A decision-analytic model for early stage breast cancer: Lumpectomy vs mastectomy

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The purpose was to construct a decision model that incorporated patient preferences over differing health state prospects and to analyze the decision context of early stage breast cancer patients in relation to two main surgical treatment options.

A Markov chain was constructed to project the clinical history of breast carcinoma following surgery. A Multi Attribute Utility Model was developed for outcome evaluation. Transition probabilities were obtained by using subjective probability assessment. This study was performed on the sample population of female university students and utilities were elicited from these healthy volunteers. The results were validated by using Standard Gamble technique. Finally, Monte Carlo Simulation was utilized in Treeage-Pro 2006-Suit software program in order to calculate expected utility generated by each treatment option.

The results showed that, if the subject had mastectomy, mean value for the quality adjusted life years gained was 6.42; on the other hand, if the preference was lumpectomy, it was 7.00 out of a possible 10 years. Sensitivity analysis on transition probabilities to local recurrence and salvaged states was performed and two threshold values were observed. Additionally, sensitivity analysis on utilities showed that the model was more sensitive to no evidence of disease state; however, was not sensitive to utilities of local recurrence and salvaged states.

The decision model was developed with reasonable success for early stage breast cancer patients, and tested by using general public data. The results obtained from these data showed that lumpectomy was more favourable for these participants.

Key words: Breast Cancer, Decision Analysis, Markov Chain, Quality of Life, Health Outcome Measurement, Utility.

Worldwide, more than 700,000 women die annually of breast cancer, and it is estimated that eight to nine percent of women will suffer from breast cancer in their lifetime.[1] On the other hand, according to the statistics of Ministry of Health, in Turkey, approximately 30,000 women are diagnosed with breast cancer every year, and it is the most common cancer in women as is the case worldwide. [2]

With technological advances, different types of treatment options have been adopted to extend survival of patients with breast cancer. Two basic treatment options are mentioned, lumpectomy and mastectomy, in the literature. In general, surgeons recommend a treatment according to their experiences and the first thing taken into account is generally the survival of patient, not the quality of life after surgery. However, their experiences may not always reflect the "best" decision, and preferences of health professionals may conflict with patient preferences. Considerable amount of research has focused on the quality of life in breast cancer patients after surgery in order to make a better-informed decision on treatment options. [3–9]

Decision Making Techniques are useful for critical decisions in health care and have been used for over thirty years around the world. In fact, the idea of using decision theory in medical practice was first proposed by Ledley and Lusted. [10–11] In Turkey, health sector is largely unexplored territory with regard to such studies.

In this study we aimed to analyze the decision context of early stage breast cancer patients in relation to two main treatment options, and to construct a decision making model that incorporates patient preferences over differing health state prospects as well as incorporating other typical complexities of such decision situations such as uncertainty.

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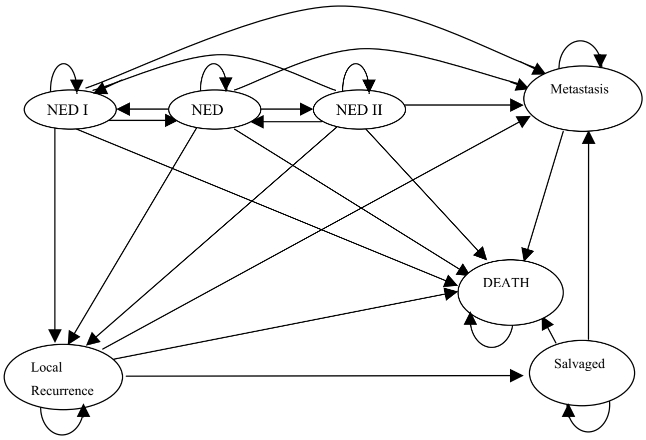

Figure 1. State transition model of the natural history of breast cancer following surgery

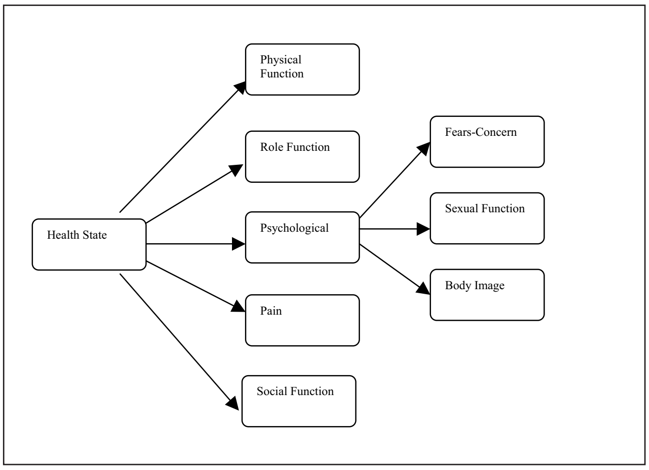

Figure 2. Multi level attribute tree for determination of any health state

Patients and methods

In this study, we considered the patients for whom both treatment options can be applicable, and hence the patient preferences can legitimately make a difference if they could be modelled into the decision making process. For this purpose, we tried to create a quantitative representation of this decision situation involving both treatment choices. This quantitative representation of the breast cancer problem allowed for incorporating of choices, uncertainty and outcome measures. Expected value of outcomes that result from the two possible treatment options can be calculated and compared in order to decide on the best option for one patient.

Disease progress modelling. The objective of the modelling of disease progress is to identify possible outcomes associated with each treatment option so that by evaluating these outcomes the optimal decision about choices of treatment for breast cancer patient can be made. In this study, the central choice-making is between lumpectomy and mastectomy operation, the Markov process incorporates all events/ decisions following a surgery and the decision analysis compares the values of two Markov processes. [12] Health states used in the model are conditions of being well (NED), having hormone therapy (NEDI) or chemotherapy (NEDII), having recurrent local disease (Local Recurrence), being salvaged after recurrence of disease (Salvaged), having distant disease (Metastasis) or death (DEATH). The resultant state transition model is depicted in Figure 1.

Outcome measuring and evaluation measure modelling . Upon identifying possible outcomes by suitable decision modelling technique, evaluation of health outcomes is the most important step. Once outcomes are measured, outcome values can be assigned as reward for each Markov state used in the model and evaluation of the Markov chain on outcome values yields the expected reward. Then, two treatment options can be compared with respect to their expected rewards.

Quality of life is measured with patient's utility (Von Neumann and Morgenstern utility [15])for each health state. By assessing the utility at each state, evaluation of Markov chain yields expected utility, total number of cycles spent in each state; each multiplied by the expected utility for that state. Thereby, the evaluation measure (comparison criterion) Quality Adjusted Life Years (QALY) is obtained, which is known to be useful to measure the effects of different medical interventions in a comprehensive way since it combines quality and quantity. [13]

Multi Attribute Utility Model (MAUM). After identifying all possible outcomes on the decision model developed as a Markov chain, a MAUM was constructed for measuring these outcomes. And the utility values for each health state were assessed by using assessment techniques of MAU theory.[6] Description of example health states is shown in Table 1. Medical expert support was obtained from the Hacettepe University Oncology Hospital oncologists and 5 main attributes and 3 sub-attributes were specified in order to characterize one health state. Multi-level attribute tree for determination of any health state can be seen in Figure 2.

Table 1. An Example Health State Description

Lumpectomy – Metastasis	
Physical function.	Needing help from another person in order to get around house, yard, neighbourhood or community; and having some limitation in physical ability to lift, walk, run, jump or bend
Role function.	Needing help to eat, dress, bath and go to the toilet; and not being able to play, attend school or work
Social function.	Having a few friends and contacts with others
Pain	Severe pain. Pain not relieved by drugs and constantly disrupts normal activities
Body Image	Having concerns about appearance, feeling clothes don't look good and discomfort because of body changes
Fear&concerns	Feeling fear of death
Sexual function.	Loss of libido and sexual dysfunction

Twelve health states, six succeeding mastectomy and six succeeding lumpectomy, were defined by feasible combination of attribute levels, and finally, multi attribute utility functions were formed for each health state. After assessing locations (i.e. identifying current health status of a specific patient along the scale), overall utility values of the health states for both treatment options can be calculated for any patient.

In order to perform validation process, global (holistic) ratings for each health state were obtained from interview results of a control group (Group 2). The values yielded by the model and the global ratings were compared. In order to assess degrees to which values of health states derived by the MAUM were consistent with the values derived by holistic procedure, in addition to comparison of two samples (Group 1 & Group 2), a random sample was drawn from control group (Group 2), and they were also applied MAUM assessment procedures (which was the task of Group 1). So, using the sample that performed both assessment methods, "construct validation" was used to determine whether subjects' holistic preference judgments were consistent with the results from the algebraic utility model. [14] Von Neumann and Morgenstern Standard Gamble technique [15] was employed for global rating. In this experiment, this procedure was applied to each participant for twelve health states: six were for after mastectomy operation and six were for after lumpectomy operation. The health state of "Death" was not included in the experiment since its utility was assigned as 0 by default.

Probability assignment. Probability estimates were based on a group of oncologists' consensus. Since transition probabilities among the health states are not constant over time, probabilities were estimated for each cycle (year) by considering 10-year survival for disease progression.

Final step is evaluation of the model according to data obtained from patient, obtaining QALY values that result from the two possible treatment options, and deciding on optimal treatment option. 10-year survival was considered, and the model in this study was evaluated by Monte Carlo simulation. Results of this simulation were analyzed and necessary sensitivity analyses were performed in order to observe the effects of parameters. The output was QALY during 10-year survival.

Table 2. Statistical Analysis of Utility Results Obtained from MAUM

PAIR		MEAN		DIFFERENCE	P VALUE
Mast.	Lump.	Mast.	Lump.		
NED	NED	88.00	96.60	-8.60	< 0.001
NEDI	NEDI	82.03	93.37	-11.33	< 0.001
NEDII	NEDII	63.07	67.67	-4.60	< 0.001
Local Rec.	Local Rec.	60.07	61.83	-1.77	0.001
Salvage	Salvage	41.20	42.77	-1.57	0.002
Metastasis	Metastasis	25.13	25.13	0	-

† Rec, Recurrence
‡ Mast, Mastectomy
§ Lump, Lumpectomy

Experimental analysis

Individual utility values were elicited from Middle East Technical University Industrial Engineering female students and overall utility values were calculated for each possible health state. For each attribute a natural scale ("phrase-anchored" scale) was constructed. The rating for the maximum level was predefined as 100 point for each attribute. The participants (Group 1) were requested to read the statements of each level, rate them according to personal judgments and mark on the scale by considering that the best level was rated as 100 point and the death was rated as 0 point. Direct Rating Technique [16] was used for evaluation of each level. This way, one-dimensional value scales were obtained for each participant. The value scales assessed in this study were used as utility scale. [17]

The relative importance of each attribute against others in the multi attribute utility function is represented by a scaling constant. The weight assigned to a criterion is a scaling factor which relates scores on that criterion to scores on all other criteria. In order to determine these scaling constants, a group of participants (Group 1) who performed the previous study were also asked to rank all attributes with respect to their relative importance by swing rating method. [16]

After eliciting individual utility values and scaling constants, by using these parameters for each attribute, utilities of each participant for each health state can be evaluated easily. As mentioned before, locations of health states were specified, and 8-attribute utility functions for each state were defined. Aggregate utility values were then calculated with respect to data obtained from Group 1 by using Matlab Version 7.2.0.232 computer program.

Statistical analysis. After obtaining aggregate utility values for each outcome, design and evaluation of the model were performed by making use of Treeage-Pro 2006 Suit software. The statistical significance of difference in utility values for each health state between two experiments was assessed with two-sample t-test and Wilcoxon rank sum test results, using statistical software package MINITAB Release 14.20. Multitrait-Multimethod Matrix method [18] (MTMM), was performed for construct validation.

Evaluation of the Markov chain developed for the disease progress yields QALY, which is total number of cycles spent in each state, each multiplied by the reward for that state, since a reward was assigned to each health state.

$$QALY= \sum t_j \times R_j$$

where
t_j: time spent in state j
R_j: reward (utility) for state j

Results

The basic configurations are the same for both treatment options since the history is the same. The only difference is in the parameter values such as utility values. Statistical analysis of utility results obtained from MAUM can be seen in Table 2. The output was QALY during 10-year survival. The runs showed that, if the subject had mastectomy, mean value for the quality adjusted life years gained (QALY-gain) was 6.42; on the other hand, if the preference was lumpectomy, the mean value for the QALY-gain was 7.00 at this time. The results showed that, QALY for lumpectomy is higher than mastectomy on the average and the difference in the total reward between lumpectomy and mastectomy increases each year. This means that patients' preferences point to lumpectomy for surgical operation. Since we performed this study on a sample consisting of university students to generate QALY values, the results reflect their preferences.

Validity. The term "validity" was meant in this study as the consistency check of the results, utility values for each health state, obtained from the MAUM. Descriptive statistics and the test results were tabulated in Table 3. Statistical difference between two population means was analyzed for each health state by considering samples both normally distributed and nonparametric. According to the test results, for six health states, MAUM results match global ratings. On the other hand, for the rest of six health states, values from MAUM and global ratings do not match. An important result from this analysis was that multi-attribute utility model gave highly correlating results especially for the no-evidence of disease health states. On the other hand, as the health state got worse, consistency of results became poorer. The reason for that may be use of general population in the analysis, because if assessing health state condition is similar to participants' current conditions, they can evaluate more objectively. However, if the assessed health status is remote from their current condition, imagining being in that health state and assessing the condition objectively becomes difficult.

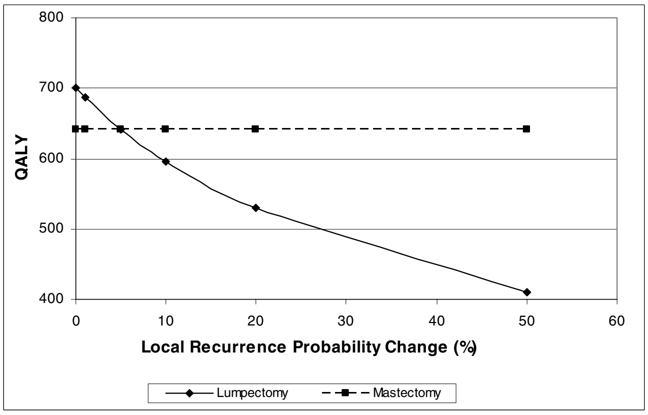

Figure 3. One-way sensitivity analysis on local recurrence probability

In order to perform more effective consistency check, in addition to statistical comparison of two samples, a random sample of 15 was drawn from control group (Group 2) and MAUM assessment procedures were also applied, so one sample of participants performed both assessment methods, and by using their results, "construct validity" was checked where "construct validity" is defined as the consistency between a subject's holistic preference judgments and results from an algebraic utility model. Using MTMM, different classes of correlation coefficients were identified and compared with each other, and some necessary conditions for validation were checked. Results were sufficient to accept that MAUM is reasonably valid.

Table 3. Descriptive Statistics of Utility Values

Variable		MAUM (N=30)			Global Rating (N=30)			Two-Sample t-Test	Mann-Whitney Test
		Mean	Median	SD	Mean	Median	SD	*p* value	*p* value
Mastectomy	U1	88.00	90	7.10	87.70	90	10.46	0.897	0.5692
	U2	82.03	83	5.89	82.00	82.5	13.59	0.990	0.6414
	U3	63.07	64	6.68	73.07	72.5	17.46	0.006	0.0014
	U4	60.07	60.5	7.66	67.27	70.0	20.80	0.084	0.0309
	U5	41.20	41	9.11	58.87	60	20.39	< 0.001	0.0001
	U6	25.13	25	8.54	44.40	45	25.84	< 0.001	0.0027
Lumpectomy	U7	96.600	98	4.149	93.77	96	7.59	0.080	0.1039
	U8	93.367	94.5	4.351	88.60	90	10.93	0.033	0.2675
	U9	67.67	68	7.95	76.97	80	14.47	0.003	0.0017
	U10	61.83	61.5	8.25	67.30	68	20.30	0.180	0.1602
	U11	42.77	42.5	9.84	59.27	57.5	19.95	< 0.001	0.0002
	U12	25.13	25	8.54	43.93	45	25.89	0.001	0.0043

† SD, Standard Deviation

‡ U1, aggregate utility value for health state NED following mastectomy; U2, aggregate utility value for health state NEDI following mastectomy; U3, aggregate utility value for health state NEDII following mastectomy; U4, aggregate utility value for health state Local Recurrence following mastectomy; U5, aggregate utility value for health state Salvaged following mastectomy; U6, aggregate utility value for health state Metastasis following mastectomy; U1, aggregate utility value for health state NED following lumpectomy; U2, aggregate utility value for health state NEDI following lumpectomy; U3, aggregate utility value for health state NEDII following lumpectomy; U4, aggregate utility value for health state Local Recurrence following lumpectomy; U5, aggregate utility value for health state Salvaged following lumpectomy; U6, aggregate utility value for health state Metastasis following lumpectomy.

Sensitivity Analysis. Utilities of health states were estimated on the basis of general population preferences and survey results; on the other hand, transition probabilities were estimated on the basis of experience of clinicians and literature review. Thus, it is important to examine how our decision might be affected by changes in those parameters.

Transition probabilities among the health states were assumed to be equal for options of mastectomy and lumpectomy for reasons of simplicity. However, it is known that the probability of transition from any state to local recurrence state (if possible) and the probability of salvaged after local recurrence are actually higher for lumpectomy. Thus, one-way sensitivity analysis was performed in order to observe the effect of the differences in those probabilities. The result was not affected by up to a 5% increase in local recurrence probability; the QALY value was still higher than that of mastectomy. However, after that point it became lower than mastectomy. It means that, threshold value was observed at 5% and threshold value for optimal decisions was 6.4111 (Figure 3).

Secondly, since the probability of salvaged after local recurrence is also higher for lumpectomy, two-way sensitivity analysis was performed on probabilities of local recurrence and salvage in order to observe the effect of these probabilities simultaneously. In this analysis, only two threshold values were observed. First one was observed when the probability of local recurrence was increased to 5% and the probability of salvage was held at its baseline (one-way). The other one was observed when the probability of local recurrence was increased to 6%, and the probability of salvage to 25%. Threshold value for optimal decisions was 6.4117 at this time.

Also, one-way sensitivity analysis was performed on the utility data for lumpectomy and mastectomy in order to observe the effect of utility of health states. It was observed that the model was much more sensitive to utility of no evidence of disease, relatively sensitive to the utilities of no evidence of disease but having hormone therapy stage, chemotherapy stage and metastasis stage, however, was not sensitive to utilities of local recurrence stage and salvaged stage.

Discussion

Breast cancer, which is the second most common malignancy in the world, represents a global public health issue. Surgical therapy for breast cancer includes mastectomy and breast-conserving surgery (BCS) such as lumpectomy. With increasing age, breast cancer survivors reported better social and emotional functioning and future perspectives but poorer physical and sexual functioning and diminished sexual enjoyment. Women undergoing mastectomy were found to have significant deterioration in physical and functional well-being. Some studies have reported that patients undergoing BCS had a better body image [19–21], while others have described better psychological adjustment in women who had mastectomy, [22–23] whereas survival for both of them did not differ.

Although surgeons have enormous influence on decisions about local therapy for breast carcinoma [22–29], our understanding of surgeons' knowledge and attitudes toward treatment options is limited. The treatment of breast cancer is a notable example in cancer care where optimal decision making requires patients' active engagement. Increasingly, patients are asked to make decisions about the type and extent of their primary surgical management. Breast cancer surgical therapy is an important area for advancing techniques of evidence-based treatment decision making for physicians and patients.

Many previous studies about patients' opinions about their treatment were published. In a study, authors developed a Markov model that describes the clinical and economic outcomes of node-positive breast cancer with and without post-mastectomy radiation therapy. [9] In another study, it was shown that prophlylactic surgery among women who test positive for a BRCA1 or BRCA2 gene mutation improves survival, but unless genetic risk of cancer is high, provides no benefit for quality of life and that prophylactic surgery is cost-effective for years of life saved compared with other medical interventions. [30]

The aim of this study was to examine patients' perceptions in the selection of surgery for breast cancer treatment. For this purpose, the decision model was developed with reasonable success for early stage breast cancer patients, and tested using general public data. The results obtained from these data showed that lumpectomy was more favourable for these participants. The most important result was that the model is applicable for determining patient preference by considering their personal parameters such as, individual utility values, and scaling constants.

We have developed a Markov model about the patients' decision-making in their treatment. The model is not perfect and cannot be considered as generic measure such as HUI indexes or QWB scales. [31–33] We performed this study to take the first steps in this area and to attract attention to using decision theoretic techniques in health care in Turkey. There were a number of factors that defined some boundaries or limitations on this study. Below is a brief discussion of these limitations.

Model: In this study seven basic health states were designated. In the real context of such a problem, there are many more health states. In addition, the principal analysis of the model focuses on early stage breast cancer patients. Patients' age interval is considered between 45-55 year-old so that they are assumed to be premenopausal. The model has been structured for defined breast cancer patients, and therefore usage of the model is limited to these patient characteristics. Although many facets of the model are similar to other types of breast cancers, the results cannot be directly applied as a policy guideline.

Attributes: Another limitation that should be considered was in the attributes used in the MAUM. In order to characterize health states a number of attributes identified in the literature. Then by consulting oncologists, some attributes were omitted since they seem irrelevant or less important than others, so that model was simplified. However, these omitted attributes could make some differences and because of that number of attributes could limit the results. Also, a valuable improvement to the present study would be to generate the outcome measure attributes entirely anew, tailored to our culture. For this purpose, as mentioned previously, identifying attributes is best done using the "objectives hierarchy" [34] uniquely constructed for this decision context.

Population: Ideally, the utilities of the health states ought to belong to the patients, because these are the only people who know what it is really like to be in these health states and therefore the only ones capable of expressing "true" preferences over them. However, this procedure may not be considered as practical because patients may be oversensitive and such interviews may affect their psychology negatively. Although, it is believed that the source of preference weights do not affect the base case results of comparison, the research shows that healthy volunteers underestimate the value of health state; because, assessing the health state condition objectively becomes difficult for people without direct experience of the health state. Thus, some deviations could be observed in results if early stage breast cancer patients performed the study. This study was not performed on patients since they may be physically overtired or oversensitive and such interviews may affect them negatively if they are not applied by an analyst who is an expert on this area. We performed this study on a sample population of female university students, and aimed to obtain an indication of preferences of population at this specific age interval.

Probabilities: Although subjective probability is scientific and accepted as a method for probability assignment, using "objective" probabilities based on hospital records could provide more realistic results. However, the data that we need was not available in an adequate and reliable way.

Reliability: Health states should ideally be measured twice with the same measurement method after a period of time, re-tested, and then we can conclude that our measurement technique is reliable if the results are consistent. However, the analysis of the reliability could not be performed for this study because of practical difficulties.

In conclusion, this decision aid can be used either for taking the preferences of a single cancer patient into account in deciding on treatment, or for reflecting a reference population's preference structure on the issue. Its best use, however, may be in training physicians' judgment on the complexities of the decision space at hand so as to improve their chances of making a wise treatment decision. As Fryback and Ransohof pointed out, decision analysis improves physicians' intuition or judgment and increases the attention focused to anticipate all possible outcomes. [11, 35] Thus, the assessment process performed in this modelling effort prepares the mind for making a correct decision. It should be noted that we do not imply that physicians currently make bad decisions; rather, we interpret our study to show that good decisions may be improved, on the average, by making use of such decision theory concepts. This model can be applied to patients by an expert or surgeon and according to results of the model, they can decide more easily for treatment option. Needless to say, results of the model cannot be mandating a decision; it can only give a well-grounded indication for the right decision. Further research about the optimal modalities for promoting patients' participation in medical decision making may be especially helpful to design appropriate regulations about patients' rights.

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