Oral Oncology 63 (2016) 10–15

Contents lists available at ScienceDirect

Oral Oncology

journal homepage: www.elsevier.com/locate/oraloncology

Expectations and preferences for palliative chemotherapy in head and neck cancers patients

Vijay Patil MBBS, MD, DM [a], Amit Joshi MBBS, MD, DM [a], Vanita Noronha MBBS, MD, DM [a], Jayita Deodhar MBBS, MD [b], Atanu Bhattacharjee PhD [c], Sachin Dhumal BHMS [a], M.V.K. Chandrakanth MBBS, MD [a], Ashay Karpe MBBS, MD, DM [a], Vikas Talreja MBBS, MD [a], Arun Chandrasekharan MBBS, MD [a], Siddharth Turkar MBBS, MD [a], Anant Ramaswamy MBBS, MD, DM [a], Kumar Prabhash MBBS, MD, DM [a,*]

[a] Department of Medical Oncology, Tata Memorial Hospital, Mumbai, India
[b] Department of Palliative Medicine, Tata Memorial Hospital, Mumbai, India
[c] Department of Biometrics, Chiltern International Limited, Bengaluru, India

ARTICLE INFO

Article history:
Received 31 August 2016
Received in revised form 20 October 2016
Accepted 31 October 2016

Keywords:
Expectations
Preferences
Palliative chemotherapy
Head and neck cancers
Decision making
Attitude to health

ABSTRACT

Background: Head and neck cancer patients undergoing palliative chemotherapy have a limited overall survival. Expectations and preferences of such patients towards palliative chemotherapy after explanation of disease prognosis and treatment options are unknown.

Methods: This was a single arm, prospective, observational study where newly diagnosed head and neck cancer patients warranting palliative chemotherapy underwent protocol defined counselling. Following counselling, they were administered chemotherapy expectation and preference proforma (CEP). The primary objective of this study was to estimate the percentage of patients opting for an increase in survival as the primary expectation from chemotherapy.

Results: We recruited two hundred patients all patients except one answered the CEP. Prolongation of life as the primary expectation from palliative chemotherapy was seen only in 82 patients (41.0%; 95% CI 34.4–47.9%). Symptom relief was the primary expectation or an equally important expectation amongst the remaining 117 patients (58.5%; 95% CI 51.6–65.1%). There was a statistically significant difference between the preferences of patients having a primary expectation of prolongation of life as opposed to symptom relief regarding the minimum expected number of patients need to treat to get prolongation of life (p value −0.00). The minimum expected increment in life expectancy for taking palliative chemotherapy was ">1 year" in 190 patients (94.5%; 95% CI 91.5–97.7%).

Conclusion: The primary expectation from palliative chemotherapy in head and neck cancer patients is not necessarily living longer in all patients. The magnitude of benefit preferred by the patients from chemotherapy far exceeded the current standards for drug approval.

Background

The literature on expectations and preferences of patients undergoing palliative chemotherapy in head and neck cancers is inadequate. Reports in breast, ovarian, colorectal and lung cancers have shown that patients expectations from palliative chemotherapy are often unrealistic [1,2]. Inadequate information on survival provided by the oncologists is one potential reason for this [2,3] Very few studies have tried to capture expectations and preferences subsequent to systematic counselling of patients [4]. Adequate knowledge about the disease status and its nature is associated with higher treatment satisfaction rates and provides autonomy in decision making [4–6]. This is of paramount importance in head and neck cancers, where standard palliative chemotherapy has limited impact on survival [7].

The priorities of head and neck cancer patients have been reported in the curative setting. "Living longer" and "being cured of cancer" remains a priority for most of the patients [8–10]. However would "Living longer" remain a priority in the palliative, non curative setting after adequate information about risk, benefit and

* Corresponding author at: Department of Medical Oncology, Tata Memorial Hospital, Parel, Mumbai 400012, India.
E-mail address: kumarprabhashtmh@gmail.com (K. Prabhash).

http://dx.doi.org/10.1016/j.oraloncology.2016.10.023
1368-8375/

cost about current treatments have been provided is questionable. These questions need to be answered as the current approval of newer agents in palliative setting is predominantly based on demonstration of prolongation in overall survival (OS) [11]. Questions that remain unanswered include the trade-off between a marginal improvement in OS versus the possible decrement in quality of life (QOL) as a result of therapy, as well as the degree of improvement in survival which should be considered clinically significant. The American Society of Clinical Oncology (ASCO) has recently formulated guidelines for defining the value of incremental survival benefit in cancer care in the palliative care setting. This guideline provides the values of increment in median survival which would be considered as clinically meaningful for various cancers in the palliative setting [12]. However head and neck cancer is not included in this guideline. But it is a paradox that the treatment of patients and selection of agents is not based on patients preferences and expectations but rather on the preferences of the treating oncologists [12]. Additionally, in a country like ours where very few patients have insurance and easy access to the health care system, preferences and expectations may differ from that of patients in developed countries [13].

Capturing patient's expectations and preferences requires a validated tool. A tool to capture such information was designed and validated by us in south India. This tool had a core question seeking the primary expectation of patient from chemotherapy, ie whether its was symptom control or living longer. Additional questions captured the patient preferences regarding the setting of chemotherapy, route of administration, side effects, cost and benefit.

We think that if >10% of patients do not opt for prolongation of life as their primary expectation then further studies are warranted. These studies should evaluate the possibility of having patient related outcome or a patient expectation fulfilling outcome as endpoints when evaluating new drugs in the palliative setting.

Methods

Eligibility criteria

We enrolled patients (> or =18 years) who had pathologically confirmed squamous cell carcinoma of the head and neck, with ECOG performance status (PS) 0–2, life expectancy below 12 months with standard palliative treatments, normal organ and bone marrow functions and warranting palliative chemotherapy in this study. Patients with uncontrolled medical comorbidities, pregnant women and patients who had already started on palliative chemotherapy were excluded. The details of inclusion and exclusion criteria are provided in the supplementary appendix.

Study design

This was a single arm, single centre, prospective study carried out in the outpatient department of Tata Memorial Centre, India. Patients who fulfilled the eligibility criteria underwent a protocol defined structured counselling (supplementary appendix). The counselling consisted of providing information regarding the stage of the disease, incurable nature of the disease, prognosis, benefits and side effects of both chemotherapy and targeted therapy, routes of administration, duration of treatment, cost of treatment and logistics and support facilities. Following counselling, the patients comprehension of the information provided was ascertained by cross questioning. After cross questioning, they were administered 3 short questionnaires. These questionnaires were filled before the start of the first cycle of palliative chemotherapy and within 24 h of the counselling.

The three questionnaires that were administered included.

1. Chemotherapy expectation and preference (CEP) proforma.
   a. The details of scope, development and validation of CEP have been previously reported by the lead author. (Manuscript accepted for publication in print) Briefly, the CEP has two parts. The first part has 4 questions while the second part has 10 questions. The first part deals with common questions identifying the primary expectation of patients from palliative chemotherapy and its magnitude. The second part dealt with questions addressing key preference issues related to chemotherapy. These include social life issues, side effect preference, preference regarding chemotherapy administration, chemotherapy cost preferences and choice regarding participation in a drug trial.
2. NCCN distress thermometer and problem list (DT).
3. FACT-Head and Neck (version 4) QOL proforma.

Responses to CEP & NCCN DT were recorded by the interviewer while the QOL proforma was self-administered Patients then received chemotherapy in accordance with the institutional protocols and were followed up at 2 monthly intervals.

Sample size

The primary objective of this study was to estimate the percentage of patients opting for an increase in survival as the primary expectation from chemotherapy. If this percentage was less than 90%, then the investigators felt that additional studies might be warranted. A sample size of 200 was required to provide 95% confidence limit of 4% for the estimated proportion assuming a binomial distribution.

Decision: If $\leqslant$172 of 200 patients opted for an increase in survival as the primary expectation from chemotherapy, the upper bound of the one-sided 95% confidence interval for the proportion of patients who opted for an increase in survival as the primary expectation from chemotherapy would be <90%, and additional studies might be warranted.

Study oversight

The study was investigator initiated. It was approved by the institutional ethics committee (IEC-III) and received an intramural grant from Tata Memorial Centre. The study was registered with CTRI (Clinical trial registry of India, CTRI/2015/11/006392). All patients provided written informed consent prior to enrollment in the study. The study was conducted in accordance with good clinical practice guidelines and the declaration of Helsinki. The data was analyzed and interpreted by the investigators. The lead author prepared the first draft of this manuscript. All authors reviewed, amended and approved the final draft. All authors vouch for completeness, accuracy and verify that the draft results are in accordance with the study plan reported in the protocol (supplementary appendix).

Statistical analysis

The statistical analysis was done on SPSS and R studio. Compliance with filling out the proforma was calculated using the following formula.

$$\text{Compliance} = \{(\text{Number of patients completing at least } 80\% \text{ or more questions}) \times k\} \div \{\text{total number of patients}\}. \quad (1)$$