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Title: A comparison of attitudes to laryngeal cancer treatment outcomes: a time trade-off study

Short title: A comparison of attitudes to laryngeal cancer treatment outcomes

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Keywords

Head and neck neoplasms

Laryngeal neoplasms

Drug therapy

Radiotherapy

Cost-Benefit Analysis

Utility theory

Decision making

Conflict of interest statement

No authors have any conflict of interest or any relationships with any companies that might have an interest in the submitted work and have no non-financial interests that may be relevant to the submitted work

Abstract

Design

Time trade-off choice experiment

Setting

Two large head and neck cancer centres

Participants

Patients who have received treatment for head and neck cancer and members of the head and neck cancer multidisciplinary team

Main outcome measures

Participants were asked to rank the outcome scenarios, assign utility values using time trade-off and rate the importance of survival on treatment choice

Results

49 head and neck cancer patients and 73 staff members were recruited. Chemoradiotherapy (CRT) optimal outcome was the most preferred health state (34/49, 69% patients and 50/73, 68% staff) and CRT with complications was least preferred (27/49 55% patients and 51/73 70% staff). Using time trade-off, mean utility values were calculated for CRT optimal outcome (0.73 for patients, 0.77 for staff), total laryngectomy (TL) optimal outcome (0.67 for patients, 0.69 for staff), TL outcome with complications (0.46 for patients, 0.51 for staff) and CRT with complications (0.36 for patients, 0.49 for staff). The average survival advantage required for a participant to change their preferred choice was 2.6 years

Conclusions.

We have demonstrated that a significant proportion of head and neck cancer patients and staff members would not choose CRT to manage locally advanced laryngeal cancer. Staff members rated the health states associated with laryngeal cancer treatment higher than patients who have experienced them, and this is particularly evident when considering the poorer outcomes. The head and neck cancer community should develop methods of practice and decision making which incorporate elicitation and reporting of patient values as a central principle.

Introduction

Laryngeal cancer is the second most common head and neck malignancy(1) and successful treatment has significant effects on a patient's swallow or voice function. Guidelines state that concomitant chemoradiotherapy (CRT) is the current non-surgical standard of care for T3 laryngeal cancer: CRT should also be considered for those with T4 disease and no spread through cartilage(2). CRT allows preservation of the laryngeal structures (and hence maintenance of normal voice production) but treatment can have a profoundly adverse effect on swallowing ability(3). As a result, patients treated with CRT are often dependent on supplementary tube feeding in the short term, with a minority requiring supplementary feeding for more than a year(4). Patients also have the option of total laryngectomy (TL); this renders the patient a neck breather, with profound consequences for communication. As survival is considered to be similar for the two options, patients are often offered CRT as a first line therapy, with TL reserved as a salvage procedure in the event of disease recurrence or for patients experiencing laryngeal dysfunction following non-surgical management. Unfortunately, those who receive surgery following radical CRT have a significantly diminished quality of life relative to primary TL, a far higher rate of fistula formation(5) and often need vascularised flap reconstruction of the surgical defect (6).

Patients will value a 'health state' such as life after CRT or TL depending on the priorities they place on their appearance, voice or swallow function. Several methods have previously been used to measure how patients value health states, with the majority of these methods generating a 'health utility'. Specifically, health utility represents the value placed on a health state and for convenience is anchored between zero (valuing the health state the same as death) and one (valuing the health state the same as normal or full health). These utility values are mostly found in health economics literature and cost effectiveness analyses(7), but are also useful in modelling decision processes. The estimation of utility values draw on a 'normative theory' of decision making, based on the philosophy that under ideal conditions, an individual will make the choice with the maximum expected utility: this is arguably not a reflection of the real-life process of decision making for patient or clinician (8). However, they provide a useful insight into the trade-offs which head and neck cancer patients face when choosing treatment modalities.

Locally advanced laryngeal cancer often provides the clinician and patient with a difficult choice, trading off differences in appearance, speech, swallow and survival. McNeil et al.(9) reported that healthy volunteers would

sacrifice survival in order to maintain a 'normal' voice, but their sample of firemen and middle managers was not representative of the head and neck cancer population. We repeated McNeil's study on a large sample of patients with chronic obstructive pulmonary disease (COPD), deemed more representative of head and neck cancer patients. Among the COPD sample, 38% reported that they would prefer to have a TL. Also, the utility values assigned to the various health states confirmed that the functional quality of the outcomes of treatment was of more importance than the modality(10). Hence, it could be concluded that a blanket application of the current non-surgical standard of care does not reflect the treatment that patients might choose based on their preferences. Here, we aimed to investigate this observation further, by interrogating populations with experience of the disease. We performed the same time trade-off experiment on head and neck cancer patients and the health professionals who treat them, allowing comparison between the two.

Methods

Ethical considerations

All participants were interviewed between June 2013 and June 2014, following written informed consent. The study was approved by Newcastle University Ethics Committee and Newcastle upon Tyne Regional Ethics Committee (ref number 13/NE/0036)

Participants

Two groups of participants were recruited from two head and neck cancer clinics in the north-east of England:

- **Group 1 - Head and neck cancer patients:** all patient participants had previously received treatment for head and neck cancer of any site and stage and had no evidence of active disease.
- **Group 2 - Head and neck cancer health professionals:** the health professional participants were all involved in the treatment of patients with head and neck cancer, either as part of the multidisciplinary team, on the ward or in the outpatient clinic

Study design

Four health state descriptors were developed depicting the treatment process and outcome for CRT optimal outcome, CRT with complications, TL optimal outcome and TL with complications (see Appendix one). The health state vignettes were compiled using extensive literature review and clinical experience, but were iteratively developed and validated through repeated rounds of design, in conjunction with patients previously treated for locally advanced laryngeal cancer and the health professionals involved in their care. Patients involved in the preparation of the health state vignettes were excluded from involvement as study participants.

Audio and video recordings of speech following TL and CRT were developed during pilot work to use alongside the vignettes, together with pictures of a tracheal stoma, skin changes due to radiotherapy and a gastrostomy. The audio and video recordings were of patients reciting a standard text (unrelated to a healthcare topic) and were the same for all participants

Firstly, participants were presented with the audio-visual information on the process and outcomes of treatment using the videos, recordings and pictures developed during the pilot work, together with a standardized explanation given by the interviewer. The four health states were then introduced, and participants were asked to carry out three exercises. In exercise one, participants ranked the four available health states alongside their own health from most to least desirable. In exercise two, participants were offered a choice between alternative 1 (to remain in one of the health states for 10 years) and alternative 2 (to retain normal health, but with a decreased survival [x years]). X was varied until the respondent became indifferent between the two alternatives, at which point the utility value for that health state was derived (11, 12). For example, a participant who felt 10 years with a laryngectomy was equivalent to seven years in their normal health state yields a laryngectomy utility value of $7/10 = 0.7$. Each of the four health states were presented similarly, in a random order to control for order of study bias (11). If the participant was under 45 years old, 25 years was used as the basis of the survival scale (with 2.5 year increments), however the utility values were generated in the same manner regardless of age. During exercise three the participant was asked again which of the two optimal outcome health states they would prefer: total laryngectomy optimal outcome, or chemoradiotherapy optimal outcome. The years of survival associated with the non-preferred option were then increased (using a similar technique to the time trade off exercise) in order to determine the number of years of survival advantage, if any, that would lead to a change in decision.

Statistical Methods

Average utility value scores were non-normally distributed and compared using Mann Whitney test. All statistical calculations were performed using SPSS v21.

Results

A total of 49 patients and 73 staff members took part in this study (see table 1). All participants were able to complete all three exercises.

Ranking exercise

When given the choice, current health was the preferred health state for all staff participants (see figure 1). 68.5% (50/73) then preferred CRT optimal outcome and 31.5% (23/73) preferred TL optimal outcome. In the patient participant group, 38.7% (19/49) preferred one of the post-treatment health states to their current health. However, if only the post-treatment health states are compared the findings are very similar to the staff group: 67.4% (33/49) preferred CRT optimal outcome and 32.7% (16/49) preferred TL optimal outcome

Utility values

There was noticeable variability in the range of responses regarding the utility values (see figure 2). The average assigned utility value for each health state is shown in figure 3. Staff members consistently rated the post-treatment health states higher than the patient group. The difference between the optimal outcome and outcome with complications was also more marked for the patient group than it was for the staff group. For both groups, CRT optimal outcome was assigned the highest utility value (0.77 for staff members, 0.73 for patients) and CRT poor outcome had the lowest utility value (0.49 for staff members and 0.36 for patients). The difference in mean utility value was not significant between staff and patient participants for any of the health states apart from CRT with complications ($p=0.026$).

Survival advantage

The survival advantage exercise took place at the end of the interview. Eleven staff participants (15.1%) changed their mind from exercise one and opted for CRT instead of TL as their preferred treatment option. No staff members changed their mind from CRT to TL. Eighteen patients (36%) changed their mind with 10 patients swapping from CRT to TL as their primary choice and eight patients swapping from TL to CRT. In the staff group, 5.5% (4/73: all of whom opted for CRT) would not change their treatment preference despite any given survival advantage, as compared with 30.6% of patients (15/49: seven who opted for TL and eight who opted for CRT). For those participants who would change treatment option if there was a survival advantage to the non-preferred option, the average survival advantage required was 2.6 years for staff and 2.8 years for patients.

Discussion

Synopsis of key findings

When presented with the treatment choices in laryngeal cancer, the majority of staff and patient participants opt for CRT, however, a significant minority (31.5% and 32.7%) would choose TL. On average, staff members

assign higher utility values to the health states associated with laryngeal cancer treatment than the patients who have experienced them and this is particularly evident when considering the poorer outcomes. Also, staff members do not have as large a difference between health states with an optimal outcome and those with complications. These data highlight that the value placed on outcomes vary significantly within patient groups and between patients and staff members which has profound implications for decision making in laryngeal cancer. Treating clinicians cannot assume that their values with respect to stoma, speech or swallow are shared by the patient that they are treating. This strengthens the argument for effective patient involvement as the health state utility value which is of most importance at the time of a treatment decision is that of the individual patient receiving the treatment.

Comparisons with other studies

To make a decision on behalf of a patient a clinician may assume that she/he shares the values and priorities for treatment, or understands the values and priorities of the individual patient in front of them; however multiple authors have suggested that this is not the case. When Mohide *et al*(13) compared the treatment priorities of 20 head and neck cancer health care professionals and 20 patients, professionals rated communication, self-image and esteem as most important, whereas patients were more concerned about the physical consequences of surgery such as tracheal mucus production. Other authors have found significant differences in ratings for the work and social functioning or pain (14, 15). A comparison of the views of patients who had undergone laryngectomy with those of healthcare providers found that more than twice the proportion of health care providers would compromise survival in order to preserve voice and quality of life compared to patients (16). This is in agreement with another study of attitudes towards chemotherapy which demonstrated that a group of newly diagnosed cancer patients expressed willingness to undergo very aggressive chemotherapy with an extremely limited survival advantage. In contrast, non-patients, oncology doctors and nurses were much less likely to opt for such a treatment with the expectation of minimal gain (17). Decision making in healthcare is driven by the value that a particular individual (professional or patient) places on health states and intervention risks. Indeed, these values often have more of an effect on the decision made than the severity of the symptom itself. Barry *et al*(18) found that patient reported symptom severity in prostate disease did sufficiently explain which patients chose to go ahead with surgical intervention. The most important indicator of the treatment chosen was how bothersome (rather than necessarily severe) the symptoms were, and how patients' attitudes varied towards the complications of surgery (e.g. the prospect of sexual dysfunction): those patients who were 'bothered' were seven times more likely to opt for surgery. In the same way, although objective pain scores

were a predictor of time to knee replacement in osteoarthritis patients, a willingness to undergo surgery or preference for surgery had a greater effect on the choice made (19).

Clinical applicability of the study

Here, we have demonstrated significant variation between staff members and patients in the value that they place on the theoretical health states encountered following treatment for laryngeal cancer: indeed, an individual staff member may hold very different values to the patient they are consulting with. If we are to accept that these values drive decision making in this setting (20) then we should focus on effective methods of eliciting values from patients, rather than driving decisions based on clinical perspectives. Time trade off is one valid method of eliciting utility values, however do not provide the whole answer, however, they do not provide significant insight into the actual process of decision making. Indeed, the use of utility optimisation and statistical thinking in decisions with imperfect information can lead to decisions which are worse than those using heuristics alone (21).

Shared decision making is a model of healthcare delivery in which the values and preferences of the patient are central to the decision made. 'Decision aids' are a central feature in the delivery of shared decision making. Some decision aids incorporate utility values as part of values elicitation but many other methods of ascertaining values and preferences of patients are available and in use. Currently, there are no tools for eliciting values in the clinical consultation for head and neck cancer. Decision aids are designed to be used before, during or after a clinical consultation by the patient with or without a clinician. In a systematic review of 115 randomised controlled trials studying the effectiveness of decision aids, their use was associated with improved patient knowledge, lower decisional conflict, a decreased proportion of patients who were passive in decision making and fewer patients remaining undecided. There was also a reported increase in patient satisfaction with the decision making encounter and improved perception of risk(22). However, it must not be assumed that the presence of a decision aid ensures shared decision making is taking place(23): for this to happen, both individual, system wide and cultural attitudes must support the process (24). Nevertheless, we have demonstrated here and previously (10)that patients and matched controls are willing and capable of engaging in values elicitation: indeed when sought, opinions are varied and often strongly held.

Patient involvement in head and neck cancer decision making is an ethical, clinical and moral imperative, and central to this process are the values that a patient places on the resultant post-treatment health states. Here, we

have demonstrated the individual variation in these health states between patients and the staff members who treat them, and between individual patients. If patient involvement and shared decision making is to be improved in head and neck cancer, methods of providing information and eliciting treatment-related values must be central to the decision making process. However, one should not underestimate the complexity of this task: head and neck cancer treatment is complex, not only in outcome of treatment but also in the process of decision making. Decisions are often made in teams with multiple health care professionals, family members and supporters involved(20); thus the process of value elicitation should take more than the methods described in this study. Indeed, the process of elicitation should consist of exploring, discussing and even challenging multiple, sometimes conflicting viewpoints. If we are to improve the decisions we make in conjunction with patients we should shift further from simply informing them about treatment options and work towards developing tools and clinical skills which help patients understand their values and make decisions with their clinicians that are informed and consistent with those values.

Conclusion

There is variation in how patients and staff members rank and value the health states encountered after treatment for laryngeal cancer and this is particularly evident for outcomes with complications. Current cancer decision making pathways make incorporation of patients' values difficult (20, 25, 26) and hence the head and neck cancer community should develop methods of practice and decision making which incorporate elicitation and reporting of patient values as a central principle.

Figure legends

Figure 1: Figure one: Ranking of all disease health states for patients and staff (%). Current health has been removed as a health state to allow meaningful comparison

Figure 2: histogram showing variation in assigned utility value for patient group

Figure 3: average utility value assigned using time trade off for staff and patient groups

Table legends

Table 1: demographics of participants

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Appendix one: health state descriptors

HEALTH STATE Surgery optimal outcome

- **Temporary side effects**
 - Pain after operation
 - Nothing by mouth until wound has healed

- **Permanent side effects**
 - Changed appearance - hole in the neck
 - Smell and taste affected or lost
 - Mucus production from stoma

- **Voice**
 - Loss of normal speech
 - Put finger on stoma, push air through mouth
 - Likely to have a good voice using this technique

- **Eating**
 - Normal to near normal diet

HEALTH STATE

Surgery outcome with complications

- **Temporary side effects**
 - Pain after operation
 - Nothing by mouth until wound has healed

- **Permanent side effects**
 - Changed appearance - hole in the neck
 - Smell and taste affected or lost
 - Mucus production from stoma

- **Voice**
 - Loss of normal speech
 - Put finger on stoma, push air through mouth
 - *May struggle using speech-valve – might need to use other ways to communicate like gesture or writing things down*

- **Eating**
 - *Softened, puréed, diet*

- **Complications**
 - *Neck-wound not healing correctly*
 - *Irritation and crusting of stoma in neck*
 - *Need for further operations*

HEALTH STATE

Chemoradiotherapy optimal outcome

- **Temporary side effects**
 - Feel tired and generally unwell
 - Red skin reaction and possibly painful lining of the mouth and throat
 - May experience difficulty swallowing
 - May experience pain swallowing
 - Possible need for a feeding tube, either through nose into stomach or directly into stomach (PEG)

- **Permanent side effects**
 - Dry mouth likely
 - Taste might be affected

- **Voice**
 - Normal speech, but weaker and more hoarse

- **Eating**
 - Near normal diet

HEALTH STATE

Chemoradiotherapy outcome with complications

- **Temporary side effects**
 - Feel tired and generally unwell – *possible hospital admission*
 - Pain swallowing
 - Red skin reaction and pain in the lining of the mouth and throat *needing strong painkillers*

- **Permanent side effects**
 - Dry mouth
 - Taste is changed or lost
 - *Difficulty swallowing*

- **Voice**
 - Normal speech, but weaker and more hoarse
 - *Might struggle to be heard when there is background noise*

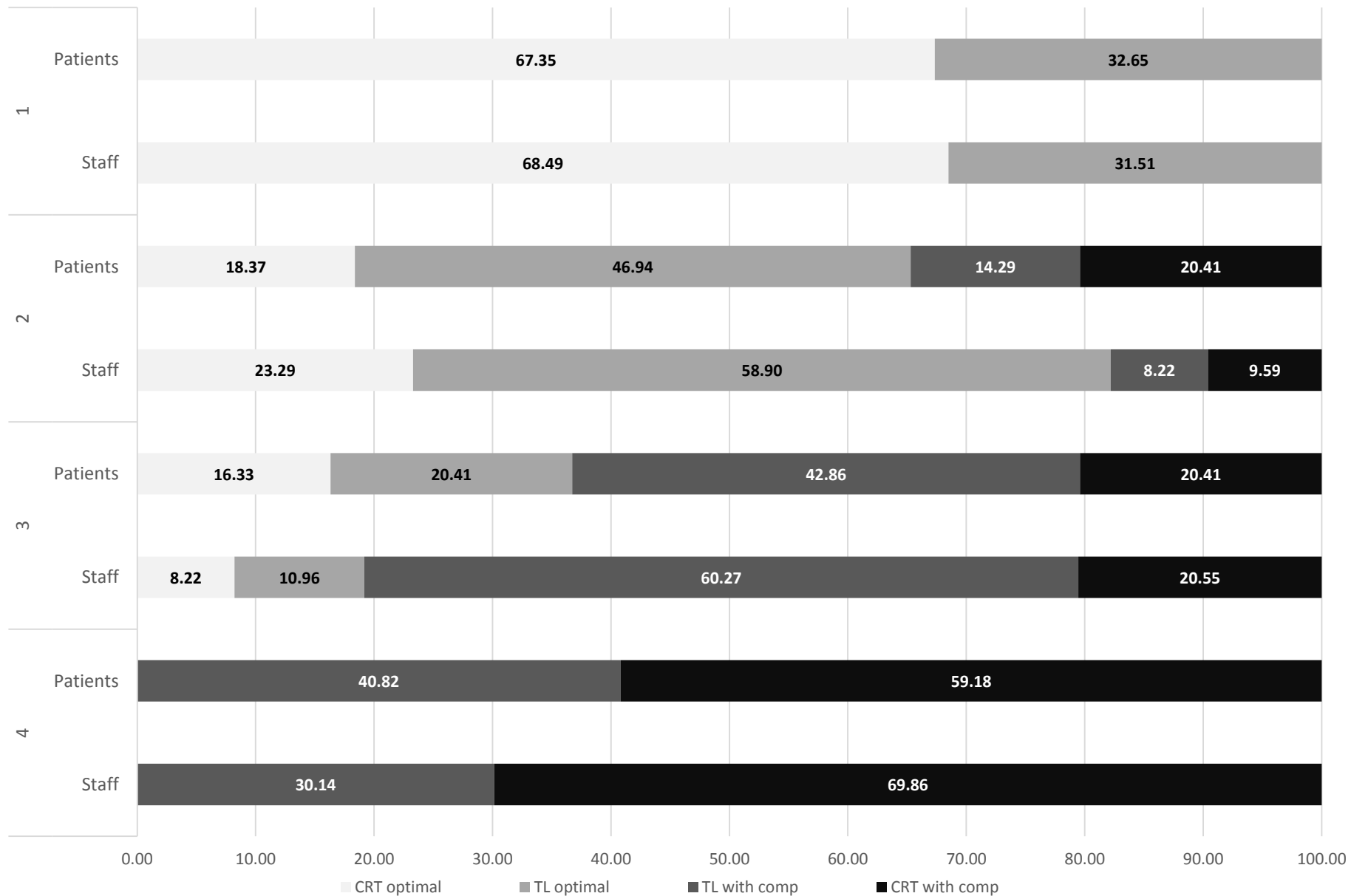
- **Eating**
 - *No food and drinks by mouth*
 - *Long-term feeding tube into stomach (PEG)*

- **Complications**
 - *Thick secretions in throat, difficult to clear*
 - *Ulcers in mouth*

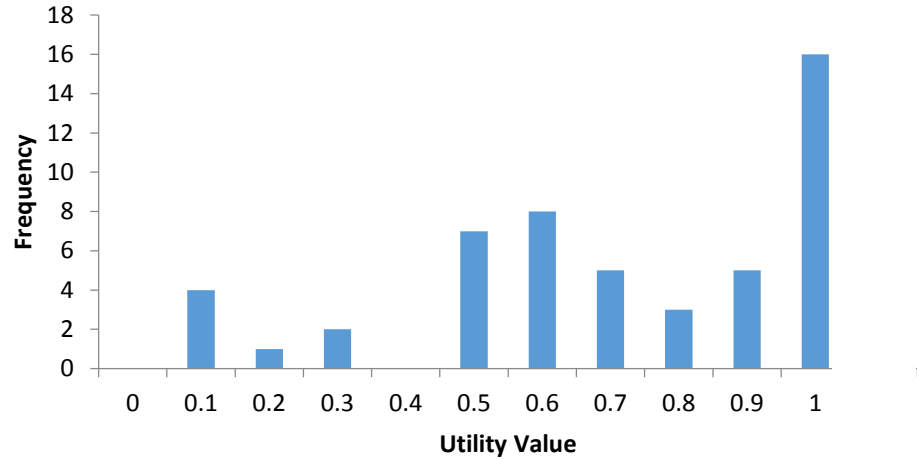
Tables

		Staff: number (%)	Patient: number (%)
Gender	Female	48 (65.8)	13 (24.5)
	Male	25 (34.2)	36 (73.5)
Age (years)		41.6 (range 20-66)	62.3 (range 48-84)
Smoking	Never	58 (79.5)	12 (24.5)
	Ex-smoker	13 (17.7)	29 (59.2)
	Current Smoker	2 (2.8)	8 (16.3)
Education	Secondary	5 (6.7)	31 (63.3)
	Certificate/diploma/college	9 (12.3)	13 (26.5)
	Degree	59 (80.8)	4 (8.2)
	Unknown	-	1 (2.0)
Occupation	Doctor	26 (35.6)	-
	Nurse	28 (38.4)	-
	Speech and Language Therapist	8 (11.0)	-
	Dietician	4 (5.4)	-
	Health care assistant	5 (6.8)	-
	Psychologist	1 (1.4)	-
	Unknown	1 (1.4)	49 (100.0)

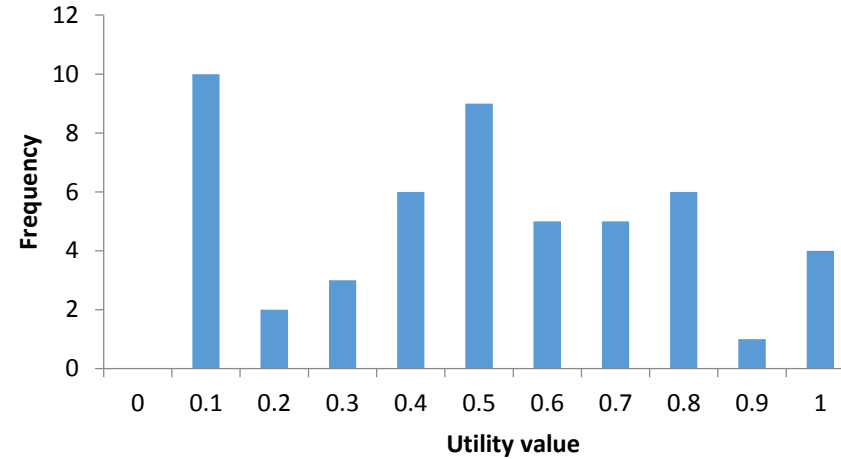
Table one: demographics of participants



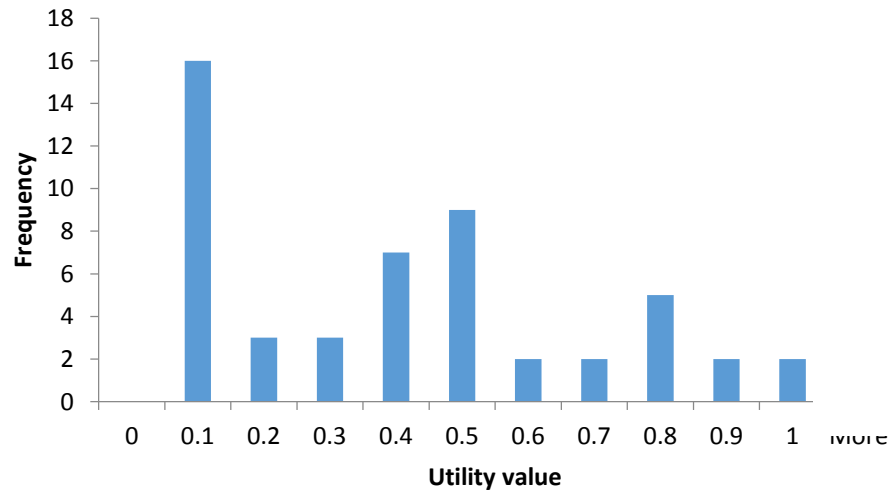
TL Optimal Outcome



TL with complications



CRT Optimal Outcome



CRT with complications

