INFORMED CONSENT IN ADVANCED LARYNGEAL CANCER

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Accepted 31 May 2006
Published online 17 January 2007 in Wiley InterScience (www.interscience.wiley.com). DOI: 10.1002/hed.20509

Abstract: Purpose. This study was designed to evaluate the relationship between the informed consent process and the treatment received by patients with advanced laryngeal cancer.

Methods. The study group was composed of 101 consecutive patients who were eligible for the Department of Veterans Affairs Laryngeal Cancer Study Group and Radiation Therapy Oncology Group/Head and Neck Intergroup (RTOG 91-11) larynx preservation clinical trials and who underwent treatment at the Mayo Clinic during the years 1985 to 2000. Records were reviewed to evaluate the effect that referral to an oncologist, discussion and documentation of treatment alternatives by the surgeon, offering a chance at a larynx conservation surgical procedure, and treatment recommendation made by the surgeon have on the treatment chosen and received by the patient.

Results. Discussion of treatment alternatives by the surgeon (p = .0054), referral to an oncologist (p < .0001), offering a chance for a larynx conservation surgical procedure (p = .047), and treatment recommended by the surgeon (p < .0001) were significantly related to the treatment received by the patient.

Conclusion. The treatment received by a patient with advanced laryngeal cancer is determined by the treatment recommended by the surgeon, referral to an oncologist, discussion of treatment alternatives by the surgeon, and offering a chance for a larynx conservation surgical procedure. ©2007 Wiley Periodicals, Inc. Head Neck 29: 230–235, 2007

Keywords: informed consent; laryngeal cancer; laryngectomy; radiation therapy

Informed consent is an essential component of excellent patient care. It is based on the ethical and legal principles of respect for individual autonomy. Its importance in Western medicine at this time is a direct reflection of the preeminence that patient autonomy receives in society’s values.1

Despite the rather strict ethical and legal definitions of informed consent, there is no uniform manner of obtaining informed consent, and there is no uniform consensus on the level of disclosure. This is particularly true in the field of oncology. For some malignancies, more than 1 treatment alternative may exist with similar survival probability but differences in quality of life and functional outcome.

Patients have the right to make decisions based on individualized goals and values using their own set of criteria and reasoning. Patients may choose different treatment alternatives when presented with multiple treatment options. This study evaluates the relationship between the informed consent process and the treatment received by patients with advanced laryngeal cancer, highlighting the importance of clear communication and patient involvement in decision-making.
with the same information. Patients can be influenced by the manner in which treatment alternatives are presented during the informed consent process. The question arises of whether it is possible for a physician, who may benefit from administering a treatment or performing a procedure, to discuss with a patient in an unbiased manner all treatment alternatives, including “competing” alternatives, and fulfill the requirements of informed consent. In an attempt to further explore this question, we reviewed the referral source, informed consent process and documentation, and referral patterns of patients with advanced laryngeal cancer.

PATIENTS AND METHODS

This study was approved by the Mayo Foundation institutional review board. In accordance with the Minnesota Statute for Use of Medical Information in Research, only those patients who consented to use of their medical records were included in the study. Individual patient records were reviewed to identify patients who would have been eligible for the Department of Veterans Affairs Laryngeal Cancer Study Group (VA) and Radiation Therapy Oncology Group/Head and Neck Intergroup (RTOG 91-11) clinical trials that evaluated various treatment alternatives for advanced laryngeal cancer. Treatment alternatives for patients eligible for these clinical trials included (1) total laryngectomy (TL) with postoperative adjuvant radiation therapy, (2) radiation therapy, (3) induction chemotherapy followed by radiation therapy, and (4) concurrent chemoradiation therapy. These trials have revealed no differences in survival by treatment alternative but better quality of life and function with larynx preservation.

The Mayo Clinic in Rochester computerized surgical index database and Department of Radiation Oncology computerized tumor registry were searched electronically to identify all patients undergoing a TL or radiation therapy for squamous cell carcinoma of the larynx between January 1985 and May 2000, which was the time period encompassed by the VA and RTOG 91-11 clinical trials. This identified 101 patients. The patient characteristics and treatment outcome were previously reported. The following information was extracted from the medical record: (1) referring physician and their specialty, (2) which physician(s) consulted with the patient prior to treatment and their specialty, (3) documentation of treatment alternatives, (4) treatment recommendation made by the consulting physician(s), and (5) treatment received by the patient. Physician-specific data were collected. Accurate data abstraction from the medical record were verified independently by 4 investigators (RLF, PDB, YIG, SHO).

The relationship between the above data and the treatment that the patient received was evaluated using contingency analysis and Pearson chi-square and Fisher’s exact (2-tailed) tests. p values <.05 were considered statistically significant.

RESULTS

All 101 patients were evaluated by a member of the Mayo Clinic in Rochester Department of Otolaryngology (MCRDO) prior to treatment. Table 1 summarizes the patterns of referral. Seven patients (7%) saw a radiation oncologist prior to referral to the MCRDO. Seven patients (7%) saw a radiation oncologist prior to referral to the MCRDO. Table 2 summarizes the patterns of referral by the Mayo Clinic head and neck surgeon (MCENT) to Mayo Clinic radiation and medical oncologists (MCO).

In 46 patients, a laryngeal conservation surgical procedure was discussed with the patient as documented in the medical record or presumed from the surgical listing; however, 41 (89%) un-
derwent a TL. A total of 81 patients underwent a TL, and 20 were treated with radiation therapy with or without concurrent chemotherapy (RT). The treatment for advanced laryngeal cancer did not vary with time throughout the period of this study (Pearson chi-square test, \( p = .59 \)). The results of the VA clinical trial were published in June 1991. Allowing 18 months for physicians to become familiar with the study results and implement them into their clinical practice, we analyzed treatment type by pre-VA study (January 1985 to December 1992) and post-VA study (January 1993 to December 2000). There was no change in treatment when these 2 time periods were compared (Fisher’s exact test, 2-tailed, \( p = .26 \)).

The MCENT’s treatment recommendation significantly correlated with the treatment received by the patient (Figure 1, Fisher’s exact test, 2-tailed, \( p < .0001 \)). Of the 85 patients whose MCENT recommended surgery, 78 patients (92%) underwent a TL. In the 6 patients for whom the MCENT recommended RT, all 6 were treated with RT. Of the 10 patients for whom a treatment recommendation was not documented by the MCENT, 7 patients (70%) elected to proceed with RT.

The documentation of treatment alternatives in the medical record by the MCENT significantly correlated with the treatment received by the patient (Figure 2, Fisher’s exact test, 2-tailed, \( p = .0056 \)). When treatment alternatives were documented, the patient was more likely to be treated with RT. In 70 patients, treatment alternatives were documented by the MCENT who initially evaluated the patient: 51 (73%) underwent a TL and 19 (27%) underwent RT. In 31 patients (31%), treatment alternatives were not documented by the MCENT: 30 (97%) underwent a TL and 1 was treated with RT. The rate of documentation of treatment alternatives by the MCENTs did not vary with time throughout the period of this study nor when compared by pre- or post-VA study publication (Pearson chi-square test, \( p = .93 \); Fisher’s exact test, 2-tailed, \( p = .15 \), respectively).

Patients were more likely to receive treatment with RT when they were seen by a multispecialty team prior to treatment (Figure 3, Fisher’s exact test, 2-tailed, \( p < .001 \)). All 71 patients who saw only an MCENT prior to treatment without refer-
ral to an MCO underwent a TL. For the 30 patients who were referred to a MCO prior to treatment, 10 underwent a TL and 20 were treated with RT. The 2 patients who were seen by a radiation oncologist at another clinic prior to seeing an MCENT and who did not see an MCO both underwent a TL.

When the MCENT included a laryngeal conservation surgical procedure as a potential surgical option, the patients were more likely to proceed with surgery (Figure 4, Fisher’s exact test, 2-tailed, \( p = .047 \)). In the 46 patients in which a laryngeal conservation procedure was offered, 41 (89%) elected to proceed with surgery but underwent a TL. In the 55 patients for whom TL was felt to be the only oncologically sound surgical procedure, 40 (73%) elected to proceed with surgery. Table 3 summarizes the data by individual MCENT.

**DISCUSSION**

Personal autonomy is highly valued in modern Western society. In medicine, this emphasis on individual self-determination finds expression in the doctrine of informed consent. Currently, informed consent is considered to consist of a process of shared decision-making involving an exchange of information. The ultimate goal of the process is to ensure “the patient’s well-being and (to show) respect for a patient’s self-determination.”

The informed consent process should include from the counseling physician a discussion of the risks and benefits and the expected course of a patient’s illness and health in relation to the intervention being considered. The expected outcome with no intervention should be discussed. Additionally, the physician needs to provide their own recommendation on how to proceed, but also, importantly, to discuss the availability of alternative procedures that are part of “mainstream” medical practice. In this regard, the practice of oncology can become a challenge in that some common malignancies may have more than 1 treatment alternative with relatively equivalent long term cure rates.

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**Table 3.** Referral pattern, treatment alternative documentation, treatment recommendation, and treatment by surgeon.

<table>
<thead>
<tr>
<th>Head and neck surgeon</th>
<th>No. of patients</th>
<th>Referred to RO/MO</th>
<th>Treatment alternatives documented</th>
<th>Treatment recommended by surgeon</th>
<th>Treatment received by patient</th>
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<tr>
<td></td>
<td></td>
<td></td>
<td>S</td>
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<td>ND</td>
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<td>30</td>
<td>70</td>
<td>85</td>
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</table>

Abbreviations: RO, radiation oncologist; MO, medical oncologist; S, surgery; TL, total laryngectomy ± RT; RT, radiation therapy ± chemotherapy; ND, not documented or patient given a choice.
Current treatment alternatives for resectable advanced laryngeal cancer include (1) TL with or without postoperative, adjuvant radiation therapy with or without chemotherapy, (2) radiation therapy, (3) induction chemotherapy followed by radiation therapy, and (4) concurrent chemoradiation therapy.\textsuperscript{2,5,10} There does not appear to be significant differences in survival between the various treatment alternatives, but there are quality of life and functional advantages to preserving the larynx.\textsuperscript{2-5}

During the years of the VA and RTOG 91-11 larynx preservation trials (1985–2000), 101 patients with advanced laryngeal cancer were evaluated and treated at the Mayo Clinic who would have been candidates for the larynx preservation clinical trials. Additional patients were referred to the MCRDO for a second opinion. Treatment recommendations were made and the patient returned to their local community to receive treatment. Our study was not designed to evaluate this group of patients. Therefore, our results apply only to patients who received their treatment at Mayo Clinic Rochester. Acknowledging that the results of the VA trial were not available until 1991, it is remarkable that 80\% of the patients underwent a TL rather than radiation therapy, since radiation therapy was considered an appropriate standard treatment in Canada, Europe, and many institutions within the United States.

All 71 patients evaluated only by an MCENT and not referred to an MCO for discussion of treatment alternatives underwent a TL. Only 2 of these patients had seen a radiation oncologist prior to evaluation at the Mayo Clinic. So the lack of referral to an MCO was not due to the patient having already seen one prior to evaluation at the Mayo Clinic. It is possible that a referral to an MCO may have been offered to the patient but the patient declined; however, this was not documented in the medical record. If a referral to an MCO was offered to the patient and the patient declined, it is possible 1 alternative was presented as superior to another. Therefore, the patient may not realize or appreciate the value of getting a second opinion from a radiation or medical oncologist. Additionally, some of the patients may have been referred to the Mayo Clinic specifically to have a laryngeal conservation surgical procedure or TL performed.

Interestingly, if a chance for a laryngeal conservation surgical procedure was offered to a patient, they were more likely to pursue surgery. It is possible that if a patient is offered the possibility of a laryngeal conservation surgical procedure, they will hope for the possibility of laryngeal conservation instead of the more likely chance a TL will be necessary.

Some questions arise about the influence of the physician during the informed consent process. Although possible explanations for our reported experience include the possibility that the patient’s decision had already been made prior to consultation with the MCENT or that the patient was referred specifically for a surgical procedure, it is conceivable that for a significant proportion of patients, the physician biased the patient for the surgical procedure that the physician was most comfortable recommending and performing. This raises the question of whether a physician who may benefit personally from performing a procedure or who may be unfamiliar with alternatives is able to provide adequate and unbiased informed consent when there are competing alternative procedures.

It is notable that 97\% of the patients with no documentation of treatment alternatives in the medical record by the MCENT underwent a TL compared with 73\% when treatment alternatives were documented in the medical record. We assume that treatment alternatives were discussed verbally but there was a failure to document the discussion in the medical record.

The MCENT recommended surgery as the best treatment in 84\% of the patients, and 92\% of them underwent a TL. This suggests that there might be a bias for surgery and against nonoperative larynx preservation therapy. While financial rewards may motivate the physician who is compensated based on clinical productivity, there are other potential motivating factors. These include the personal satisfaction of performing a procedure for which the physician is trained and may have special skills, prestige among and recognition from colleagues and patients for special skills and a high volume productive clinical practice, high clinical volume justifying retention or acquisition of needed allied health staff and new state of the art equipment, and service to referring physicians. Physicians can also be biased by institutional history and preference, geographical practice patterns, and by personal training and experience.\textsuperscript{11,12} This raises the question as to whether or not a physician who will benefit from performing a procedure can discuss “competing” treatment alternatives without bias. In the 6 patients in which the head and neck surgeon recommended radiation therapy, all 6 were treated...
with radiation therapy. Of the 10 patients for whom the surgeon’s recommendation was not documented, 70% elected to proceed with nonoperative larynx preservation therapy. This underscores the influence that a physician may have on a patient’s decision during the informed consent process and discussion of treatment alternatives.

A patient who has just been diagnosed with cancer naturally feels varying degrees of stress and duress. They may have the impression that the cancer is growing rapidly and may become inoperable or metastasize if it is not treated urgently. They may feel pressure to quickly make a treatment decision especially if 1 treatment alternative is offered the next day. For these reasons a patient may not want to delay treatment in order to undergo complete staging or to seek consultation for a second opinion or to discuss treatment alternatives unless this is encouraged by their physician. However, there is a need for all patients to assimilate a great deal of information from more than 1 source in a relatively short period of time. Under these circumstances do patients feel comfortable requesting a second opinion or referral to another specialty to discuss alternatives? Most likely only the best educated, most persistent, and emotionally and psychologically self-reliant patients will be able to do this. A possible solution is a multidisciplinary clinic led by a third party physician. This could be an efficient practice with the patient seeing 2 or 3 specialists at the same time or during the same day. The patient could receive information about treatment alternatives from the specialists who perform the treatments. A third party primary care physician who does not stand to benefit from the patient’s decision could help guide them through the decision process in a setting where patient autonomy is respected. It would seem prudent and in the patient’s and physician’s best interest to see more than 1, if not all, specialists that perform each of the treatment alternatives when more than 1 exists in a timely manner in a multidisciplinary setting.

REFERENCES