A Phase III Randomized Trial Comparing Patient Reported Toxicity and Quality of Life (QOL) During Pelvic IMRT as Compared to Conventional RT


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IMRT for post-operative pelvic RT

• IMRT reduces the dose delivered to small bowel in center of pelvis.
• Retrospective studies show lower rates of acute and chronic GI toxicity with IMRT as compared to standard 4-field RT.
• RTOG 0418 found IMRT to be feasible with a favorable rate of acute 2+ GI toxicity (25%).
Study Schema

Eligibility

Women with endometrial or cervical cancer requiring post-op pelvic RT or chemoRT

Stratification Factors

XRT Dose: 45 Gy, 50.4 Gy

Chemo: No chemo, 5 cycles of weekly cisplatin at 40mg/m²

Disease Site: Endometrial, Cervix

RANDOMIZE

IMRT pelvic radiation treatment

4-field pelvic radiation treatment
Treatment Planning

- IMRT planning
  - Nodal CTV
    - RTOG atlas
  - Vaginal
    - ITV w bladder full and empty
  - 7mm PTV expansion
  - OARs: Bone marrow, bowel, bladder, rectum

- Standard RT

Rapid review of contours and plans required on the first case on each arm for a site.
EPIC Bowel Questions

Bowel Function:

- rectal urgency?
- uncontrolled leakage of stool?
- stools that were loose?
- bloody stools?
- your bowel movements been painful?

How many bowel movements have you had on a typical day?
How often have you had crampy pain in your abdomen or pelvis?

Bowel Bother:

- has each of these issues been for you?
- have your bowel habits been for you?

How big of a problem...
EPIC Bowel Score

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Week 3 of RT</th>
<th>Week 5 of RT</th>
<th>4-6 weeks post-RT</th>
</tr>
</thead>
<tbody>
<tr>
<td>IMRT</td>
<td>128</td>
<td>113</td>
<td>111</td>
<td>102</td>
</tr>
<tr>
<td>4 Field</td>
<td>148</td>
<td>132</td>
<td>130</td>
<td>125</td>
</tr>
</tbody>
</table>

p-value = 0.048
Pro-CTCAE Results

Percent of patients with PRO-CTCAE Score ≥3 at 5 weeks

- Abdominal pain
- Diarrhea
- Fecal incontinence

- Frequency
- Interference

Standard vs. IMRT

*, p <0.05
Use of Anti-Diarrheal Medications

![Bar chart](chart.png)

Percentage of patients

- Number of anti-diarrheal medications daily
  - 0 or 1
  - 2 or 3
  - 4 or more

- Standard
- IMRT

Statistical Significance: p < 0.05
## Quality of Life: FACT-Cx

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical well-being</td>
<td>Energy, pain, feeling ill, time in bed, nausea, meeting needs of family</td>
</tr>
<tr>
<td>Social well-being</td>
<td></td>
</tr>
<tr>
<td>Emotional well-being</td>
<td></td>
</tr>
<tr>
<td>Functional well-being</td>
<td>Work, enjoy life, accept illness, sleep well</td>
</tr>
<tr>
<td>Additional treatment related concerns</td>
<td>Vaginal symptoms, interest in sex, body appearance, urinary fxn, appetite</td>
</tr>
</tbody>
</table>
## Quality of Life: FACT-Cx

<table>
<thead>
<tr>
<th>Change in FACT-Cx</th>
<th>IMRT</th>
<th>4 Field</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial Outcome Index (n=86) (n=106)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>-8.8</td>
<td>-12.8</td>
<td>0.06</td>
</tr>
<tr>
<td>Std. Dev.</td>
<td>14.4</td>
<td>14.3</td>
<td></td>
</tr>
<tr>
<td>Physical Well-Being (n=86) (n=106)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>-4.2</td>
<td>-6.1</td>
<td>0.03</td>
</tr>
<tr>
<td>Std. Dev.</td>
<td>6.0</td>
<td>6.1</td>
<td></td>
</tr>
<tr>
<td>Add’l treatment concerns (n=87) (n=104)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>-2.7</td>
<td>-4.9</td>
<td>0.01</td>
</tr>
<tr>
<td>Std. Dev.</td>
<td>6.1</td>
<td>6.5</td>
<td></td>
</tr>
</tbody>
</table>
Conclusions

• Pelvic IMRT reduces acute patient reported GI and GU toxicity compared to standard pelvic RT.

• Pelvic IMRT reduces need for anti-diarrheal medications as compared to standard pelvic RT.

• Pelvic IMRT improves quality of life with regard to physical functioning and other treatment effects during treatment.

• Longer term follow up will be needed to determine if these differences in acute toxicity result in lower rates of late toxicity.