A Simple Blood Test for Mucosal Healing Monitoring is Accurate in Post-Operative Crohn’s Disease

Further results from the POCER Study

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Conflict of interest:

- Non-financial support and other: Prometheus Laboratories Inc provided the testing, during the conduct of the study
Crohn’s Disease Requires Monitoring After Surgical Resection

- Crohn’s Disease recurs after surgery
- POCER Study (Lancet 2015) demonstrated value of monitoring
- Disease surveillance is usually by colonoscopy
- A blood test that reflects recurrence would simplify monitoring

*We explored the utility of a 13-biomarker panel - the Mucosal Healing Index (MHI) - in the post-operative setting where there is a low disease burden*
The POCER Cohort and MHI Testing

• 132 patients: 439 serum samples from 0 to 18 months
• Recurrence: Rutgeerts Score $\geq i2$
• Recurrence: 32% at 6 months
  41% at 18 months

• POCER was a large post operative study demonstrating value of post op monitoring and intensification of therapy (Lancet 2015)

• Monitr™ Test (Prometheus Laboratories Inc.) measures: CEACAM1, VCAM1, CRP, SAA, Ang-1, Ang-2, MMP-1, -2, -3, -9, EMMPRIN, TGF-$\alpha$, IL-7

• The Mucosal Healing Index is calculated from these 13 biomarkers measured using immunoassays: MHI range 0-100
No disease i0 vs Severe Recurrence i3-i4

Rutgeerts i0

Rutgeerts i4

MHI Reflects Endoscopic Disease Recurrence
MHI has Sufficient Accuracy to Detect or Exclude Disease Recurrence

**COMBINED OUTCOMES AT 6 & 18 MONTHS**

Normality (i0) vs Severe Recurrence (i3 - i4)

*(n = 81)*

**AUROC: 0.752**

<table>
<thead>
<tr>
<th>MHI Cut-off</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Positive Predictive Value</th>
<th>Negative Predictive Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>87.5</td>
<td>47.4</td>
<td>41.2</td>
<td>90</td>
</tr>
<tr>
<td>40</td>
<td>25</td>
<td>93</td>
<td>60</td>
<td>74.7</td>
</tr>
</tbody>
</table>
MHI is Useful for Serial Monitoring

Status:
- Remission → Remission (n=32)
- Remission → Recurrence (n=13)

p-value:
- $0.01 < p \leq 0.05$
- $0.001 < p \leq 0.01$
- $p \leq 0.001$
Conclusions

• The Mucosal Healing Index (Monitr™) is a new non-invasive multi-marker serum test that has sufficient accuracy to be clinically useful in monitoring for post-operative Crohn’s disease recurrence

• MHI is significantly higher in patients with post-op recurrence compared with patients without recurrence

• MHI needs prospective testing as an adjunctive tool, for example in conjunction with faecal calprotectin testing