The use of Probiotics versus Fybogel™ in achieving rectal volume consistency during prostate radiotherapy: A Retrospective Study


Epworth Radiation Oncology, Melbourne, Australia.
Introduction: Prostate Radiotherapy

- Dose-response relationship exists for prostate cancer (Zietman 2005)

- Dose escalation requires greater onus to ensure preservation of nearby Organs At Risk (OAR)

- Rectal toxicity is one of the major factors limiting further dose escalation in prostate radiotherapy (Stasi 2006)

- Bowel preparation from simulation to end of treatment
Introduction: Probiotics and Fybogel™

• Department bowel protocol in 2012: Fybogel
• Fybogel
  – Fibre (insoluble) supplement
  – Used to aid constipation
  – Improve bowel regularity
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What are Probiotics?

- Probiotics and Radiation Therapy
  - Symptom and treatment-related side effect reduction
    (Delia et al 2000; Delia et al 2007)
  - Increased Colonic Transit Time and Regularity
    (Bouvier et al 2001; Verdenelli et al 2011)
  - Reduced flatulence
    (Nobaek et al 2000)

Results in consistency in filling similar to Fybogel™?
Aim

To assess consistency of

1. Rectal volume &

2. Rectal wall displacement

throughout treatment for patients in a **probiotics** and **Fybogel™** group by analysing Cone Beam CTs (CBCT)
Materials

- Retrospective Review (N= 10)
- Ethics Approval (Epworth HREC)
- Prostate Cancer Patients:
  - 65-78 years old
  - 90 CBCTs

Group 1) Fybogel (N=5)

Group 2) Probiotics (N=5)
# Methodology: Bowel Preparation

<table>
<thead>
<tr>
<th></th>
<th>Fybogel™</th>
<th>Inner Health Plus™</th>
</tr>
</thead>
<tbody>
<tr>
<td>Planning CT</td>
<td>1 sachet nightly, commencing one week before planning CT</td>
<td>Taking 1 tablet/day as part of daily supplement regime</td>
</tr>
<tr>
<td>Treatment</td>
<td>1 sachet nightly throughout treatment</td>
<td></td>
</tr>
</tbody>
</table>
| Active Ingredients | *Ispaghula husk*                                                          | *Lactobacillus acidophilus (NCFM)*  
*Bifidobacterium lactis (Bi-07)*  
*Colostrum Powder (Bovine)* |
Methodology

- Weekly CBCT scans prior to treatment @
  - Fx 1, 2, 3, 8, 13, 18, 23, 28, 33 (Total 9 CBCTs)
  - Co-registration with planning CT
  - Online daily zero action threshold
  - Treatment
Methodology

• CBCTs analysed in Eclipse™ (Varian Medical Systems)

• Rectal structures contoured on all CBCTs
  - Single Observer (SG)

• Data Collection
  - Rectal volume
  - Centre of mass
  - Rectal wall displacements

• Data Analysis
  - Unpaired T-Test
Methodology: Rectal Volume & Bounding Box technique

Rectal Centre of Mass

Epworth HealthCare
Methodology: Rectal Volume & Bounding Box technique
Methodology: Rectal Volume & Bounding Box technique

Bounding Box (Antolak 1998)
Methodology

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Results: Differences in volume

FYBOGEL GROUP

Difference from Planning CT volume (cc)

<table>
<thead>
<tr>
<th>Mean</th>
<th>SD</th>
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<tbody>
<tr>
<td>-5.81</td>
<td>11.86</td>
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</table>
Results: Differences in volume

PROBIOTICS GROUP

Difference from Planning CT volume (cc)

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<tr>
<td>-0.98</td>
<td>23.71</td>
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Rectal Wall Displacements

FYBOGEL GROUP

Patient 6

Patient 7

Patient 8

Patient 9

Patient 10
Rectal Wall Displacements

PROBIOTICS GROUP

Patient 1

Patient 2

Patient 3

Patient 4

Patient 5
Rectal Wall Displacement
FYBOGEL VERSUS PROBIOTICS

### Fybogel Group

<table>
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<tr>
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<tr>
<td>Mean (cm)</td>
<td>-0.22</td>
<td>0.13</td>
<td>-0.10</td>
<td>-0.09</td>
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<tr>
<td>Mean STD</td>
<td>0.21</td>
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<td>0.20</td>
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### Probiotics Group

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<td>-0.08</td>
<td>-0.06</td>
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<tr>
<td>Mean STD</td>
<td>0.30</td>
<td>0.22</td>
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## Rectal Wall Displacement
### FYBOGEL VERSUS PROBIOTICS

#### Fybogel Group

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Discussion: Rectal Volume

- Difference between ‘mean differences from planning volume’ was inconclusive, however;

- Variation in rectal volumes from planning was significantly lower for the *Fybobel™* group compared to the *probiotics* group.

Comparison of groups: 95% CI for the difference between treatment group STDs

![Diagram showing comparison of groups with 95% CI for the difference between treatment group STDs. The x-axis represents the difference between treatment group STDs, ranging from -5 to 20. The y-axis is not shown. The diagram includes a diamond marker labeled 'Diff (Prob-Fybo)' at the end of the 95% CI range. P<0.05 is indicated.]
Rectal Wall Displacements

PROBIOTICS & FYBOGEL: BEST VERSUS WORST

Patient 3

\[
\begin{align*}
\Delta \text{ANT STD} &= 0.30 \\
\Delta \text{POST STD} &= 0.23 \\
\Delta \text{LEFT STD} &= 0.32 \\
\Delta \text{RIGHT STD} &= 0.22
\end{align*}
\]

Patient 6

\[
\begin{align*}
\Delta \text{ANT STD} &= 0.22 \\
\Delta \text{POST STD} &= 0.15 \\
\Delta \text{LEFT STD} &= 0.41 \\
\Delta \text{RIGHT STD} &= 0.29
\end{align*}
\]

- PLANNING CT
- CBCT
- INTERVENTION
Discussion: Rectal Displacement

• Four interventions (90 CBCTs)
  - 3 Probiotics
  - 1 Fybogel

• Differences in anterior, left and right limits from planning were more consistent in the Fybogel™ group

• Increased volume → Lateral Expansion
Limitations

• Sample size of 5 patients per arm

• Estimated 50 patients per arm needed

• Rectal volume size at planning as a variable not analysed (Sripadam 2009)

• Rectal volume assessment methodology – unpartitioned structure (Stasi 2006)

• Anterior edge of rectum at prostate level (CBCT contouring)
Future Direction

• Future randomised prospective study between current protocol (Coloxyl and Senna) and Fybogel™ with greater sample size

• Improvements to Record & Verify usage and documentation

• Dosimetric analysis

• Bowel Toxicities

• Time of Day Factor
Conclusions

• Retrospective exploring the potential use of probiotics for bowel preparation

• Empirical evidence in support of Fybogel usage over probiotics alone

• Greater sample sizes necessary to demonstrate any conclusive clinical difference

• Suggests that probiotics as a bowel preparation should not be used in isolation
Acknowledgements

Sean McGuigan, Biostatistician, Clinical Trials Unit, Epworth Healthcare

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Department of Medical Imaging and Radiation Sciences, Monash University, Clayton, Victoria.
References


Thank you for your attention. Questions?

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