

SELECTION OF OUTCOME VARIABLES IN PROSPECTIVE STUDIES IN PALLIATIVE CARE

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Object of the study: Cancer patients with advanced, metastatic disease have a severe symptom burden. Pain and fatigue are frequently reported, and associated with impaired quality of life (QoL) in general. A recent study has shown that pain treatment in cancer patients had no major influence on aspects of health related QoL (HRQoL) other than pain (1). A similar finding was demonstrated when we explored the effect of palliative radiotherapy on pain and QoL in cancer patient with bone metastases. In the present study we explored a subgroup of cancer patients that reported significant pain reduction after palliative radiotherapy, in order to investigate whether pain reduction leads to reduced fatigue and improved overall QoL.

Method: The study population comprises patients with advanced cancer and painful bone metastases (n=238) included in a prospective randomized study of palliative radiotherapy. Pain, fatigue and QoL were assessed with EORTC QLQ-C30, physical and mental fatigue was additionally assessed with Fatigue Questionnaire. Patients reporting pain relief of 20 or more on the 0-100 scale on the EORTC-QLQ-C30 were classified as pain responders. Patients completed the questionnaires before treatment, and every 4 weeks for 28 weeks or until death. The assessment at baseline and after 4, 8 and 12 weeks were used in this analysis.

Results: After palliative radiotherapy, the pain responders reported less insomnia and increased overall QoL after 4 weeks, and then the levels persisted. A slight decrease in fatigue was observed after 12 weeks. No other HRQoL dimensions were influenced by pain relief after palliative radiotherapy.

Conclusion: When designing prospective studies in palliative care, outcomes need to be selected with caution. A specific symptomatic treatment needs a primary outcome that fits the aims of the study. Other HRQoL domains should be treated with caution as outcomes because improvements may not be expected.

1) Klepstad P, Borchgrevink PC, Kaasa S. Effects on cancer patients' health related quality of life after the start of morphine therapy. *J Pain Symp Manage* 2000;20 (1):19-26.