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Original Research

Structural distress screening and supportive care for patients with lung cancer on systemic therapy: A randomised controlled trial

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KEYWORDS

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Abstract ***Introduction:*** Gaining regular insight into the nature and severity of distress by a psychosocial nurse coupled with referral to psychosocial and/or paramedical healthcare provider(s) is an experimental supportive care approach. We sought to examine the effects of this approach on quality of life (QoL), patient's mood and satisfaction, end-of-life care and survival in patients with lung cancer.

Methods: Patients with newly diagnosed or recurrent lung cancer starting systemic therapy were randomly assigned to receive usual care or the experimental approach. Patients were followed up at 1, 7, 13 and 25 weeks after randomisation with the EORTC-QLQ-C30, the European Quality of Life-5D, the Hospital Anxiety and Depression Scale and the Patient Satisfaction Questionnaire-III. Primary outcome was the mean change in the EORTC-QLQ-C30 global QoL-score between 1 and 25 weeks.

Results: A total of 223 patients were randomised of whom 111 (50%) completed all four assessments (44% in the usual care group versus 55% in the experimental group). No significant difference was found in the mean change global QoL-score (−2.4, 95% CI: 12.1−7.2; $P = 0.61$), nor in the other patient-reported outcomes. Fewer patients in the experimental group received chemotherapy shortly before the end-of-life, and median survival was comparable (10.3 versus 10.1 months, $P = 0.62$). Of the 112 dropouts, 33 died and 79 discontinued participation for other reasons.

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Conclusions: This supportive care approach neither improved QoL nor other patient-reported outcomes in patients with lung cancer. However, it reduced the use of chemotherapy shortly before the end of life. Possibly, (late) side effects of systemic therapy may have obscured effects of our intervention on QoL.

Clinical trial registration: NTR3540.

1. Introduction

The integration of supportive care is increasingly recognised as important in comprehensive cancer treatment to improve patients' quality of life (QoL) and well-being [1–4]. However, barriers still exist when integrating supportive care into usual care, and there is no consensus on the optimal timing and the most appropriate mode [5].

Currently, no uniform definition of best supportive care practice exists, and it is often poorly defined. A recent review does provide a set of consensus-based domains offering a framework for supportive care practices. Four key domains are defined in this framework: multidisciplinary care, supportive care documentation, symptom assessment and symptom management [6]. Nonetheless, current supportive care practices within oncology still vary with regards to implementation, scope and intensity.

Approximately 60% of patients with lung cancer experience distress during or after treatment [7,8]. Distress itself is defined as 'a multifactorial unpleasant emotional experience of a psychological, social and/or spiritual nature that may interfere with the ability to cope effectively [9]. We hypothesised that providing additional supportive care *via* an approach aimed at alleviating distress would improve the QoL of patients with lung cancer.

The basis for such an approach is postulated in the guideline on 'Screening of Distress and Referral Need' [10]. This approach consists of three steps: 1) gaining regular insight into the level and nature of patients' distress by a self-administered distress screening tool, 2) discussion of its responses with a dedicated nurse and 3) referral to psychosocial and/or paramedical health caregivers if needed or wished by the patient. It is aimed at reducing distress and is thereby thought to improve the QoL of patients with cancer. Timely detection of potential sources of distress (e.g. pain or feelings of sadness) and provision of targeted interventions are key to this process. We used the guideline on 'Screening of Distress and Referral Need' as the basis for our intervention and sought to compare this experimental approach to usual care alone by examining the effects on QoL, mood, patient satisfaction and the impact on end-of-life care in patients with lung cancer on systemic therapy.

2. Methods

2.1. Patients and procedure

All patients consecutively diagnosed in the University Medical Center Groningen with newly diagnosed (stage Ib to IV) or recurrent lung cancer were eligible when starting either chemotherapy, adjuvant chemotherapy, chemo-radiotherapy or treatment with biologicals and having an Eastern Cooperative Oncology Group performance score between 0 and 2. Patients were excluded if there was actual psychiatric co-morbidity, as diagnosed by a psychiatrist, or when already receiving care from a palliative team.

Eligible patients were informed about the study by their treating physician and invited to participate within a week after start of therapy. All patients were asked to complete questionnaires at home at four time points coinciding with scheduled outpatient visits: 1, 7, 13 and 25 weeks after randomisation (T1 at baseline, through T4). Since improvements in QoL are not likely during the administration of systemic therapy (generally 12 weeks), we chose a relatively late outcome at 25 weeks to observe effects on QoL after cessation of systemic therapy.

Randomisation, questionnaire distribution and data management were performed by the Netherlands Comprehensive Cancer Organisation (IKNL). The hospital medical ethics committee approved the protocol and all patients provided written informed consent.

2.2. Randomisation

Patients were randomised to receive either usual care or the experimental approach in a 1:1 ratio. Performance score and disease stage were used as stratification factor [11]. The randomisation schedule was generated by a validated system (PMX CTM, release 3.3.0 HP2, Propack Data) with the use of a pseudo–random number generator and a supplied seed number.

2.3. Usual care

Usual care for patients consisted of medical and (psycho-)social care offered by the treating physician every 3 weeks. Specific psychosocial care was not routinely