Consent Forms Project

A working party consisting of members of the ORF and led by Dr David Sherriff, was set up to assist in the development of a comprehensive set of site-specific consent forms which would be available to download from the College’s website. The listing of specific early and late side-effects was felt to be vital in view of the considerable variation across the country with regard to written documentation of side-effects, particularly second malignancy [www.rcr.ac.uk/content.aspx?PageID=727](http://www.rcr.ac.uk/content.aspx?PageID=727).

A consent form which explicitly lists the expected early/late side effects could be seen as a check-list to ensure that all relevant details are discussed. It would be expected that further information e.g. Cancerbackup booklets and/or departmental leaflets would also be offered.

After reviewing the available literature we produced examples of consent forms for breast, gynae/pelvis, head & neck, oesophagus, rectum, anus and pituitary. These were reviewed at meetings of the ORF and Patients Liaison Group. There was concern that the proposed forms might over-estimate the magnitude of risk of side effects if the evidence base used relied upon trials using out-dated techniques or equipment. Ideally, as a result of local audit, centres would know the expected percentage risk of early/late effects in their population.

Following further discussion it was decided that attempting to introduce standardised consent forms was impractical but that it would be useful to develop the project work into a training and information resource which is presented here. This includes examples of the consent forms and an assessment of the quality of evidence for some of the sites, complete with references.
Possible side-effects during and after radiotherapy to the breast (and lymph nodes)

**Early:**

**Common:**
- □ Tiredness
- □ Red, sore skin of breast

**Less common:**
- □ Breast swelling
- □ Skin breakdown
- □ Dry cough and shortness of breath (<1%)

**Late:**
- □ Change in breast shape
- □ Change in skin appearance
- □ Breast/chest wall tenderness

**Rarely:**
- □ Fracture of underlying ribs
- □ Scarring of lung (<1%)
- □ Effects on heart (Left breast only, usually 10 years later)
- □ Small risk of cancer due to radiation

**If lymph nodes treated:**
- □ Shoulder stiffness
- □ Swelling of arm/hand (lymphoedema)
  (approximately 9% risk if RT alone or RT plus node sampling, up to 38% if RT plus node clearance)
- □ Small risk of damage to nerves in arm (<1%)

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Type of evidence</th>
<th>Dose/Fractionation</th>
<th>Number</th>
<th>Modern technique?</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>prospective</td>
<td>40Gy 15#</td>
<td>334</td>
<td>yes</td>
<td>Leeds.</td>
</tr>
<tr>
<td>2</td>
<td>Literature review</td>
<td></td>
<td></td>
<td></td>
<td>79 references</td>
</tr>
<tr>
<td>3</td>
<td>prospective</td>
<td>45Gy 25#</td>
<td>1022</td>
<td>mainly</td>
<td>Indian</td>
</tr>
<tr>
<td>4</td>
<td>RCT</td>
<td>40Gy 15# 50Gy 25#</td>
<td>2215</td>
<td>yes</td>
<td>START B</td>
</tr>
</tbody>
</table>
References:


Possible side-effects during and after short-course pre-operative radiotherapy for rectal cancer:

**Early:**

- Diarrhoea (less than 2%)
- Delayed healing of skin if Abdomino-perineal resection performed (up to 30%)
- Temporary nerve pain/numbness in legs (less than 1%)

**Late:**

(Many of these symptoms are experienced following surgery alone but may be more pronounced or more frequent with the addition of radiotherapy)

- Loose and/or frequent stools (common)
- Reduced bowel control/anal leakage – mild (rarely) to severe (daily) (up to 60%)
- Passage of mucus or blood (up to 30%)
- Reduced bladder control/urine leakage – mild (rarely) to severe (daily) (up to 30%)
- Reduced sexual function (common)
- Infertility and early menopause – if appropriate (100%)
- Bowel damage/narrowing requiring operation (< 5%)
- Narrowing of blood vessels impairing circulation (rare)
- Small risk of secondary cancer due to radiation

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Type of evidence</th>
<th>Dose/Fractionation</th>
<th>Number</th>
<th>Modern technique?</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>RCT</td>
<td>25Gy 5#</td>
<td>695</td>
<td>yes</td>
<td>Dutch TME Acute SE</td>
</tr>
<tr>
<td>2</td>
<td>Prospective/Questionnaire</td>
<td>25Gy 5#</td>
<td>597</td>
<td>yes</td>
<td>Dutch TME Late SE</td>
</tr>
<tr>
<td>3</td>
<td>Retrospective</td>
<td>25Gy 5#</td>
<td>156</td>
<td>yes</td>
<td>Birmingham</td>
</tr>
</tbody>
</table>

**References:**


**Possible side-effects during and after pelvic radiotherapy for gynaecological cancers (locally advanced uterine cervix):**
Early:
Common:
- Tiredness
- Red, sore skin
- Dysuria (burning sensation on passing urine)
- Diarrhoea
- Loss of pubic hair

Less common:
- Nausea
- Rectal bleeding or mucus

Late:
- Change in bowel habit and rectal symptoms (<10%)
- Passing urine more often
- Vaginal dryness
- Vaginal narrowing/ulceration (10-15%)
- Early menopause
- Infertility
- Lymphoedema (swelling of legs)

Rarely (<5%):
- Narrowing of bowel
- Abnormal passage between organs (fistula)
- Blood in urine
- Narrowing of urethra
- Weakness of pelvic bones, causing fracture or pain
- Small risk of secondary cancer due to radiation

<table>
<thead>
<tr>
<th>Ref.</th>
<th>Type of evidence</th>
<th>Dose/Fractionation</th>
<th>Number</th>
<th>Modern technique?</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Prospective audit</td>
<td>45Gy 25#</td>
<td>57</td>
<td>yes</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Retrospective review</td>
<td></td>
<td>1784</td>
<td>no</td>
<td>POP 98%</td>
</tr>
<tr>
<td>3</td>
<td>Prospective audit</td>
<td>45Gy 25#</td>
<td>59</td>
<td>mainly</td>
<td>POP 35%</td>
</tr>
<tr>
<td>4</td>
<td>Prospective</td>
<td>45Gy 25#</td>
<td>195</td>
<td>mainly</td>
<td>POP/4-field</td>
</tr>
<tr>
<td>5</td>
<td>Meta-analysis</td>
<td>1.8 – 2.5Gy/#</td>
<td>8 RCT’s</td>
<td>mainly</td>
<td>50% SE reported</td>
</tr>
</tbody>
</table>

References:


**Possible side-effects during and after radiotherapy (with chemotherapy) for cancer of the anus**
Early:

- Tiredness (very common)
- Sore skin with breakdown in skin creases (up to 100%)
- Painful skin with ulceration and bleeding (up to 50%)
- Loose/frequent bowel motions (up to 100%)
- Anal discharge with /without blood staining (up to 100%)
- Increased frequency of passing urine/cystitis (up to 100%)
- Loss of pubic hair (up to 100%)
- Severe diarrhoea possibly with reduced bowel control (up to 10%)

Late:

Common:

- Loose/frequent bowel motions (up to 50%)
- Occasional leakage from anus (approximately 20%)
- Impotence in men (30-50%)
- Early menopause and reduced sexual function in women
- Infertility

Less common:

- Loss of bowel control (approximately 5%)
- Ulceration of anal area (less than 10%)
- Increased frequency of passing urine (less than 10%)
- Ulceration of skin/groins (less than 5%)
- Severe thickening of skin in groins/genital area (less than 5%)
- Swelling of legs – lymphoedema (less than 10%)
- Bowel damage/narrowing requiring operation (less than 5%)
- Small risk of secondary cancer due to radiation

- Failure of treatment to control tumour – possibly requiring surgical treatment (up to 35%)

Chemotherapy causes additional side-effects and will be discussed separately.

References:


**Possible side-effects during and after radiotherapy for head and neck cancers**
Early:

Common:
- Tiredness
- Red, itchy skin
- Dry mouth
- Stringy saliva
- Taste change
- Loss of hair in treatment area
- Painful swallowing

Less common:
- Skin breakdown (up to 10%)
- Soreness of mouth (severe in 20-40%)
- Change / loss of voice (15-20%)
- Cough

Late:
- Dry mouth (severe in up to 20%)
- Change in appearance of skin (severe in 1-2%)
- Swelling of face and neck (lymphoedema) (severe in 2-7%)
- Tightening of jaw muscles (up to 20%)
- Thinning/tightening of soft tissues of mouth (severe in 1-2%)
- Difficulty swallowing (5-7%)
- Voice problems (6-8% if larynx treated)
- Necrosis of larynx (1-2%)
- Breakdown of jaw bone (osteo-radionecrosis) (1-2%)
- Transient or permanent damage to spinal cord (< 1%)
- Hypothyroidism corrected by thyroxine tablets (up to 30%)
- Dental decay (up to 10%)
- Cataracts (only if lens treated)
- Hearing problems
- Small risk of secondary cancer due to radiation

Chemotherapy causes additional side-effects and will be discussed separately.

References:


**Possible side-effects during and after radiotherapy for pituitary tumours**

**Early:**
- ☐ Tiredness
- ☐ Nausea
Headache
Red, sore skin on scalp
Some hair loss

Late:
Need for replacement hormones eg. Thyroxine (50% at 20 years)
Visual problems due to radiation (1-2%)
Increased risk of stroke (up to 4 times general population risk)
Small risk of secondary cancer due to radiation

References:

Possible side-effects during and after radiotherapy for oesophageal cancer

Early:
Tiredness (common)
Nausea (severe in 15-20%)
Painful swallowing (severe in 10-25)
Chest discomfort
- Hair loss over treatment area
- Redness of skin
- Breathlessness / coughing (less than 5%)
- Risk of abnormal passage between oesophagus and the airways (less than 1%)

**Late:**
- Scarring of the lung (1-3%)
- Difficulty swallowing which may require dilatation/stenting (<5%)
- Damage to the heart (2-5%)
- Hypothyroidism requiring treatment (if neck treated)
- Small risk of secondary cancer due to radiation

*Chemotherapy (if given) causes additional side-effects and may be discussed separately*

**References:**


Dr David Sherriff