- So is one approach better than (or inferior to) the others?
- Not so fast – this we don't know the case mix for each group
  - Maybe PPV had more difficult cases
  - Maybe SB or PPV/SB had more favorable cases
  - Need to look at "moderately complex" RRDs
Definitions for RRDs of “moderate complexity”

- Single or multiple tears
- Largest tear less than 2 clock hours
- RD area too large for laser, up to total RD
- Macula on or off
- Either phakic and pseudophakic (after SPR results, rare to see SB performed in pseudophake)
  - Note diff between phakic and pseudophakic exclusions
  - VH, posterior tears, mod cataract, prior PPV – phakic
  - PVR, GRT - both

Moderately complex RRD

- Limit cases to ones that a reasonable surgeon could repair with PPV, PPV/SB, or SB – then it’s apples to apples

Phakic 49 yo man (MC)

- Recent floaters, macula on, superior field cut

Phakic 49 yo man (MC)

- Recent floaters, macula on, superior field cut

Phakic 61 yo post-LASIK

- Macula on, emmetrope, clear lens

Phakic 47 yo woman

- Acute RD, macula recently split
Phakic 47 yo woman

Acute RD, macula recently split

Pseudophakic 64 yo (CK)

Macula recently off, emmetropic after recent CS

Phakic vs pseudophakic RRD

- Since SPR study, which showed PPV superior to SB in pseudophakes
  - Almost no pseudophakic RRD gets an SB (0.7%)
  - Phakic patients (slightly) more likely to get SB
  - Increased likelihood of SB:
    - Age under 40
    - No PVD
  - Increased likelihood of PPV or PPV/SB
    - VH, multiple tears, PVR, surgeon training site and era
    - Presence of cataract

1. Phakic subset

- RRD is managed with multiple methods
- Pneumatic retinopexy
  - Office procedure, not done often in Midwest
  - We did not look at this in all sites
  - Typically, lower success rates
  - But more cost-efficient
  - We use for fairly simple cases
- Laser or cryopexy
  - Also used more rarely, and only for simple cases

Phakic subset

- We wanted to compare three OR techniques
- Approximately 95% of RRD cases in our area go to the OR
- Procedures:
  - SB – encircling, segmental, radial buckle
  - PPV – almost all done with 23 or 25g MIVS now
  - PPV/SB – encircling buckle, and 23 or 25g MIVS
- We excluded cases that skewed towards SB or PPV
  - SB – under age 40 (less likely PVD)
  - PPV – VH, mod or worse cat, PVR, large or post tears...
Demographics

- Of 2190 total cases
  - 1206 were phakic
    - 731 met criteria: moderately complex RRD, absent VH, minimal PVR, etc.
    - 655 met criteria, and were age 40 and over
- Mean age was 59 (±8) years
- 58% were male

Anatomic outcomes

- SB used in 160 (24%) of patients
  - SSAS in 149 (93%)
- PPV used in 227 (34%) of patients
  - SSAS in 227 (84%)
- PPV-SB used in 268 cases
  - SSAS in 242 (90%)
- Retina attached at final visit in 99%
- SB and PPV/SB were superior to PPV (p<0.03).

Visual outcomes

- Mean final visual acuity
  - SB = 20/31
  - PPV = 20/51
  - PPV-SB = 20/59
- Outcomes favored SB (p<0.03)

Visual outcomes

- Since visual outcomes in PPV and PPV-SB phakic cases are limited by cataract progression, we excluded patient with progressing cataracts
- Mean final visual acuity correcting for presence of only mild cataract or post-cataract surgery:
  - SB = 20/31
  - PPV = 20/49
  - PPV-SB = 20/58
- Still significant favoring SB (p<0.05).

Phakic conclusions

- SB had excellent anatomic outcomes
- SB had best visual outcomes
- PPV/SB and SB had SSAS that was superior to PPV
- PPV/SB and PPV had equal visual outcomes
  - Inferior to SB

Phakic 49 yo man (MC)

- Recent floaters, macula on, superior field cut
Case MC

- 49 yowm seen 10/6/10
  - Phakic, -6.00 myope
  - Contact lens intolerant
- 20/30 OS
- 4 days symptoms
- Has had PVD
- RD inferotemporally
  - Flap tear at 4

Procedure?

- Radial sponge

Advantages
- Minimal refractive change
- No cataract
- No gas bubble
- Rapid return to work

20/40 6 days P.O.
Phakic 61 yo post-LASIK

Macula on, emmetrope, clear lens

Case DE

- 61 yo very active woman, seen 8/13/12
- Inf field OD cut for 1 day
- Post-Lasik, clear lens, emmetropic OD, 20/30
- Some mild inferior vitreous hemorrhage
- Has had PVD
- Planning trip to NZ in one month

Recommendations?

- Pneumatic retinopexy?
- Vitrectomy?
- PPV/SB?
- Scleral buckling?
  - Chose SB, used #41 band, and #506 sponge
  - Local anes, outpatient
  - 0.4cc SF6
- Drained SRF

Postoperative course

- Attached day 1
- Gas gone at 1 week
- No cataract
- Traveled, hiked, bungee-jumped
- 20/60 uncorrected, -0.75 myope, 20/20 corrected
Phakic 47 yo woman

- Seen Aug 2017, Tues AM
- Underwent SB same day (convenience)
- SB chosen because no PVD was present
- Retina reattached, one operation
- Seen 1/23/2018
  - 20/30 OD, still pocket of SRF under fovea

Note attached posterior hyaloid

2. Pseudophakic subset

- To evaluate outcomes of primary RRD occurring in pseudophakic patients treated with either pars plana vitrectomy (PPV) or PPV combined with scleral buckle (PPV-SB)
- Since SPR study, very few RRD repaired with SB only in this cohort

Note attached vitreous (arrows), pocket of SRF

Methods

1. Retrospective cohort study of all patients in 2015 from multiple retina practices with RRD
2. Inclusion criteria: 90 days follow-up, pseudophakia, treatment with PPV, or PPV-SB
3. Exclusion criteria: Proliferative vitreoretinopathy, previous invasive glaucoma surgery, giant retinal tears
4. Main outcome measures: single surgery anatomical success (SSAS), visual acuity (VA)
Methods

5. Single surgery anatomic success (SSAS) was defined as no other RRD surgery within 90 days
   - Pearson’s X² test: Assess significance of treatment type on SSAS
   - Multiple logistic regression: Assess significance of treatment type, after accounting for macular status, age, and sex

6. Visual outcome:
   - Welch Two Sample T-test: Assess significance of treatment type on VA
   - Multiple Linear Regression: Assess significance of treatment type on VA, after accounting for macular status, age, and sex

Results: Sample size

- 2094 Total Patients (from earlier analysis)
- 858 Pseudophakic (41%)
- 629 Eligible (71%)
  - No PVR
  - No Prior Glaucoma Surgery
  - No GRT
  - ≥ 90 day follow-up

Results: Demographics

- Surgery Type
  - 75.5% PPV (N=475)
  - 24.5% PPV-SB (N=154)
- 68.0% male
- Mean age 64.8 (±10.7) years
- 50.3% right eyes

Results: tamponade %

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<thead>
<tr>
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<th>AIR</th>
<th>SF6</th>
<th>C3F8</th>
<th>OIL</th>
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<tr>
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<td>0.65</td>
<td>54.2</td>
<td>41.5</td>
<td>3.4</td>
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<tr>
<td>PPV-SB</td>
<td>0.6</td>
<td>38.7</td>
<td>51.7</td>
<td>8.0</td>
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Results: anatomic outcome

<table>
<thead>
<tr>
<th>Percent SSAS</th>
<th>PPV</th>
<th>PPV-SB</th>
<th>Total</th>
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<tbody>
<tr>
<td>Macula On</td>
<td>90.2%</td>
<td>98.2%</td>
<td>91.6%</td>
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<tr>
<td>Macula Off</td>
<td>81.1%</td>
<td>89.9%</td>
<td>85.9%</td>
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<tr>
<td>Total</td>
<td>86.1%</td>
<td>92.9%</td>
<td>87.8%</td>
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- Pearson’s X² test:
  - SSAS was significantly higher for PPV-SB compared to PPV (p = 0.038)
  - SSAS significantly lower for macula-off (p = 0.005)
Results: visual acuity

- Mean visual acuity

<table>
<thead>
<tr>
<th></th>
<th>PPV</th>
<th>PPV-SB</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
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<td>20/31</td>
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<td>20/33</td>
</tr>
<tr>
<td>Macula Off</td>
<td>20/58</td>
<td>20/50</td>
<td>20/58</td>
</tr>
<tr>
<td>Total</td>
<td>20/42</td>
<td>20/49</td>
<td>20/43</td>
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- Welch two sample T-Test
  - VA not significantly different across surgeries (p = 0.134)
  - VA significantly worse for macula-off (p < 0.001)

Pseudophakic RRD: conclusions

In pseudophakic RRDs:
- Anatomic outcomes were superior in PPV-SB
- Anatomic outcomes were superior in macula-on patients
- Visual outcomes were superior in macula-on patients
- Visual outcomes were similar for both PPV and PPV-SB

Case CK - pseudophake

- Bilaterally pseudophakic 64 yo man
- Temporal, macula-off RD OD
- Moderate inferior VH
- Plano OU
  - 20/200 OD, 20/20 OS

Recommendations?

- Vit alone supported by most literature
  - 25-GAUGE SUITURELESS VITRECTOMY VERSUS 20-GAUGE VITRECTOMY FOR THE REPAIR OF PRIMARY RHEGMAATGENOUS RETINAL DETACHMENT
  - RETINA 29:444–450, 2009 (Washington DC)
  - ~95% success (1-op) with either 25g or 20g surgery
  - Phakic or pseudophakic patients

Recommendations?

- Vit alone supported by most literature
  - RETINA 36:1064–1069, 2016 (Haifa)
  - 96% single-surgery success, inferior breaks
  - Most were phakic
  - But PPV alone was not as successful in our study
Recommendations?

- SB alone higher risk for failure
- Adding SB to PPV of no benefit?
  - Conflicting reports
  - Definite benefit in our study (PRO)
- PR low success rate
  - Not recommended

Surgical procedure

- Vit/20% SF6/laser 22ga
  - Desire was to keep patient emmetropic
- Vitreous not shaved aggressively
- 20/20 at 6 weeks, insignificant ERM

Case RS – PCL, mac-ff RD

- 79 yo man
- Poor (HM) vision 2 days
- Pseudophakic OU
- 20/20 OS

Recommendations?

- Vit + SB
  - Vit alone too likely to fail
  - SB alone nonsensical
- #41 band planned
  - Used microscope to record SB placement
Conclusions – PRO Study
phakic subset

- SB had excellent results
  - Anatomic (93% SSAS)
  - Visual (even after controlling for lens status)
- This approach is probably underutilized
- Will need to look into detail at middle-age myopes re SB vs. PPV and PPV/SB
- Also need to look at PPV outcomes to determine cases in which it would work best

Conclusions – PRO Study
pseudophakic subset

- PPV/SB had anatomic outcomes superior to PPV
  - Despite PPV being done more often
  - And, PPV/SB often used in more complex cases
- Need to look in detail at which anatomic variants had similar outcomes between PPV and PPV/SB
  - And which cases favored PPV/SB
Conclusions - overall

- Increasing numbers of RRD cases done as PPV alone
- But outcomes of PPV inferior to SB and PPV/SB
  - At least in this large study
- Both PPV/SB and SB had > 90% SSAS
  - If PPV results > 90%, that would be acceptable outcome
- This large dataset has the potential to answer many clinical questions regarding RRD management
  - Analysis is just starting, multiple reports anticipated

Thank You!