

Best supportive care: Do we know what it is?

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One of seven groups commissioned to undertake systematic reviews of clinical and cost effectiveness for the National Institute for Health and Clinical Excellence (NICE) in the UK

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Historical perspective

- **LRiG have conducted a number of clinical and cost-effectiveness reviews of lung cancer treatments**
- **Comparator in lung cancer trials**
 - Best supportive care (BSC)**
 - Active supportive care (ASC)**
- **There is no definition of BSC for use in clinical and economic comparisons**

Best supportive care

“Supportive care for cancer patients is the multi professional attention to the individual’s overall physical, psychosocial, spiritual and cultural needs, and should be available at all stages of the illness, for patients of all ages, and regardless of the current intention of any anti-cancer treatment”.

EORTC - Ahmed et al 2004

Objective of this review

To identify the **clinical** and **economic** factors associated with the availability and delivery of best supportive care (BSC) for patients with lung cancer in published randomized controlled trials (RCTs)

Systematic review methods

Databases searched (1995-2005)

- **Medline, EMBASE, Science Citation Index and Cochrane Library**

Inclusion criteria

- **Randomised controlled trials, systematic reviews or economic evaluations of lung cancer treatments. All of the studies had to include a comparator arm of BSC**

Clinical review: RCTs (n=26)

- **A variety of chemotherapy regimens**
- **1997-2005**
- **BSC, ASC, SC**
- **Definition of treatment**
All studies provided description
- **Definition of BSC**
12 studies did not describe BSC
14 studies briefly described BSC

Definition of chemotherapy in RCTs

Clearly defined treatment protocol

- **Dose**
- **Number of cycles**
- **Duration of treatment**
- **Guidelines for treatment of adverse events**

Definitions of BSC in RCTs

- **“...at the discretion of the attending physician...”**
- **...according to standard practice at the collaborating centres...”**
- **...investigators were free to choose BSC...”**
- **“...whichever therapy was judged to be appropriate by the treating physician...”**

Clinical review: systematic reviews (n=13)

- **Variety of chemotherapy regimens**
- **1995-2004**
- **BSC,SC**
- **Definition of BSC**
 - 10 reviews did not define BSC*
 - 3 reviews briefly defined BSC*

Definitions of BSC in SRs

- **“...any appropriate therapy that did not include chemotherapy...”**
- **“...any palliative therapeutic modality that may be offered to the patient with NSCLC excluding chemotherapy but including radiotherapy and non-cytotoxic medication...”**

Economic results

- **Full economic evaluations (n=19); cost analyses (n=9); literature reviews (n=10); miscellaneous (n=3)**
- **1995-2005; 27% UK papers**
- **Hospitalisations, outpatient visits etc**
- **Definition of BSC**
 - 13 studies included a definition of BSC**
 - 24 studies failed to describe BSC at all**
 - 4 studies identified individual components of BSC**

Economic results: Definitions of BSC

- **“...no chemotherapy was administered...”**
- **“...supportive nursing care with no treatment interventions...”**
- **“BSC consisting of analgesics and antibiotics...”**
- **“...any form of supportive care deemed appropriate by the treating physicians”**

Conclusions

- **Published clinical/economic papers fail to define or describe BSC packages that are used in RCTs**
- **Difficult to assess whether similar patients receive similar care either within or across trial arms (e.g. anti-emetics/antibiotics)**
- **Difficult to assess whether similar patients receive similar care across trial centres**
- **Access to palliative care services within RCTs is limited/unreported**
- **Problematic for secondary research**

Questions...

- **Ethical**

Is it ethical to recruit patients into clinical trials if we do not provide them with a clear picture of treatments available?

Questions...

- **Economics:**

By failing to appropriately cost BSC we cannot calculate valid/true estimates of cost effectiveness

Questions...

- Indirect comparisons:

To conduct valid indirect comparisons there must be a common comparator



- If we can't provide *a priori* definitions of BSC..
- Then we **MUST** at least report the care that has been provided

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