Efficacy of internal limiting membrane peeling 1 DD versus 2 DD for treatment of large full thickness macular hole: Randomized Clinical Controlled Trial: preliminary report

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Introduction

Macular = center of vision

Ø An idiopathic full-thickness macular hole (FTMH) represents a defect in the fovea.
Ø Untreated macular hole, it often leads to severe central visual loss.
Ø Aim of the treatment were to improve visual function and macular hole was closed.

Introduction

Ø Treatment of FTMH stage 4: Pars plana vitrectomy + Internal membrane peeling + intraocular gas tamponade+ postoperative prone position.
Ø Anatomic success closure of the macular holes ranged from 58 – 100 %.
Ø Several surgical technique have been reported to improve anatomic outcome and functional outcome.

Objective

Ø To evaluate the anatomic closure rate and visual outcome in patients undergoing pars plana vitrectomy (PPV) with internal limiting membrane (ILM) peeling 1DD and 2 DD for treatment of large full thickness macular hole.
Ø To detect the predictive factors determining the surgical outcome.

Materials and methods

- A hospital-based, double-blinded, randomized clinical trial controlled.
- This trial followed the tenets of Helsinki Declaration and approved by the Khon Kaen University Ethics Committee HE 551124 for Human Research (KKUEC).
- All patients with large FTMH (> 500 µm) treated at KKU Eye Center, Khon Kaen University from Oct 2012 to July 2014 were recruited for the study.

Sample size

\[ N = \frac{2p (1-p) (Z_\alpha^2 + Z_\beta^2)}{ (p_1 - p_2)^2} \]

- \( Z_\alpha = 0.05, Z = 1.64 \)
- \( Z_\beta = 0.02, Z = 0.84 \)
- Power of study = 80
- \( p_1 - p_2 = 0.2 \)
- \( N = 45 \) (drop out 10% \( \rightarrow \) \( N = 50 \))

Inclusion criteria

- Age > 20 yrs
- FTMH size > 500 µm
- Capable of giving informed consent

Exclusion criteria

- One-eyed patient
- Hx of intraocular Sx within 12 mos
- Ocular disease eg. Intraocular inflammation, glaucoma, etc
- Significant cular media opacity eg. corneal scar, cataract etc.
- Macular disease eg. CSR, AMD, PCV, etc
- Uncooperative patient
- Patients who can’t do post-operative face down position
Materials and methods

- **Primary outcome**
  - mean BCVA (ETDRS charts).

- **Secondary outcomes**
  - anatomic closure rate.
  - predictive factors for surgical outcomes.

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**Eligible cases**

Recruited cases (n = 100)

- ILM peeling 1 DD (n = 50)
- ILM peeling 2 DD (n = 50)

<table>
<thead>
<tr>
<th></th>
<th>Closed</th>
<th>Unclosed</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>23</td>
<td>3</td>
</tr>
<tr>
<td>N</td>
<td>20</td>
<td>19</td>
</tr>
</tbody>
</table>

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**Result**

- 46 patients with large FTMH were recruited.
- 35 patients (76.09%) completed the 6-month follow-up.
- Size of macular hole was 643.20 ± 118.96 µm.
- Baseline characteristics were not significantly different between 2 groups (table 1).

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<table>
<thead>
<tr>
<th>Variable</th>
<th>ILM peeling 1 DD group</th>
<th>ILM peeling 2 DD group</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender: Male (%)</td>
<td>10(43)</td>
<td>9(43)</td>
<td>0.20</td>
</tr>
<tr>
<td>Gender: Female (%)</td>
<td>13(57)</td>
<td>17(57)</td>
<td></td>
</tr>
<tr>
<td>Age (mean SD)</td>
<td>61.08±13.20</td>
<td>58.22±15.04</td>
<td>0.97</td>
</tr>
<tr>
<td>Eye: Right (%)</td>
<td>14(60)</td>
<td>7(47)</td>
<td>0.07</td>
</tr>
<tr>
<td>Eye: Left (%)</td>
<td>6(23)</td>
<td>17(77)</td>
<td></td>
</tr>
<tr>
<td>Duration of Symptom, mean(SD), month</td>
<td>10.31±7.43</td>
<td>9.54±7.35</td>
<td>0.86</td>
</tr>
<tr>
<td>Hole size</td>
<td>634.96±121.50</td>
<td>664.59±115.09</td>
<td>0.87</td>
</tr>
<tr>
<td>Intraocular pressure</td>
<td>12.17±2.53</td>
<td>12.22±2.50</td>
<td>0.76</td>
</tr>
<tr>
<td>Visual acuity, mean(SD) ETDRS chart</td>
<td>7.35±7.12</td>
<td>5.18±6.24</td>
<td>0.16</td>
</tr>
</tbody>
</table>

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**Result**

- The majority of cases (84.8%) had anatomical success with one operation.
Result

- Complications included hyphema and iatrogenic retinal breaks were found in 3 patients (8.57%).
- Multivariable regression analysis identified that preoperative visual acuity and hole size were significant predictors of surgical success.

Discussion

- Meta-analysis suggested that pars plana vitrectomy with ILM peeling and intraocular gas tamponade is an effective treatment of FTMH stage 4, 1-3.
- Previous studies: Varied surgical techniques
  - Small numbers of stage 4 FTMH
  - No study of FTMH stage 4 only
  - No large prospective RCT

Discussion

- Several studies show ILM peeling improve surgical and functional outcome but the optimal size of the area of peeling is still being debated.¹
- Our study showed that anatomical and functional outcome in ILM peeling 1 DD was no significantly differ from ILM peeling 2 DD.
- The strength of our study
  - The first prospective comparative RCT
  - Limitation of the present study
    - Small numbers of patients

Conclusion

- PPV with ILM peeling 1 DD may be sufficient for treatment of large FTMH (> 500 um).
- Preoperative VA and macular hole size can predict the surgical outcome after surgery.
- Further study and longer follow-up are needed.

Discussion

- Multicenter Retrospective Study: 1,100 eyes

<table>
<thead>
<tr>
<th>Stage of FTMH</th>
<th>No. (eyes)</th>
<th>Closure rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>197</td>
<td>98.5</td>
</tr>
<tr>
<td>3</td>
<td>611</td>
<td>95.9</td>
</tr>
<tr>
<td>4</td>
<td>292</td>
<td>87.3</td>
</tr>
</tbody>
</table>

Not mention how to measure the hole size
4 surgeons, 4 centers, many surgical techniques.

References:

Thank you for your attention