QUALITY OF LIFE IN EARLY-STAGE ORAL CANCER: interim results from the COOLS Trial

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Introduction

The COOLS Trial

The Canadian Optically-guided approach for Oral Lesions Surgical Trial (COOLS) is a pan-Canadian randomized study which will recruit four hundred participants from 9 sites across Canada. Patients eligible for the trial are people with a severe dysplasia, a carcinoma in situ, or an invasive squamous cell carcinoma of the mouth, who have not been diagnosed with another cancer, and whose cancer is not metastatic.

Participants in the trial are randomized into two arms: they will either receive surgery based on margins drawn with the FV tool, or they will have surgery based on standard practice of margins drawn with white light. The surgeons performing these procedures will also be blinded to which method has been used.

Participants will be followed up every 3 months until the 2-year mark, and then every 6 months after that. Their surgical site will be investigated for evidence of recurrence.

Trial Goals

1. Establish clinical efficacy of fluorescent visualization (FV) tool compared to standard white light (WL) visualization technique for drawing surgical margins.
2. Collect molecular evidence of pathology in surgical margins
3. Collect evidence on the new technology’s cost-effectiveness compared to WL visualization
4. Conduct a knowledge translation exercise for clinicians adopting the new technology

Cost-Effectiveness Goal

The cost-effectiveness component of the COOLS Trial involves calculating the incremental cost-effectiveness ratio (ICER) of FV-guided surgery, compared to WL-guided surgery. Cost-effectiveness ratios are commonly expressed in terms of incremental cost (in dollars) divided by incremental effectiveness (in life years gained – LYG, or quality-adjusted life years gained – QALYs).

Quality of Life

Patient quality of life (QoL) is a crucial component in assessing the morbidity impact of disease. Oral cancer is under-studied, with very little information on patient quality of life available in the medical literature. Furthermore, QoL information is needed to calculate Quality-adjusted life years (QALYs), a common health economic and policy measure. It is also worthwhile to explore how QoL changes over time, as a measure of post-surgical recovery.

This poster summarizes the COOLS Trial QoL data for accrued trial participants to the end of August, 2013. Participants who had complete survey responses at all three time points of interest were included in this analysis (n = 206). A final analysis will include data over a 24-month observation period.

Methods

COOLS Trial participants were asked to complete a battery of QoL surveys at baseline (before surgery), and at 6 weeks and 3 months following surgery. The questionnaires ask them to respond on a Likert agreement scale to various statements about their quality of life at that point in time. The EQ-SD and Head and Neck module of the FACT questionnaire were used.

An interim subset of the results were analyzed, with some relevant subgroups compared. Only participants with complete data from all three observation points were included.

Results

Interim findings are presented here. Overall, QoL dipped slightly at the 6-week point, but recovered over time. Figures are scaled to present items with different values on a scale from “best possible QoL” to “worst possible QoL” along the Y axis.

Dimensional analysis

It may be more interesting to examine the subscales of the instruments than the aggregate values, given that “Quality of Life” is a construct made up of a number of different dimensions that may change relative to each other over time. Changes in the subscales may also reveal important and useful information about specific areas where patient QoL needs particular attention.

EQ-SD dimensions

Findings from the dimensions of the EQ-SD suggest that, while aggregate QoL (or utility, in this case) does not change over time, there is meaningful and interesting change in the subdimensions of the tool, and that the pattern changes across clinically-relevant subgroups.

Conclusions

The above interim results suggest that the COOLS Trial is collecting useful data on patient QoL in people treated for early-stage cancers of the oral cavity. Some care should be taken in interpreting these findings, as they are predominantly from our Vancouver site and do not reflect the entire cohort.

Data collection will continue through Fall, 2015. Regression modeling techniques will be used to quantify the change in QoL over time, in the context of relevant demographic and clinical confounders. QoL measures from 12 and 24 months following surgery will also be included in the analysis.

It is our hope that this and other findings from the trial will result in meaningful, positive, and cost-effective change in oral cancer surgical practice. We will also use the pan-Canadian network established in this trial to further knowledge generation and academic co-operation across Canada.